Patent Conflicts in User-Driven Biotechnology:

Examining Knowledge Management Strategies for Patentable Research Resources to Stimulate DIY Bio and Other Social Production in Biotechnology

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Abstract

Since 2000, digital technology and other technological advances such as 3D printing have improved non-traditional scientists' participation in biotechnology and life science research and development. Non-traditional scientists, including amateur scientists, students and graduates from the life sciences, artists, programmers, engineers, and entrepreneurs, have rapidly increased under the Do-It-Yourself biotechnology (DIY bio) movement. These DIY biotechnologists or DIYers increase biotechnology research and life science inventions in society by encouraging open and cooperative development.

Biotechnology research and development (R&D), especially in healthcare and agricultural biotechnology, suffers from patent proliferation with fragmented and overlapping rights that cover upstream research resources and research tools which can enable downstream developments. The proliferation of patents and related rights protecting upstream research can be detrimental to progress and citizens' welfare because they can increase the cost of R&D, interfere with access to upstream research tools, and allow R&D to be concentrated around the issues found in developed nations. Many DIYers depend on self-funding and community resources to experiment with biotechnology. Proprietary research tools and equipment are harder to access. Some of them operate alongside proprietary R&D in a research area by building on off-patent technologies and inventing around patents. Some DIYers have made significant contributions in science that benefit other biotechnology researchers and developers, such as developing and manufacturing open source versions of proprietary research tools and equipment.

Nonetheless, they can risk inadvertent patent infringement by working in competitive biotechnology research areas with heavy patent coverage. The presence of patent thickets in biotechnology can also discourage volunteers' initial participation in open R&D. When third party patents develop around open and cumulative development, the risk of patent infringement increases for downstream development and commercial activities based on upstream open R&D. Alternative knowledge management strategies, such as open source patent licensing, clearinghouses and contract-based compensatory liability regimes, allow open innovation communities to create a protected commons of shared resources. However, these do not resolve problems in biotechnology patent law, such as fragmented and overlapping rights on cumulative technologies and strategic patent use. Government actions can address these problems, such as broadening outdated patent law exceptions, which can discourage unnecessary patenting and reduce the risk of infringement in alternative innovation environments.

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Chapter 1: Introduction

This thesis explores possible conflicts between the biotechnology patent landscape and newly emerging user-driven, socially produced open biotechnology (such as Do-It-Yourself or DIY Bio). It moves on to examine knowledge management strategies that can improve access to patentable research resources in the open research and development (R&D) environment, such as open source patent licensing, clearinghouses and compensatory liability regimes. It considers whether the biotechnology patent landscape can interfere with, be detrimental to or cause hardships in this alternative innovation environment and whether alternative knowledge management strategies protect against third party patent interference while ensuring freedom of research and development in this open innovation environment. This thesis is an interdisciplinary research project that explores theories, policies and norms in patent law, biotechnology and open innovation.

Digitally enhanced, socially produced life science R&D projects in the twenty-first century encourage volunteer contribution in science.[1] "Social Production" means non-market based, loosely organized, open and cooperative development.[2] Social production in biotechnology emerged in the 2000s.[3] Its examples include DIY bio, community research projects, life science hackathons and citizen science. Scholars note that there are similarities

[1] Alessandro Delfanti, *Biohackers: The Politics of Open Science* (NY: Pluto Books, 2013) at 3-4; Michael Nielsen, *Reinventing Discovery: The New Era of Networked Science* (Princeton, NJ: Princeton University Press, 2012) [Multiple terms have been used to describe such activities: Do-It-Yourself biotechnology (DIY bio), citizen science, Science 2.0, public participatory science and open source biotechnology].
[2]Yochai Benkler, *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven, CT: Yale University Press, 2006) at chap 1; Aleksi Aaltonen & Giovan Francesco Lanzara, "Building Governance Capability in Online Social Production: Insights from Wikipedia" (2015) 36:12 Organization Studies 1649 at 1650.
[3]Stefano Golinelli & Guido Ruivenkamp, "Do-it-yourself biology: Action research within the life sciences?" (2016) 14:2 Action Research 151 at 21; Delfanti, *supra* note 1 at 113.

between this development model and the open science practices in academic research.[4] Both encourage open and cumulative discovery, and reputational rewards or other non-pecuniary benefits incentivize participation. User-driven social production, where citizens manage R&D, typically operates outside of corporate and institutional science, although collaboration can occur between them. These projects encourage citizen-participants to tinker with science and to apply science and technology to solve real-world problems.[5] They encourage open sharing and cooperation between diverse contributors who have different skills, resources and education, including amateurs, entrepreneurs, academic and public sector researchers, artists, engineers, programmers, governments and private sector organizations.[6]

Some governments have already acknowledged the innovation potential and other benefits of social production in science. For example, the municipal government of Paris offered public funding and a 900-square foot lab space in downtown Paris to a DIY bio community lab in Paris, La Paillasse, to try to stimulate entrepreneurship.[7] Moreover, the U.S. *Crowdsourcing and Citizen Science Act* encourages U.S. federal agencies to use crowdsourcing and citizen science to

[4]Eric von Hippel, *Democratizing Innovation* (Cambridge, MA: The MIT Press, 2005); Eric von Hippel & Georg von Krogh, "Open Source Software and the 'Private-Collective" Innovation Model: Issues for Organization Science" (2003) 14:2 Organization Science 209 at 215 citing Georg von Krogh, "The communal resource and information systems" (2002) 11:2 J Strategic Inform Systems 85 and Josh Lerner & Jean Tirole, "Some Simple Economics of Open Source" (2000), NBER Working paper series, WP 7600, Harvard University, which was later published as Lerner & Tirole, "Some Simple Economics of Open Source" (2002) 50:2 J Indus Econ 197; Eric S Raymond, *The Cathedral & the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary*, 2d ed (Cambridge, Mass: O'Reilly, 2001) at 106-110.

[5]Golinelli & Ruivenkamp, *supra* note 3 at 153; Delfanti, *supra* note 1 at 119.

[6]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 10; Delfanti, *ibid* at chap 1; Andrea Wiggins & Kevin Crowston, "Developing a Conceptual Model of Virtual Organizations for Citizen Science" (2010) Int J Org Design &Eng, online: <http://crowston.syr.edu/sites/crowston.syr.edu/files/WigginsCrowstonIJODE2010.pdf> at 2.

[7]Daniel Grushkin, Todd Kuiken & Piers Millet, "Seven Myths & Realities about Do-It-Yourself Biology" (2013), online: Woodrow Wilson International Center for Scholars <https://www.wilsoncenter.org/publication/seven-myths-and-realities-about-do-it-yourself-biology-0> at 22 citing Virginia Gewin, "Biotechnology: Independent Streak" (2013) 499 *Nature* 509.

advance their missions.[8] The *Act* also encourages federal science agencies to publicly share data and innovation created from crowdsourcing or citizen science in order to stimulate open R&D.[9]

The examination of patent conflicts between biotechnology patents and social production and alternative patentable knowledge management in this thesis will be based on the DIY bio movement. DIY bio operates outside of big bio or institutional science, and many of its participants follow open science principles.[10] The Federal Community of Practice on Crowdsourcing and Citizen Science describes DIY as an action that "shares methods of creating, modifying, or repairing things without the aid of professional experts".[11] Delfanti states that DIY bio is "based not only on the American amateur science tradition, but also on explicit references to hacking and OSS from which it borrowed practices that it then applied to the life sciences."[12] The DIY bio movement is not just a tool or a method of performing open scientific R&D among volunteers. It embodies the traditional open norms of academic research and the norms of open source software (OSS) development, promoting the cumulative discovery of knowledge and technology by creating open access to existing science and technology (see Chapter Two). These activities are receiving more attention and rapidly gaining popularity in recent years.[13] The DIY bio movement consists of intrinsically-motivated volunteers interested in biotechnology R&D.[14] Individuals can carry out an independent DIY project or collaborate and combine resources in

[8] *Crowdsourcing and Citizen Science Act,* 15 US Code §3724 (2016).
[9] *Ibid* at ss 6, 7.
[10] Ana Delgado, "DIYbio: Making Things and Making Futures" (2013) 48 FUTURES 65 at 66; Lisa C Ikemoto, "DIY Bio: Hacking Life in Biotech's Backyard" (2017) 51 UC Davis L Rev 539 at 539, 543-6 [DIY bio occurs apart from biotechnology R&D conducted in "academic, corporate, or government spaces."]; Grushkin, Kuiken & Millet, *supra* note 7 at 5.
[11] The Federal Community of Practice on Crowdsourcing and Citizen Science, "Strategic Plan", Goal5: DIY, online: The Federal Community of Practice on Crowdsourcing and Citizen Science (FedCCS) <http://www.stratml.us/carmel/iso/CCSCoPwStyle.xml>.
[12] Delfanti, *supra* note 1 at 2.
[13] Golinelli & Ruivenkamp, *supra* note 3 at 21.
[14] Delgado, "DIYbio: Making Things and Making Futures", *supra* note 10; Ikemoto, *supra* note 10 at 543; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 6 [e.g. to express "creativity, curiosity, and enthusiasm" for science]; Raymond, *supra* note 4 at 106-109.

loose-knit groups.[15] DIY bio, hackathons, and community research projects can supply the next generation of scientists, engineers, and innovators[16] and create a pool of ideas and innovation that can benefit society.

Open science and open innovation projects, such as DIY bio, stimulate cumulative development by creating access to a pool of resources that can be combined together. Open science and open innovation projects traditionally released new discoveries into the public domain, allowing anyone to build on them. On the other hand, patents are commonly used to protect life science inventions, they protect many key technologies in biotechnology, and patent ownership in biotechnology is spread across the public and private sector research. As it will be discussed in Chapter Three, scholars expressed that the development of patent proliferation on upstream research resources in biotechnology with fragmented and overlapping rights can frustrate subsequent R&D efforts by blocking researchers' and developers' access to research tools and upstream research needed for downstream R&D. The development of biotechnology patents that block access to upstream research resources can also disrupt commons-based biotechnology R&D, such as DIY bio and community projects. Moreover, third party patents can also develop over time to disrupt downstream DIY bio R&D and commercialization. The presence of these potential conflicts suggests that DIY scientists may need to incorporate a knowledge management strategy (or strategies) that improves and safeguards access to shared patentable research resources. Hence, this thesis will evaluate the use of open source patent licensing, clearinghouses and compensatory liability regimes in DIY bio.

[15] Aaltonen & Lanzara, *supra* note 2 at 1650; Neil Savage, "Gaining Wisdom from Crowds" (2012) 55:3 Comm ACM 13.
[16] Delfanti, *supra* note 1; Nielsen, *Reinventing Discovery, supra* note 1; Ikemoto, *supra* note 10; Grushkin, Kuiken & Millet, *supra* note 7.

This introduction is followed by five substantive chapters. Chapter Two examines open and cooperative research and development in society and the emergence of social production in biotechnology. This chapter begins by reviewing two important influences in DIY bio: the traditional norms of academic research (i.e. the open science model) and the OSS movement. This chapter also reviews the user innovation literature, which explores the motivations of user innovators to freely release their discoveries and improvements into the world. User innovators in society are end-users or product users who innovate out of curiosity and enjoyment or to address some needs that are unmet by market solutions. Many DIYers, open scientists, and OSS developers are also considered user innovators. The user innovation literature explains that contrary to the traditional theories on innovation incentives in society (i.e. private investment and collective action models), it is economically sound for user innovators to freely share their discoveries in society.

Following this, Chapter Two provides a general introduction to social production in biotechnology. The Internet and other emerging technologies, such as 3D printing, open source software and hardware tools, are transforming life science R&D by making it possible for non-traditional scientists (e.g. amateurs, programmers and engineers) to experiment with biotechnology. Modern technology allows active public participation, broader collaboration, and more interdisciplinary approaches in life science R&D. Non-traditional scientists or DIYers can contribute to biotechnology through various activities, including self-funded independent DIY bio projects and participation in hackathons and collaborative community lab projects. Volunteers can also contribute research resources, data and problem-solving skills to crowdsourced research projects.

Social production in biotechnology can create multiple benefits in society. These activities improve access to scientific information, technology and research tools. They also encourage efficient knowledge discovery and entrepreneurship. Social production in biotechnology is inclusive science; it encourages diverse participants with different skills, resources and background education to contribute to biotechnology R&D. Social production in biotechnology also empowers consumers by increasing their ability to innovate and produce goods. This development can pressure manufacturers to exercise fair business practices. Social production in science can generate other benefits in society, including the democratization of science and technology, encourage cooperation, empower citizens and improve their ability to exercise important rights in a democratic society, such as free speech, freedom of thought and self-determination.

Chapter Three reviews patent law developments since the late twentieth century in the United States, international patent law and Canada. It moves on to review how biotechnology patent proliferation affects academic research and the delivery of life science inventions. These discussions focus on American experiences and influences. The United States is an important jurisdiction in this discussion because the biotechnology industry began in the United States, and many biotechnology patents are still filed first in the United States. Many studies on biotechnology patents and their effects on subsequent R&D have been conducted in the United States.[17]

Patents offer important protection in biotechnology research. The patent landscape consists of large numbers of biotechnology patents owned by private and public sector

[17]Matthew Herder & E. Richard Gold, "Intellectual Property Issues in Biotechnology: Health and Industry" (Paper prepared for the OECD International Futures Project on 'The Bioeconomy to 2030: Designing a Policy Agenda', Third Meeting of the Steering Group, Paris, 7-8 February 2008) at 13 [In this paper, Herder and Gold also note that the evidence surrounding IP rights and the access issue in biotechnology predominantly comes from the United States which they assume to represent the situation in other developed nations].

researchers. Biotechnology patents grew exponentially between the 80s and the 90s in the United States following the adoption of an economic policy in patent law to encourage public-private partnerships. Thousands of patents are issued each year around the world. Internationally, the U.S. led trade-focused upward IP harmonization through bilateral and multilateral treaties is criticized for not balancing the economic interest of inventors against the public interest. Nonetheless, multinational corporations in knowledge industries argue that strong patent protection is needed to encourage innovation, even though their argument is based on limited evidence. There are also other potential problems with biotechnology patents in private and public sectors: cumulative industry patents are more conflict-prone because they provide poor notice of scope and boundaries, aggressive and strategic patent enforcement, and limited and vague research exceptions in patent law that vary by nation.

Scholars suggest that the development of patent proliferation in biotechnology with fragmented and overlapping patent rights can threaten technological progress and reduce social benefit. In a biotechnology patent landscape, patent users can experience patent access barriers to upstream research tools and increased inadvertent patent infringement. In academic research, more efforts to propertizing research resources in the life sciences disrupt research sharing. Moreover, many patents cover key technologies that can be used as research tools in biotechnology. Such upstream patents can seriously hinder downstream R&D. Scholars considered the presence of the tragedy of the anticommons due to the proliferation of fragmented and overlapping patent rights and other property rights that protect upstream research resources. The tragedy of the anticommons occurs when there are too many rights owners who can exclude downstream users from accessing a resource. While some empirical studies concluded that patents do not impede biotechnology research, patents are still detrimental to scientific progress.

Upstream patents can create additional costs for subsequent research and cause researchers to waste time trying to avoid patent infringement. More emphasis on proprietary management of academic research also increased other property rights that can protect upstream research (e.g. data access agreements and MTAs), and these rights alone or in conjunction with patents can impede researchers from accessing upstream research. Biotechnology patents also interfere with the equitable provision of healthcare, global food security, and traditional agricultural practices.

Chapter Four explores possible conflicts between biotechnology patents and the social production of biotechnology. DIY bio is fairly new. I did not observe patent conflicts that stem from these activities in my research. However, we may be informed of possible future developments based on the cost-benefit analysis of patent enforcement applied to OSS development, another user-driven open innovation environment, and research sharing practices (or patent ignorance) in academic research.

Patent proliferation in biotechnology with fragmented and overlapping rights makes it difficult for DIYers to access research tools, invent around patents and build on off-patent technologies. The proliferation of patents creates a risk of inadvertent patent infringement for subsequent inventors. Moreover, subsequent patents can develop around socially produced open biotechnology inventions to block subsequent open R&D and commercialization. The open norms encourage research sharing, which is practiced and encouraged in DIY bio. However, when an invention is freely revealed over the Internet, the inventor cannot protect ongoing access to the open invention or control the subsequent use. Third party patents can interfere with subsequent development and commercialization. An invention in the public domain may establish prior art to defeat subsequent patent applications for the same invention. However, an

open invention does not defeat subsequent patent applications of the same invention if it is ignored by patent examiners or judges.

The cost-benefit analysis suggests that different types of open innovation participants can experience different patent risks upon infringement because patentees may be deterred by patent enforcement costs or benefits they gain from the infringers' activities. Commercial patentees and patent trolls will likely not pursue actions against non-commercial infringers who cannot pay for settlement costs or damages because the cost of enforcement outweighs possible benefits. However, the development of patent proliferation in a research area can still discourage the initial participation of some open innovators who do not want to risk infringement. Participants with commercial motivations face legitimate patent risks unless their activities benefit the patentee. Furthermore, another factor that influences patent enforcement in academic research is the research sharing norms. The cost-benefit of patent enforcement and the norms in scientific research operate together to allow most academic researchers in biotechnology to ignore academic and private sector patents without experiencing enforcement. This chapter considers how both factors may influence patent access and use in DIY bio.

Instead of free revealing, some open science and open innovation communities protect access to shared resources by implementing alternative knowledge management using IP licences, contracts and/or central access and management of resources. Before considering these mechanisms for DIY bio in Chapters Five and Six, Chapter Four briefly discusses supporting organizations' various functions in commons-based development communities, which can improve cooperative development and knowledge sharing. Organizations as neutral intermediaries can help bottom-up loose-knit groups incorporate central control. Supporting organizations also improve the infrastructure for open development by providing functions and

services, such as encouraging cooperation and open sharing by defining community rules, norms and law, mediating disputes between collaborators, transacting with third parties on behalf of open projects, and managing shared resources and properties.

Chapter Five considers open source licensing of patentable inventions as a possible knowledge management solution in DIY bio. This chapter starts by introducing the open source licensing strategy in general. Open source licensing was originally designed for OSS development to allow open source software to be disseminated for free to an indefinite number of users while protecting its open access status (it is also known as viral licensing). This chapter will also examine how the licensing strategy protects and incentivizes open and cumulative development, the licence enforceability, and subsequent uses that extend the licensing strategy in other contexts, including in open biotechnology. Open source licences grant royalty-free, non-exclusive, non-discriminating open source access to users. OSS and other commons-based projects successfully used this licensing scheme to create a self-binding commons and to minimize intellectual property disputes with those on the inside and outside of open development. The copyright protection in software allows the OSS community to enforce this licensing scheme in copyright law. OSS licensing is generally accepted in software development and considered legally enforceable. A contract-based regulation of information or technology that does not rely on IP law is sometimes used in open science or open development (i.e. user agreements). However, it is not easy to regulate access to shared resources and control subsequent use with contracts when people can reproduce the resources. There has been an attempt to reproduce open source licensing in the maker community to protect patentable inventions such as open source hardware tools.

Open source patent licensing may be used to increase access to patented upstream research resources for open biotechnology or social production. The cooperation and consent of existing patentees in the public and private sectors of biotechnology are needed to improve access to already patented research tools and resources. Upstream patentees who recognize the innovation potential of this environment may be willing to use this licensing scheme. Patentees in biotechnology with nearly expired patents, patents generating no revenues or purely defensive patents are also good candidates who should be encouraged to open source license patents.

Open source software licences protect copyright-protected works; therefore, their design reflects copyright law protection. For DIYers to implement and use open source patent licences in their projects, they need to patent any new and non-obvious DIY bio inventions to access protection offered by patent law. They will need to incur the costs of obtaining and maintaining patent protection, and they may experience difficulty demonstrating patent eligibility for open and collaborative inventions. Moreover, they can experience possible patent resistance from some participants who resist increasing proprietary rights in a field of endeavour.

While essential open source licensing conditions can be implemented for simple patentable inventions, it may be inappropriate or impossible to open source license complex technologies and modified life forms in biotechnology. The presence of overlapping patents can still interfere with defensively patented open source inventions. Furthermore, in some research areas, participants need to obtain consent from all rights holders who hold the key rights of an upstream resource suffering from fragmented rights before the resource can be distributed as open source technology. Another concern that can arise from promoting open source licensing in biotechnology is that since there are many different types of biotechnology inventions, licence proliferation can develop, leading to licence incompatibility and technology interoperability.

Self-perpetuating, open source licences may seem like an ideal approach for creating a protected commons because it does not require ongoing supervision or administration. Nonetheless, there are additional complexities when open source licensing is used to create a protected-commons of patentable biotechnology inventions. This patentable knowledge management strategy does not eliminate possible third party patent interferences in the social production of biotechnology. Some may implement open source-inspired contracts to regulate access to shared resources to avoid the difficulties of implementing open source patent licences in open science or open innovation. However, a contractually regulated commons is less efficient at promoting the free flow of shared resources compared to an IP-protected commons.

Aside from using open source-inspired IP licences and contracts to regulate shared resources, DIYers can implement and use centralized resource management to address patent risks. Chapter Six considers clearinghouses and compensatory liability regimes. Two types of clearinghouses are considered with examples. An information clearinghouse provides access to patent-related information in research fields, which can help DIYers avoid patent infringement and plan their R&D around existing patents. On the other hand, a clearinghouse can be established to centrally administer access to a group of patents and other research resources in one or more research areas. A patent clearinghouse can create standardized access to a pool of resources and remove individual negotiations between resource owners and users.

A compensatory liability regime can be organized with contracts and a neutral intermediary that oversees the use of shared resources. Compensatory liability regimes enforce a liability rule (i.e. an entitlement to be compensated). Under this strategy, upstream resources are available to users for any purpose as long as downstream users agree to equitably compensate the upstream resource owners when they create profit from using the resources. This entitlement to

be compensated encourages upstream resource owners to share resources, stimulating downstream developments. This scheme allows downstream users to access upstream resources in the semi-commons without entering into negotiations or obtaining licences.

Patent clearinghouses and compensatory liability regimes still depend on patentees' cooperation in relevant research areas to create access to patents and remove patent access barriers. If a research area suffers from fragmented and overlapping patent rights that cover essential upstream research tools, it will be challenging to establish a patent clearinghouse. There are costs to establish and operate intermediary organizations that oversee resource sharing. They also do not protect DIY bio participants from strategic patentees or patent trolls. Aside from implementing alternative knowledge management to reduce patent risks in DIY bio, nations can readjust the patent incentives by amending the patent law. Scholars agree that updating the very outdated patent exceptions in domestic patent law should improve access to patented research resources, discourage unnecessary patenting, and reduce patent risks in open R&D.

Chapter 2: The Emergence of Social Production in Biotechnology

2.1 Introduction

DIY bio and related commons-based open collaboration in biotechnology are technology-supported, open and cooperative R&D activities. They allow ordinary citizens and non-professional scientists to contribute to biotechnology. This chapter reviews open and cooperative development activities that have influenced the DIY bio movement. This is followed by a general introduction to social production in biotechnology.

Commons-based open innovation activities, such as DIY bio and OSS development, revive the traditional norms of academic research, which encourage cooperation between scientists in the research community and open sharing of research for efficient and cumulative knowledge discovery. Before there was a DIY bio movement, the OSS movement established an alternative innovation environment for open software development based on the traditional norms of academic research. OSS encourages volunteers to share their time, skills, and resources over decentralized networks to create software, which is made openly accessible to others to use, modify and redistribute. This development model stimulates ongoing open and cumulative discovery of knowledge and innovation. The success of the OSS movement inspired other bottom-up, loose-knit open collaboration, including DIY bio.

The user innovation literature is relevant to understanding commons-based development activities. User innovators are end-users of products and services offered by commercial entities (i.e. individual customers and business customers) who invent to try to address some needs that are unmet by existing market solutions. They are distinguished from commercial manufacturers

who innovate to develop marketable products and services.[18] For instance, scientific researchers who create new research tools for their experiment needs are user innovators. Many OSS developers and DIYers are also user innovators. User innovators may also seek to address real-world problems they observe in life or explore problems to satisfy personal needs or curiosity. They are considered excellent downstream developers; user innovation can encourage commercial activities in society. And these inventors are more likely to invent new and disruptive technology than existing manufacturers. The user innovation literature has examined the possible motivations of individuals and businesses that freely and openly share potentially valuable user innovations in society. It explains that user innovators freely reveal potentially valuable and commercially interesting discoveries to the world because they can derive private benefits that outweigh potential losses caused by free riding. For instance, when user innovation is freely shared with the world, individuals can gain non-pecuniary benefits, and firms can gain commercial advantages.

Some have questioned whether open R&D or social production in biotechnology can produce meaningful or useful results because biotechnology is considered an industry that requires high investment in R&D, scientists with lengthy formal education and training, and access to expensive research equipment. However, the Internet and other technological advances have lowered the threshold for some biotechnology R&D, allowing non-traditional scientists, such as amateur scientists, programmers and engineers, to actively contribute to technological progress. Some of these new open R&D activities can use the peer production model from OSS development because cumulative discovery is built into biotechnology, and research questions can be designed to take modular and granular inputs. The bottom-up and open R&D can be combined with more traditional R&D approaches as well.

[18]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 2, 4-6, 115; Benkler, *Wealth of Networks*, *supra* note 2 at 5.

The DIY bio movement is responsible for taking biotechnology R&D outside of the institutional setting. It is a growing network of non-traditional scientists (i.e. DIYers) exploring biotechnology for fun or to solve problems by applying biotechnology. DIY bio encourages participants to cooperate and openly share science. DIYers contribute to the progress in biotechnology in multiple ways: openly sharing self-funded DIY projects, participating in group discussions and research events like hackathons, and organizing and partaking in community projects. Anyone interested in scientific research can also contribute research tools and other research resources to crowdsourced projects like citizen science. These social production activities in biotechnology increase diverse participation in R&D, cooperation between people, and democratize science and technology.

2.2 Open and Cooperative Development in Science and Technology

DIY bio and other commons-based projects encourage community members' cooperation and open sharing of previous discoveries for the cumulative development of information and knowledge.[19] Open sharing of new discoveries between collaborators also makes the R&D process more efficient by allowing peer review, verifications and efficient allocation of resources and reducing redundant efforts. This model of knowledge development can be traced back to earlier sociological studies of academic research and OSS development. While the open science model does not accurately describe the entire academic research community, this model continues to influence academic researchers and open innovation communities. Open and

[19]Delfanti, *supra* note 1 at 12-13; Nielsen, *Reinventing Discovery, supra* note 1 at 187; OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science* (2011), online: OECD <https://www.oecd.org/sti/biotech/48665248.pdf>at 30; Arti Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94 Nw UL Rev 77; Ikemoto, *supra* note 10 at 545 ["Many DIY biologists embrace an open science approach."].

decentralized peer production of OSS evolved with the Internet, and its information production process and ideology have also inspired other open innovation activities, such as DIY bio.

2.2.1 The Open Science Model

The open science model encourages cooperation and research sharing between scientists to achieve efficient knowledge discovery.[20] Scientific research is a cumulative process that involves "a continuous cycle driven by complex interactions among many participants, present and future."[21] These interactions are important to improve the quality of scientific knowledge. Petherbridge describes open science as "a framework for innovation directed to providing liberal, low-cost access to intangible [sic] property for the purpose of the creation and accretion of new and useful information and materials that meaningfully advance the state of knowledge and skill in a relevant technological area."[22] Thus, under the open science model, scientists are encouraged to freely and openly share their discoveries with other members of the research community to advance science and technology in society. The open science model describes a process of

[20]Paul A David, "The Historical Origins of 'Open Science': An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution" (2008) 3:2 Capitalism & Society Article 5 at 6, 10-11 [Modern science emerged from the Scientific Revolution that occurred at the end of the sixteenth century and the beginning of the seventeenth century. It replaced the medieval practice of conducting science in secrecy. The shift towards open dissemination of scientific knowledge in modern science was motivated by the increasing awareness of the inherent information asymmetry between scientists and the increasing complexity of scientific problems that made it difficult for a single person to figure out all of nature's secrets]; Lee Petherbridge, "Road Map to Revolution? Patent-Based Open Science" (2007) 59 Me L Rev 339 at 361; Helga Nowotny, "The Changing Nature of Public Science" in Helga Nowotny et al, eds, The Public Nature of Science under Assault: Politics, Markets, Science and the Law (Berlin: Springer, 2005) at 4; Robert K Merton, "Priorities in Scientific Discovery: A Chapter in the Sociology of Science" (1957) 22 Am Soc Rev 635 at 639-640.

[21]Thomas Mandeville, *Understanding Novelty: Information, Technological Change, and the Patent System* (New Jersey: Ablex, 1996) and Stephen Hilgartner, "Access to Data and Intellectual Property: Scientific Exchange in Genome Research" in N R Council, ed, *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington, DC: National Academic Press, 1997) cited in Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Cambridge, MA: Harvard University Press, 2008) at 82-85.

[22]Petherbridge, *supra* note 20 at 359; Amy Kapczynski, "Order without Intellectual Property Law: Open Science in Influenza" (2017) 102 Cornell L Rev 1539 at 1548.

knowledge discovery in public or open science, and it is distinct from the proprietary model in private sector research that incentivizes development by excluding access to R&D outputs.[23]

By the 1940s, sociologists began to suggest that academic research was governed by a set of norms.[24] Notably, Robert Merton's work on this topic provided the foundation for the open science model (also referred to as the "traditional norms of academic research" or "Mertonian norms").[25] Robert Merton characterizes academic research as a knowledge discovery process that, while requiring the independent actions of scientists to produce original contributions, to perform peer reviews, and to maintain objectivity and avoid conflicts of interest, scientists must also cooperate with the other members of the scientific community and exchange research discoveries in order to find universal truths in incremental steps. Merton describes academic research as depending on a set of norms practiced by scientists in their research: communalism, universalism, disinterestedness, originality and organized scepticism (CUDOS).[26] Among these norms, according to Merton, the most important rule is that scientific results should be treated as common property between scientists.[27] This argument received much attention in subsequent works.[28] Thus, the traditional norms of academic research encourage scientists to release new

[23]Kapczynski, *ibid* at 1591-1592; Rai, "Regulating Scientific Research", *supra* note 19 at 93.
[24]David, *supra* note 20 at 9-10; Merton, "Priorities in Scientific Discovery", *supra* note 20; Rai, *ibid* at 89.
[25]Robert K Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (Chicago: University Press, 1973); Merton, "Priorities in Scientific Discovery", *ibid*.
[26]Merton, *The Sociology of Science, ibid* at chap 13 cited in David, *supra* note 20 at 10 [Communalism refers to the importance of scientists to cooperate with the other members of the scientific community to discover universal truths; universalism refers to permitting all competent scientists to participate in the knowledge discovery process; disinterestedness refers to the scientists' exercise of objectivism and avoiding conflicts of interest in research (i.e. no personal agenda for knowledge inquiry); originality means each scientist should strive to make an original contribution to the overall scientific progress; and scepticism refers to peer-review that must occur to verify new discoveries].
[27]Merton, *The Sociology of Science, ibid* at 274-75 cited in Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1591.
[28]Partha Dasgupta & Paul A David, "Toward a New Economics of Science" (1994) 23 Res Pol'y 487, also discussed in Kapczynski, "Order without Intellectual Property Law", *ibid*; Bernard Barber, *Science and the Social Order* (London: Allen & Unwin, 1953) at 153-4 and Warren O Hagstrom, "The scientific community" (1965) discussed in Rai, "Regulating Scientific Research", *supra* note 19 at 89-90.

discoveries into the public domain.[29] Academic researchers are encouraged to freely and openly share publicly funded new scientific discoveries in a timely manner, typically through journal publications.[30] The practice of open sharing in research is sustained by reputational rewards and sanctions where reputation is rewarded based on the priority of discovery, while reputational sanctions are applied to scientists who violate the norms.[31] While reputational rewards are non-pecuniary, scientists can turn their reputation into pecuniary benefits such as access to research funding, better salaries and better job opportunities.[32] Communalism in academic research also means that a researcher would be discouraged from seeking property rights in new scientific inventions and other discoveries to avoid blocking other scientists' access to them since scientific information and knowledge belong to the community.[33] It would be considered immoral to impose exclusive rights on new scientific discoveries or to keep them from other researchers because scientists need to access and use existing knowledge to add to the cumulative development of scientific knowledge.[34]

Openly sharing research discoveries also improves the scientific process. It allows other scientists to verify, validate and certify new discoveries.[35] The public access allows other scientists to re-examine a scientific discovery through objective and independent inquiry without

[29]Merton, "Priorities in Scientific Discovery", *supra* note 20 at 644; Rai, *ibid*.
[30]David, *supra* note 20 at 6, 10-11; Petherbridge, *supra* note 20 at 361; Nowotny, *supra* note 20 at 4;
[31]David, *ibid* at 52-56; Merton, "Priorities in Scientific Discovery", *supra* note 20; Rochelle C Dreyfuss, "Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm" (2010) 31:5 Cardozo L Rev 1437 at 1446; Dasgupta & David, "Toward a New Economics of Science", *supra* note 28 at 498; Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1600-1601 [Norm violators may be outcasted or ostracized from the research community].
[32]Dan L Burk, "Intellectual Property in the Context of e-Science" (2007) 12 J Comp-Mediated Comm 600 at 604; Jerome H Reichman & Ruth L Okediji, "When Copyright Law and Science Collide: Empowering Digitally Integrated Methods on a Global Scale" (2012) 96 Minn L Rev 1362 at 1427-1428; Nowotny, *supra* note 20 at 5; Von Hippel, "*Democratizing Innovation*", *supra* note 4 at 168.
[33]Rai, "Regulating Scientific Research", *supra* note 19 at 88-90.
[34]Barber, *Science and the Social Order*, *supra* note 28 at 92 and Sissela Bok, "Secrecy and Openness in Science: Ethical Considerations" (1982) Sci Tech & Hum Values 32 cited in Rai, *ibid*.
[35]Nowotny, *supra* note 20 at 4.

external influence.[36] Constant peer review within the scientific research community creates quality control because the peer review system discourages scientists from fudging data, fixing scientific results, or falsely reporting an outcome since other scientists will eventually discover such actions.[37] Open sharing of research discoveries also increases efficiency by reducing unnecessary duplicate efforts.[38] The combined effect of peer reviews from the scientists in the research community is greater accuracy and truthfulness of scientific knowledge.[39] Thus, this interactive and cumulative process of knowledge discovery in academic research increases the value and the quality of knowledge in the science commons.[40]

On the other hand, the characterization of academic research as a process dictated by the open norms has been criticized as being idealized and not consistent with reality.[41] Another criticism of the norm-based account of academic research is that it does not adequately explain why scientists cooperate and exchange knowledge.[42] After all, academics are not more cooperative or altruistic than ordinary people; not all share their research findings purely for the sake of scientific progress or to allow others to build on prior efforts.[43] Other incentives can discourage scientists from sharing research discoveries. Academic researchers may not be

[36]Rai, "Regulating Scientific Research", *supra* note 19 at 88-92.
[37]Merton, "Priorities in Scientific Discovery", *supra* note 20 at 650; Henry H Bauer, "Three Stages of Modern Science" (2013) 27 J Sci Exploration 505.
[38]Bok, *supra* note 34 at 33 cited in Rai, "Regulating Scientific Research", *supra* note 19; Raymond, *supra* note 4 at 107.
[39]*Ibid*; Nowotny, *supra* note 20 at 4-5; David, *supra* note 20 at 20.
[40]David, *ibid*; Rai, "Regulating Scientific Research", *supra* note 19 at 92.
[41]Dasgupta & David, "Toward a New Economics of Science", *supra* note 28 at 492; Stephen Turner, "Scientists as Agents" in Philip Mirowski & Esther-Mirjam Sent, eds, Science Bought and Sold: Essays in the Economics of Science (IL: The Univ of Chicago Press, 2002); Paul A. David, "The Republic of Open Science: The Institution's Historical Origins and Prospects for Continued Vitality" (2014), SIERP Discussion Paper No. 13-037, online: Stanford University < https://siepr.stanford.edu/sites/default/files/publications/13-037_0.pdf>.
[42]Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1599-1606.
[43]For example, scientists can barter new discoveries rather than gift them to the rest of the research community. Also, scientists with competing interests will refrain from sharing information. It has been noted that professional researchers are usually good at sharing ideas with other researchers until they are offered commercial opportunities, such as the possibility of private funding and industry research partnerships. See Welsh, "Close Enough but not too Far", *supra* note 48 at 1854-1855 and James A Evans, "Industry Collaboration, Scientific Sharing, and the Dissemination of Knowledge" (2010) 40:5 Societal Studies of Sci 757.

willing to readily and frequently disclose new discoveries to other researchers because they have to compete for funding and job opportunities.[44]

Moreover, although sociologists have argued in the past that most norm violations in academic research can be corrected through reputational sanctions, such sanctions cannot always deter them.[45] Scientists do not have an equal ability to effectively punish norm violators within the scientific community because of varying professional reputation and influence within the community. Sometimes reputational sanctions against norm violators may be withheld because excluding norm violators from the overall scientific process may be too costly for society. Reputational sanctions are more difficult to carry out, especially when scientific collaboration occurs across multiple jurisdictions, and scientists cannot easily observe each other's activities.[46] It is also far more difficult to detect researchers who violate the open norms by patenting collaborative research results because academic researchers do not normally monitor patent applications and lack the legal expertise and the time to evaluate patents in their research area.[47]

Merton's description of the open science model is not a dominant view of academic research in biotechnology.[48] The economic policy to encourage public-private partnerships and

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[44]Nowotny, *supra* note 20 at 7-8; Opderbeck, "The Penguin's Genome", *supra* note 48 at 190-191, 197; Nielsen, *Reinventing Discovery, supra* note 1 at 8; Timothy Caulfield, Shawn HE Harmon & Yann Joly, "Open Science Versus Commercialization: A Modern Research Conflict?" (2012) 4:17 Genome Medicine, online: Genome Medicine < http://genomemedicine.com/content/4/2/17> at 6.

[45]Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1599-1601.

[46]*Ibid*.

[47] *Ibid*.

[48]Rai, "Regulating Scientific Research", *supra* note 19 at 112-113; David, *supra* note 20 at 10; Carol Tenopir et al, "Changes in data sharing and data reuse practices and perceptions among scientists worldwide" (2015) 10:8 PLoS ONE, online: PLoS < https://doi.org/10.1371/journal.pone.0134826>; David W Opderbeck, "The Penguin's Genome, or Coase and Open Source Biotechnology" (2004) 18 Harvard J L & Tech 167 at 189; Jerome H Reichman & Paul F Uhlier, "A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment" (2003) L & Contemp Prob 315 at 404-407; Delfanti, *supra* note 1 at 22; Rick Welsh, "Close Enough but not too Far: Assessing the Effects of University-Industry Research Relationships and the Rise of Academic Capitalism" (2008) 37 Research Policy 1854 at 1854-1855 [The university –industry research partnership highlights the tension between the goal of serving the public good by disseminating scientific and technical knowledge widely verses the goal of enhancing the performance of an industry through development and research].

the corresponding patent law developments since the 80s in the United States and at the international level[49] encouraged academic researchers to move away from the open norms and to focus on competition and turning research into marketable goods (see Chapter Three below).[50] The legal developments led to a significant increase in biotechnology patents spread across public and private sector research post-1980 in the United States and eventually spreading worldwide. Access to patent protection for biotechnology inventions has disrupted the traditional norms of academic research and diminished the view that research is communal property.[51]

Nonetheless, the traditional norms of academic research continue to have a residual effect on academic research.[52] Moreover, as discussed below, the norms inspire open science projects and open innovation communities. The cumulative knowledge discovery process in scientific research depends on researchers having adequate access to prior research. Hence, economists and sociologists generally agree that there should not be unnecessary restrictions for scientists to access existing research and other materials they need to conduct scientific research to encourage scientific progress.[53] Rai notes that major research universities in the United States continue to embrace the research sharing norms and are reluctant to patent upstream research tools in biotechnology that could be used to develop useful products or research discoveries that are far

[49]For example, patents becoming available for biotechnology research outputs (*Apotex v Sanofi-Synthelabo Canada Inc*, [2008] 3 SCR 265) and strengthening IP rights and the upward harmonization of IP law through international IP and trade treaties (e.g. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, U.N.T.S. 299, 33 I.L.M. 1197).
[50]Opderbeck, "The Penguin's Genome", *supra* note 48 at 186-9; Rai, "Regulating Scientific Research", *supra* note 19 at 94-115.
[51]Rai, *ibid* at 112-113; John P Walsh, Ashish Arora & Wesley M Cohen, "Effects of Research Tool Patents and Licensing on Biomedical Innovation" in Wesley M Cohen & Stephen A Merrill, eds, *Patents in the Knowledge-Based Economy* (Washington, D.C.: National Academies Press, 2003); Carol Nottenburg, Philip G Pardey & Brian D Wright, "Accessing other people's technology for non-profit research" (2002) 46:3 Aust J Agri & Resource Econs 389; Opderbeck, *ibid*.
[52]Rai, *ibid*; David, *supra* note 20 at 10; Tenopir et al, *supra* note 48; Opderbeck, *ibid* at 186-189; Reichman & Uhlier, "A Contractually Reconstructed Research Commons", *supra* note 48 at 404-407; Delfanti, *supra* note 1 at 22; Nielsen, *Reinventing Discovery, supra* note 1 at 6-7 [e.g. In 1996, the world's leading biologists agreed to publicly share human genetic data online to benefit scientific development under the *Bermuda Agreement*, and they also convinced major funding agencies to mandate funding recipients researching human genomes to share research data].
[53]Hope, *Biobazaar*, *supra* note 21 at 9.

from commercialization.[54] International organizations also encourage increasing access to publicly funded research, and many nations have adopted policies that require publicly funded research data to be publicly accessible.[55]

2.2.2 Open Source Software Movement

The Mertonian norms of academic research have been wholly embraced in the free and open source software movement.[56] The OSS movement adopted a model of software development based on Merton's description of academic research. OSS developers practise free and open sharing of valuable and proprietary information (i.e. programming source code) for cumulative, bottom-up and open development of software over the Internet. Participants form loose-knit groups around each project in this alternative innovation environment. Within this peer production or social production model, developers also share time, energy and creativity. As with academic research, the quality of a contributor's gift is judged by peers. Raymond suggests that this gift culture may have resulted among OSS developers or hackers because they are exposed to the customs of academic research during their education.[57] The similarities between the open science model and OSS development may also be attributed to the fact that this model allows

[54]Rai, *ibid* citing Lita Nelsen, "Policy and Pragmatism at a University Licensing Office" (Presentation delivered at the Conference on Biotechnology and the Law: New Perspectives on Public Access and Proprietary Rights, 20 February 1998) [e.g. research tools such as expressed sequence tags (ESTs), single- nucleotide polymorphisms (SNPs) and cell receptors in genetic research].
[55]Natasha Susan Mauthner & Odette Parry, "Open access digital data sharing: principles, policies and practices" (2013) 27 Social Epistemology 47 at 48 also citing R Ruusaleep, "A Comparative study of international approaches to enabling the sharing of research data" (2008) ["Data preservation and sharing is becoming a matter of national policy within and beyond the UK, including Australia, USA, Canada and Europe, where research funding agencies are responsible for developing and implementing data sharing policies"]; Caulfield et al, "Open Science Versus Commercialization", *supra* note 44 at 5 [e.g. The International Organization of Human Genome (HUGO), which promotes genetic data as global public goods, and the Organisation for Economic Co-operation and Development]; OECD, *OECD Principles and Guidelines for Access to Research Data from Public Funding,* OECD/LEGAL/0321 (2007), online: OECD <http://www.oecd.org/dataoecd/9/61/38500813.pdf>.
[56]Delfanti, *supra* note 1 at 60; Hope, *Biobazaar*, *supra* note 21 at 75; Raymond, *supra* note 4 at 106-110; Yann Joly, "Open Source Approaches in Biotechnology: Utopia Revisited" (2007) 59 Me L Rev 385 at 403.
[57]Raymond, *ibid*.

non-proprietary development of high-quality creative works based on the laws of nature and behavioural norms in society. For example, when participants pursue what they are interested in rather than being told to work on a particular task, the intrinsically motivated actions are more likely to yield creative works.[58] Raymond notes that both intrinsic incentives and reputational incentives encourage hackers to participate in OSS development. [59] Most hackers are intrinsically motivated to contribute to the OSS commons because they enjoy this activity, and reputational rewards also motivate hackers to contribute and cooperate with others at the psychological level.

The principle that technology should be free without discrimination is a fundamental rule in OSS development.[60] OSS developers generally agree that "software that is freely redistributable and can readily evolve and be modified to fit changing needs) [sic] is a good thing and worthy of significant and collective effort."[61] Open access to software is central to organizing cumulative open and decentralized development as it allows anyone to build on previous efforts, users can modify or improve existing works without incurring a high cost (i.e. they only need access to a computer and the Internet), and this scheme benefits everyone since subsequent users contribute back to the OSS commons. Thus, it is crucial to protect ongoing access to OSS (i.e. its source code) to motivate and encourage more contribution.

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[58] *Ibid*.
[59] *Ibid* at 79, 82-86; Lerner & Tirole, "Some Simple Economics of Open Source", *supra* note 4; Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 401-403 [Reputational incentives also encourage businesses to participate in open source projects. Contributing businesses can enhance the reputation and public relations by associating with the open source community].
[60] Lawrence Rosen, *Open Source Licensing: Software Freedom and Intellectual Property Law* (NJ: Prentice Hall, 2004), online: Rosen Law< https://rosenlaw.com/open-source-licensing-software-freedom-and-intellectual-property-law/> at 9-11; Stephen Levy, *Hackers: Heroes of the Computer Revolution* (Cal: O'Reilly Media, 2010); Delfanti, *supra* note 1 at 12-13 [The hacker ethics also include principles such as "access to computers should be unlimited and complete; all information should be free; mistrust authority; hackers should be judged by their hacking, not bogus criteria such as degrees, age, race, or position; you can create art and beauty on a computer; [and] computers can change your life for the better."]. Also, see discussions in Chapter Five below.
[61] Raymond, *supra* note 4 at 67.

Benkler raises several reasons why peer production or social production is an efficient model of information production.[62] Unlike proprietary development of knowledge, a commons-based project depends on volunteers sharing "expertise, resources, and knowledge", and the resulting information or cumulative technology is freely released into the world. Therefore, the commons-based model does not suffer from deadweight losses in market-based proprietary production, which prices goods above the marginal cost, because the commons resources are accessed without a royalty charge and do not require individual negotiations.[63] Moreover, it is efficient because free access to resources encourages people to reuse, modify and improve them to suit their needs, and it reduces unnecessary and wasteful duplication of efforts.[64] As for commercial contributors, they gain free volunteer labour to develop technology they can use to improve their business and create profit.[65] Free access to technology also encourages the development of complementary goods and services in the marketplace.[66] According to Benkler, another reason why peer production is more efficient than proprietary models of knowledge development is that peer production is better at allocating both human and technological resources for solving problems.[67] Peer production can efficiently allocate human resources because contributors can choose a project, and contributors know what knowledge they have and what jobs would be best for them. The self-selection of a project significantly reduces transaction

[62]Benkler, *Wealth of Networks*, *supra* note 2 at 107-116; Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 401-403.
[63]*Ibid*; William M Landes & Richard A Posner, *The Economic Structure of Intellectual Property Law* (Cambridge, MA: Belknap Press of Harvard University Press, 2003).
[64]Joly, *ibid*.
[65]*Ibid*.
[66]*Ibid*.
[67]Benkler, *Wealth of Networks*, *supra* note 2 at 107-116.

costs in innovation. Peer production is also efficient because the overall cost of information production is distributed among many contributors who share computing resources.[68]

The hacker ethos is an important element of the OSS movement. Hackers in OSS development are individuals with expert computer programming skills who believe that access to computers and technology should be widely available to allow people to take apart and study things that can teach them about how the world works and to use this knowledge to create improvements and new and interesting things.[69] Levy notes that hackers "resent any person, physical barriers, or law that tries to keep them from doing this."[70] Although software hacking was once tied to the anti-establishment ideology of the Free Software Movement, this culture has evolved to include a more pragmatic approach to open source software that separates the practice of open source software development from the anti-establishment ideology (see Chapter Five below).[71] Hacking includes actions that represent ideological and practical changes that reshape information production. Hence, some consider DIY bio as part of the hacker culture where participation is also a criticism of the existing establishment for information production.[72]

2.3 User Innovation Theory

According to von Hippel, the term "user innovator" refers to consumers or the end-users (both firms and individuals) of products and services offered in the market who develop new inventions or modify or improve existing goods to satisfy their needs (e.g. user improvements for

[68] *Ibid*; Sara Boettiger & Dan L Burk, "Open Source Patenting" (2004) 1 JIBL 221 at 221-225; David Vaver, *Intellectual Property Law*, 2d ed, (Toronto, ON: Irwin Law, 2011) at 223.
[69] Levy, *supra* note 60 at chap 2.
[70] *Ibid*.
[71] Raymond, *supra* note 4 at 68-71.
[72] Delfanti, *supra* note 1 at 2, 12-13, 111-112; Grushkin, Kuiken & Millet, *supra* note 7 at 8; Andrea Wiggins & Kevin Crowston, "Describing public participation in scientific research" (2011) Working Paper, Syracuse University School of Information Studies, online: Syracuse University < https://crowston.syr.edu/node/425>.

medical devices).[73] User innovation is distinguished from innovation from commercial manufacturers who invent to market and sell products and services. According to the user innovation literature, user innovation often occurs because there are heterogeneous user needs in society that are not being met by market solutions.[74] User innovation can also occur from individuals who experiment with existing technology out of curiosity and enjoyment.[75] Von Hippel notes that end-users are excellent downstream developers, and approximately 40% of end-users engage in user innovation.[76] User innovators invest their resources, time and money to find solutions to a problem, which also allows them to avoid the cost of hiring someone else to build a solution (i.e. agency costs).[77] For example, scientific researchers are user innovators when they develop, modify or improve research tools or equipment they need for conducting research experiments (e.g. "scientific instruments, agricultural equipment, and automated clinical chemical analyzers").[78] DIYers and OSS developers are also user innovators when they innovate in order to solve their or other people's problems. The DIY bio movement is largely considered a user-directed initiative, which seeks to address real-world problems or to fulfill one's curiosity,

[73]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 4-6, 115; Fred Gault & Eric von Hippel, "The prevalence of user innovation and free innovation transfers: Implications for statistical indicators and innovation policy" (2009) MIT Sloan School of Management Working Paper #4722-09 at 3.
[74]Von Hippel, *ibid* at 146-147.
[75] Raymond, *supra* note 4 at 106-110; G Hertel, S Niedner & S Herrmann, "Motivation of Software Developers in Open Source Projects: An Internet-Based Survey of Contributors to the Linux Kernel" (2003) 32:7 *Research Policy* 1159; Von Hippel, *ibid* at 4-5, chap 4.
[76] Stacey Kuznetsov & Eric Paulo, "Rise of the Expert Amateur: DIY Projects, Communities, and Cultures" (NordiCHI 2010: Extending Boundaries - Proceedings of the 6th Nordic Conference on Human-Computer Interaction, 2010), online: StaceyK.org <http://www.staceyk.org/hci/KuznetsovDIY.pdf>; Eric von Hippel & S N Finkelstein, "Analysis of Innovation in Automated Clinical Chemistry Analyzers" (1979) 6 Sci &Pub Poli 24 and Kwanghui Lim, "The Many Faces of Absorptive Capacity" (2000) Working Paper, MIT Sloan School of Management cited in von Hippel, *ibid* at 19-22, 79 [e.g. Medical personnel who use Technicon Corporation's automated clinical chemistry analyzers in medical diagnostic have freely revealed major improvements of the equipment and the clinical tests of the equipment processes].
[77]Von Hippel, *ibid* at 168.
[78] Boru Douthwaite, *Enabling Innovation: A Practical Guide to Understanding and Fostering Technological Change* (London, UK: Zed Books, 2002) at 2-42, 164-212 and Eric von Hippel, *The Sources of Innovation* (Oxford: Oxford University Press, 1988) cited in Hope, *Biobazaar*, *supra* note 21 at 244.

needs or desires rather than theoretical and abstract research questions that academic researchers tend to explore in the life sciences.[79]

Empirical studies show that user innovators often generate commercially attractive inventions (or their precursors) that others may also find useful.[80] Also, disruptive technology tends to come from user innovators rather than existing commercial manufacturers because user innovators tend to generate functionally novel products unavailable in the marketplace. On the other hand, incumbent manufacturers tend to choose cost-effective business tactics, such as incremental development of existing products to maximize profit from upstream R&D. User innovators are also more likely to develop products ahead of the market trend because end-users have more information about consumer needs that are unfulfilled by available goods in the market.

It was discussed above that open and cumulative knowledge development depends on contributors being able to access existing discoveries and R&D resources for subsequent development. Unlike the private sector that tends to propertize R&D outputs through IP rights and contracts, as noted above, participants in open innovation create open access to or "freely

[79] Heidi Ledford, "Life Hackers" (2010) 467 Nature 650; Golinelli & Ruivenkamp, *supra* note 3 at 153.
[80] See Sonali Shah, "Sources and Patterns of Innovation in a Consumer Products Field: Innovations in Sporting Equipment" (2000) Sloan Working Paper #4105, MIT Sloan School of Management, online Flosshub < https://flosshub.org/sites/flosshub.org/files/shahsportspaper.pdf>; Christian Lüthje, "Customers as Co-Inventors: An Empirical Analysis of the Antecedents of Customer-Driven Innovations in the Field of Medical Equipment"(Proceedings of the 32th EMAC Conference, Glasgow.2003); Christian Lüthje, "Characteristics of Innovating Users in a Consumer Goods Field: An Empirical Study of Sport-Related Product Consumers" (2004) 24:9 Technovation 683; PD Morrison, JH Roberts & Eric von Hippel, "Determinants of User Innovation and Innovation Sharing in a Local Market" (2000) 46 Management Science 1513; Nikolaus Franke & Eric von Hippel, "Finding Commercially Attractive User Innovation" (2003) Working Paper, MIT Sloan School of Management; von Hippel, *Democratizing Innovation*, *supra* note 4 at 4, chap 2; Ashish Arora, Wesley M Cohen & John P Walsh, "The Acquisition and Commercialization of Invention in American Manufacturing: Incidence and Impact" (2014) Working Paper 20264, NBER Working Paper Series [This empirical study of 6000 American manufacturing and service firms found that "of the 16% of the U.S. manufacturing firms that innovated (i.e., had introduced a new or significantly improved product to the industry) between 2007 and 2009, 49% report that their most important new product originated from an identified outside source"].

reveal" new discoveries, thus encouraging subsequent R&D and commercialization.[81] Von Hippel characterizes user innovators as often exercising "free revealing": voluntary sharing of privately funded and discovered innovations at no charge.[82] The user innovation literature explores possible explanations for this behaviour. Free revealing refers to voluntarily giving up all rights in the freely revealed information. The information is considered a public good, with everyone having equal access to it.[83] Free revealing can be performed by 1) releasing information into the public domain and 2) creating open access to information with no conditions attached to users to ensure the public-good status of the information.[84] The term "open access" is sometimes used outside of the user innovation literature to refer to free revealing.[85] Von Hippel notes that free revealing grants royalty-free access to users, but users may need to pay information delivery fees.[86] These include situations where recipients must pay the subscription fee to a journal or where recipients may need access to physical materials that enable the use of an invention. Nonetheless, when information is released into the public domain, anyone can appropriate the information. Therefore, once information is freely revealed, it becomes difficult for the initial user innovator to influence or control the direction of subsequent development.

[81] Clark D Asay, "Enabling Patentless Innovation" (2015) 74 Md L Rev 431 at 443-4.
[82]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 77-80. Also, see D Harhoff, J Henkel & Eric von Hippel, "Profiting from Voluntary Information Spillovers: How Users Benefit by Freely Revealing Their Innovations" (2003) 32:10 Research Policy 1753.
[83] Von Hippel, *ibid*.
[84] *Ibid* [According to von Hippel, open source software does not qualify as free revealing because "[s]ome conditions are attached to open source code licensing to ensure that the code remains available to all as an information commons. Because of these added protections, open source code does not quite fit the definition of free revealing". Von Hippel still considers open source software developers as user innovators when discussing the motivations for free revealing].
[85] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31; Ester van Zimmeren, "Clearinghouse Mechanisms in Genetic Diagnostics: Conceptual Framework" in Geertrui van Overwalle, Ed, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regime* (Cambridge: Cambridge University Press, 2009); Kapczynski, "Order without Intellectual Property Law", *supra* note 22.
[86]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 77-78.

Traditionally, two innovation models were used to describe innovation incentives in society and situations in which property rights are important to incentivize innovation: the private investment model and the collective action model. However, these models cannot adequately explain the motivation of some user innovators, such as OSS developers and some participants in socially produced biotechnology, to openly release valuable discoveries. Contrary to these traditional theories, the user innovation literature states that user innovators freely reveal an invention in society because they can gain sufficiently large private benefits, which are not diminished by free riding.[87]

According to the private investment model, inventors will be motivated to invest and innovate when they can generate profits from their inventions.[88] This assumption justifies the creation of IP rights in society because IP rights allow creators and innovators to create profits by excluding others from using their IP in the marketplace. IP rights encourage people to make private investments in R&D. In exchange, society bears the burden of IP monopoly, which can limit other citizens' access to IP-protected resources in society (see Section 3.3.1 below). Under the private investment model, innovators will try to avoid free revealing or uncompensated spillovers of proprietary information because such actions reduce their opportunity to create profits from the proprietary information. However, this model does not explain intentional free revealing or open sharing of proprietary information in society.[89] The private investment model does not explain what motivates participants in open and collaborative activities, such as OSS

[87] *Ibid* at 91; Carliss Baldwin & Eric von Hippel, "Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation" (2011) 22:6 Organization Science 1399.
[88] Harold Demsetz, "Towards a theory of property rights" (1967) 57 Am Econ Rev 347; Kenneth J Arrow, "Economic welfare and the allocation of resources for inventions" in R R Nelson, ed, *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton, NJ: Princeton University Press, 1962), online: NBER <https://www.nber.org/chapters/c2144.pdf>. Also, see von Hippel & von Krogh, *supra* note 4 at 212-213 and von Hippel, *Democratizing Innovation*, *supra* note 4 at 89.
[89] Von Hippel, *ibid* at 80.

development and DIY bio, to voluntarily and freely release new knowledge or innovation into the commons.

Another traditional theory is the collective action model, which describes the creation of a common pool of public goods (a public good being characterized by non-excludability and nonrivalry).[90] Public goods can be consumed by multiple users at once; one user's consumption does not bar another user's access to it. Under the collective action model, community members create common pool resources by giving up all of their rights in the goods released into the commons.[91] Unlike the private investment model, this model does not suffer from the social loss created by IP rights when IP rights interfere with access to innovation in society.[92] The main concern under the collective action model is how to motivate contributors to generate public goods because potential contributors can always wait for someone else to create public goods and free ride on it rather than making their own contributions.[93] Some scholars suggest that it is important to deploy appropriate recruiting strategies to avoid this problem.[94] Others suggest using social conditioning to deter free riding[95] (e.g. emphasizing group fate over individual fate) and using selective incentives to recruit contributors (e.g. special credentials assigned based on a contributor's efforts and skills or reputational rewards).[96] Collective action projects are best

[90] Mancur Olson, *The Logic of Collective Action: Public Goods and the Theory of Groups* (Cambridge, MA: Harvard University Press, 1967) at 14 cited in von Hippel & von Krogh, *supra* note 4 at 212-3; Paul Pecorino, "Olson's Logic of Collective Action at Fifty" (2015) 162 Public Choice 243 at 245.
[91] Von Hippel & von Krogh, *ibid*; von Hippel, *Democratizing Innovation*, *supra* note 4 at 89.
[92] Von Hippel & von Krogh, *ibid*.
[93] *Ibid*; Olson, *The Logic of Collective Action, supra* note 90; von Hippel, *Democratizing Innovation*, *supra* note 4 at 89 [Free riders engage in market activities with unauthorized imitations].
[94] P E Oliver & G Marwell, "The Paradox of Group Size in Collective Action: A Theory of the Critical Mass II" (1988) 53 Am Soc Rev 1, M Taylor & S Singleton, "The Communal Resource: Transaction Costs and the Solution of Collective Action Problems" (1993) 21:2 Poli & Soc 195 cited in von Hippel, *ibid* at 90; von Hippel & von Krogh, *ibid* at 215.
[95] M Schwartz & S Paul, "Resource Mobilization versus the Mobilization of People" in A D Morris & C McClurg, eds, *Frontiers in Social Movement Theory* (CT: Yale University Press, 1992) cited in von Hippel & von Krogh, *ibid*.
[96] P E Oliver, "Rewards and Punishment as Selective Incentives for Collective Action: Theoretical Investigations" (1980) 85 Am J Soc 1356 and D Friedman & D McAdam "Collective Identity and Activism: Networks, Choices, and the Life of a Social Movement" in A D Morris & C Clurg, eds, *Frontiers in Social Movement Theory* (CT: Yale

executed in small groups because selective incentives work best in small groups where people can easily monitor each other's contributions and adjust the selective incentives accordingly.[97] Scholars consider traditional academic research a collective action activity;[98] informal sharing of research in the research community depends on researchers being able to monitor other researchers to carry out reputational sanctions.

The collective action model still does not explain why contributors freely share proprietary information in open collaboration, such as OSS and the social production of science.[99] Contrary to the collective action literature, OSS and DIY bio projects typically do not actively recruit volunteer contributors.[100] Moreover, these projects may have small or large numbers of participants in loose-knit groups, where observing one another's activities may be difficult.[101] Also, possible free riding does not seem to discourage participation in OSS development and other commons-based projects.[102] OSS projects explicitly allow anyone to use and disseminate the source code for any purpose, including commercial uses, without royalty charges.[103]

Scholars have explored possible motivations behind why some user innovators like OSS developers and DIYers would publicly release valuable proprietary information they have discovered through private investment rather than propertizing it to generate profits.[104] Free

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University Press, 1992) cited in von Hippel & von Krogh, *ibid* ["Individuals may then gain private benefits from such credentials in the form of enhanced social relations, enhanced reputation, privileged access to social relations, and so on."].

[97] Olson, *The Logic of Collective Action, supra* note 90 at 43-52; Taylor & Singleton, *supra* note 94 and Elinor Ostrom, "A Behavioral Approach to the Rational Choice Theory of Collective Action" (1998) 92:1 Am Poli Sci Rev 1 cited in von Hippel & von Krogh, *ibid*.

[98] Von Hippel & von Krogh, *ibid* at 213.

[99] Von Hippel, *Democratizing Innovation*, *supra* note 4 at 90; von Hippel &von Krogh, *ibid* at 215.

[100] *Ibid*; Delfanti, *supra* note 1; Grushkin, Kuiken & Millet, *supra* note 7.

[101] *Ibid*.

[102] Von Hippel, *ibid*.

[103] See Chapter Five below.

[104] Von Hippel, *Democratizing Innovation*, *supra* note 4 at chap 6; K R Lakhani & Eric von Hippel, "How Open Source Software Works: 'Free' User-to-User Assistance" (2003) 32:6 Research Policy 923.

revealing in user innovation is economically sound because it is often the most practical choice for user innovators to disseminate their discoveries, and there are non-pecuniary and pecuniary benefits that outweigh free riding.[105] Hence, user innovators like OSS developers and DIYers may freely reveal privately funded new inventions or discoveries because free revealing does not represent a loss of benefit under the private investment model. Moreover, contrary to the collective action model, participants are motivated by private benefits that outweigh the benefits of free riders.

Free revealing may be preferred when people are eventually going to have access to an invention or information. Von Hippel notes that inventors in a field of endeavour have access to similar information to build on, and they can create substitutes from publicly accessible principles, outlines and other partially relevant information.[106] People who create user innovation using easily accessible resources and materials may fit this description. Von Hippel notes that free revealing is a practical choice in these circumstances because it is difficult for most user innovators (both individuals and firms) to prevent others from creating "direct or approximate imitation".[107]

Von Hippel notes that even if a user-generated invention is not easily substitutable, free revealing may still be a practical way for individuals and firms to disseminate innovation into the wider world.[108] Patent law protects new inventions. In exchange for publicly disclosing an invention, patentees can regulate all market activities related to their invention, including free riding. However, perhaps with the exception of pharmaceutical and chemical businesses that

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[105] *Ibid*.
[106]Von Hippel & von Krogh, *supra* note 4 at 216; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 10, 81.
[107] Von Hippel, *ibid* at 81-82; Edwin Mansfield, "How Rapidly Does New Industrial Technology Leak Out?" (1985) 34 J Industrial Econ 217 at 219-220 [This study of 100 businesses found that information related to development decisions were leaked to competitors within about 12 to 18 months and information about products and processes were leaked within a year.]; Von Hippel, *ibid* at 82-85.
[108] *Ibid*.

incur high R&D costs,[109] multiple survey studies show that patents in most industries do not offer adequate value to patentees.[110] Some innovators have expressed that patents cannot effectively exclude free riding or return royalties, and patents do not encourage more investment in R&D.[111] Also, the high cost of obtaining a patent and the delays from the patent application process make it impractical for some innovators to seek patent protection, such as new entrepreneurs, DIYers, open innovation communities, and small to medium-sized firms.[112] Firms may also choose to engage in free revealing if their R&D output is not patent-eligible, and freely revealing it does not benefit their competitors.[113] Therefore, von Hippel argues that other than in exceptional circumstances, free revealing for inventors does not necessarily result in a loss of significant profit.[114]

Furthermore, von Hippel notes that free revealing proprietary information is practical nowadays because it is easy to spread digitized information around the world over the Internet.[115] Nonetheless, user innovators can actively incur additional costs to disseminate their discoveries (e.g. free and open source software programmers writing documentation and fixing bugs before distributing software). According to von Hippel, this type of behaviour suggests that there must

[109] Statista Research Department, "Forecast on U.S. annual chemical industry R&D expenditures 2016-2020" (11 December 2015), online: Statista < https://www.statista.com/statistics/407851/forecast-for-annual-r-and-d-spending-in-chemical-industry-in-the-us/>; Lori Knowles, Westerley Luth & Tania Bubela, "Paving the road to personalized medicine: recommendations on regulatory, intellectual property and reimbursement challenges" (2017) 4 J L & Biosci 453.
[110] Ashish Arora, Andrea Fosfuri & Alfonso Gambardella, "Markets for Technology and their Implications for Corporate Strategy" (2000), online: SSNR <http://dx.doi.org/10.2139/ssrn.204848>; Wesley M Cohen, Richard R Nelson & John P Walsh, "Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)", NBER Working Paper 7552, online: NBER <https://www.nber.org/papers/w7552.pdf>. Also, Mansfield, *supra* note 107 and A Arundel, "The Relative Effectiveness of Patents and Secrecy for Appropriation" (2001) 30 Research Policy 611.
[111] *Ibid* [There are some high-tech business exceptions, such as IBM].
[112] Harhoff, Henkel, and von Hippel, *supra* note 82 cited in von Hippel, *Democratizing Innovation*, *supra* note 4 at 84 ["Obtaining a patent typically costs thousands of dollars, and it can take years"].
[113]Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76; Von Hippel, *ibid* at 85-88.
[114] Von Hippel, *ibid*.
[115] *Ibid*.

be some private benefit sufficiently large for a user innovator to incur the additional costs to freely reveal an invention and not be discouraged by possible free riding that can follow.

For instance, individual-inventors can gain both intrinsic and extrinsic non-pecuniary benefits by free revealing user innovation.[116] User innovators are motivated by non-monetary rewards to freely and openly share proprietary information. A person's intrinsic rewards from freely revealing valuable information may be sufficiently large to outweigh the activity's cost and encourage this behaviour.[117] The literature on commons-based activities emphasizes the intrinsic motivation of contributors as an important driver of these activities.[118] Intrinsic motivations arise from within the person.[119] One significant difference between institutional science and social production in biotechnology is that the latter relies on intrinsically motivated public participants who voluntarily contribute, for instance, as a way to express "creativity, curiosity, and enthusiasm".[120] Intrinsically motivated participants may freely contribute to a project to experience enjoyment, personal satisfaction and a sense of community.[121]

Moreover, non-pecuniary extrinsic benefits, such as enhanced reputation, education and improved market offerings, can encourage user innovators to freely reveal inventions.[122] As discussed above, open sharing in academic research and OSS development is encouraged by reputational rewards. Von Hippel notes that freely revealed research is used and cited more

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[116] *Ibid*.
[117]M Jordan Raddick et al, "Galaxy Zoo: Motivations of Citizen Scientists" (2010) 9 AER 010103-1; David J Coleman, Yola Georgiadou & Jeff Labonte, "Volunteer Geographic Information: The Nature and Motivation of Produsers" (2009) 4 Int J Spatial Data Infra R 332; Jeffrey P Cohn, "Citizen Science: Can Volunteers Do Real Research?" (2008) 58:3 BioScience 192 at 194.
[118] Raymond, *supra* note 4 at 110; von Hippel & von Krogh, *supra* note 4; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 6; Benkler, *Wealth of Networks*, *supra* note 2 at 92-99; Delgado, "DIYbio: Making Things and Making Futures", *supra* note 10; Ikemoto, *supra* note 10 at 543; Asay, "Enabling Patentless Innovation", *supra* note 81 at 442.
[119] Benkler, *ibid* at 94.
[120] Delgado, "DIYbio: Making Things and Making Futures", *supra* note 10; Ikemoto, *supra* note 10 at 543; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 4-6; Raymond, *supra* note 4 at 79.
[121]Von Hippel & von Krogh, *supra* note 4 at 216; Benkler, *Wealth of Networks*, *supra* note 2 at 94.
[122] See Jack Hirshleifer, "The Private and Social Value of Information and the Reward to Inventive Activity" (1971) 61:4 Am Econ Rev 561; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 86.

often,[123] whereas other scholars observed that IP rights do appear to interfere with the free flow of scientific knowledge since the citation rates declined after research published in scholarly articles become patented.[124] Then, scientists have more opportunities to gain reputational benefits from freely revealed research than scientists who have harder to access, IP-protected research. Furthermore, amateurs may contribute to open innovation projects and be motivated to participate in an R&D process when they think the overall experience will be educational.[125] User innovators can also benefit when commercial manufacturers increase the robustness and reliability of freely shared user innovations or offer related products and services (i.e. maintenance and repair).[126] User innovators may freely reveal to encourage existing manufacturers to improve and sell user innovation in the marketplace at a price no higher than the cost user innovators would have incurred to produce it themselves.[127]

Although profit-generating firms mostly operate under the private investment model whereby they disclose proprietary information only to earn profits, some firms can be motivated by alternative private benefits to freely reveal their innovation.[128] The free revealing of technology encourages wide use and adoption in the industry, creating positive network effects where technology's value goes up with more users.[129] For example, firms benefit from freely revealing technology when it becomes widely used or an informal industry standard because

[123]Von Hippel, *ibid* at 89.
[124] Fiona Murray & Scott Stern, "Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge: An Empirical Test of the Ant-Commons Hypothesis" (2005), Working Paper 11465, NBER Working Paper Series at.4.
[125] Von Hippel, *Democratizing Innovation*, *supra* note 4 at 85-88; Delfanti, *supra* note 1 at 119.
[126] Harhoff, Henkel & von Hippel, *supra* note 82 cited in von Hippel, *Democratizing Innovation*, *supra* note 4 at 87.
[127] *Ibid.*
[128]Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 78-79, 86-88 [An early example is the firms in the 19th century English iron industry that publicly revealed furnace designs with professional societies (the companies benefited by their proposed improvements). Other examples include freely sharing steam engines' improvements in the 1800s, IBM's support of open source software that they incorporate into their hardware products, and free revealing of automated clinical chemistry analyzers in medical diagnosis and sporting equipment].
[129]Von Hippel, *ibid* at 86-88.

businesses can still profit from selling subsequent versions of it or complementary or related products and services. Being the first to reveal an innovation can encourage wide adoption; therefore, this advantage encourages firms to share user innovation with the public without delays.[130]

Sometimes competing firms may cooperate and work together to create public access to privately funded innovation when those firms can jointly benefit from it.[131] Such arrangements can help firms eliminate duplication of efforts and the cost of accessing privately controlled upstream research resources.[132] For example, private sector organizations in biotechnology were willing to cooperate with academic researchers to create public access to upstream research tools in the HapMap Project, the Human Genome Project, the Single Nucleotide Polymorphism (SNP) Consortium and the Structural Genomics Consortium (SGC).[133] All contributors in these projects considered it necessary to prevent privatizing these upstream research resources to avoid the development of extremely fragmented upstream rights, which can burden all downstream developers.[134] Some firms may be motivated to join an open access research partnership or consortium because they may be able to exert greater influence in a particular research area to direct future development, to gain public funding or to increase public funding in the research area, and to benefit from the discoveries made by other researcher partners.[135]

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[130] *Ibid*.
[131] *Ibid*.
[132] *Ibid*; Rai, "Regulating Scientific Research", *supra* note 19 at 91.
[133]Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76; Rai, *ibid* at 112—115; Hope, *Biobazaar*, *supra* note 21 at 40; Boettiger & Burk, *supra* note 68 at 222.
[134]*Ibid*.
[135]Johan Weigelt, "The Case for Open-Access Chemical Biology"(2009) 10:9 EMBO Reports 941 at 943.

2.4 The Social Production of Biotechnology

In 1977, Everett Mendelsohn used the term "social production of science" to describe the production of scientific knowledge because it is an activity of human beings that requires action and interaction.[136] Therefore, Mendelsohn argued, scientific knowledge is fundamentally social knowledge. In recent years, the terms "social production" and "peer production" have often been used in the context of OSS to describe the open, decentralized, cumulative and cooperative development of software.[137] The newly emerging, commons-based, open and cooperative social production of biotechnology, such as the DIY bio movement, represents a transformation taking place in the life sciences.[138] These activities revive the traditional norms of academic research (i.e. the Mertonian norms) and try to apply the OSS development model and the hacking culture to scientific R&D.[139] New technologies aid this transformation by improving communication, R&D sharing and collaboration between citizens around the globe, creating better access to research tools and equipment, and increasing digitization and interdisciplinary research in biotechnology. These changes allow amateur scientists or DIYers who operate outside of corporate or institutional science to participate actively in scientific R&D, and DIYers can contribute to biotechnology in multiple ways. They can independently pursue and share self-funded DIY projects, participate in group discussions, and be part of collaborative R&D projects with other scientists, such as community projects, short-term collaboration in hackathons or massively collaborative crowdsourced citizen science projects. These actions can benefit society by improving access to science and research tools, increasing diversity and inclusivity in

[136]Everett Mendelsohn, Peter Weingart & Richard Whitley, eds, *The Social Production of Scientific Knowledge* (MA: Reidel Publishing Company, 1977) at 3-4.
[137]Aaltonen & Lanzara, *supra* note 2 at 1650; Benkler, *Wealth of Networks*, *supra* note 2 at 60.
[138]*Ibid*.
[139]Delfanti, *supra* note 1 at 2, 12-13, 111-112; Grushkin, Kuiken & Millet, *supra* note 7 at 8; Wiggins & Crowston, "Describing public participation in scientific research", supra note 72; Raymond, *supra* note 4 at 68-71.

biotechnology R&D, improving access to life science inventions in society, democratizing science and technology, promoting cooperation between people, and empowering citizens in a democratic society.

2.4.1 Technology and the Emergence of Social Production in Life Science

Modern technology in the information era is changing how science is performed in society.[140] Digital technology and other modern tools enable DIY bio and other social production of science in the twenty-first century. Open and cooperative science, such as DIY bio and crowdsourced science, emerged near the end of the last century, which coincides with the movement in academic research where some shifted away from patent-protected, proprietary R&D in the life sciences.[141] The Internet and other information and communications technologies (ICTs) have lowered the costs of both accessing and disseminating scientific information and organizing group discussions and collaborative R&D. These tools allow the participation of citizens and experts from other disciplines in the life science R&D. Open source software and hardware[142] and 3D printing offer DIYers with easy to access components for building larger projects, including research tools and equipment. Moreover, emerging technologies allow scientists to conceive new interdisciplinary approaches in science, such as bioinformatics, which applies computer technology to extract information from biological data, and synthetic biology, which combines biology, engineering and information technology.[143]

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[140] Delfanti, *ibid* at 32-34; Winnie Poncelet, "The onset of open biotech" (2017), online: Edgeryders <https://edgeryders.eu/t/the-onset-of-open-biotech/6606>.
[141] *Ibid*.
[142] The Open Source Hardware Association (OSHWA) defines "open source hardware" as "anything physical that has public source files", such as machines, devices, or other physical things. See online: OSHWA <https://www.oshwa.org/definition/>.
[143] Anne E Osbourn et al, "Synthetic Biology" (2012) 196 New Phytologist 671 at 671; Ikemoto, *supra* note 10 at 547; Opderbeck, "The Penguin's Genome", *supra* note 48 at 176, 185.

The Internet and ICTs improve access to science and allow like-minded individuals around the globe to network, share, organize and participate in open innovation communities. Today, scientists can access many online and offline sources that offer free and open scientific knowledge and information.[144] For example, biolabprotocols.com is a comprehensive life science network that publishes "protocols, methods, techniques, bioproducts and service, as well as other innovative life science technologies" gathered from the following sources: "published literatures, laboratory submissions, as well as individual experimental data".[145] Open access journals like the Public Library of Science (PLoS) and online archives and databases allow scientists to publicly share scholarly articles and research data. Blogs, DIY platforms (e.g. Makezine or Instructables) and other popular content hosting services, such as YouTube, GitHub, SourceForge, Thingiverse and Appropedia, are online tools for DIY science; these allow DIYers to self-publish and share independent or group projects. There are also online message or discussion boards and open science community websites where DIYers can contact and communicate with other scientists.[146] Openly sharing scientific content online allows other interested individuals to review, verify, reuse, modify and improve them. Individuals can use search engines to search and find openly published scientific information online, and DIY science websites and web tools help DIYers coordinate information production at a global level.[147]

The Internet, ICTs and software tools also allow scientists to crowdsource research resources and funding. Crowdsourcing taps into the private resources of volunteers who can be

[144] Poncelet, *supra* note 140.
[145]Online: BioLabProtocols <http://www.biolabprotocols.com/about-us.html>.
[146] E.g. The Polymath Project used online collaboration to solve math problems, at <https://gowers.wordpress.com/2009/01/27/is-massively-collaborative-mathematics-possible/>; Ciara Franzoni & Henry Sauermann, "Crowd Science: The Organization of Scientific Research in Open Collaborative Projects" (2013), online: Research Policy <http://dx.doi.org/10.1016/j.respol.2013.07.005> at 6-7.
[147] Benkler, *Wealth of Networks*, *supra* note 2 at 33.

reached online.[148] The Federal Community of Practice on Crowdsourcing and Citizen Science defines "crowdsourcing" as "a process of obtaining needed services, ideas, or content by soliciting contributions from a large group of people, and especially from an online community".[149] Wikipedia is a well-known example of a volunteer-based crowdsourced website, which relies on volunteers to contribute their knowledge and editing skills to develop the Wikipedia content.[150] Unlike traditional research, which takes place in laboratories by a small group of researchers, crowdsourced research tries to complete large or time-consuming research or problem-solving tasks by combining small independent contributions from a large number of public participants. Open and massively collaborative crowdsourced research projects (also known as citizen science or public participatory science) such as Foldit, eBird, Galaxy Zoo and SETI@Home have asked volunteers to contribute research funding, to perform problem-solving tasks, to collect and submit samples and data from local environments, and to share unused computing cycles on volunteers' personal computers.[151]

Open source software and hardware are important enabling tools in DIY bio and for other scientists to digitize research experiments and to build and customize research tools, equipment and machines at low costs. Lowering the cost of research tools and equipment can encourage greater participation in scientific R&D.[152] Traditionally, building a piece of automated research equipment, even one that performs simple tasks, has been a difficult (if not impossible)

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[148] Aniket Kittur et al, "The Future of Crowd Work" (Proceedings from CSCW '13: The 16th ACM Conference on Computer Supported Cooperative Work and Social Computing, 2013), online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2190946>.

[149] "Federal Crowdsourcing and Citizen Science", online: DigitalGov <https://www.digitalgov.gov/communities/federal-crowdsourcing-and-citizen-science/>.

[150] Aaltonen & Lanzara, *supra* note 2.

[151] Franzoni & Sauermann, *supra* note 146 at 1-2; Teresa Scassa & Haewon Chung, "Managing Intellectual Property Rights in Citizen Science: A Guide for Researchers and Citizen Scientists" (2015) Research Series Vol 3, Commons Lab, Woodrow Wilson International Center for Scholars; Online: The Pieris Project <http://www.pierisproject.org/> [Also, the Pieris Project ran a crowd-funding campaign for 30 days to collect the research funding of $6000 to build a toolkit for collecting samples].

[152] Grushkin, Kuiken & Millet, *supra* note 7 at 11.

undertaking for scientists in the life sciences because they do not usually have advanced programming and engineering skills necessary to program and build automated equipment and it is difficult to obtain such skills.[153] Scientists have been dependent on scientific equipment manufacturers.[154] Since these manufacturers were supplying research equipment to a small customer base of professional research labs, the price of research equipment remained high, and the equipment could not be accessed without first gaining access to wealthy research labs that can afford it.[155] Some DIYers have taken to purchasing used proprietary research equipment and machines from university labs or through a professional connection, rebuilding and customizing broken and used machines, and even stealing to use such research equipment.[156]

Open source software and hardware tools improve access to expensive and sophisticated research equipment, making it possible for hobbyists, students and even professional scientists with insufficient funding to build open source research tools and equipment. Scientists can purchase already assembled open source tools and equipment from an online vendor for a low price. Nowadays, DIYers can search online to find information about how to build research equipment, such as an open source Polymerase Chain Reaction or PCR machine, using easy to find materials. They can also search through online forums such as the PLOS Open Source Toolkit global forum[157] and Tekla Labs DIY Guide Library.[158] They can also look at offline sources, such as Joshua M. Pearce's *Open-Source Lab,* that have information about how to use OSS, 3D printing and open source microcontrollers to build and design personal research tools

[153] Joshua M Pearce, *Open-Source Lab: How to Build Your Own Hardware and Reduce Research Costs* (MA: Elsevier, 2014) at 59.
[154] *Ibid*.
[155] *Ibid*.
[156]Delfanti, *supra* note 1 at 122.
[157] Online: PLoS <https://channels.plos.org/open-source-toolkit>.
[158] Online: Tekla Labs <https://guides.teklalabs.org/>.

and equipment.[159] A popular open source hardware tool in the DIY or maker community like Arduino microcontroller (i.e. a programmable mini-computer that can automate functions in a machine) allows DIYers to build automated machines, such as medical devices, appliances and power tools.[160] For example, by combining Arduino with other pieces of hardware, DIYers have built research-grade environmental chambers for a significantly lower cost.[161] Since Arduino is an open source project, its hardware design and programming language are both openly available to allow anyone to use, modify and improve them. Open source software and hardware have the advantage of being flexible because anyone can use, modify and improve them for various situations and needs, and open source users give back to the commons by sharing any subsequent modifications or improvements with the world.[162]

3D printing technology is another useful tool for creating DIY research tools and equipment.[163] Since 3D printers replicate physical objects, they allow DIYers to print custom research tools or physical components for building larger research equipment and machines. DIYers can buy a 3D printer for approximately $2000.[164] RepRap, a low-cost open source 3D printer, is a popular tool in the maker community.[165] It is controlled by an open source microcontroller and is capable of printing plastic objects.[166] Individuals can also find multiple guides online on how to build variations of RepRap.[167]

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[159] Pearce, *Open-Source Lab*, *supra* note 153.
[160] Joshua M Pearce, "Building Research Equipment with Free, Open-Source Hardware" (2012) 337:6100 Science Magazine 1303. [Arduinos costs approximately $20 to $50 USD. It comes with open source software to program the hardware]; Pearce, *Open-Source Lab*, *ibid* at 60.
[161] Pearce, *Open-Source Lab*, *supra* note 153 at 71-93 [i.e. Polar Bear Open Source Environmental Chamber can be used in experiments that require temperature and humidity control. An environmental chamber is an important tool in biological and civil engineering experiments].
[162] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1072; Rosen, *supra* note 60 at 9-11.
[163] Pearce, *Open-Source Lab*, *supra* note 153 at chap 5.
[164] *Ibid*.
[165] Online: RepRap <https://reprap.org/wiki/RepRap>.
[166] Pearce, *Open-Source Lab*, *supra* note 153 at 96-97; *Ibid*.
[167] Pearce, *ibid* at chap 5; *Ibid*.

Advances in technology also allow interdisciplinary research that combines biotechnology with computer science and engineering. For example, bioinformatics involves applying advanced computer science to build, analyze and interpret biological data.[168] Bioinformatics technologies allow scientists to extract information from the large amount of biological data that accumulated since the late twentieth century.[169] It is applied in many research areas, such as "chemistry, genomics, brain mapping, pharmacology, proteomics and structural biology."[170] Software that extracts information from a large set of biological data significantly reduces the time it takes to solve biological questions.[171]

Another example is synthetic biology, which applies engineering principles to biology.[172] Synthetic biologists engage in discovering "new biological parts, devices and systems, and [redesigning] existing natural biological systems for useful purposes."[173] Examples of synthetic biology projects include programming bacteria to take photographs, to count the number of times cells split, or to form visible patterns.[174] Synthetic biology has applications in healthcare (e.g. creating accurate AIDS tests and new drugs for treating malaria) and the development of

[168] Opderbeck, "The Penguin's Genome", *supra* note 48 at 176, 185.
[169] Suneeta D'Souza, "Gene Meets Machine: Intellectual Property Issues in Bioinformatics" (2004) 12:2 Health L Rev 34.
[170] *Ibid* at 34.
[171] *Ibid*.
[172] Nielsen, *Reinventing Discovery, supra* note 1 at 10; Osbourn et al, *supra* note 143 at 671 ["Synthetic biology is the engineering of biology: the synthesis of complex, biologically based (or inspired) systems, which display functions that do not exist in nature. This engineering perspective may be applied at all levels of the hierarchy of biological structures – from individual molecules to whole cells, tissues and organisms. In essence, synthetic biology will enable the design of 'biological systems' in a rational and systematic way."].
[173] Ikemoto, *supra* note 10 at 547 citing Stephanie Joyce, Anne-Marie Mazza & Stephen Kendall, "Positioning Synthetic Biology to Meet the Challenges of the 21st Century*"* in Nat'l Research Council & Nat'l Acad. of Eng'g eds., Summary report of a six academies symposium series 2 (2013); "Synthetic Biology", online: Nature < https://www.nature.com/collections/fjabichgaf >.
[174] Arti Rai & James Boyle, "Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons" (2007) 5 PLoS Biology 389 at 389 citing A Levskaya et al, "Synthetic biology: Engineering *Escherichia coli* to see light" (2005) 438 Nature 441 and S Basu et al, "A synthetic multicellular system for programmed pattern formation" (2005) 434 Nature 1130.

industrial products such as biofuels.[175] Creating standardized biological parts is one of the primary goals of synthetic biology. For example, the BioBricks Foundation, which was established in 2006 by scientists and engineers, operates a registry of open access standard biological parts (i.e. blocks of genetic material, also known as "biobricks").[176] Scientists can synthesize and mix standardized parts in different combinations to produce new artificial biological devices and systems.[177] Standardization in synthetic biology allows more people to experiment with creating synthetic organisms because it lowers the requisite amount of scientific knowledge needed before one can design a synthetic biological system.[178] Hope notes that students learning synthetic biology do not always need biology backgrounds; some participants have studied "mechanical or electrical engineering or media arts and sciences."[179] Standardization also increases efficiency in developing biotechnology products.[180] Synthetic biology offers a novel interdisciplinary approach to experimenting with biological parts, and has the potential to enable a future in which DIYers practice sophisticated biotechnology experiments and produce a variety of bioengineered organisms.[181]

2.4.2 Open and Cooperative R&D in Biotechnology

Although the OSS movement has demonstrated that high-quality software can be produced through social production, it has been argued that open R&D outside of traditional institutional

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[175] Rai & Boyle, *ibid*.
[176] *Ibid* at 391; Online: Biobricks Foundation< https://biobricks.org/bpa/faq/>.
[177]Rai & Boyle, *ibid* at 389.
[178] *Ibid* [E.g. "A live polio virus 'created from scratch using mail-order segments of DNA and a viral genome map that is freely available on the Internet'"]; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 32; Aaron Dy, "Engineered Probiotics as Living Medicine", online: PLOS Synbio Community Blog <http://blogs.plos.org/synbio/2017/01/11/engineered-probiotics-as-living-medicine/>.
[179] Hope, *Biobazaar*, *supra* note 21 at 206-207.
[180] Rai & Boyle, *supra* note 174.
[181] Grushkin, Kuiken & Millet, *supra* note 7 at 18; Golinelli & Ruivenkamp, *supra* note 3; Ledford, "Life Hackers", *supra* note 79; Kuznetsov & Paulo, *supra* note 76.

science cannot generate meaningful innovation in biotechnology because biotechnology R&D requires access to expensive and specialized equipment, high investment, and scientists who have many years of formal education and training.[182] Nonetheless, recent developments and experiences contradict some of these presumptions about biotechnology R&D. As noted above, DIYers have been trying to improve access to research tools and equipment in biotechnology by sharing instructions on how to build open source versions.

Compared to OSS development, life science research may require more funds. However, Hope notes that the cost of biotechnology research can vary by research goals and the strategy used. [183] The amount of physical capital required to carry out a commons-based scientific research project depends on the research design. A scientific question can be approached with various strategies, and some problem-solving methods are more expensive than others. She notes that biotechnology research is "still remarkably cheap", and the cost of physical tools to carry out biotechnology research is falling rapidly.[184] Also, a significant portion of biotechnology research is performed on computers nowadays.[185] As noted above, developments in bioinformatics reduce biotechnology R&D costs. Crowdsourced projects, such as SETI@home, have demonstrated that highly computational biotechnology can also be carried out over a decentralized network with a large number of public participants who are willing to share computing and other research resources.[186] Crowdsourcing technology makes it possible for some biotechnology research to be

[182] Opderbeck, "The Penguin's Genome", *supra* note 48 at 182-4.
[183] Hope, *Biobazaar*, *supra* note 21 at 197-198.
[184] *Ibid*.
[185] *Ibid*.
[186] *Ibid* [Some types of research in biotechnology are performed entirely on computational tools, and these research projects can take advantage of the social sharing of computing resources like in open source software to solve scientific problems]; SETI@home, online: The University of California, Berkeley < http://setiweb.ssl.berkeley.edu/>.

designed as a cumulative, and sometimes interactive, project with a large group of contributors sharing the research cost.[187]

According to Hope, biotechnology can apply the peer production model of OSS because biotechnology research also has the requisite characteristics of the peer production process, namely cumulative development, modularity of a problem and granularity of individual tasks.[188] Petherbridge also notes that there are many variables in scientific research that can be adjusted to allow peer production.[189] The knowledge discovery process in scientific research already occurs cumulatively with peer review and verification, and modularity is already part of scientific research.[190] The modularization of a scientific problem allows multiple researchers to collaborate on a larger problem (e.g. sequencing of DNA).[191] Hope notes that modularity and granularity in scientific research depend on how researchers cast the problem and define its scope.[192] The cost of integrating and organizing multiple inputs can be mitigated by technological means, such as using OSS tools to capture, collect, store and analyze multiple inputs or using an online database to publish and record all communications between collaborating partners.[193]

Moreover, long-term formal education in the life sciences is not always a requirement before performing biotechnology research.[194] For example, Hope notes that the Human Genome Project allowed individuals with low-level training to carry out research tasks such as

[187] E.g. Foldit discussed in Savage, *supra* note 15; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 13; Benkler, *Wealth of Networks*, *supra* note 2 at 107-116; *Ibid.*
[188] Hope, *Biobazaar*, *supra* note 21 at 202; Petherbridge, *supra* note 20 at 363-366.
[189] Petherbridge, *ibid*.
[190] Hope, *Biobazaar*, *supra* note 21 at 202-5.
[191] *Ibid*.
[192] *Ibid* [The nature of the subject matter may limit how a problem can be modularized and divided into finely grained tasks, and the granularity of a scientific problem may be restricted by whether contributors have skills and formal education in scientific research to carry out particular research tasks].
[193] *Ibid* at 212.
[194] *Ibid*.

synthesizing DNA.[195] Participants with the skills to program can develop OSS research tools and contribute to bioinformatics research.[196] Engineers can contribute to biotechnology by developing hardware designs for research equipment.[197] As noted above, synthetic biology increases opportunities to experiment with biological systems for those who do not have an educational background in biology.

Still, some biotechnology projects may not be appropriate as a bottom-up, non-proprietary social production project for the following reasons: it needs high capital costs; it is a long-term project; the scientific problem is too abstract; and/or it requires expensive and costly regulatory testing for marketing.[198] On the other hand, some of these issues may be remedied by contracting out some R&D tasks to non-profit or commercial organizations (e.g. tasks that require centralized organization such as regulatory testing), finding sponsors, or partnering with bigger research institutions and life science businesses that can share research responsibilities and funding.[199]

2.4.3 Amateur Scientists in the Twenty-First Century

The scientific research community generally accepts that amateur contributions are important to scientific progress.[200] Today, amateur scientists can experiment with science in DIY projects and

[195] *Ibid* [The project "reportedly made substantial use of researchers trained through a six-month course at a local community college where they were taught how to synthesize DNA, make plasmids, transform bacteria, and extract the inserted DNA." Moreover, the project's UK branch recruited even less skilled people and taught them the necessary skills to work on the project].
[196] Opderbeck, "The Penguin's Genome", *supra* note 48 at 176, 185.
[197] Hope, *Biobazaar*, *supra* note 21 at 197-8.
[198] *Ibid* at 188-190.
[199] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1609 [e.g. open innovation communities can contract out some research tasks such as clinical testing to be done by a corporation selected through bidding].
[200]Kingsley Purdam, "Citizen Social Science and Citizen Data? Methodological and Ethical Challenges for Social Research" (2014) 62:3 Current Sociology 374 at 377; Petherbridge, *supra* note 20 at 360 [Ordinary skilled people are capable of developing new technology in life science that can serve as common research resources]; Michael J

organize and participate in online discussion groups, research events, research communities and collaborative projects. Amateur scientists or hobbyists who experiment with science for fun or apply biotechnology to solve real-world problems are also known as DIYers or DIY biologists, garage scientists, biohackers, and citizen scientists.[201] Commentators note that DIY bio participants are capable of contributing innovative ideas and producing technical, scientific, educational, and commercial achievements.[202]

The DIY bio movement started around 2000, and it has spread rapidly since 2010.[203] DIY bio is rooted in the American amateur science tradition.[204] Similar to OSS development, DIY bio projects are self-organizing and sustained by loosely-connected volunteers.[205] DIY bio consists largely of user-directed initiatives, and these projects are carried out outside of corporate and institutional R&D.[206] Following the hacker tradition in OSS development, DIY biologists also support open access to science and technology.[207] Both the North American and European versions of the DIYBio Code of Ethics promote open access to biotechnology and cooperative

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Madison, "Commons at the Intersection of Peer Production, Citizen Science, and Big Data: Galaxy Zoo" in Brett H Fischmann, Michael J Madison & Katherine J Strandburg, eds, *Governing Knowledge Commons* (New York: Oxford University Press, 2014) at 215-216 [e.g. Early citizen science examples include the original Oxford English Dictionary that was created with the contributions of thousands of volunteer lexicographers, William Whewell's 'great tidal experiment' in 1830 that had the help of volunteers collecting data in more than 650 locations, and Darwin's use of volunteer collected data to confirm his theory of evolution by natural selection]; Coleman, Georgiadou & Labonte, supra note 117 at 193.

[201]Golinelli & Ruivenkamp, *supra* note 3 at 153; Kuznetsov & Paulo, *supra* note 76; Delfanti, *supra* note 1 at 1.

[202] Grushkin, Kuiken & Millet, supra note 7 at 12; Thomas Landrain et al, "Do-It-Yourself Biology: Challenges and Promises for an Open Science and Technology Movement" (2013) 7 Systems and Synthetic Biology 115; Delfanti, *ibid* at 113.

[203]Grushkin, Kuiken & Millet, *ibid* at 5, 8.

[204] Delfanti, *supra* note 1 at 2; Grushkin, Kuiken & Millet, *ibid* at 5.

[205] Delfanti, *ibid* at 23; Grushkin, Kuiken & Millet, *ibid* at 6, 8.

[206] Delfanti, *ibid* at 2; Grushkin, Kuiken & Millet, *ibid* at 5; Delgado, "DIYbio: Making Things and Making Futures", *supra* note 10 at 66; Ikemoto, *supra* note 10 at 539, 543 [DIY bio occurs apart from biotechnology R&D conducted in "academic, corporate, or government spaces."].

[207] Delfanti, *ibid*; Grushkin, Kuiken & Millet, *ibid* at 15.

approaches to R&D.[208] These scientists often rely on self-funding, occasional sponsorship and the use of innovative fundraising such as crowdfunding to sustain their operations.[209]

Graduate students with science backgrounds founded the DIY bio movement, one of the largest networks of biotechnologists.[210] While DIY bio is considered to be amateur science, participants' scientific education and research experience vary from little to extensive.[211] Some DIYers have little or no scientific background or education, while others have undergraduate, graduate or doctoral degrees in life sciences.[212] According to a 2013 survey study of DIY bio contributors,[213] when compared to the general population, DIYers had more postsecondary education[214] and were younger on average.[215] Many DIYers are scientists who have access to academic, corporate or government labs.[216] Participants can have different goals and motives for making contributions to DIY bio or other open science projects, such as creating art by applying biotechnology, tinkering with existing technology or experimenting with genetics, and commercializing open science outputs.[217] Many DIYers are currently learning and experimenting with basic tasks in biotechnology (e.g. experimenting with bacteria and simple organisms) and dabbling in synthetic biology.[218] On the other hand, DIYers with engineering and programming skills have already made important contributions by creating open source software and hardware

[208] Online: DIY Bio < https://diybio.org/codes/>.
[209] Grushkin, Kuiken & Millet, *supra* note 7 at 22.
[210] Online: DIYBio < https://diybio.org/>.
[211] Grushkin, Kuiken & Millet, *supra* note 7 at 4, 6-7
[212] Ikemoto, *supra* note 10 at 541.
[213] Grushkin, Kuiken & Millet, *supra* note 7 at 6, 24 [An online survey was conducted for 3 months in 2013 of DIY participants reached through "the DIYBio.org message board, online forums at hackerspaces and community labs, and direct contact with DIYbio community leaders." At the time, the number of participants in the DIY bio was 3000-4000 people based on subscription to the DIY bio and the estimates of community labs. The survey received 359 responses, which is approximately 10% of the DIY bio community].
[214] *Ibid* at 6-7 ["19 percent have obtained a doctorate level degree (i.e. MD, PhD, JD), 27 percent have obtained a master's degree, and 37 percent have completed college."].
[215] *Ibid* ["15 percent are under 25 years gold, 21 percent are between 25-35 years old, 42 percent are between 35 and 45 years old, and 23 percent are 45 and older."].
[216] *Ibid*.
[217] *Ibid* at 4.
[218] *Ibid* at 18; Golinelli & Ruivenkamp, *supra* note 3 at 153.

research tools for biotechnology that can be made much cheaper than manufactured versions.[219] Delfanti notes that contributions within the DIY bio network mostly come from three categories of contributors: "young biologists, such as graduate or even undergraduate students; computer scientists and geeks who want to tinker with biology; and bioartists interested in applying the critical approach of DIY to biology."[220]

Delfanti notes that DIY bio participants once had struggled to be accepted into the larger scientific research community, but this is changing.[221] For example, although DIYers were not allowed to compete alongside the teams of undergraduate students in the 2009 International Genetically Engineered Machine (iGEM) Competition, an annual synthetic biology competition held by MIT, by 2012, the competition had become open to DIYers and entrepreneurs.[222] The iGEM Competition and the Urban Barcoding Project are science competitions that encourage students and DIYers to work with DNA technology.[223] These research events offer DIYers opportunities to experiment with new research resources, to contribute back to the science commons, to collaborate and network with other scientists, and to access funding or prizes that can support future DIY bio projects.[224] Some professional researchers and research institutions are also expanding more efforts to collaborate with non-traditional scientists and to encourage their R&D endeavours. For instance, some professionals aid DIY scientists by offering access to

[219] *Ibid* at 11, 15.
[220]Delfanti, *supra* note 1 at 116.
[221] Delfanti, *ibid* at 123; Grushkin, Kuiken & Millet, *supra* note 7 at 11.
[222] *Ibid*.
[223] Hope, *Biobazaar*, *supra* note 21 at 20; Delfanti, *ibid*.
[224] For example, the iGEM Competition provides participants with access to standard biobricks over the summer period and challenges them to design and build biological systems and to operate them in living cells. New biobrick parts discovered by participants in each competition are deposited to a publicly accessible repository for synthetic biology for future use. Online: iGem <https://igem.org/>; Linda J Kahl & Drew Endy, "A Survey of Enabling Technologies in Synthetic Biology" (2013) 7 J Bio Eng, online: Journal of Biological Engineering < http://www.jbioleng.org/content/7/1/13> at 3; Delfanti, *ibid* at 123.

research labs and allowing virtual connections to their lab equipment to run experiments.[225] Some researchers have created developer or research toolkits that can improve others' access to biotechnology.[226]

Grushkin et al. consider the term "Do-it-yourself" bio to be a misnomer; rather, this network should be called "Do-it-together" bio.[227] DIYers depend on other DIYers and scientists who have shared ideas, information, and other scientific resources, tapping into the pool of resources for DIY bio projects. Only a small percentage of respondents in the 2013 survey worked solely from home (approximately 8% of respondents).[228] Most DIY bio projects were conducted in labs accessible to a group of scientists who can observe DIYers' work, such as community labs, hackerspaces, and academic, corporate and government labs.[229] Also, many participants used more than one lab to conduct their experiments.[230] Even when DIYers operate solely out of home labs, they networked and shared scientific information and ideas with other scientists. They actively engaged in online discussions, published scientific experiments, instructions and discoveries to online platforms, and participated in DIY bio communities

[225]Jamil Salmi, "Study on Open Science: Impact, Implications & Policy Options" (Aug, 2015) Research & Innovation, European Commission, online: European Union < https://ec.europa.eu/research/innovation-union/pdf/expert-groups/rise/study_on_open_science-impact_implications_and_policy_options-salmi_072015.pdf> at 26.
[226] E.g. The GeneDesign Toolkit Project, see Sarah M Richardson et al "GeneDesign 3.0 is an Updated Synthetic Biology Toolkit" (2010) 38:8 Nucleic Acids Res 2603, online: NCBI <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2860129/>; Cornell University also provides toolkits for citizen science (http://www.birds.cornell.edu/citscitoolkit); Von Hippel, *Democratizing Innovation*, *supra* note 4 at 147-164.
[227] Grushkin, Kuiken & Millet, *supra* note 7 at 9; Morgan Meyer, "Domesticating and Democratizing Science: A Geography of Do-It-Yourself Biology" (2013) 18 J Material Culture 117 at 131 [Meyers also agrees that DIYers' relationship with others in the DIY science community is important. For example, "in order to set up a laboratory in a garage or basement, people depend on other people interested in do-it-yourself biology, on scientific institutions, the sharing of information, the circulation of objects, internet platforms, emails, donations, etc… you yourself have to be connected: the form of individualism that we observe is a sort of 'connected individualism', halfway between individual practices and group practices, the logics of autonomy and the logics of networks. While people might build their own laboratory at home, and might even do so in opposition to institutionalized science, they still need to tap into the emerging collectives of people, ideas and objects"].
[228] Grushkin, Kuiken & Millet, *ibid*.
[229] *Ibid*.
[230] *Ibid* at 7-9 [Also, almost 75% reported that they conduct DIY bio from more than one location].

through online and offline events.[231] For example, Instructables,[232] Make:[233] and SparkFun[234] are large DIY platforms where individuals can publish information about their scientific experiments, such as making and modifying wearable technology,[235] building a robot,[236] making tools and goods with a 3D printer,[237] building DIY medical devices such as blood pressure monitors,[238] isolating their DNA at home,[239] building low-cost homemade research tools, and hacking existing tools and equipment.[240]

Local community labs are volunteer-sustained organizations that promote DIY bio.[241] They are an important part of the DIY bio network. Local community labs provide online and offline gathering places for "[a]mateurs, inventors, activists, entrepreneurs, students, and anyone else" to share information, knowledge and research resources, to advocate for science, to learn from each other, and to communicate about and explore creative aspects of science.[242] These labs have also been described as DIY science communities, open community labs, hackerspaces for science and "science by the people".[243] Gallegos et al. note that community bio labs can be found in most major metropolitan cities of North America and Europe, and they are spreading around

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[231] *Ibid*.
[232] Online: Instructables<http://www.instructables.com>.
[233] Online: Make:<http://makezine.com/>.
[234]Online: Sparkfun<https://learn.sparkfun.com/resources>.
[235]Online: Instructables <http://www.instructables.com/id/Boot-Projectors/>.
[236]Online: Instructables <http://www.instructables.com/id/Robotic-Arm-Fish-Feeder/> and <http://www.instructables.com/id/Robotic-Drink-Mixer/>.
[237]Online: Instructables <http://www.instructables.com/id/Spring-Heel-Shoes-3d-Print/> and <http://www.instructables.com/id/3D-Printed-Digital-Night-Vision-The-OpenScope/>.
[238]Online: Make: <http://makezine.com/projects/make-29/diy-blood-pressure-monitor/>.
[239]Online: Make: <http://makezine.com/projects/home-molecular-genetics/>.
[240] Online: Sparkfun <https://learn.sparkfun.com/tutorials/tags/science>.
[241]Grushkin, Kuiken & Millet, *supra* note 7 at 5-8.
[242]Lisa Valikangas & Michael Gibbert, *Strategic Innovation* (NJ: Pearson Education, 2015) at 124-126; Online: GitHub <https://github.com/DIYScience/DIYScience>.
[243] Poncelet, *supra* note 140; Delfanti, *supra* note 1 at 20; Candice D Wilderman, "Models of Community Science: Design Lessons from the Field" (Presentation delivered at the Citizen Science Toolkit Conference, Cornell Lab of Ornithology, 20-23 June 2007), online: Citizen Science Central < http://www.birds.cornell.edu/citscitoolkit/conference/proceeding-pdfs/Wilderman%202007%20CS%20Conference.pdf/view> at 5.

the world.[244] Community labs around the world operate with vastly different goals, structures and levels of formality.[245] Many are largely user-directed, volunteer-sustained initiatives that operate independently as non-profit organizations.[246] Some community labs are overseen by public research institutions or academic researchers, such as Denver Biolabs, a community lab project hosted by the University of Colorado in Denver.[247] Community labs offer access to research tools, training, and gathering spaces to exchange information and resources, and some of these organizations offer access to professional-scale wet labs equipped with expensive research equipment for biotechnology.[248]

Furthermore, community labs host community research projects, which openly invite collaborators, and scientists with advanced education may participate as consultants.[249] These projects belong to the community: the community defines the R&D problem, designs the experiments, and collects, analyzes and interprets samples.[250] Community labs also offer entrepreneurs a space to explore their business ideas using biotechnology.[251] Some community labs work proactively to promote research safety among biohackers and to encourage responsible

[244] Jenna E Gallegos et al, "The Open Insulin Project: A Case Study for 'Biohacked' Medicines" (2018) 36 Trends in Biotech 1211, online: Cell Press Reviews <https://doi.org/10.1016/j.tibtech.2018.07.009> at 1212 [For example, GeneSpace is the first community bio lab that was started in 2009 in Brooklyn, New York. Other DIY bio communities in North America include ARC (Houston, TX), BioBridge (San Francisco, CA), BioCurious (Mountain View, CA), BOSSLab (Boston, MA), and LA Biohackers (Los Angeles, CA). Internationally, there are Lapaillasse in France, Biologigaragen in Denmark and MadLab in Manchester.]; Grushkin, Kuiken & Millet, *supra* note 7 at 5-8.
[245] Gallegos et al, *ibid*; Wilderman, *supra* note 243 at 5.
[246] Gallegos et al, *ibid*.
[247] *Ibid*.
[248] Poncelet, *supra* note 140; Delfanti, *supra* note 1 at 20; Wilderman, *supra* note 243 at 5.
[249]Wilderman, *ibid* at 3, 12-13 [E.g. some professional scientists and graduate and undergraduate students can participate in community projects as project consultants]; Andrea Wiggins & Kevin Crowston, "From Conservation to Crowdsourcing: A Typology of Citizen Science" (Proceedings of the 44th Hawaii International Conference on System Sciences – 2011) at 5.
[250]Wilderman, *ibid* at 5.
[251]Valikangas & Gibbert, *supra* note 242 at 124-126.

bio-innovation practices through codes of conduct and consulting with experts who can advise on safe research practice.[252]

For example, BioCurious is a large bio-hackerspace and a non-profit organization that initially started as a garage DIY-bio project in 2010 but has expanded over time by crowdfunding on Kickstarter. The organization has built laboratories for the public to experiment with biotechnology, and it adopted open innovation as an operational model to stimulate scientific inquiries among a diverse group of participants.[253] BioCurious has spawned multiple community projects: an open source DIY cell printer and microscope, bio-engineering milk protein, and sequencing cuttlefish RNA.[254] MadLab, a DIY bio group in Manchester, England, has experimented with DNA barcoding of sushi (for identifying the species of the fish sold at sushi restaurants),[255] a project that explores our environment and restaurant practices. Other community projects have explored "converting street food carts in Singapore into mobile public laboratories, experimental aquaculture in Indonesia, playing Pacman with bacteria and printing DNA with a modified inkjet printer."[256] Valkangas and Gibbert note that some research projects from community labs or open science communities are serious research that grew into award-winning projects.[257]

[252]*Ibid*.
[253]*Ibid*; Delfanti, *supra* note 1 at vi.
[254]Online: Biocurious <http://biocurious.org/projects/>; Delfanti, *ibid* at 20.
[255]Asa Calow, "Manchester's MadLab spends time with the FBI", *The Guardian* (18 June 2012) online: The Guardian <https://www.theguardian.com/uk/the-northerner/2012/jun/18/manchestermetropolitanuniversity-biology-diybio-madlab-fbi-california-conference>; Jacob H Lowenstein, George Amato & Sergio-Orestis Kolokotronis, "The Real Maccoyii: Identifying Tuna Sushi with DNA Barcodes" (2009) PLOS One <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0007866>.
[256] Calow, "Manchester's MadLab", *ibid*; Online: OpenWetWare <https://openwetware.org/wiki/DIYbio/FAQ/Projects>.
[257]Valikangas & Gibbert, *supra* note 242 at 126.

DIYers can also organize and participate in hackathons, which are intense collaborative events taking place over a short period, usually one or more days.[258] Hackathons originate from the software hacker community, and this collaborative development model has also been used for life science projects in recent years.[259] A hackathon is associated with the hacker culture, which promotes free and open source access to technology. For example, Science Hack Day events are organized worldwide, allowing scientists, marketers, designers, and computer programmers to collaborate on building something with science or workable prototypes within a short period.[260] Participants in a hackathon are usually organized into teams or groups which explore many lines of research inquiries or approaches within a given subject matter. Hackathons are a good way to bring together a group of people to brainstorm and solve difficult and interdisciplinary problems. These events are ideal for interdisciplinary projects because they encourage information exchange and active collaboration between individuals with different backgrounds. These events can bring together people who may not normally collaborate together. At the end of a hackathon, participants can produce outputs, such as ideas, concepts, prototypes, documents, and designs, to solve a given problem. For example, a hackathon organized in 2015 with participation from a startup company and a group of biohackers found a way to create a cheaper open source version of a digital microfluidics system sold for more than $40,000.[261] Hackathon participants may share their work at the end of the event by presentation, and hackathon organizers or the participants themselves may create public access to hackathon projects online.[262] Real-world

[258]Andre Bourque, "What is a hackathon, and why should you care?", *CIO Magazine* (25 January 2017) online: CIO < https://www.cio.com/article/3160704/what-is-a-hackathon-and-why-should-you-care.html>.
[259] Stoltzfus et al, "Phylotastic! Making tree-of-life knowledge accessible, reusable, and convenient" (2013), 14 BMC Bioinformatics 158); Peter B Nichol "Hacking the future of health at Yale", *CIO Magazine* (26 January 2017) online: CIO < https://www.cio.com/article/3161844/hacking-the-future-of-health-at-yale.html>.
[260]Online: Science Hack Day <http://sf.sciencehackday.org/>.
[261] Nina Papakonstaniou, "What happens at a microfluidics hackathon?" (2015), online: Waag <https://waag.org/en/article/what-happens-microfluidics-hackathon>.
[262]Joshua Tauberer, "How to run a successful hackathon", online: <https://hackathon.guide/>.

problems are often difficult to solve in the short period of a hackathon. There is also not enough time to test each submission during the event to verify that it works. Therefore, initial discoveries from these events may encourage participants to improve and expand their work as open science projects or commercial projects.[263]

Citizens can also voluntarily contribute to scientific research by participating in crowdsourced science or citizen science. As noted above, citizen science projects reduce the overall research costs by crowdsourcing research resources and distributing the workload between many volunteers.[264] Crowdsourcing allows project operators/managers to gain expensive and difficult to obtain research resources, such as human intelligence and insight, computing resources, many hours of manual labour, data, and physical samples.[265] Citizen science projects usually have project managers who design, setup and oversee the research process.[266] Currently, project managers are often professional researchers, although this is not a requirement.[267] Anyone, including DIYers, can design and setup crowdsourced research projects online to receive research input from the public. Sometimes, citizen science projects started and

[263]Alan Steele, "Who owns hackathon inventions"(2013), online: Harvard Business Review <https://hbr.org/2013/06/who-owns-hackathon-inventions>; Papakonstaniou, *supra* note 261; Denise Deveau, "After the hackathon: Five ways leaders can drive meaningful outcomes", *Financial Post* (29 November 2017) online: Financial Post <http://business.financialpost.com/executive/leadership/after-the-hackathon-five-ways-leaders-can-drive-meaningful-outcomes>.

[264] Anne Bowser, Andrea Wiggins & Robert D Stevenson, "Data Policies for Public Participation in Scientific Research: A Primer" (DataOne Public Participation in Scientific Research Working Group, August 2013), online: Cornell University <http://www.birds.cornell.edu/citscitoolkit/toolkit/policy/Bowser%20et%20al%202013%20Data%20Policy%20Guide.pdf> at 2; Katherine Xue, "Popular Science", *Harvard Magazine* (Jan-Feb 2014) online: Harvard Magazine <http://harvardmagazine.com/2014/01/popular-science>.

[265] Wiggins & Crowston, "Developing a Conceptual Model of Virtual Organizations" *supra* note 6; Wilderman, *supra* note 243 at 4-5; Wiggins & Crowston, "Typology of Citizen Science", *supra* note 249 at 1; Savage, *supra* note 15 at 13; FedCCS, *supra* note 11 [Individual citizen scientists may contribute to a project by "identifying research questions, making new discoveries, collecting and analyzing data, interpreting results, developing technologies and applications, or problem solving."].

[266] Wilderman, *supra* note 243 at 4-5 [Project managers can define the research question, its design and goals, and the scientific methodology; at the end of the project, they aggregate, analyze and interpret volunteer contributions].

[267] Wiggins & Crowston, "Developing a Conceptual Model of Virtual Organizations" *supra* note 6; Madison, supra note 200 at 215 ["Citizen science" also refers to "the contributions of nonprofessionals to the work of professional scientists" and it is a process where citizens participate in "*science* in some meaningful sense."].

managed by academic researchers become citizen-managed projects with ordinary citizens taking on the role of project managers as projects grow.[268] In citizen science projects, public participants may be asked to perform small modularized tasks that do not usually require participants to have special skills or advanced education in science, provide data or donate research resources. Public participants in these projects are like workers or "technicians" performing small, pre-defined and usually trivial tasks within larger research.[269] Sometimes hundreds or thousands of volunteers contribute to a citizen science project.[270] Projects may attract more volunteers to participate in citizen science when each contributor's workload and commitment to a project are small. Professionally organized citizen science can provide public participants with opportunities to actively participate in advanced scientific research, to actively collaborate and communicate with professional researchers, and to obtain scientific education and training.[271] Data sharing is generally encouraged in citizen science.[272] It should be noted that unlike the DIY bio movement, which promotes open sharing of R&D and cooperation and has been known to be associated with the hacking culture, not all citizen science projects may follow the open science model. Some citizen science projects may not create open access to the entire research process or research outputs.[273] Non-proprietary management of patentable outputs, which will be discussed in the following chapters, may be relevant to citizen science project managers who intend to share patentable research results openly.

[268] Raddick et al "Galaxy Zoo", *supra* note 117.
[269] Wilderman, *supra* note 243 at 10.
[270] Raddick et al "Galaxy Zoo", *supra* note 117.
[271] *Ibid*; Von Hippel, *Democratizing Innovation*, *supra* note 4 at 3, 85-88; Delfanti, *supra* note 1 at 119; Wiggins & Crowston, "Developing a Conceptual Model of Virtual Organizations" *supra* note 6.
[272] Wiggins & Crowston, "Typology of Citizen Science", *supra* note 249 at 1-2, 7.
[273] *Ibid*.

2.4.4 Benefits of the Social Production of Biotechnology

Social production activities in biotechnology can create scientific progress and public benefits. Open and cooperative social production in biotechnology can increase publicly available scientific information and knowledge in the commons and improve access to research tools and equipment for all types of scientists in both developed and developing nations. Therefore, open sharing in social production may encourage traditional and non-traditional scientists to produce R&D.[274] As noted above, open sharing in scientific R&D allows efficient knowledge discovery and improves the quality of the R&D outputs by enabling peer review. Also, as observed in OSS development, creating open access to socially produced biotechnology may encourage entrepreneurship and commercial activities to build around it.[275]

The DIY bio movement encourages diverse participants who may possess different skills, knowledge and resources to cooperate and solve real-world problems using science.[276] An open invitation to participate allows amateurs, artists, software programmers, engineers, professional researchers, entrepreneurs, and public and private sector organizations to give resources, time and brainpower for scientific R&D. This diverse membership is considered a significant benefit and the source of more creativity.[277] Diversity in science is becoming increasingly important as scientific problems are becoming complex and difficult to solve and require interdisciplinary approaches.[278] Social production activities in biotechnology also encourage inclusivity in science because these activities allow individuals with different skills and expertise and different levels

[274] David, *supra* note 20 at 21.
[275] Asay, "Enabling Patentless Innovation", *supra* note 81 at 443.
[276]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 9-10; Delfanti, *supra* note 1 at chap 1; Wiggins & Crowston, "Developing a Conceptual Model of Virtual Organizations" *supra* note 6 at 2; Nielsen, *Reinventing Discovery, supra* note 1 at 25-28.
[277]Valikangas & Gibbert, *supra* note 242 at 127; Stephen M Maurer, "Open Source Drug Discovery: Finding a Niche (or Maybe Several)" (2007) 76 UMKC L Rev 405.
[278] Von Hippel, *Democratizing Innovation*, *supra* note 4 at 9-10.

of scientific education, training and experience to contribute as much or little as they want in a scientific project of their choice.

Non-traditional scientists or DIYers can also benefit society by encouraging diverse R&D in biotechnology.[279] Their activities provide an alternative forum for scientific knowledge discovery away from market-oriented R&D. Social production in biotechnology and follow-on efforts may fill R&D gaps and raise awareness of research areas overlooked by academics and businesses in the past.[280] These activities can promote R&D to improve conditions in underserved markets and neglected research areas

Furthermore, the social production of science and emerging technologies can adjust the relationship between consumers and commercial manufacturers because they improve the consumers' ability to innovate and manufacture goods for their needs.[281] Social production in biotechnology may help citizens worldwide solve problems they face in their own communities by improving access to biotechnology and research resources.[282] These changes can pressure commercial entities to practice fair business in the marketplace, to produce more goods, and to avoid charging excessively high prices for products and services.

It is possible that as social production in biotechnology grows, citizens' access to important life science inventions may improve due to fair market practices and socially produced open biotechnology inventions. Life science inventions (e.g. environmental, agricultural and healthcare products) raise ethical and human rights issues as humanity's welfare depends on a wide and equitable distribution of goods that serve fundamental human needs.[283] For example,

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[279] Golinelli & Ruivenkamp, *supra* note 3 at 153-154.
[280]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 5; Delfanti, *supra* note 1 at 2; Valikangas & Gibbert, *supra* note 242 at 126.
[281]Von Hippel, *ibid* at 1; Katherine J Strandburg, "Patent Fair Use 2.0" (2011) 1 UC Irvine L Rev 265 at 288.
[282] Golinelli & Ruivenkamp, *supra* note 3 at 153-154.
[283] Anthony S Taubman, "Several kinds of 'should': the ethics of open source in life sciences innovation" in van Overwalle, *Gene Patents and Collaborative Licensing Models*, *supra* note 85 at 219; UN General Assembly.

genetic testing patents raise concerns about the equitable delivery of healthcare because they raise the cost of genetic testing for various diseases that may not be afforded by everyone.[284] Poor populations in developed and developing nations are most likely to be affected by stronger patent rights, which can pose access barriers to life science inventions.[285] Access to these inventions is important to allow people to exercise their fundamental human rights.

Open science and open innovation communities encourage the democratization of science and technology and cooperation between people in society. These activities rely on transparent processes and democratic decision-making.[286] These communities offer forums for like-minded individuals to gather, exchange valuable information and pursue shared goals. The transparency allows others to monitor these activities and encourage people to contribute. This process also allows contributors to influence the direction of a project towards meeting their needs, thereby increasing the democratization of science and technology.[287] Furthermore, open science and open innovation encourage people to cooperate with others and learn to work with others. Participants

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Universal Declaration of Human Rights, 217 (III) A. Paris, 1948, Article 27; UN General Assembly, International *Covenant on Economic, Social and Cultural Rights, International Covenant on Civil and Political Rights and Optional Protocol to the International Covenant on Civil and Political Rights*, 16 December 1966, A/RES/2200, Article 15; UN Educational, Scientific and Cultural Organisation (UNESCO), *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, Article 15 [These international laws recognize that there is an obligation to share scientific knowledge and people have the right to benefit from them]; Laurence R. Helfer & Graeme W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press, 2011) at 18; Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology" (2006), online: BIO-NICA < http://www.bio-nica.info/biblioteca/BIO2006BiotechGuide.pdf> at 124.

[284] Hope, *Biobazaar*, *supra* note 21 at 61.

[285] *Ibid*; Pedro Roffe, Christoph Spennerman & Johanna von Braun, "Intellectual property rights in free trade agreements: moving beyond TRIPS minimum standards" in Carlos M Correa, ed, *Research handbook on the protection of intellectual property under WTO rules* (Northampton, MA: Edward Elgar, 2010).

[286] Von Hippel, *Democratizing Innovation*, *supra* note 4; Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 402.

[287] Von Hippel, *ibid*; Benkler, *Wealth of Networks*, *supra* note 2 at 130; Golinelli & Ruivenkamp, *supra* note 3 at 161-162.

can develop a sense of community from joining these activities.[288] Increased cooperation between people may also increase the pace of innovation.[289]

Moreover, the social production of science is politically significant because it empowers citizens, enhancing their ability to exercise their rights in a democratic society.[290] Delfanti notes that some DIYers consider their participation in the DIY bio movement as politically significant because open science is a form of free speech. [291] Some DIYers consider DIY bio or biohacking as a protest against big bio's monopoly of the market. Moreover, the decentralized open development process allows more people to participate in public conversation.[292] Open science also allows a person to exercise freedom of thought and self-determination.[293] Benkler notes that "[t]he networked information economy makes individuals better able to do things for and by themselves"; therefore, individuals can better dictate their lives within a networked society.[294] For example, some DIYers have sequenced their children's genomes to figure out ways to help their illness.[295] Social production encourages individuals to use science to improve their lives rather than depend on institutional science and private industry.

2.5 Conclusion

Newly emerging open, cooperative and inclusive R&D such as the DIY bio movement establishes an alternative innovation environment in biotechnology. These activities have

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[288]Von Hippel & von Krogh, *supra* note 4 at 216; Benkler, *ibid* at 94.
[289]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 2, 11, 77.
[290]Golinelli & Ruivenkamp, *supra* note 3 at 161-162; Raymond, *supra* note 4; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1449.
[291]Delfanti, *supra* note 1 at 123-124.
[292] Benkler, *Wealth of Networks*, *supra* note 2 at 130.
[293] *Ibid*.
[294] *Ibid*.
[295]Amy Harmon, "My Genome, Myself: Seeking Clues in DNA" (17 November 2007), online: NY Times <http://www.nytimes.com/2007/11/17/us/17dna.html?action=click&contentCollection=Opinion&module=RelatedCoverage&region=EndOfArticle&pgtype=article; http://quantifiedself.com/2007/11/personal-genomics-my-daughters/>.

inherited the key elements from the open science norms and OSS development: non-proprietary development with volunteer contribution and open sharing of valuable information, knowledge and innovation to encourage cumulative open development. These activities encourage people to cooperate and combine intelligence, knowledge and other resources to explore biotechnology and solve real-life problems using biotechnology. According to the user innovation literature, inventors may be motivated to freely share self-funded inventions even when there is a risk of free riding because they can receive private benefits from freely revealing their inventions with others.

Advances in technology aid non-traditional and amateur scientists actively pursue and contribute to open biotechnology R&D outside of corporate and institutional science. They can pursue a variety of activities, choosing their own project and the level of commitment. DIYers can post self-funded DIY bio projects online, join discussion groups and community projects, participate in hackathons and other research events, and add to crowdsourced citizen science. Promoting these social production activities in biotechnology can benefit society in several ways: replenishing knowledge and research resources in the science commons, promoting diversity in biotechnology R&D, bringing public attention to neglected or new R&D areas, encouraging cooperation in society, improving access to life science inventions that may improve citizens' wellbeing, democratizing science and technology, and helping citizens exercise their political rights. The social production of biotechnology is still relatively new, with many DIYers exploring basic tasks in biotechnology. As these non-traditional R&D activities grow and produce increasingly advanced R&D outputs, they may conflict with patent-protected biotechnology. The following chapter will review the development of biotechnology patents and their effect on technological and social progress.

Chapter 3: Development of Biotechnology Patents

3.1 Introduction

A complex and dynamic patent landscape has emerged in biotechnology. Patent proliferation in biotechnology and increased propertization of upstream research resources can potentially delay progress by impeding access to upstream discoveries and increasing researchers' exposure to threats of patent infringement litigation. These developments raise the possibility that DIY bio and other commons-based biotechnology projects will also experience patent interferences that disrupt these activities and expose contributors and users of socially produced biotechnology to threats from patentees. This chapter examines biotechnology patent-related issues that can affect technological and social progress.

Since the late twentieth century, scholars have criticized patent law developments for strengthening patentees' economic rights and without adequately balancing the public interest and encouraging the rapid increase in biotechnology patents across the public and private sectors.[296] They argue that problems in patent law include: trade-focused upward IP harmonization through bilateral and multilateral treaties without an adequate balancing of economic and social welfare[297] and the expansion of patentable subject matter to include cumulative and complex technologies, such as software and biotechnology inventions. Still, multinational corporations in knowledge-intensive industries heavily lobby to strengthen patent rights to protect their commercial interests. This chapter will trace patent law developments at

[296] Helfer & Austin, *Human Rights and Intellectual Property*, *supra* note 283 at 31-42; Margaret Chon, "Intellectual Property and the Development Divide" (2006) 27 Cardozo L Rev 2821 at 2829–2839; Ruth L Okediji, "Public Welfare and the International Patent System" in Ruth L Okediji& Margo A Bagley, eds, *Patent Law in Global Perspective* (New York: Oxford University Press, 2014); Jerome H Reichman & Rochelle C Dreyfuss, "Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85.

[297] *Ibid.*

the international level and in the United States and Canada. While pro-patent advocates rely on economic justifications to argue for strong patent protection, critics argue that there is not enough evidence to understand how patents influence innovation in different industries. Economically motivated patent reform can also deter open innovation.

Moreover, researchers and developers may experience difficulty navigating the patent landscape in biotechnology due to fragmented and overlapping patent rights and difficulty ascertaining the scope of patent protection. Cumulative R&D activities in science and technology tend to flourish when information can be exchanged at low costs. However, these patent issues raise transaction costs and the chance of inadvertent infringement for patent users. Furthermore, aggressive and strategic enforcement of patents by commercial patentees and patent trolls can also raise the risk for potential infringers. Abusive use of patent rights excessively rewards patentees while disrupting product development and discouraging those who innovate in society. Patent law has limited exceptions to balance competing interests in society. Nonetheless, patent law provides no provisions to encourage and protect alternative innovation environments. Research or experimental use exceptions in many nations may not be broad enough to encourage a variety of activities in the social production of biotechnology. The research or experimental exception's scope varies by nation, it is often not extended to commercially motivated research, and many nations do not excuse unauthorized use of patented research tools. Scientists may also struggle to figure out the scope of the exception in relevant jurisdictions.

The shift to encourage public-private partnerships increased the proprietary management of biotechnology research resources in academic research. This development threatens the research sharing norms in the research community. Moreover, the proliferation of patents and related property rights in biotechnology may deter downstream R&D by blocking access to

upstream research tools. Scholars considered the possibility of the tragedy of the anticommons in biotechnology, which occurs when too many fragmented rights protect upstream technologies.[298] If so, innovation is stifled and resources become underused because the cost of securing access to all of the fragmented rights to access a resource becomes prohibitively high. Commentators also criticized biotechnology patents for causing detriment to citizens' welfare.[299] Healthcare and agriculture are two prominent industry sectors that engage in biotechnology R&D.[300] The existing patent landscape in biotechnology can cause inequitable access to healthcare inventions, interfere with global food security, and disrupt traditional agricultural practices in developing nations. Patent law can also fail society when patents interfere with DIYers who apply biotechnology to address real-world problems ignored by patent-driven R&D.

3.2 Patent Law Developments in Biotechnology

Patent rights are territorial rights that protect inventions, which means that inventors must file a patent application and obtain a patent from each jurisdiction in which they seek to enforce a patent.[301] After an inventor files a patent application with a national patent office, it goes through a rigorous examination process where a patent examiner determines whether the invention satisfies all of the statutory requirements in domestic patent law.[302] The Canadian *Patent Act* defines a patent-eligible "invention" as: "any new and useful art, process, machine, manufacture

[298] Michael A Heller & Rebecca S Eisenberg, "Can Patents Deter Innovation? The Anti-commons in Biomedical Research" (1998) 280 Science 698; Rebecca S Eisenberg, "Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research" (2008) 45:4 Houston L Rev 1059 at 1075.
[299] Taubman, *supra* note 283 at 220-222; Helfer & Austin, *Human Rights and Intellectual Property*, *supra* note 283 at 31-42.
[300] Hope, *Biobazaar*, *supra* note 21 at 53.
[301] Graham Dutfield, "The Limits of Substantive Patent Law Harmonization" in Okediji & Bagley, *supra* note 296 at 130.
[302] Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 603.

or composition of matter or any new and useful improvement [thereof]".[303] Thus, a patentable invention must qualify as one of the five patentable subject matters listed in this definition in Canada. Moreover, it must fulfill other statutory requirements, such as novelty, non-obviousness and utility.[304]

A patent owner is granted the exclusive right to control "making, constructing, and using the invention and selling it to others to be used" and engaging in these acts without the patent owner's permission is patent infringement.[305] The patent monopoly lasts for 20 years from the application filing date and allows an inventor to control all market activities that involve the patented invention within the patent term.[306] Patent law applies strictly, and patent infringement will be found even where an infringer had no knowledge of existing patents or any intention to infringe them.[307] Therefore, unlike copyright law, which has an independent creation defence, patent law does not excuse an infringer who uses a patented invention without copying or learning from a patent.[308]

Patents provide important IP protection in biotechnology. Biotechnology patents, especially for upstream research discoveries, appeared with the adoption of the economic policy promoting commercialization of government-funded research and the expansion of patent protection in the United States in 1980. The U.S.-led campaign by developing nations for a protectionist IP regime and upward harmonization of IP law at the regional and international

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[303] *Patent Act*, RS C 1985, c P-4, s 2 "Invention".
[304] *Ibid*; Rai, "Regulating Scientific Research", *supra* note 19 at 106-109.
[305] *Patent Act, supra* note 303, s 42.
[306] *Agreement on Trade-Related Aspects of Intellectual Property Rights* [TRIPS], 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (entered into force 1 January 1995), arts 28, 33 [According to Article 28, a patent owner can prevent a third party from "making, using, offering for sale, selling or importing" the invention. Article 33 defines the patent term as 20 years from the filing date]; *Patent Act, ibid* [Every patent grants "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used"].
[307] Vaver, *Intellectual Property Law*, *supra* note 68 at 375.
[308] *Ibid* at 271; Asay, "Enabling Patentless Innovation", *supra* note 81 at 434; Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614.

levels resulted in many nations having to adopt the higher patent standards of developed nations and to recognize the IP rights of developed nations. Patent law developments at the domestic and international levels since 1980 have encouraged the development of a complex patent landscape in biotechnology and increased privatization of research resources in biotechnology.

3.2.1 Early Developments in the United States

Biotechnology supported businesses began to develop and grew rapidly around the same time when pro-patent policies shifted the law. Biotechnology consists of techniques and industrial applications that use living organisms, their parts or derivatives.[309] Today, the term biotechnology is most often used in the sense of genetic engineering. Biotechnology supports product development in multiple industries, including the markets of healthcare and agriculture, food technology, industrial and environmental applications (e.g. biofuels and biomaterials), national security, and research tools.[310] Healthcare and agricultural biotechnology industries have received the most significant amount of private investment.[311]

[309] *The Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 69, Article 2 "Use of Terms" [This provision defines Biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify". This definition is also used to describe biotechnology inventions in s. 17.01 of CIPO, "Manual of Patent Office Practices (MOPOP)" (last revised April 2018), online: CIPO < https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html>].
[310] Hope, *Biobazaar*, *supra* note 21 at 52-54; Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283.
[311] Hope, *ibid* ["It is worth bearing in mind that the present pattern of investment is an outcome of historical contingencies as well as perceived technological potential; under different industry conditions—such as a full-scale open source revolution—other applications might become more prominent."].

The first genetically engineered organisms were created in 1973 by Herbert Boyer and Stanley Cohen, which translated into a successful commercial venture and a marketable product (i.e. the synthesis of human insulin in bacterial cells) when one of the researchers partnered with a venture capitalist to establish Genentech.[312] The success of this early venture encouraged the development of a biotechnology industry in the United States, with more than eighty new biotechnology businesses having formed by 1981.[313] The number of biotechnology businesses in the United States has increased rapidly since 1992, and the commercialization of biotechnology has spread globally.[314] The number of biotechnology patents rose exponentially in the United States between the 1980s to the 1990s.[315] The exponential rate of growth flattened out by 1998, but thousands of biotechnology patents are still issued each year in the United States and around the world.[316] The United States is still an important hub of biotechnology R&D, and many biotechnology patents are filed first in the United States.[317]

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[312] Hope, *ibid* at 32.

[313] "History of the Industry", online: BayBIO website <http://www.baybio.org/wt/home/Industry_Statistics>; Brigitte van Beuzekom & Anthony Arundel, *OECD Biotechnology Statistics 2009* (Paris: OECD, 2009); According to the "World Intellectual Property Indicators 2016", between 2005 to 2014, published patent applications worldwide in biotechnology grew from 38,550 to 50,423 and the number of applications in pharmaceuticals grew from 73,295 to 90,242. Moreover, medical technology, which includes medicines, vaccines and medical devices, is the field of technology with the fifth most published patent applications in 2016 (118,700). See online: WIPO < https://www.wipo.int/publications/en/details.jsp?id=4138> at 49-50.

[314] Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283 at 3 ["The biotechnology industry has mushroomed since 1992, with U.S. health-care biotech revenues increasing from $8 billion in 1992 to $39 billion in 2003."].

[315] Van Beuzekom & Arundel, *supra* note 313 at 70; Rai, "Regulating Scientific Research", *supra* note 19 at 109 ["in the period from 1980 to 1992, the number of patents granted per year to universities increased from fewer than 250 to almost 2700"]; Hope, *Biobazaar*, *supra* note 21 at 34-35 also citing Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283 at 5 ["In 1978 the USPTO granted fewer than 20 patents in the field of genetic engineering. By 1989 the total number of biotechnology patents being granted each year had risen to 2,160, increasing even further to 7,763 new patents in 2002. Despite a flattening out of the [exponential growth] curve since 1998, the average remains at more than 7000 new patents issued per year in the United States alone."].

[316] Biotechnology Industry Organization, *ibid*; Van Beuzekom & Arundel, *ibid* [Based on biotechnology PCT patent applications, the authors note that biotech PCT patent applications "decreased from more than 11500 applications in 2000 to 8700 in 2006"]; Walsh et al, "Effects of Research Tool Patents", *supra* note 51 at 293-94; S Tina Piper, "The Tools and Levers of Access to Patented Health Related Genetic Invention in Canada" (2009) 30 Wash U J L &Pol'y 43 at 44 [e.g. "Many valuable genetic technologies are patented, principally in the United

The United States was one of the developing nations that led the campaign to set the international patent norms in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) (see below). Also, the availability of patent protection for biotechnology and software inventions in the United States created pressure on other nations to offer the same patent protection for technological progress.[318] Thus, early pro-patent developments in the U.S. patent law has influenced other nations' patent law. In the United States, the pro-patent shifts began in the 1980s with the enactment of the *U.S. Bayh-Dole Act*,[319] the establishment of a specialist federal court, the Court of Appeals of the Federal Circuit (CAFC), to deal with patent appeals and a string of pro-patent case law.[320] The *Bayh-Dole Act*, enacted in 1980, was designed to promote a policy of encouraging commercialization of federally funded research results through private appropriation.[321] Before the *Bayh-Dole Act*, federally funded research was disseminated through government ownership or by releasing results into the public domain.[322] The *Act* allows funding recipients to retain the patent ownership of federally funded research results, provided that they act diligently to file patent applications and to promote commercial

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States and other jurisdictions. Over time, biotechnology patents on genetic invention have increased globally and encompass more and more of the genome. In the United States, for example, more than 13,000 biotechnology patents were granted in 2000, up from 2,000 in 1985. This demonstrates the rapid growth of patents on research tools that surround drug development"]; Matthew Herder, "Emerging Academic Scientists' Exclusionary Encounters with Commercial Law, Policy, and Practice" in B Courtney Doagoo et al, eds, *Intellectual Property for the 21st Century: Interdisciplinary Approaches* (Toronto, ON: Irwin Law, 2014) at 466 [In 2013, for every $100,000 federal research expenditures, Canadian institutions' patent filing rate was 0.042 (total patent filed =1025, federal research expenditure=$2.42billion) and the Americans had 0.0615 (total patent filed=24555, federal research expenditure=$39.9billion)]; Association of University Technology Managers, "AUTM Licensing Activity Survey: FY2013", online: Association of University Technology Managers <http://www.autm.net/resources-surveys/research-reports-databases/licensing-surveys/fy-2013-licensing-survey/>.

[317] Van Beuzekom & Arundel, *supra* note 313 at 71 [e.g. "The United States contributed to 41.5% of all biotechnology PCT patent applications in 2006."]; Piper, *ibid* at 58.

[318] Margo A Bagley, "Patent Barbarians at the Gate: the Who, What, When, Where, Why and How of US Patent Subject Matter Eligibility Disputes" in Okediji & Bagley, *supra* note 296.

[319] Chapter 18 – Patent Rights in Inventions Made with Federal Assistance, 35 U.S.C. §§ 200–12 (2000).

[320] Hope, *Biobazaar*, *supra* note 21 at 32-34; Rai, "Regulating Scientific Research", *supra* note 19 at 102-103.

[321] Rebecca S Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research" (1996) 82 Va L Rev 1663 at 1663-6.

[322] *Ibid*.

development of research discoveries.[323] By 1997, 70% of university patenting and licensing of federally funded research results in the United States had come from the life sciences.[324]

Then a trilogy of cases expanded patentable subject matter: *Diamond v. Chakrabarty* (1980)[325]*, Diamond v. Diehr* (1981)[326] and *State Street Bank & Trust Co v. Signature Financial Group* (1998).[327] Before the *Bayh-Dole Act*, case law focused on granting patent protection for new and useful applied technology rather than basic research discoveries. This distinction is based on the policy that scientists need access to the basic tools of scientific and technological work, such as natural phenomena, mental processes and abstract intellectual concepts.[328] Similarly, algorithms and mathematical formulas were also excluded from the patentable subject matter because they are like laws of nature.[329] Excluding the basic tools from the patentable

[323] *Ibid*; 35 U.S.C. §§ 202(a), (c); Rai, "Regulating Scientific Research", *supra* note 19 at 95.
[324] Council on Governmental Relations, 'The Bayh-Dole Act: A Guide to the Law and Implementing Regulations" (1 Oct 1999), online: COGR < https://www.cogr.edu/bayh-dole-act-guide-law-and-implementing-regulations> at 8 [A 1997 survey of the Association of University Technology Managers "reports that 70% of the active licences of responding institutions are in the life sciences"]; Charles R McManis & Brian Yagi, "Early stage patenting, the US Bayh-Dole Act and the anti-commons hypothesis" in Duncan Matthew & Herbert Zech, eds, *Research Handbook on Intellectual Property and the Life Sciences* (UK: Edward Elgar, 2017) at 207.
[325] *Diamond v. Chakrabarty,* 447 U.S. 303 (1980) at 309 [This case considered the patentability of a genetically modified living organism, an oil-slick devouring bacterium. The U.S. Supreme Court held that this invention was patentable and articulated the rule that "anything under the sun that is made by man" is patentable subject matter]; Rai, "Regulating Scientific Research", *supra* note 19 at 102 [This case "put to rest any lingering doubts about whether living materials could be patented"].
[326] *Diamond v. Diehr*, 450 U.S. 175 (1981) [SCOTUS granted patent protection for a process for curing synthetic rubber which relies on a well-known mathematical algorithm for calculating curing time. This case overruled *Parker v. Flook*, 437 U.S. 584 (1978) at 589, which had held that a mathematical algorithm is not patentable and the use of a mathematical algorithm is patent-eligible only if there is some inventive concept in its application. In *Diehr,* SCOTUS held that mathematical algorithms can be patented if it is applied for a particular use].
[327]*State Street Bank & Trust Co v. Signature Financial Group,* 149 F.3d 1368 (Fed. Cir. 1998) at 1373-4; Leo L Raskind, "The State Street Bank Decision: The Bad Business of Unlimited Patent Protection for Methods of Doing Business" (1999) 10 Fordham IP Med & Ent LJ 61[The Federal Circuit held that a business method, a practical application of mathematical algorithms, is patentable if it involves some practical application and produces a useful, concrete and tangible (UCT) result. The case opened the door for a flood of business method and software patent applications. The UCT part was overruled in *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q. 2d 1385 (Fed. Cir. 2008)].
[328] *Gottschalk v. Benson*, 409 U.S. 63 (1972) at 67 [SCOTUS rejected the patentability of a computerized method for converting binary code because patent protection does not extend to abstract scientific or mathematical principles and formula]; *Parker v. Flook*, *supra* note 326 at 589 [Applying the principle that mathematical algorithms are not patentable, the SCOTUS rejected patent protection for a method for calculating the limits during hydrocarbon catalytic conversion processes].
[329] *Ibid*.

subject matter preserves the public domain and makes them free to build with, leaving patents available for "useful arts" or "inventions with a practical use".[330]

However, the trilogy of cases expanded patent-eligible subject matter by permitting patents for genetically engineered living organisms as well as algorithms that produce a useful result even if they were not applied to or limited by particular physical elements or process steps.[331] These cases opened up patent protection to cumulative technologies like software and biotechnology inventions, making it possible to obtain patents on biotechnology inventions at a time when more researchers were able to seek patents on research results under the *Bayh-Dole Act*.[332] Also, they had a global effect on biotechnology patents due to the fact that the United States has the world's biggest market for biotechnology.[333]

Another significant development in U.S. patent law is the creation of the CAFC in 1982, a specialist court in the Federal Circuit that would hear all patent appeals.[334] Before the court was established, patent proponents in knowledge-intensive industries had argued that "the stronger patent rights created by a more uniform interpretation of patent law were necessary for economic growth and international competitiveness."[335] Extending the Supreme Court of United States' (SCOTUS) expansive approach in cases such as *Diamond v. Chakrabarty* (1980), the CAFC relaxed the statutory standards such as utility and non-obviousness, making it possible to patent

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[330] *Brenner v. Manson*, 383 U.S. 519, 532-36, 86 S. Ct. 1033, 16 L. Ed. 2d 69, 1966 Dec. Comm'r Pat. 74 (1966); Lionel Bently, "Introduction" in WIPO, Standing Committee on the Law of Patents, *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights,* SCP/15/3, 2 September 2010, online: WIPO< https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=141352> at 45.
[331] *State Street Bank*, *supra* note 327 at 1373; Richard Gold & Yann Joly, "The Patent System and Research Freedom: A Comparative Study" in WIPO, Standing Committee on the Law of Patents, *ibid* at 15-16.
[332] Hope, *Biobazaar*, *supra* note 21 at 33; Petherbridge, *supra* note 20 at 346.
[333] Peter Drahos & John Braithwaite, *Information Feudalism* (VA: Earthscan Publications Ltd, 2002) at 158.
[334] Rai, "Regulating Scientific Research", *supra* note 19 at 102-103 [The Congress had been motivated to remedy the problem of divergent patent case law and forum shopping that had resulted from patent appeals being heard by various regional federal courts of appeal. The single forum was seen as a way to increase the certainty of patent rights].
[335] *Ibid*.

incremental discoveries in upstream biomedical research.[336] The court also allowed patents on full gene sequences and purified or isolated forms of naturally occurring products even though these were basic upstream research that is far from having commercial applications.[337] The CAFC decisions strengthened the power of patent owners, as defendants were more likely to lose in patent infringement lawsuits. The number of patents held as valid doubled in the first five years of the court's operation, and more severe penalties were given to patent infringers.[338] These developments made patent rights more valuable in the United States, and the threat of patent infringement more effective against potential infringers. Rai notes that the CAFC's pro-patent stance also encouraged more patenting and "imaginative claiming strategies".[339]

The troubling aspect of these U.S. case law developments was that they encouraged researchers and firms to try to patent basic genetic research tools and gene fragments (e.g. expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs) and cell receptors).[340] Such patents would grant patentees substantial ability to influence all uses of patented research

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[336] Arti Rai & Rebecca Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine" (2003) 66 L & Contemp Probs 289 at 290 citing *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995) ["usefulness in patent law . . . in the context of pharmaceutical inventions, necessarily includes the expectation of future R&D"] and *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ["A general incentive [to try] does not make obvious a particular result."]; Rai, "Regulating Scientific Research", *supra* note 19 at 107-8 citing *Cross v. Izuka*, 753 F.2d 1040 (Fed. Cir 1985) at 1050, *In re Bell*, 991 F.2d 781 (Fed Cir 1993) and *Ex parte Deuel*, 33 USPQ2d 1445 (Bd. Pat. App. & Interf. 1993).

[337] Rai, *ibid* at 104 citing *Genentech, Inc v. Wellcome Found Ltd*, 29 F.3d 155 (Fed. Cir. 1994) [allowed patenting of a purified form of a naturally occurring protein] and *Scripps Clinic & Research Found v. Genentech, Inc*., 927 F.2d 1565 (Fed Cir. 1991) [permitted patenting of a purified form of a naturally occurring factor involved in the human blood clotting process]; Other cases that considered the patentability of gene sequences include *Genentech, Inc. v. Chiron Corp*., 112 F.3d 495 (Fed. Cir. 1997) and *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991).

[338] Rai & Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine", *supra* note 336 at 290; Hope, *Biobazaar*, *supra* note 21 at 34; Alexander E Silverman, "Intellectual Property Law and the Venture Capital Process" (1990) 5 High Tech LJ 157 at 162-3[e.g. upholding "stiffer penalties for infringement", especially greater damage awards for willful infringement]; Maureen A O'Rourke, "Toward a Doctrine of Fair Use in Patent Law" (2000) 100 Colum L Rev 1177 at 1178-9.

[339] Rai & Eisenberg, *ibid*.

[340] Rai, "Regulating Scientific Research", *supra* note 19 at 104-109 [e.g. Genome companies, such as Incyte Inc. and Human Genome Sciences, Inc., have filed broad patent applications on thousands of gene fragments (ESTs), the full gene and future uses of the gene]; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 36 [The authors anticipate the trend of patenting at earlier stages of the biotechnology research to continue; "Stem cell technology, synthetic genomics and nanobiotechnology are pushing this trend further."].

tools or all future research that uses patented fragments.[341] The establishment of a specialist federal court and a string of early pro-patent case law encouraged the development of patents in upstream biotechnology research results that do not have clear and narrow commercial applications.

3.2.2 International Developments

At the international level, the upward harmonization of IP law through IP and trade treaties required nations to adopt the high IP standards of developed nations.[342] This agenda seeks to achieve stronger IP rights and more uniform IP law across nations despite different levels of technological and economic development as well as different historical backgrounds of the nations. Prior to the TRIPS, there were few limitations on the patentable subject matter at the international level, allowing nations to exercise greater flexibility to define the patentable subject matter and exclusions in domestic patent law to serve their own policy interests.[343] Since TRIPS, most domestic substantive patent laws share many similarities because TRIPS sets the minimum patent standards that must be implemented by nations who are members of the World Trade Organization (WTO).[344] The United States headed the campaign for stronger IP protection in TRIPS, which benefits developed nations that lead in innovation and large businesses that

[341] Rai, *ibid* citing *Cross v. Izuka*, *supra* note 336 at 1050 [The court permitted patenting of a new compound by accepting a lower utility standard, which can be satisfied if there is a probability that in vivo testing would be successful]; Heller & Eisenberg, *supra* note 298 at 699.
[342] Roffe, Spennerman & von Braun, *supra* note 285; Okediji, "Public Welfare and the International Patent System", *supra* note 296 at 28.
[343] Bently, "Introduction", *supra* note 330 at 18- 19 [The only limitation in the *Paris Convention* was in Article 4, which stated that "[t]he grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from domestic law."].
[344] Dutfield, *supra* note 301 at 132; O'Rourke, *supra* note 338 at 120; Also, *Patent Cooperation Treaty*, 19 June 1970, TIAS 8733, 28 UST 7645, 9 ILM 978 [The PCT creates a uniform procedure for inventors wishing to file patent applications in multiple jurisdictions].

secured their strong market position using large IP portfolios.[345] Okediji notes that TRIPS shifted the global patent norms "from a benign tolerance of domestic public interest tenets to an explicit restraint of such interests at the national level."[346]

The upward harmonization of IP law is problematic for developing and least-developed nations because it forces these nations to adopt high IP standards even when they lack the infrastructure to support a strong IP regime.[347] The upward harmonization of patent law forces developing nations to recognize the IP rights of developed nations. Such an IP regime does not maximize the public benefit for these nations because it does not necessarily suit their culture, politics or economic conditions.[348] IP owners in developed nations can block developing nations' opportunities to address domestic needs by copying technologies or accessing knowledge.

For example, Article 27 of TRIPS expands patentable subject matter by requiring nations to make patents available for inventions in all fields of technology subject to a few exceptions (see below).[349] This provision achieves substantive harmonization of patentable subject matter among WTO nations.[350] Before TRIPS, developing nations used subject matter exclusions in domestic patent law to address the nations' needs. Post-TRIPS, developing nations are no longer able to exclude traditionally unpatentable subject matters from patent law, such as process and product patents in pharmaceuticals, chemicals and foods, which have allowed these nations to maximize access to medicine and food before TRIPS.[351]

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[345] Dutfield, *supra* note 301 at 127.
[346] Okediji, "Public Welfare and the International Patent System", *supra* note 296 at 2.
[347] Roffe, Spennerman & von Braun, *supra* note 285.
[348] *Ibid*; Okediji, "Public Welfare and the International Patent System", *supra* note 296 at 15.
[349] TRIPS, *supra* note 306, art 27.
[350] Bently, "Introduction", *supra* note 330 at 23 ["from the outset …the extension of patentability, particularly to pharmaceuticals…was a major objective of the proponents….The very existence of the TRIPs Agreement can probably be attributed to the active lobbying of the pharmaceutical industry"].
[351] Bently, *ibid* at 31, 54; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 27 [For example, like many developing nations before TRIPS, India had excluded pharmaceutical products from patent protection to maintain a strong generic drug manufacturing industry. Post-TRIPS, India changed its patent law in

There are flexibilities in TRIPS that allow nations to try to implement domestic patent law to satisfy their own developmental needs.[352] Articles 7, 8 and the preamble of TRIPS state the treaty's underlying objectives and principles, which are relevant for interpreting other provisions in TRIPS.[353] A group of developing nations strongly pushed for the inclusion of the language in Article 7, which recognizes following a balanced approach to IP law.[354] Thus, nations can promote innovation growth through IP law while limiting the negative consequences of IP law on national economic and social welfare. Furthermore, Article 8 of TRIPS expressly authorizes nations to exercise discretion to adopt necessary measures to achieve several public policy objectives, such as public health, economic and technological development and curtailing the abuse of IP rights, as long as the measures are consistent with the provisions of TRIPS.[355]

Article 27(2) and (3) of TRIPS explicitly allow nations to create exclusions in domestic patent law on the grounds of *ordre public* or morality[356] as well as exclusions for certain biological inventions, such as diagnostic, therapeutic and surgical methods to treat humans or animals and plants and animals and essential biological processes for the production of plants and animals.[357] For example, many European nations include a list of the excluded patentable

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2005 to offer patent protection for products in all fields of technology. *The Patents (Amendment) Act*, 2005 No. 15 of 2005].

[352] Bently, *ibid* at 23; Dutfield, *supra* note 301.

[353] Panel Report*, Australia – Tobacco Plain Packaging (Cuba)* (2018), WT/DS441/R, WT/DS441/R/Add.1, and WT/DS441/R/Suppl.1 at para 7.2302; Carlos M Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (Oxford, UK: Oxford University Press, 2007) at 93.

[354] TRIPS, *supra* note 306, art 7; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 29.

[355] TRIPS, *ibid* at art 8; Herder & Gold, *ibid*.

[356]TRIPS, *ibid* at art 27(2) ["including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."]; *Convention on the Grant of European Patents*, October 5, 1973, 13 INT'L LEGAL MATS. 268 (1974), Art 53 [The European Patent Convention].

[357]TRIPS, *ibid* at arts 27(2) &(3); Bently, "Introduction", *supra* note 330 at 25; Also, Article 73 of TRIPS allows nations to exclude armaments and nuclear technology; *EC Biotechnology Directive* Art 6(2) also prohibits patenting on the basis of contrary to *ordre public* or morality on inventions such as processes for cloning humans, processes for modifying the germline genetic identity of humans, the use of human embryos for industrial or commercial purposes, and certain animals; Bagley, "Patent Barbarians at the Gate", *supra* note 318 at 151; Graham Dutfield, Lois Muraguri & Florian Leverve, "Exploring the flexibilities of TRIPS to promote biotechnology in developing

subject matter under the grounds of *ordre public* and morality, including biotechnological inventions such as the "human body, at the various stages of its formation and development" and "uses of embryos for industrial purposes".[358] Furthermore, TRIPS does not define "technology" under Article 27(1), which extends patent protection to inventions in "all fields of technology". Thus, some have questioned whether "computer programs or animals or higher life-forms or isolated genes or cells" even fall within the definition of "technology" under Article 27(1) of TRIPS.[359] Some argue that nations can exclude non-technological discoveries from the patentable subject matter, such as "scientific theories, mathematical methods, aesthetic creations, methods of performing mental acts and methods of doing business".[360]

Developing nations have expressed their discontent with the development of international patent law post-TRIPS and have demanded global IP reform through multiple international venues.[361] Non-governmental organizations, inter-governmental organizations and transnational pressure groups have also raised their concerns about the negative consequences of IP law on human welfare.[362] These efforts have at least resulted in the adoption of the *Doha Declaration on the TRIPS Agreement and Public Health*[363] , which affirms TRIPS flexibilities for nations to

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countries" in Correa, ed., *Research Handbook on the Protection of Intellectual Property under WTO Rules*, *supra* note 285 at 570-585.

[358] EC, *Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, O.J. Legislation (1998) No L213 at 13, Articles 5(1) and 6(2)(c); Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 26.

[359] Bently, "Introduction", *supra* note 330 at 23-4; Bagley, "Patent Barbarians at the Gate", *supra* note 318.

[360] Bently, *ibid*.

[361] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 25; Laurence R. Helfer, "Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking" (2004) 29 Yale J Int L 1 at 81-82.

[362] Ruth L. Okediji, "History Lessons for the WIPO Development Agenda", in Neil Weinstock Netanel, ed, *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford University Press, 2009) at 139-140.

[363] WTO, *Declaration on the TRIPS Agreement and Public Health* [Doha Declaration], WT/MIN(01)/DEC/W/2 (2001).

circumvent TRIPS in order to create better access to essential medicines.[364] WTO members also agreed to amend TRIPS with Article 31bis based on the *Doha Declaration*, although it is the only amendment to TRIPS to date.[365] Moreover, developing nations have proposed and supported the adoption of a development agenda by the World Intellectual Property Office (WIPO), which includes recommendations to protect the public domain and to close the digital divide.[366] Furthermore, developing nations have challenged international patent law in other international venues, such as the World Health Organization (WHO), to try to supplement the law in regards to "biodiversity, plant genetic resources, public health, and human rights."[367]

Presently, there are still some differences in domestic patent regimes since each nation is responsible for implementing and enforcing the TRIPS obligations under domestic patent law. These include different wordings and provisions in national patent statutes that implement the TRIPS obligations and judicial interpretation of the patent legislation by domestic courts.[368] Nonetheless, nations can struggle to take full advantage of TRIPS flexibilities or to make changes to the international patent norms set by the TRIPS Agreement.[369] Commentators note that reforming domestic patent law to improve national welfare is difficult even for powerful

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[364] *Ibid* at paras 4-5 [The *Doha Declaration* states that "the TRIPS Agreement does not and should not prevent [WTO] Members from taking measures to protect public health." The flexibilities in TRIPS that can be used for this purpose include the customary rules of interpretation of public international law, the right to grant compulsory licences (subject to the conditions in Article 31 of TRIPS), the right to determine what constitutes a national emergency or other circumstances of extreme urgency, and the right to establish a national regime for the exhaustion of IP rights].

[365] TRIPS, *supra* note 306, art 31bis [This provision allows nations with the capability to produce generic medicines to export them under compulsory licensing to the least developed nations that lack this capacity].

[366] "WIPO Development Agenda: Background (2004-2007)" online: WIPO <https://www.wipo.int/ip-development/en/agenda/background.html>; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 25-26 ["the Development Agenda exemplifies the shift to a broader understanding of the role of IP systems in developing countries."].

[367] Herder & Gold, *ibid*; Helfer, "Regime Shifting", *supra* note 361 at 81-82; WHO, "The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property", online: WHO <https://www.who.int/phi/implementation/phi_globstat_action/en/>.

[368] Herder & Gold, ibid [e.g. the patent statutes of European nations include a list of excluded patentable subject matter which is not part of the U.S. patent law. Also, as noted above, EU *Directive 98/44/EC on the legal protection of biotechnological inventions* lists excepted biotechnology inventions for "*ordre public*" or "morality", such as human body and use of human embryos for industrial purposes].

[369] Okediji, "Public Welfare and the International Patent System", *supra* note 296 at 9.

governments, such as the United States because there are institutional incompetence and heavy lobbying from knowledge-intensive businesses invested in the current patent system to maintain their dominant market presence.[370] Developing and least-developed nations may be pressured or bound by bilateral or multilateral trade treaties that require them to implement higher patent standards (also known as TRIPS Plus Standards), which reflect the trade-focused IP standards of developed nations.[371] TRIPS Plus Standards can limit nations' actual use of TRIPS flexibilities.

Moreover, Drahos notes that the administration of developing nations' patent offices is influenced by the patent offices of the United States, Europe and Japan (i.e. the Trilaterals) due to years of technical assistance being provided by the Trilateral patent offices.[372] Drahos notes that this practice has allowed trust to build between the assistance-giving and the assistance-receiving patent offices, which encourages patent examiners in developing nations to look to the decisions of the Trilateral patent offices to rule on a patent application.[373] Such practice results in the patent offices of developing nations (i.e. technical assistance-receiving nations) making decisions about domestic patents to benefit the interest of the Trilaterals rather than achieving national policy objectives.[374] The years of building trust allow the Trilaterals to impose a

[370] Okediji, *ibid*; Hope, *Biobazaar*, *supra* note 21 at 94-96.
[371] Okediji, *ibid* at 29, 35; Roffe, Spennerman & von Braun, *supra* note 285 [Regional and bilateral free trade agreements expand the minimum standards of TRIPS in areas such as public health and patents on life forms]; Bently, "Introduction", *supra* note 330 at 28. [The U.S., EU and Japan frequently encourage TRIPS Plus standards, which can require patents for plants and animals and broader medical patents]; Daniel J Gervais, "Patentability criteria as TRIPS flexibilities: the examples of China and India" at 337-339 and Srividhya Ragavan, "Diverse Harmonization: India example" at 372-3 in Okediji & Bagley, *supra* note 296 at 542; Pedro Paranagua, "Understanding the Brazilian patent reform" in Matthew & Zech, eds, *Research Handbook on Intellectual Property and the Life Sciences*, *supra* note 324.
[372] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 24-25; Peter Drahos, "'Trust Me': Patent Offices in Developing Countries", online: SSRN <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1028676 > at 3.
[373] Drahos, *ibid* at ss 2 & 3.
[374] Drahos, *ibid* at 4, 16-17.

significant influence on the development of patent examination standards at the international level.[375]

3.2.3 Biotechnology Patents in Canada

Two major Supreme Court of Canada (SCC) cases have considered the patentability of living organisms. In *Harvard College v. Canada* (2002),[376] the SCC considered the patentability of a genetically modified higher life form (i.e. multicellular plants and animals) to decide on Harvard's patent application for the oncomouse. Harvard had already acquired the patent for the oncomouse as a patentable composition of matter in the United States in 1988 and also in numerous other nations.[377] The SCC did not follow the U.S. approach as it was concerned about unique policy issues that would be raised by making higher life forms such as animals and plants patent-eligible, and the court ruled against patenting the oncomouse with the reason that Parliament could not have intended to include higher life forms as patentable inventions under section 2 of the *Patent Act* even if lower life forms are patentable.[378]

Nonetheless, two years after *Harvard College*, the SCC in *Monsanto v. Schmeiser* (2004)[379] modified their approach when the court considered the infringement of patents on the genes and the modified cells of a genetically modified plant. The gene and cell patents were valid because patent claims to genes and cells of a plant are not the same as patent claims to the plant itself, which is an unpatentable higher life form.[380] The majority, which included three out of four dissenting justices in *Harvard College*, held that Schmeiser infringed the gene and cell

[375] *Ibid*.
[376] *President and Fellows of Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 45.
[377] United States Patent No. 4,736,866, 12 April 1988.
[378] *President and Fellows of Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 45 at paras 155, 201; MOPOP, *supra* note 309 at s 17.02.01.
[379] *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902.
[380] *Ibid* at 22, 89.

patents through his unauthorized use of the plants and seeds. This determination has the practical effect of overruling *Harvard College* because gene or cell patents of plants and animals would allow the patentee to assert control over the use of the actual plant or animal and not just the patented gene or cell in its isolated form.[381] The dissenting opinion in *Harvard College* had noted that it would be good public policy to recognize higher life forms as patent-eligible to harmonize Canadian patent law with comparable jurisdictions, thus increasing mobility of capital and technology.[382] Also, the massive private sector investment in the R&D to produce oncomouse is the sort of innovative activity the *Patent Act* aims to promote.[383] The majority opinion in *Schmeiser* also expressed the same agendas of international harmonization of patent law and protection of the patent incentive to encourage development and commercialization.

Chapter 17 of the Manual of Patent Office Practice (MOPOP) provides guidance on Canadian Intellectual Property Office (CIPO) practices in regards to patent applications on biotechnology and medicinal inventions, which can involve inventions featuring living matter.[384] Per *Harvard College*, it states that CIPO also distinguishes between lower life forms (unicellular)[385] and higher life forms (multicellular),[386] where the former is generally deemed to be a patentable subject matter under section 2 of *Patent Act* while the latter is not.[387] However, it states that a cell that could be part of a higher life form should not necessarily be construed as a claim to the higher life form and that determination should be made using purposive construction of the claim. Also, methods or processes for producing or using a higher life form may be

[381] *Ibid* at para 17; Norman Siebrasse, "Comment on *Monsanto Canada Inc. v. Schmeiser*" (2004) La Revue du Barreau Canadien 967 at 976-977.
[382] *President and Fellows of Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 45 at paras 12-13, 18; *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 at para 90.
[383] *Ibid*.
[384] MOPOP, *supra* note 309 at s 17.01-2.
[385] *Ibid* [e.g. "microscopic algae; unicellular fungi (including moulds and yeasts); bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic, pluripotent and multipotent stem cells."].
[386] *Ibid* [e.g. animals at any stage of development, "plants, mushrooms, fertilized eggs and totipotent stem cells."].
[387] *Ibid* at s 17.02.01.

statutory subject matter while the higher life form itself remains non-statutory.[388] Canada has accepted patent applications for a variety of biotechnology inventions acquired through human intervention, including genes, modified cells and enzymes, proteins, molecules, and processes for producing life forms.[389] Moreover, other biotechnology-related patentable inventions include processes for making food and medicine,[390] chemical compounds,[391] research equipment and software research tools,[392] products such as devices or drugs for medical treatment[393] (but not for methods of medical treatment),[394] and any new uses of existing patents.[395]

Aside from amending the patent statute to try to strike a balance between patent rights and the public interest in light of the changing innovation landscape, courts try to respond to new developments by interpreting and adjusting the application of patent doctrines. For instance, in *Apotex v. Sanofi-Synthelabo* (2008),[396] the SCC revised the tests for novelty and non-obviousness standards in Canada. After noting that the "obvious to try" test was relevant to the

[388] *Ibid* at ss 17.02.01, 17.02.03.
[389] *Ibid* at chap 17; Vaver, *Intellectual Property Law*, *supra* note 68 at 294 citing *Continental Soya Co Ltd v JR Shor Milling*, [1942] SCR 187; *President and Fellows of Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 SCR 45at 201; *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 at 87-89.
[390] Vaver, *ibid* at 305.
[391] *Gilead Sciences, Inc v Idenix Pharmaceuticals, Inc*, 2015 FC 1156.
[392] *Canada (Attorney General) v Amazon.com Inc*, 2011 FCA 328, [2012] 2 FCR 459, 340 DLR (4th) 577.
[393] *Apotex Ltd. v. Wellcome Foundation*, [2002] 4 SCR 153; *Merck& Co v Apotex Inc*, (1994) 59 CPR (3d) 133.
[394] *Tennessee Eastman Co et al v Commissioner of Patents*, [1974] SCR 11, 8 CPR (2d) 202; *Imperial Chemical Industries Ltd. v. Canada (Patent Commissioner)*, [1986] 3 FC 40, 9 CPR (3d) 289 (CA)*; AbbVie Biotechnology Ltd v Canada (Attorney General)*, 2014 FC 1251 at para 114 [affirmed the rule that any claim directed to the exercise of professional skill and judgment is not patentable]; MOPOP, *supra* note 309 at s 17.03 [surgical, medical, dental and physiotherapeutic methods of treatment are not patentable subject matter].
[395] *Patent Act, supra* note 303, s 2; *Shell Oil Co v Commissioner of Patents,* [1982] 2 SCR 536, 142 DLR (3d) 117, 44 NR 541 [new uses of a known substance are patentable]*; Apotex Ltd. v Wellcome Foundation*, 2002 SCC 77, [2002] 4 SCR 153 [new medical uses of known drugs are patentable]; Janet Hope, *Open Source Biotechnology* (PhD Thesis, The Australian National University, 2004) at 96 [According to WIPO, "[s]pecific classes of patentable biotechnology inventions include classical microbial technologies, 'new' biotechnologies based on recombinant DNA (genetic engineering) or hybridoma (cell fusion) technology, and therapeutic molecules used as drugs."].
[396] *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at paras 9 -10 [This case involved a selection patent, which is important in pharmaceutical or biotechnology, where a patent is granted for a selection of chemical compounds from the originating patent that describes in general terms a class of compounds or reactions].

obviousness inquiry under U.S. and UK jurisprudence,[397] the SCC accepted that the test could be one of the relevant factors in the obviousness inquiry in Canadian jurisprudence for inventions from fields that engage in experimentation.[398] The obviousness inquiry from *Beloit v. Valmet* (1986),[399] a leading authority on obviousness until *Sanofi-Synthelabo,* would not accommodate this test.[400] This modification raises the non-obvious standard for some inventions, producing a rule that can disadvantage patent applicants in pharmaceutical, chemical or biological fields that innovate by experimentation as they must demonstrate that their invention is not obvious to try in order to satisfy non-obviousness. It may also achieve the public policy objective of improving the public domain by leaving obvious-to-try claims in it.

3.2.4 Recent Developments in U.S. Patent Law

Although the trend is not observed at the international level, commentators note that some nations appear to have made efforts to reverse the uniform, pro-patent, and upward harmonization of patent law in response to the criticisms.[401] In the United States, there were

[397] E.g. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct 1727 (2007) at 550 U.S. 421; *Novartis AG v Generics (UK) Ltd (trading as Mylan)* [2012] EWCA Civ 1623 at 55.
[398] *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at paras 66-71; David Vaver, "Being Old and Obvious: Apotex v. Sanofi SCC" (2010) 3 Osgoode Hall Rev L & Pol'y 3.
[399] *Beloit Canada Ltd v Valmet OY* (1986), 8 CPR (3d) 289 (FCA).
[400] *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at paras 52 [*Beloit, ibid* at 294 defines a person skilled in the art as "the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right" and this person must be able to come to the solution of the invention without the teachings of the patent].
[401] Joshua D Sarnoff & Christopher M Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents" (2008) 23 Berkeley Tech L J 1299 at 1337; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 35; Strandburg, "Patent Fair Use 2.0", *supra* note 281 at 269-270; Bagley, "Patent Barbarians at the Gate", *supra* note 318; Paranagua, "Understanding the Brazilian patent reform", *supra* note 371 at 340-2, 350 [India and China have raised the patentability standards and implemented pre-grant opposition to patents by reforming their Patent Acts, India in 2005 and China in 2007. Moreover, in 2007, Brazil issued its first compulsory licence to supply Merck's patented antiretroviral efavirenz.]; Ragavan, "Diverse Harmonization: India example", *supra* note 371 at 374-8 [Post-TRIPS, India enforces higher non-obviousness standard than the United States, see the Indian Patents Act (n 26) § 2(ja). Section 3(d) of the Indian Patents Act also excludes patenting of new forms of known substances to prevent evergreening, "wherein several patents are obtained on different forms of one compound and obtained to expire in a staggering manner with a view to extend

some legislative and case law developments in recent years, which seem to have been motivated in this manner. For instance, Congress reformed patent law with the enactment of the *Leahy-Smith America Invents Act*, which included provisions expanding post-grant reviews to challenge the validity of patents.[402] U.S. courts have also made some effort to reduce the reach of patent protection by adjusting patent standards and patentable subject matter and making it difficult for patentees to access harsher remedies.[403] For instance, SCOTUS raised the non-obviousness standard in *KSR International Co. v. Teleflex Inc.* (2007) [404] and made it more difficult for patentees to obtain injunctions for patent infringement in *eBay Inc. v. MercExchange* (2006).[405]

U.S. courts have had more opportunities to consider the patentability of biotechnology inventions than Canadian courts; however, even these recent U.S. cases may be too few to clarify

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the life of the compound beyond the 20 years." Moreover, implementing Article 31 of TRIPS, India issued compulsory licences for patented drugs for kidney and liver cancer].

[402] *Leahy-Smith America Invents Act,* Pub. L. No. 112-29, 125 Stat. 284 (2011).

[403] *In re Bilski*, *supra* note 327 and *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) [*In re Bilski*, the Federal Circuit rejected *State Street Bank*'s patent eligibility test (i.e. the useful, concrete and tangible test), which had made it possible to patent well-known mathematical formulas and abstract ideas applied to a particular use such as business methods.]; *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012); *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 134 S. Ct. 2347 (2014) [This case also invalidated patents on computer implemented business methods as unpatentable abstract ideas]; Christopher M Holman, "Patent Eligibility as a Policy Lever to Regulate the Patenting of Personalized Medicine" in Michael B Abramowicz, James E Daily & F Scott Kieff, eds, *Perspectives on Patentable Subject Matter* (New York: Cambridge University Press, 2014) at 132-6 [In *Bilski v. Kappos*, SCOTUS struck down the Federal Circuit's bright line test for patent eligibility (i.e. machine or transformation test) and replaced it with more flexible and "loosely defined standards (i.e. whether the patent claims an unpatentable fundamental principle) that can be applied in a more discretionary manner on a base-by-base basis." The flexible approach to the patent eligibility would allow lower courts and patent examiners to use the standard as a policy lever to achieve the public policy objectives of the patent system.]; Lucas S Osborn, Joshua M Pearce & Amberlee Haselhuhn, "A Case for Weakening Patent Rights" (2015) 18 St. John's L Rev 1185 at 1250; Strandburg, "Patent Fair Use 2.0", *supra* note 281 at 270-2.

[404] *KSR v Teleflex, supra* note 397 at 550 U.S. 417-18 [SCOTUS held that the patent claim of an invention that combines vehicle control pedal and electronic sensor for throttle control was obvious. The court also rejected a bright-line test for obviousness and advocated an expansive and flexible analysis instead].

[405] *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) at 391-92 [To determine whether to issue a preliminary injunction in U.S. law before *eBay*, if the copyright owner demonstrates the likelihood of success on the merit of a copyright infringement claim, the irreparable harm from the infringement was presumed. See LGS *Architects, Inc. v. Concordia Homes of Nev*., 434 F.3d 1150, 1155-1156 (9th Cir. 2009). Post-*eBay*, the Supreme Court rejected the presumption of irreparable harm and endorsed a case-by-case, 4-step analysis that would make injunctions available in accordance with the principles of equity.]; Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403 at 1250 [This decision was motivated to limit the patent trolls' ability to threaten businesses].

the law on biotechnology patents.[406] In biotechnology, the Federal Circuit *In re Fisher* (2005) dismissed a patent application on ESTs by holding that it lacked utility and enablement, thereby raising the utility requirement for this basic genetic research tool.[407] In *Mayo Collaborative Services v. Prometheus Labs* (2012), SCOTUS narrowed the patentability of diagnostic tests.[408] SCOTUS had held in *Diamond v. Diehr* (1981) that while a law of nature is not patent-eligible, an application of a law of nature may deserve patent protection.[409] The court's application of this distinction to the facts of *Mayo* resulted in the court holding that the method claims of a diagnostic invention were unpatentable law of nature. The decision may have the effect of narrowing the patentability of diagnostic tests and achieving the public policy objective of increasing the public's access to such medical tests.[410] Moreover, SCOTUS in *Association for Molecular Pathology v. Myriad* (2013)[411] considered the validity of Myriad's patents on BRCA 1 and 2 and held that the claims for isolating a naturally occurring DNA segment are not valid as these claim a product of nature. However, the court held that the claims for synthetically creating non-naturally occurring complementary DNA (cDNA) are valid. While this decision discourages some patents on DNA, commentators note that the underlying reasoning for the distinction is

[406] Piper, *supra* note 316 at 53; Bagley, "Patent Barbarians at the Gate", *supra* note 318.
[407] Strandburg, "Patent Fair Use 2.0", *supra* note 281 at 271-2; *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005); Also, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co*., 598 F.3d 1336 (Fed. Cir. 2010), the Federal Circuit invalided a patent on a transcription factor, a protein, which is relevant to study many human diseases, for lack of sufficient disclosure.
[408] *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012) at 1294, following Justice Breyer's dissenting opinion in *LabCorp v. Metabolite, Inc*, 548 U.S. 124 (2006) at 129 [According to the court, the claimed methods for treating autoimmune diseases by measuring the metabolite levels in the patient's blood to determine the effective drug dosage did not have inventive additional features that are necessary to transform an unpatentable law of nature into a patentable invention. One could not obtain a patent on a process that consists of a law of nature by adding the instruction "apply the law"; that would usurp the use of the natural law. *Mayo* was followed in *Ariosa v. Sequenom*, 788 F.3d 1371 (Fed.Cir. 2015) which examined the patentability of methods for diagnosing fatal abnormalities by detecting paternal DNA in plasma]; James E Daily & F Scott Kieff, "Anything under the Sun Made by Humans Patent Law Doctrines as Endogenous Institutions for Commercializing Innovation" in Matthew & Zech, eds, *Research Handbook on Intellectual Property and the Life Sciences*, *supra* note 324.
[409] *Diamond v. Diehr, supra* note 326 at 185.
[410] Daily & Kieff, *supra* note 408 at 413; Holman, "Patent Eligibility as a Policy Lever", *supra* note 403 at 132-6.
[411] *Association for Molecular Pathology v. Myriad, supra* note 415; Bagley, "Patent Barbarians at the Gate", *supra* note 318 at 155.

unclear.[412] Before the decision, Myriad's BRCA patents allowed the company to administer the BRCA1/2 test exclusively in the United States.[413] Commentators note that the overall impact of the decision on access to diagnostic testing for genetic diseases is unclear as the decision had upheld most of Myriad's patent claims, and Myriad went on to sue competing U.S. test providers for patent infringement after the decision.[414]

Some of the recent case law developments in the U.S. may discourage patent use in biotechnology by raising uncertainties about the patentability of some biotechnology inventions and challenges enforcing patents in the United States.[415] On the other hand, it has been suggested that adjusting patent law through case law to discourage patenting or reduce the reach of patent rights in biotechnology may not be adequate or precise.[416] Case law is shaped by commercial litigants who can pursue a highly costly patent infringement lawsuit; the interests of individual researchers, small-to-medium-sized firms and open innovation communities usually do not heavily influence the development of case law. Also, the effect of a case as a precedent in subsequent cases is unclear as the outcome of a case depends on the facts before the court as well as various other factors, including the nature of the legal system and the level of court.[417]

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[412] Bagley, *ibid* ["Unfortunately, the reasoning underlying the Court's distinction between the patent eligibility of gDNA and cDNA could generously be called opaque."]
[413] Lara Cartwright-Smith, "Patenting Genes: What does *Association for Molecular Pathology v. Myriad Genetics* Mean for Genetic Testing and Research?" (2014) 129(2) Public Health Reports 289, online: National Center for Biotechnology Information <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3982540/>.
[414] *Ibid* [After the decision, more testing providers offered the BRCA1/2 test at a lower price, but Myriad's patent on the cDNA itself enables it to sue competing test providers or researchers who independently create the same cDNA. It was noted that this patent would stifle research on the diagnostic test itself and allow a monopoly on the test].
[415] Jack Ellis, "Supporting innovation in next-generation medicines" (June 2017), online: WIPO Magazine <https://www.wipo.int/wipo_magazine/en/2017/03/article_0007.html> [stated in reference to *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 132 S. Ct. 1289 (2012), *eBay Inc. v. MercExchange, L.L.C.*, *ibid*, and *Association for Molecular Pathology v. Myriad,* 569 U.S. 576 (2013)].
[416] Piper, *supra* note 316 at 52-3.
[417] Piper, *ibid* [These factors include "the nature of the legal system (common or civil law), the reputation of the judge deciding the case, the level of court, the legal framing of the dispute at hand, and even the accessibility and clarity of the written judgment"].

3.3 Economic Justifications of Patent Law

Patent proponents in knowledge-intensive industries have relied on the economic justifications to campaign for stronger and uniform patent protection in nations.[418] This pro-patent stance has been criticized because the role of patents in innovation growth is complex, and strong patent rights can also interfere with alternative innovation outside of the patent system, such as open innovation communities.[419] It is difficult to justify strengthening patent protection across the industries and imposing patent monopoly costs on global citizens in light of these criticisms. This section will review the economic theories of patent law and criticisms against shaping patent law based on economic justifications.

3.3.1 Economic Theories of Patent Law

Economic theories of patent law suggest that patent monopolies are necessary because patents promote innovation in society. The first three theories discussed below (utilitarian, disclosure, and development and commercialization theories) aim to solve free-riding: patent law tries to secure patentees' effort to create, disclose, develop and commercialize inventions by granting the exclusive right to exploit their invention during the patent term and protection against imitators or free riders in the marketplace.[420] The prospect theory, however, explains patents as a tool to promote innovation in society by allowing an upstream or initial inventor to efficiently allocate

[418] O'Rourke, *supra* note 338 at 1178; James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers put Innovation at Risk* (New Jersey: Princeton University Press, 2008) at 74.
[419] Asay, "Enabling Patentless Innovation", *supra* note 81 at 439-441.
[420] William Fisher, "Theories of Intellectual Property" in Stephen R Munzer, ed, *New Essays in the Legal and Political Theory of Property* (Cambridge, UK: University Press, 2001) at 2; William Landes & Richard Posner, "An Economic Analysis of Copyright Law" (1989) 18 J L Studies 325; Dreyfuss "Does IP need IP", *supra* note 31 at 1440.

innovation resources for others to engage in follow-on development and commercialization.[421] This argument has been made in favour of early stage biotechnology inventions.[422]

According to the utilitarian theory, patent law encourages inventors to make the initial investment in R&D because patents make it possible for patentees to recoup their R&D investment in the marketplace by excluding others from participating in market activities with the patented invention.[423] It is assumed that without patent protection, an inventor would not make the initial investment in R&D due to the risk of free-riding when a novel invention enters the market.[424] Hence, society benefits from patents because patent protection incentivizes inventions that would not exist otherwise.[425] Nonetheless, in exchange, society must bear the costs of patent monopolies.[426] For instance, patents create a deadweight loss, which results when patentees charge higher than the price in a competitive market to sell patented inventions; this monopoly pricing forces some purchasers to forego purchasing patented inventions because they cannot or will not pay the higher price.[427] Patents also create indirect costs in society, such as hindering competition by raising market entry costs, deterring downstream R&D, and interfering with markets for substitutions.[428] Society must also incur the cost of administrating the patent system.[429]

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[421] Edmund W Kitch, "The Nature and Function of the Patent System" (1977) 20 J L & Econ 265 at 275-280; Asay, "Enabling Patentless Innovation", *supra* note 81 at 439-443.
[422]R D Nelson & R Mazzoleni, "Economic Theories about the Benefits and Costs of Patents" in National Research Council, Intellectual Property Rights and Research Tools in Molecular Biology (Washington, DC: National Academy Press, 1997) cited in Hope, *Biobazaar*, *supra* note 21 at 71.
[423] Asay, "Enabling Patentless Innovation", *supra* note 81 at 439-441; Fisher, *supra* note 420; Robert P Merges & Richard R Nelson, "On the Complex Economics of Patent Scope" (1990) 90 Colum L Rev 839 at 870; Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403 at 1187; Bessen & Meurer, *Patent Failure*, *supra* note 418 at 6.
[424] *Ibid*.
[425] *Ibid*.
[426] Landes & Posner, *The Economic Structure of Intellectual Property Law*, *supra* note 63 at 74-76; Fisher, *supra* note 420 at 2.
[427] *Ibid.*
[428] Okediji, "Public Welfare and the International Patent System", *supra* note 296 at 6.
[429] *Ibid.*

A related economic justification is the disclosure theory, which states that patent protection also allows inventors to publicly disclose the details of their inventions without sacrificing their value or suffering free riding.[430] If an inventor had chosen to keep the invention as a trade secret, society would not have gained access to technologically valuable information. By contrast with trade secrecy, patent protection enables public disclosure of new, non-obvious and useful inventions by offering patentees the right to exclude others from using the invention in the marketplace during the patent period.[431] The burden of patent monopoly is justified since society gains access to new information that it would not have gained otherwise.[432]

Another related economic justification is the development and commercialization theory. This theory assumes that patents are justified because they encourage patentees to invest in further development and commercialization of patented inventions.[433] For instance, it is argued that patents on life science inventions encourage patentees to pursue further development and commercialization, and patent monopolies are justified as society would benefit from the downstream efforts and additional commercial products.[434]

The prospect theory of patent law, on the other hand, holds that patent rights are justified because they allow patentees to efficiently allocate innovation resources to coordinate subsequent R&D and commercialization efforts in society.[435] An upstream invention opens up the possibility of discovering a range of follow-on inventions, and according to Kitch, unless there is a broad patent on the initial upstream invention, subsequent discoveries that can follow

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[430] Fisher, *supra* note 420; Nelson & Mazzoleni, *supra* note 422.
[431] *Ibid*.
[432] *Ibid*.
[433] Michael Abramowicz, "The Danger of Underdeveloped Patent Prospects" (2007) 92 Cornell L Rev 1065; Nelson & Mazzoleni, *supra* note 422 at 1 cited in Hope, *Biobazaar*, *supra* note 21 at 71; Asay, "Enabling Patentless Innovation", *supra* note 81 at 440.
[434]Bessen & Meurer, *Patent Failure*, *supra* note 418 at 6; Hope, *ibid* at 72-3; Welsh, "Close Enough but not too Far", *supra* note 48 at 1854-1855.; Rai, "Regulating Scientific Research", *supra* note 19 at 95.
[435]Kitch, *supra* note 421; Hope, *ibid*; Asay, "Enabling Patentless Innovation", *supra* note 81 at 439-443.

will occur in a wasteful manner (i.e. where multiple inventors compete to invent and patent follow-on inventions).[436] Hence, the prospect theory encourages broad patents to be granted to an early stage invention to allow upstream patent owners to efficiently coordinate innovation resources for follow-on R&D that falls within the scope of their patent claims.[437] The efficient allocation of innovation resources can be organized if the patent information is publicly available, and its breadth is reasonably clear.[438] According to this theory, society gains by granting broad patents to early stage inventions because such patents allow upstream patentees to efficiently and centrally coordinate subsequent R&D and commercialization efforts in society. The prospect theory is argued in favour of broadly patenting upstream biotechnology inventions, which are far from having a narrow and specific commercial application (e.g. gene fragments).[439] It is also argued that the prospect theory benefits university researchers because broad patents on upstream university discoveries allow university researchers to benefit from eventually and share in the gains from downstream commercial activities that use the patented research.[440]

3.3.2 Limitations and Criticisms of Patent Reform Driven by Economic Justifications

Economic theories that justify patents as necessary to incentivize innovation do not always reflect reality. Although many nations accept the policy that patents encourage innovation with the underlying assumption that patent rights are economically efficient,[441] scholars argue that in many industries, the effect of patents on economic growth seems to be very limited or unclear

[436] Kitch, *supra* note 421; Nelson & Mazzoleni, *supra* note 422.
[437] Nelson & Mazzoleni, *ibid.*
[438] Kitch, *supra* note 421 at 275-280; Hope, *Biobazaar*, *supra* note 21 at 72-3; Asay, "Enabling Patentless Innovation", *supra* note 81 at 439-443; Petherbridge, *supra* note 20 at 352.
[439] Nelson & Mazzoleni, *supra* note 422.
[440] Eisenberg, "Public Research and Private Development", *supra* note 321 at 1712.
[441] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 6 citing E Richard Gold et al, "The Unexamined Assumptions of Intellectual Property: Adopting an Evaluative Approach to Patenting Biotechnological Innovation" (2004) 18 Public Affairs Quarterly 299 at 307.

and cannot adequately justify the cost of patent monopoly in society.[442] Scholars argue that patent rights do not have the same kind of effect on economic growth as a tangible property system.[443] Bessen and Meurer note that their impact on economic growth is far more qualified by "the details of the laws, institutions, technologies, and industries involved."[444] Moreover, the pro-patent argument is supported by a "modest body of evidence" even in the pharmaceutical and biotechnology industries, which are often identified as sectors that require strong IP protection due to reasons such as high R&D costs and long-term product development before marketing.[445] For instance, there is inadequate empirical data to know precisely how patent law affects the development of new drugs. Bubela et al. note that Canada expanded IP rights for pharmaceutical innovation in the late 80s and the 2000s, but this did not result in an increase in R&D or more products.[446] Instead, patients, healthcare providers and scientists argue that patents on drugs and diagnostics block innovation in personal medicine and devices, create patent thickets, and block patients' access to personalized treatments and diagnostic testing.[447] Industry leaders and international organizations in recent years have called for encouraging innovation by improving the flow and the use of knowledge rather than enhancing IP rights in biotechnology.[448]

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[442] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 91-94.
[443] *Ibid* at 92 ["intellectual property rights have at best only a weak and indirect effect on economic growth."].
[444] *Ibid* at 75-6.
[445] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 5, 8-10 citing E Richard Gold et al, "Needed: models of biotechnology intellectual property" (2002) 20:8 TRENDS in Biotechnology 327, AJ Glass & K Saggi, "Licensing versus Direct Investment: Implications for Economic Growth" (2002) 56 J Int Econ 131, Nancy Gallini & Suzanne Scotchmer, "Intellectual Property: When is it the Best Incentive System" in Adam B Jaffe, Josh Lerner & Scott Stern, eds, *Innovation Policy and the Economy*, Vol 2 (MA: MIT Press, 2002), and Keith E Maskus, "Intellectual Property Rights in the Global Economy", Institute for International Economics (2001).
[446] Tania Bubela, Garret A FitzGerald & E Richard Gold, "Recalibrating Intellectual Property Rights to Enhance Translational Research Collaboration" (2012) 4:122 Science Translational Medicine; Norman Kalant & Ian Shrier, "Research Output of the Canadian Pharmaceutical Industry: Where has all the R&D Gone?" (2006) 1:4 Healthcare Policy 21, online: NCBI < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2585348/>; E Richard Gold et al, "Are Patents Impeding Medical Care and Innovation?" (2009) 7 PLoS Medicine 1 at 2.
[447] Knowles, Luth & Bubela, *supra* note 109.
[448] Bubela et al, *supra* note 426.

The economic theories presume that patent law rewards a sole inventor working in isolation to create a significant invention that justifies the patent monopoly.[449] However, according to Lemley, strengthening the patentees' rights based on such justifications contradicts the reality of how most inventions are discovered.[450] Lemley criticizes the economic theories based on historical observation that most inventions, even pioneering technologies, are incremental improvements in society that are discovered by multiple inventors who are working simultaneously and independently.[451] Lemley also notes that the exceptions from a sole inventor are not from conscious efforts of a sole inventor as presumed by the patent theories; instead, they are accidental inventions of an individual.[452]

Moreover, some of the economic theories are designed on the presumption that patent protection is needed because free-riding is easy and cheap, but this is not always true in biotechnology. New technologies in an emerging industry like biotechnology may not be copied because people are unable to judge their market value.[453] If the market exchange is uncertain due to the unclear value of new technology, non-market exchanges of information (e.g. open exchange and research collaboration) may better facilitate its dissemination.[454] Also, some technologies cannot be easily imitated or transferred because they are too complicated, or they are still underdeveloped abstract concepts.[455] For example, it is difficult to develop generic biologic drugs because, unlike traditional pharmaceuticals based on simple molecules, biologics

[449] Mandeville, *supra* note 21 cited in Hope, *Open Source Biotechnology*, *supra* note 395 at 27.
[450] Asay, "Enabling Patentless Innovation", *supra* note 81 at 440-1; Mark A Lemley, "The Myth of the Sole Inventor" (2012) 110 Mich L Rev 709 at 711.
[451] Lemley, "The Myth of the Sole Inventor", *ibid* at 715-716, 735 citing Amy L Landers, "Ordinary Creativity in Patent Law: The Artist Within the Scientist" (2010) 75 Mo L Rev 62 at 62-69.
[452] Lemley, *ibid* at 733-735.
[453] Mandeville, *supra* note 21 cited in Hope, *Open Source Biotechnology*, *supra* note 395 at 27; Bessen & Meurer, *Patent Failure*, *supra* note 418 at 89; Dan L Burk & Mark A Lemley, *The Patent Crisis and How the Courts Can Solve It* (Chicago, IL: University of Chicago Press, 2009) at 44.
[454] *Ibid*.
[455] *Ibid*.

have complex structures that are impossible to replicate exactly.[456] Hence, biologic drugs allow the original biologic drug manufacturer to enjoy a considerable first-mover advantage.[457] Bessen and Meurer also note that if there are other ways of restricting access to an invention, such as limiting access to complementary information that enables people to practice the invention, an imitator can incur high entry costs.[458] Hence, difficulty accessing complementary information in some industries can discourage free riding.

It is difficult to accept the disclosure theory as a justification for society bearing the costs of patent monopoly when inventors ordinarily do not learn about the state of the art from reading patent claims.[459] Bessen and Meurer note that patent law is not the dominant method of disseminating technical information.[460] Patent claims are drafted by patent lawyers with difficult and vague words that are not traditionally used by industry participants and researchers in order to try to avoid prior art and to maximize the scope of patent protection.[461] As noted above in Section 2.2.1, academic researchers commonly share their research by publishing scholarly articles and do not usually monitor patenting in their research areas. Moreover, if it is possible for businesses to keep technical information as a trade secret for longer than the patent duration of 20 years, patent disclosure is not attractive.[462]

Some have argued for broadening patent rights for cumulative upstream technology under the prospect theory and the development and commercialization theory because broad

[456] Duncan Matthews, "Exclusivity for Biologics" in Matthew & Zech, eds, *Research Handbook on Intellectual Property and the Life Sciences*, *supra* note 324 at 104.
[457] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 10.
[458] Bessen & Meurer, *Patent Failure*, supra note 418 at 89.
[459] Jason Schultz & Jennifer M Urban, "Protecting Open Innovation: The Defensive Patent License as a New Approach to Patent Threats, Transaction Costs, and Tactical Disarmament" (2012) 26 Harvard J L & Tech 1 at 28; Lemley, "The Myth of the Sole Inventor", *supra* note 450at 745-7.
[460] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 233-234; Burk & Lemley, *The Patent Crisis, supra* note 453 at 66.
[461] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 28; Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 745-7.
[462] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 233-234; Burk & Lemley, *The Patent Crisis, supra* note 453 at 66.

upstream patents can incentivize other businesses and patentees to invest in the development and commercialization of downstream products instead of commercializing public domain knowledge, which can be exploited by anyone.[463] As noted above, the prospect theory is argued in biotechnology because broad upstream patents may allow researchers to attract the large investment needed for further development and commercialization. Moreover, broad upstream patents in academic research may help university researchers share the profits generated by downstream applications.

Nonetheless, it is also possible that broad patents on upstream inventions can interfere with subsequent innovation, especially in cumulative technologies.[464] Dreyfuss notes that biotechnology patents create an "upstream/downstream problem", which is a relatively new problem in patent law.[465] In the past, the question of whether there is adequate access to patents focused on examining whether a standalone patent can be invented around to develop an alternative invention.[466] For cumulative technology, however, researchers need liberal access to upstream research resources that can enable cumulative downstream R&D in biotechnology.[467] The upstream/downstream problem in biotechnology can be difficult to resolve because some inventions can serve as an upstream research tool as well as a final downstream product.[468]

Arguments for broadening patent rights for cumulative upstream technology assume that upstream and downstream inventors are able to negotiate among themselves to share the benefits

[463] Nelson & Mazzoleni, *supra* note 422; Eisenberg, "Public Research and Private Development", *supra* note 321 at 1669.
[464] Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 743-4; Petherbridge, *supra* note 20 at 354.
[465] Rochelle C Dreyfuss, "Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course" (2003), Public Law & Legal Theory Research Paper Series No. 59, NY University at 4-6; Heller & Eisenberg, *supra* note 298.
[466] Dreyfuss, "Varying the Course", *ibid*.
[467] *Ibid*.
[468] *Ibid*.; Hope, *Biobazaar*, *supra* note 21 at 302-3 [e.g. germplasm is both a research tool and a final product].

of accessing upstream patents.[469] However, the presumption in patent law that market mechanisms are the best option for exchanging information does not always hold up in reality.[470] Upstream patentees can interfere with downstream development by imposing licensing and negotiation costs on follow-on inventors. An initial inventor who patents an upstream invention often delays follow-on development and commercialization to maximize profit from the initial upstream invention.[471] Patentees can also engage in rent-seeking or withhold licensing opportunities for potential competitors who are engaged in downstream development.[472] These strategic behaviours lead to market failures. If the patentee of research tools has a reach-through right to collect benefits from research tool users, such licensing terms may disincentivize subsequent R&D.[473] Some argue that because patent law already grants too many patent incentives for initial inventors of cumulative technology, patent law reform should focus on increasing incentives for subsequent inventors.[474] Lemley also rejects these theories on the ground that upstream patentees are not always good at organizing subsequent development or commercialization.[475] Contrary to Kitch's argument, a patent holder of a broad upstream patent may not have the cognitive capacity to organize and exploit all patent claims thoroughly.[476] Thus, strengthening patent protection can hinder technological progress by creating higher transaction costs, which interfere with the exchange of technology.

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[469] Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 743-4.
[470] Mandeville, *supra* note 21 cited in Hope, *Open Source Biotechnology*, *supra* note 395 at 27.
[471] Asay, "Enabling Patentless Innovation", *supra* note 81 at 440-1; Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 739-42.
[472]Gregory D Graff, Gordon C Rausser & Arthur A Small, "Agricultural Biotechnology's Complementary Intellectual Assets" (2003) 85:2 Rev Econ & Stat 340 at 350; Burk & Lemley, *The Patent Crisis*, *supra* note 453 at 75-76; Lemley, "The Myth of the Sole Inventor", *ibid* at 741; Mark A Lemley, "The Economics of Improvement in Intellectual Property Law" (1997) 75 Texas L Rev 989 at 1048-72.
[473] Lemley, "The Myth of the Sole Inventor", *ibid* at 743-4.
[474] John H Barton, "Reforming the Patent System" (2000) 287 Science 1933 at 1934.
[475] Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 739-42.
[476] Dreyfuss "Does IP need IP", *supra* note 31 at 1442; Merges & Nelson, "On the Complex Economics of Patent Scope", *supra* note 423 at 871-5.

Furthermore, it has been argued that patent law reform driven by economic reasons may disrupt alternative innovation activities. There is a tension between patent law and the presence of alternative open innovation environments. Patent law allows patentees to exclude others from using the patented invention during the patent period. On the other hand, open innovation communities operate outside of patent law, freely exchanging innovation often without patent protection.[477] The freedom to access and use information and knowledge encourages people to contribute to cumulative development.[478] Open innovation encourages resource sharing and reduces wasteful duplication of resources. Asay notes that the disclosure of information in open innovation communities sometimes contains more useful information than disclosure through patents.[479] Dreyfuss adds that if disclosure of a research tool is inevitable in a field of research, there is no need to extend patent protection to incentivize its development.[480] Also, commercial activities can occur around open innovation without tightly controlling the underlying innovation with patent rights and contracts (e.g. OSS based businesses like RedHat or IBM, and open source hardware vendors).[481] Unlike patents, which exclude access to inventions to control subsequent use and development, open innovation communities influence subsequent development and commercialization by granting broad access to and use of inventions with little to no restrictions.[482]

While patent law excuses some infringing uses (e.g. research or experimental use exception; see below), patent law does not explicitly acknowledge the presence of such alternative innovation paradigms and the possibility that these activities will need to access

[477] Asay, "Enabling Patentless Innovation", *supra* note 81 at 436.
[478] Asay, *ibid* at 444-5.
[479] Asay, *ibid* at 443-4.
[480] Dreyfuss "Does IP need IP", *supra* note 31 at 1470.
[481] Asay, "Enabling Patentless Innovation", *supra* note 81 at 443-4.
[482] *Ibid*.

existing inventions to create innovation in society.[483] Since patents can exclude access to upstream inventions and research tools, patents can interfere with open innovation by creating access barriers on essential innovation resources and exposing open innovation participants to inadvertent patent infringement. Hence, open innovation communities have traditionally held the belief that patent rights impose taxes on open innovation, creating unnecessary hardships for these communities.[484] They argue that if other non-market incentives operate sufficiently to encourage innovation outside of the patent system, patents may only interfere with the free flow of information in alternative innovation systems. [485]

3.4 The Notice Function in Patent Law

In addition to stronger patent protection and patent proliferation in biotechnology, which can lead to patent access barriers to upstream research resources and increase inadvertent patent infringement for researchers and developers (including DIYers), navigating around the existing patent landscape in biotechnology can be difficult because of patent thickets. Bessen and Meurer note that patent rights fail as a property system because they fail to provide clear notice of their scope and boundaries.[486] Poorly defined boundaries result in difficulty negotiating patent licences (thereby increasing transaction costs) and enforcing patents.[487] Poorly defined boundaries also increase uncertainty about a patent's validity and the chance of inadvertent infringement.[488] According to Bessen and Meurer, patent law works better in chemical and

[483] *Ibid*.
[484] *Ibid* at 432-3; Yochai Benkler, "Coase's Penguin, or, Linux and The Nature of the Firm" (2002) 112 Yale L.J. 369.
[485] Bently, "Introduction", *supra* note 330 at 51-52; Dreyfuss, "Does IP need IP", *supra* note 31 at 1466-8.
[486] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 46; Graff, Rausser & Small, *supra* note 472 at 351.
[487] *Ibid*.
[488] Bessen & Meurer, *ibid* at 54, 61-63 [The poor notice function is exacerbated in U.S. patent law by the availability of continuing applications, which allow an applicant to amend the claims with different claims without updating the published applications].

pharmaceutical industries because these patents provide clearer notice of the boundaries of the patent right.[489] In contrast, the notice function is poor in the biotechnology and software industries, resulting in higher rates of litigation in the United States. Cumulative technology patents have a poor notice function because whereas conventional pharmaceutical patents tend to have a one-to-one patent to product ratio, cumulative industries such as biotechnology and software suffer from fragmented and overlapping patent rights.

The failure of the notice function can also result from improvident patents, which contribute to the problem of patent thickets.[490] As the practice of patenting grows globally, patent examiners who have a limited number of hours to examine a patent application may allow some patent claims that do not satisfy the statutory requirements in patent law to pass through the examination process.[491] While there have been proposals to improve the patent examination process at national patent offices, including creating different reward systems for patent examiners and improving their training,[492] others suggest that improving the patent examination process may not be humanly or financially possible due to the volume of patent applications in some jurisdictions.[493] Lemley argues that improving the patent examination process is not cost-effective because most patents are unused or obtained as tools to secure financing.[494]

Patents can fail to provide clear notice of their boundaries when patent applicants try to maximize their benefit by using broad and ambiguous language in patent claims. Bessen and Meurer note that broad patent claims can be found particularly in early stage technologies in biotechnology, which can help inventors gain investment to refine the technologies and to

[489] *Ibid* at 152-155; Burk & Lemley, *The Patent Crisis, supra* note 453 at 33, 80-81.
[490] *Ibid*.
[491] Mark Lemley, "Rational Ignorance at the Patent Office" (2001) 95 NW U L Rev 1495.
[492] Robert P Merges, "As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform" (1999) 14 Berkeley Tech LJ 577 at 606-9.
[493]Lemley, "Rational Ignorance at the Patent Office", *supra* note 491 at 1511-2; O'Rourke, *supra* note 338 at 1239-1241.
[494] Lemley, *ibid*.

develop downstream applications.[495] Broad patent claims are problematic when the claims allow patentees to own exclusive rights in an invention they may not have invented yet, such patent claims receive different interpretations as technology advances, and they block and interfere with a subsequent innovator's R&D attempts.[496] When patents have broad claims, it might also be impossible to invent around them.[497] Moreover, patent applicants may draft their patent claims in ambiguous language that can be construed narrowly or broadly to suit their needs.[498] These claim practices increase uncertainty and the risk of legal disputes for follow-on researchers and developers.[499] Although the enablement or sufficiency of disclosure requirement in patent law (i.e. the obligation that a patent applicant must sufficiently disclose information to enable a person skilled in the art to make and use the invention) should prevent broad or ambiguous patent claims, patent offices may enforce relaxed disclosure and enablement in patent law, resulting in patents that provide poor notice of their scope.[500]

Different courts can also have different opinions about the boundaries of a patent.[501] Courts determine whether there has been an infringement by looking at the patent claims. According to Vaver, it is easy to determine when a patent infringement occurs when an infringer engages in acts that literally match the patent claims but more often, the patent claims are

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[495] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 66-7.
[496] *Ibid*; Robin Feldman, "Intellectual Property Wrongs" (2013) 18 Stan J Law Bus & Fin 250 at 259; Vaver, *Intellectual Property Law*, *supra* note 68 at 393.
[497] Bessen & Meurer, *ibid* at 47, 66-67 [e.g. In *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, Amgen's broad patent claimed for "all non-naturally occurring" erythropoietin (EPO) was held to be infringed by a competitor who developed a different method of producing EPOs. Bessen and Meurer note that this was how the case was decided despite Amgen's inability to replicate the competitor's method of producing EPOs].
[498] *Ibid* at 57.
[499] *Ibid* at 68.
[500] Bessen & Meurer, *ibid* at 224; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 22; USPTO, "Requirement for a Disclosure of the Best Mode" (20 September 2011) Memorandum, online: USPTO <https://www.uspto.gov/sites/default/files/aia_implementation/best-mode-memo.pdf> [35 U.S.C. §112(1) states that a patent applicant should provide the best mode for carrying out the invention. Section 15 of the *Leahy-Smith America Invents Act* amended 35 U.S.C. §282 by removing a patent infringement defence that the failure to disclose in the best mode cannot invalidate patent claims].
[501] Bessen & Meurer, *ibid* at 68.

difficult to construe as they have broad and general language peppered throughout them, and the infringing activity likely does not involve literal execution of all steps in a patent claim.[502] Canadian courts use purposive construction of patent claims to determine the scope of a patent, which entails distilling the essential elements of the patent claims interpreted with regard to fairness and predictability of the patent scope from the point of view of the reasonable person skilled in the art and with the view that what is not claimed is disclaimed.[503] Vaver notes that with non-literal infringement, courts struggle to purposively construe patent claims to determine whether an offending activity is a substantial infringement with immaterial variants or non-infringement, and different courts have reached different conclusions on the same patents.[504] Vaver also notes that uncertainties in claim construction are often applied expansively in court.[505]

Moreover, different jurisdictions can apply different approaches to claim interpretation. For example, U.S. patent law has the doctrine of equivalents, which strengthens the patentee's position because it expands the scope of the patent claims by extending patent protection to non-literal use of patents where a person uses inventions that accomplish substantially the same function in substantially the same way to obtain the same result.[506] Bessen and Meurer note that the chance of inadvertent infringement increases under the doctrine of equivalents.[507] The doctrine has been criticized for extending patent protection beyond what was originally claimed; it allows the courts to "occasionally recast claims to achieve the overarching purpose of the

[502] Vaver, *Intellectual Property Law*, *supra* note 68 at 385, 391-3.
[503] *Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024; *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067; *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 at paras 119-128.
[504] Vaver, *Intellectual Property Law*, *supra* note 68 at 387-391.
[505] *Ibid* at 391-3 citing *Catnic Components Ltd v Hill & Smith Ltd*, [1982] RPC 183.
[506] *Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co.,* 520 U.S. 17 (1997); *Festo Corp. v. Shoketsu*, 535 U.S. 722 (2002); Rai, "Regulating Scientific Research", *supra* note 19 at 140.
[507] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 61-63.

invention."[508] The doctrine of equivalents has also been criticized for creating patent thickets, which describe multiple overlapping patents that protect a single technology.[509]

Even when a patent user hires a patent expert to determine the coverage of relevant patents to avoid infringement, this advice is not conclusive since the actual scope of a patent cannot be accurately ascertained until it is litigated and determined by the court.[510] When fragmented or overlapping patent rights are prevalent, as is the case in biotechnology, the costs to search, negotiate and license all relevant patents before engaging in R&D may be prohibitively high. Bessen and Meurer note that these costs increase when boundaries are not clear due to broad and ambiguous patent claims and when a field suffers from many dubious patents of uncertain validity.[511] Also, inadvertent infringement due to unclear patent claims leads to costly litigation rather than encouraging early settlement.[512]

3.5 Abusive Use of Patents

Another development in the last few decades is the monetization of patents by strategic and opportunistic enforcement. For instance, more businesses are engaging in aggressive enforcement of their patents to profit more from them. They are enforcing patents against potential infringers beyond the relevant industry and the users of potentially infringing products rather than product manufacturers.[513] There are also patent trolls (or rights aggregators)[514] whose

[508] *Ibid*; Vaver, *Intellectual Property Law*, *supra* note 68 at 389 citing M Adelman, R. Rader & G. Klancnik, *Patent Law* (St Paul, Minn: Thomson West, 2008) at 373.
[509] Burk & Lemley, *The Patent Crisis, supra* note 453 at 89-90.
[510] Bessen & Meurer, *Patent Failure*, *supra* note 418 at 49-51, 55; Nele Berthels, "Case 8. CAMBIA's Biological Open Source Initiative (BiOS)" in van Overwalle, *Gene Patents and Collaborative Licensing Models*, *supra* note 85 at 197.
[511] Bessen & Meurer, *ibid* at 70-71.
[512] Bessen & Meurer, *ibid* at 123; Burk & Lemley, *The Patent Crisis, supra* note 453 at 28.
[513] Carl Shapiro, "Navigating the patent thicket: cross licenses, patent pools, and standard setting" in Josh Lerner & Scott Stern, eds, *Innovation Policy and the Economy,* Vol 1 (Cambridge, Mass: MIT Press, 2001) at 121; Feldman,

goal is to maximize revenues by amassing a large patent portfolio, which is not used for innovation or development but to collect high settlements from potential infringers by threatening and pursuing patent infringement litigation.[515] Patent trolling is considered an abusive use of patent rights and acts in bad faith because their opportunistic behaviour interferes with innovation.[516] Such uses of patents waste societal resources and drive up the price of products for consumers. Furthermore, aggressive and opportunistic enforcement of patents can also disrupt open innovation activities and increase patent risks for open innovation contributors and users. Patent trolling is often seen as a problem in the high-tech, component-driven industries (e.g. software and semiconductor).[517] Nevertheless, Feldman argues that as time passes, patent trolling will also disrupt other fields such as biotechnology.[518]

Feldman notes that patent law presumes the role of an inventor as someone who obtains a patent to manufacture and market an invention or, where the inventor lacks the means to bring a product to market, licenses the patented invention to a third party who is able to commercialize it.[519] In these scenarios, society benefits from patents by being able to access new products in the marketplace. However, Feldman notes that this is not how patent rights are often exercised under

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"Intellectual Property Wrongs", *supra* note 496 at 254 ["these patent holders are able to approach people who have little information about patents and little ability or incentive to do anything but pay."].

[514] I.e. rights aggregators do not contribute to innovation or product development but use large patent portfolios to accumulate wealth by threatening patent infringement lawsuits against potential infringers who are innovating and commercializing technologies.

[515] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 265-8; Stephen H Haber & Seth H Werfel, "Why do Inventors Sell to Patent Trolls? Experimental Evidence for the Asymmetry Hypothesis" (2015) Working Paper Series No. 15009, Hoover Institution Working Group on Intellectual Property, Innovation, and Prosperity, Stanford University, online: HooverIP2 < http://hooverip2.org/wp-content/uploads/ip2-wp15009-paper.pdf> at 2.

[516] Mark A Lemley, "Are Universities Patent Trolls?" (2008) 18 Fordham IP Med & Ent LJ 611; Sulan Wong, "Patents and Scientific Research: Five Paradoxical Scenarios" in Oswaldo Teran & Jose Aguilar, eds, *Societal Benefits of Freely Accessible Technologies and Knowledge Resources* (PA: IGI Global, 2015) at 141; Feldman, *ibid* at 279, 304 ["this type of rent-seeking behaviour, in which patent holders seek a return above the economic value of their patents, can have an extensive effect on consumer prices and consumer welfare."].

[517] Lemley, "Are Universities Patent Trolls?", *ibid* at 613.

[518] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 268-9.

[519] Feldman, *ibid* at 257-8.

the modern patent regime.[520] Participants in the modern patent system include large corporations that amass large patent portfolios to increase their bargaining power over competitors and patent trolls who do not contribute to innovation and development. The patent landscape has changed from the majority of patents being never actualized, unasserted, and not generating direct profits for patent owners to a landscape where more patents are monetized and used as bargaining chips.[521]

While some patentees do allow their patents to be exploited efficiently,[522] the presumption of a patent owner as a rational actor who exploits the patent in an economically efficient manner to maximize social benefit does not always hold up in reality.[523] Not all patentees respond altruistically to address social needs, even when doing so maximizes private gain from patents. It is in the economic interest of patentees to non-exclusively license research resources or enabling technologies to collect licensing fees from many individuals, and doing so also increases competition between licensees, encourages improvements, and maximizes the public benefit from making an invention widely available.[524] However, patentees' actions do not always coincide with actions that are rational or economically efficient. They can lead to market failures. Patentees can refuse to license the patent for the development of alternative or disruptive inventions that might threaten their economic position. Also, patentees can interfere with scientific progress by imposing reach-through conditions to control subsequent

[520] *Ibid* at 262-8; Haber & Werfel, "Why do Inventors Sell to Patent Trolls?, *supra* note 515 at 2.
[521] *Ibid*; Hope, *Biobazaar*, *supra* note 21 at 89.
[522] Dreyfuss, "Varying the Course in Patenting Genetic Material", *supra* note 465 at 1-3 [e.g. During the event of the anthrax scare, Bayer, who holds rights to the anthrax cure known as Cipro, voluntarily agreed to supply the drugs at low prices before being forced by the government to do so under compulsory licensing. Other pharmaceutical companies, such as Pfizer, Eli Lilly and GlaxoSmithKline, also agreed to lower the drug costs for low-income patients].
[523] *Ibid* [Dreyfuss describes a rational patent owner as follows: "If there is unfilled demand for a patented invention, the patentee can be counted on to expand production; if the invention has other applications, the patentee will enter these other fields. Even if the patentee cannot, for some reason, engage in such activities, its economic interest lies in finding licensees who can." Also, see Sendhil Mullainathan and Richard H. Tahler, "Behavior Economics", (1998) 50 Stan L Rev 1471].
[524] Lemley, "Are Universities Patent Trolls?", *supra* note 516 at 617-8; *Ibid*.

developments.[525] Such conditions discourage subsequent R&D, restrict freedom of research and potentially reward upstream researchers more than the value of their actual contribution.[526] Patentees may also grant a licence subject to conditions such as time limitation and territorial and field of use restrictions, which can reduce its usefulness in downstream activities like collaborative R&D that takes place in multiple jurisdictions.[527] Even universities can holdout for higher royalty when licensing patented academic research rather than spurring various downstream developments.[528] Universities or academic researchers may choose to license exclusively with a business, sell university patents to patent trolls, and some may not offer to license at all.[529]

Commercial patentees and patent trolls can pressure businesses to pay for licensing fees, to give up their rights, or to opt-out of competition by relying on uncertain boundaries of patent rights, high costs of patent litigation, and the possibility of high damage awards.[530] In biotechnology, patentees benefit from the fact that it is difficult to accurately identify the true value of an IP right because intangible goods with uncertain future uses are difficult to assess unless they are embodied in a tangible form.[531] "Measurement difficulties, information

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[525] Dreyfuss, *ibid* at 4-5; Piper, *supra* note 316 at 46-50; Fiona Murray et al, "Of Mice and Academics: Examining the Effect of Openness on Innovation" (2006) Working Paper 14819, NBER Working Paper Series; Rai, "Regulating Scientific Research", *supra* note 19 at 111; Michael Carrier, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* (Oxford University Press, 2009) at 283.
[526] Carrier, *ibid* [Problems with reach-through provisions include "their tendency to reduce scientists' incentives to conduct research. The provisions could limit scientists' freedom to pursue lines of inquiry because they no longer own their research results. They also could inadequately compensate scientists for their efforts. Finally, they could offer windfalls for material providers, who could wind up with greater rights than the sponsors that provided funding for the entire project. Reach through rights… also reduce the likelihood of future research funding."].
[527] Hope, *Biobazaar*, *supra* note 21 at 46-7.
[528] Lemley, "Are Universities Patent Trolls?", *supra* note 516.
[529] Lemley, *ibid* [universities agree to exclusive licensing more often than non-exclusive licensing]; Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 388; Lemley, "Ignoring Patents", *supra* note 34 at 26; Heller & Eisenberg, *supra* note 298 at 700; Dreyfuss, "Varying the Course in Patenting Genetic Material", *supra* note 465 at 3; Hope, *Biobazaar*, *supra* note 21 at 46-7; Feldman, "Intellectual Property Wrongs", *supra* note 496 at 268-9.
[530] Feldman, *ibid* at 283; Asay, "Enabling Patentless Innovation", *supra* note 81 at 448; Wong, "Patents and Scientific Research", *supra* note 516 at 141.
[531] Feldman, *ibid*; Heller & Eisenberg, *supra* note 298.

imbalances, transaction costs and other factors" can permit patentees to charge licensees more than the actual value of their patents.[532]

Large corporations invest resources to build a large patent portfolio because it can be used to discourage or remove competition (e.g. by blocking competing activities and charging high licensing fees) and applied defensively to avoid patent infringement claims from competitors.[533] When patent disputes occur between industry participants, small to medium size firms likely lack the resources to fight long and expensive legal battles in court against larger corporations.[534] The incumbents in an industry may also cooperate and combine their patents to keep start-up companies and disruptive technology from entering the market.[535] Such uses of patents create a chilling effect on innovation. Large corporations in the pharmaceutical, chemical and agricultural industries rely on university research and buy up patented research developed with government funding.[536] When these companies enforce their patents to keep start-ups and disruptive technologies from entering the market, they are potentially using publicly-funded research to discourage innovation and new product development.

Patent trolls, on the other hand, are non-practising entities that accumulate patents to build a large portfolio, not to engage in innovation or product development in the market but to seek rents from those who are doing so.[537] A patent troll will attempt to purchase important or influential patents in order that they may be more likely to be found valid if challenged in court

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[532] *Ibid*.
[533] Drahos & Braithwaite, *Information Feudalism, supra* note 333 at chaps 3, 10; Hope, *Biobazaar*, *supra* note 21 at 89-91.
[534] Carrier, *Innovation for the 21st Century*, *supra* note 525 at 131-133.
[535] *Ibid*.
[536] Hope, *Biobazaar*, *supra* note 21 at 92-94.
[537] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 279; Robert P Merges, "The Trouble With Trolls: Innovation, Rent-Seeking, and Patent Law Reform" (2009) 24 Berkeley Tech LJ 1583 at 1591 ["Typically, the troll waits until a technology is fully entrenched before scouting around for patents to acquire or asserting the patents it holds."].

as well as patents that are likely to have many potential infringers.[538] A U.S. study shows that patent infringement lawsuits by patent trolls have increased from 22% to 40% of all patent disputes from 2007 to 2011.[539] Feldman notes that these cases may represent a small portion of patent trolling behaviour because patent trolls can send out hundreds of demand letters against market participants to obtain settlement fees, and only a few may be litigated in court.[540] Also, patent trolling may be hidden behind complex business arrangements and subsidiaries, and patent trolls avoid publicizing their actions with non-disclosure agreements enforced against infringers.[541]

Patent trolls are difficult opponents in patent litigation. A business being sued by a patent troll cannot counterclaim that the troll infringed its patents because patent trolls do not engage in innovation development and commercialization where possible infringement could occur (i.e. they are non-practicing entities).[542] Furthermore, normally, a possible deterrent to patentees threatening a lawsuit against potential infringers is the possibility of having their patent declared invalid in litigation.[543] However, this defence does not benefit individual inventors and small-to-medium sized firms that may not have the resources to finance a highly costly patent infringement lawsuit against patent trolls or large corporations.[544] A potential infringer can request a post-grant review or opposition of patents, which is not nearly as costly as defending an

[538] Michael Risch, "Patent Troll Myths" (2012) 42 Seton Hall L Rev 457at 481 [According to Risch, empirical evidence shows that the quality of patents in a patent troll's portfolio looks similar to other patent litigants and is not worse as some had claimed that trolls rely on trivial patents].
[539] Sara Jeruss, Robin Feldman & Joshua Walker, "The America Invents Act 500: Effects of Patent Monetization Entities on US Litigation" (2012) 11 Duke L & Tech Rev 357.
[540] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 312.
[541] *Ibid* at 279, 312 [Also, a business can engage in patent trolling by secretly creating a third party corporation, transferring its IP rights to it, and having the new corporate entity go after any of its competitors for IP infringement. Such a tactic shields the business from potential losses it can incur from engaging in patent litigation with competitors, and it can avoid the risk of its patents being declared invalid from counter-infringement lawsuits].
[542] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 279.
[543]Lemley, "Ignoring Patents", *supra* note 34.
[544]*Ibid* at 281-284; Hope, *Biobazaar*, *supra* note 21 at 50.

infringement lawsuit; however, such an option may not be available in all jurisdictions.[545] Also, the rules of post-grant review or opposition procedure vary by jurisdiction. An infringer may not be able to benefit from such a procedure because there may be a time limitation or a limited number of grounds for filing a petition, and the party filing a petition is not always allowed to participate in the post-grant review process.[546]

While pursuing a large business may return a larger settlement for the patent troll, some patent trolls may specifically target smaller businesses by sending out demand letters that seek licensing fees because these businesses may not understand patented upstream technologies and likely do not have the finances to pursue patent litigation.[547] Even when a troll's patent portfolio consists of minor peripheral patents rather than essential or core patents of a larger technology or patents that have questionable validity and breadth, potential infringers may settle nonetheless rather than pursue litigation because a business can suffer early losses by choosing to litigate, such as a drop in its stock value over future uncertainties created by the lawsuit.[548] By carefully choosing their targets, patent trolls can accumulate a string of settlements, which can enhance their bargaining power against a new target and improve their position in court.[549]

Biotechnology R&D supports multiple industries, including healthcare, agriculture, industrial and environmental applications, and biodefence.[550] Feldman notes that it was the conventional view that the pharmaceutical industry is safe from patent trolling, but healthcare

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[545] *Patent Act, supra* note 303, s 48.1; MOPOP, *supra* note 309 at chap 23; *The European Patent Convention*, *supra* note 356, articles 52-57; EPO, "Oppositions", online: EPO <https://www.epo.org/applying/european/oppositions.html>; 35 U.S.C. §§282(b)(2) -(3), 321; USPTO, "Post Grant Review", online: USPTO <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/post-grant-review>.
[546] *Ibid*.
[547] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 286-7.
[548] *Ibid* at 264, 275 [e.g. Microsoft's patent dispute with Barnes & Noble for the latter's Nook electronic reader involved non-significant patents owned by Microsoft, which Microsoft used to eventually gain stakes in this product and a deal to develop it for Windows].
[549] *Ibid* at 293.
[550] Hope, *Biobazaar*, *supra* note 21 at 53.

biotechnology may be targetted by patent trolls.[551] Feldman notes that the traditional pharmaceutical drug manufacturing based on small-molecule drugs was considered less penetrable by patent trolls due to a one-to-one patent to product ratio (rather than hundreds of patents protecting a product). On the other hand, as noted above, biotechnology is a cumulative technology where upstream patents can be used to stifle follow-on developments. Moreover, scholars have raised concerns about the anticommons problem in biotechnology, where resources become underused due to the development of too many upstream fragmented rights. Most patent owners in biotechnology are businesses and universities.[552] University-owned patents can be tapped by patent trolls who acquire the rights and enforce them against businesses that commercialize technology that potentially falls within the scope of these patents. Patent trolls may obtain university-owned patents that can disrupt healthcare biotechnology businesses, such as active ingredient patents for drugs, patents on new uses of marketed drugs, and patents on the methods used during a drug manufacturing process.[553] In the United States, there is evidence of patent trolls purchasing university-owned biotechnology patent portfolios.[554] High R&D investments in healthcare biotechnology make these businesses a good target to patent trolls because these businesses would pay a settlement fee to avoid disruption in their R&D process rather than abandon it. Major bio-pharmaceutical firms can also contribute to patent trolling by making their non-essential patents available to a third party entity that can turn these patents into

[551] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 268-9; Robin Feldman & W Nicholson Price II, "Patent Trolling – Why Bio & Pharmaceuticals are at Risk" (2014) 17 Stan Tech L Rev 773.
[552] *Ibid*; Lemley, "Are Universities Patent Trolls?", *supra* note 516; Adam Hayes, "When Universities Patent Their Research" (20 November 2017), online: IPwatchdog <http://www.ipwatchdog.com/2017/11/20/universities-patent-research/id=90200/ >; Heidi Ledford, "Universities struggle to make patents pay" (23 September 2013), online: Nature <https://www.nature.com/news/universities-struggle-to-make-patents-pay-1.13811>.
[553] Feldman & Price, *supra* note 551.
[554] Feldman, "Intellectual Property Wrongs", *supra* note 496 at 268-9, 277 [e.g. "the PTO assignment database shows that CalTech sold a large group of patents to Intellectual Ventures in September of 2008." Feldman notes that Intellectual Ventures, a patent troll, is the largest and most secretive business that accumulated a massive number of patents, owning the fifth largest patent portfolio in the United States. It has established more than 1000 shell companies]; Tom Ewing & Robin Feldman, "The Giants Among Us" (2012) Stan Tech L Rev 1.

monetizers.[555] Patent trolling in healthcare biotechnology is detrimental to society as these behaviours ultimately increase healthcare costs for citizens.[556]

3.6 Patent Exception: Research or Experimental Use

Exceptions in patent law excuse patent infringement in certain situations where the public benefit from doing so outweighs the patentee's interest.[557] These users' rights exist to improve the balance of the interests of patentees and users in patent law and to prevent patentees from excessively benefitting from patent rights or oppressively using patents.[558] Bently notes that exceptions in patent law can serve public policy objectives such as preserving the public domain, incentivizing innovation, and protecting domestic socio-economic developmental priorities.[559] Patent exceptions are still vulnerable to being overridden by contracts (where there is no statutory prohibition), and their nature, scope and judicial interpretation vary by nation.[560] As noted above, patent law in WTO nations must comply with TRIPS.[561] Article 30 of TRIPS allows nations to create limited patent exceptions "provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[562]

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[555] *Ibid*; Feldman & Price, *supra* note 551 at 776.
[556] *Ibid*.
[557] O'Rourke, *supra* note 338 at 1198; Vaver, *Intellectual Property Law*, *supra* note 68 at 397.
[558] Bently, "Introduction", *supra* note 330 at 11; Bagley, "Patent Barbarians at the Gate", *supra* note 318 at 151.
[559] *Ibid*.
[560] Boettiger & Burk, *supra* note 68 at 221; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 38-9, 47; Ester van Zimmeren & Geertrui van Overwalle, "False Sense of Security Offered by Zero-Price Liability Rules? Research Exceptions in the United States, Europe, and Japan in an Open Innovation Context" in Ruth L Okediji& Margo A Bagley, eds, *Patent Law in Global Perspective* (New York: Oxford University Press, 2014) at 379.
[561]Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 46,
[562] TRIPS, *supra* note 306, art 30.

Common exceptions in domestic patent law include the Safe Harbor/Bolar exception,[563] prior use[564] and research or experimental use.[565] Some nations also recognize a private non-commercial use exception.[566] Gold and Joly note that while non-commercial use is a criterion that is often tied to a research use exception, the private non-commercial use exception as a separate exception can excuse non-experimental uses, such as repairs, modifications and customizations.[567] The private non-commercial use exception is sound in policy because it is difficult to locate private users to enforce patents against them.[568]

A research or experimental use exception in patent law is important to academic researchers and open scientists. It permits some free, unauthorized use of patents for research or experimental purposes. Therefore, it ensures some research freedom to encourage advances in science and technology.[569] The research use exception in patent law allows researchers to access patents without authorization, avoiding transaction and licensing costs.[570] This exception can reduce researchers' risk of committing inadvertent infringement; thus, it may increase legal certainty and reduce patent disputes.[571] It can also reduce additional costs in research that could accrue from having to implement coping strategies to avoid infringement, such as travelling to

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[563] *Patent Act, supra* note 303, s 55.2(1); Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 39; [This provision allows pharmaceutical companies to use patents before the expiry date to generate data they must submit to regulatory agencies to obtain authorization to market pharmaceutical products].
[564] *Patent Act, ibid* at s 56; Gold & Joly, *ibid* at 45-6; [A prior use exception in patent law allows a user to continue using an invention despite subsequent patenting by another. In jurisdictions that provide this exception, businesses that kept an invention as a trade secret are exposed to less risk after another entity patents the same invention].
[565] *Micro Chemicals* v *Smith Kline & French Inter-American Corp*, (1971), 2 CPR (2d) 193, [1972] SCR 506, 1971 CanLII 180 (SCC); *Dableh v Ontario Hydro* (1996), 68 CPR (3d) 129 (FCA) at 149; *Merck et al v Apotex* ([2006] FCA 323; *Patent Act, ibid* at s 55.3(1); Gold & Joly, *ibid*.
[566] E.g. *Patents Act 1977* (U.K.), 1977, c 37, s 60(5)(a).
[567] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 32.
[568] Bently, "Introduction", *supra* note 330 at 57.
[569] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 46; Bently, "Introduction", *ibid* at 36-39; Panel Report, *Canada-Patent Protection of Pharmaceutical Products* (2000), WT/DS114/R at 4.37 "(3)(b)(ii) The 'scientific/experimental use' exception" [The research use exception in patent law is an acceptable limited exception under Article 30 of TRIPS].
[570] Dreyfuss, "Varying the Course in Patenting Genetic Material", *supra* note 465 at 3; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 385-6.
[571]Van Zimmeren & van Overwalle, *ibid*.

another jurisdiction to use patents or developing workarounds. Van Zimmeren and van Overwalle note that a balanced research exception in patent law can mitigate patent access barriers to research resources and inadvertent infringement from the development of patent thickets or patentees' refusal to license for follow-on R&D.[572] Nevertheless, van Zimmeren and van Overwalle note that there has not been enough attention paid to this part of patent law by legislators in developed nations, a situation which needs to change as scientific and technological progress depends on there being sufficient access to upstream discoveries for R&D.[573] Improving research exceptions in patent law may also encourage open innovation by increasing access to patented upstream research resources.[574]

Currently, nations often distinguish between research use *on* and use *with* a patent as well as non-commercial versus commercial purposes of use. Many jurisdictions exempt use *on* a patent but not use *with* a patent in research, and also exempt research use for non-commercial purposes but not for commercial purposes.[575] If the exception permits research use *on* a patent, it excuses unauthorized patent use for experiments on a patented invention itself or to verify its claims.[576] If a domestic research exception permits research use *with* a patented invention, the exception will allow unauthorized use of a patented invention for unrelated purposes, such as using a patented research tool to pursue research that is not related to the tool itself.[577] Excusing research *on* a patent is commonly justified on the policy ground that research *on* a patent can verify fraudulent or erroneous patent claims.[578] Many nations do not extend a research use

[572]Van Zimmeren & van Overwalle, *ibid*.
[573]Van Zimmeren & van Overwalle, *ibid* at 415.
[574] Dreyfuss, "Does IP Need IP", *supra* note 31 at 1470.
[575]Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 386; Bently, "Introduction", *supra* note 330 at 39 -40.
[576] *Ibid*.
[577] *Ibid* [E.g. Belgian *Patent Act*, art 28(1)(b) (enacted on April 25, 2005)].
[578] Rebecca Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 U Chi L Rev 1017 at 1075.

exception to research tool patents. While it is argued that research *with* a patent is not permitted in order to protect the patent incentive to invent research tools, others argue that there is no evidence to support this argument.[579]

Furthermore, research exceptions in many jurisdictions usually only extend to research for non-commercial purposes because non-commercial researchers do not threaten or interfere with the patentee's legitimate interest to exploit patents in the marketplace.[580] Research with commercial or mixed non-commercial and commercial purposes, such as creating downstream applications and improving a patented process or the performance of a product patent, may be considered an encroachment on the patent owner's rights.[581] The distinction between commercial and non-commercial use in research is not always easy to draw as academic and non-commercial research can gain commercial purposes as the research progresses.

Open innovation or social production activities encourage the participation of diverse individuals who may have non-commercial and/or commercial motivations. One of the ways that DIYers actively contribute to scientific research is by improving access to research tools and equipment by making open access, DIY versions.[582] When there is a patent landscape of fragmented and overlapping patent rights, it becomes difficult to work around existing patents, and participants can inadvertently infringe third party patents. Nonetheless, those who infringe research tool patents cannot rely on a research exception in many jurisdictions. Research exceptions that do not extend to commercially motivated research uses can also discourage businesses from using and developing around social production projects. Therefore, research

[579] Nicholas Short, "A Research Exemption for the 21st Century" (2016) 50 U Mich J L Reform Caveat 1 at 10; Dreyfuss, "Varying the Course in Patenting Genetic Material", *supra* note 465 at 4-5; Bently, "Introduction", *supra* note 330 at 57; Vaver, *Intellectual Property Law*, *supra* note 68 at 400.
[580] Bently, *ibid*; *Micro Chemicals* v *Smith Kline, supra* note 565 at 519; *Merck et al v Apotex*, *supra* note 565 at paras 159-161; O'Rourke, *supra* note 338 at 1194.
[581] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 386.
[582] Golinelli & Ruivenkamp, *supra* note 3 at 153-154.

exceptions in most jurisdictions may not sufficiently encourage innovation and entrepreneurship from social production.

Research exceptions are not harmonized at the international level, and some jurisdictions do not recognize a general research exception.[583] Different scope and interpretations of research exceptions in nations can create confusion and may interfere with multi-jurisdictional collaboration. Scientists and DIYers, who usually do not have patent expertise, can struggle to figure out the scope of a research exception in relevant jurisdictions. Also, collaborating researchers may not have equal access to upstream research resources. Hope notes that researchers in developed nations often mistakenly believe that their research activities are exempted by the research use exception in domestic patent law, when in fact, the exception's scope varies by nation and may not always exempt all of the academic researchers' activities.[584] On the other hand, Hope notes that researchers in less developed nations can overestimate the patent coverage in their research area despite no corresponding patents in their jurisdiction.[585] This false perception of patent barriers may discourage researchers from carrying out research.[586]

Gold and Joly note that research exceptions also suffer from uncertainty because many jurisdictions do not clearly define what types of acts are excused research uses in patent law.[587] After reviewing research exceptions in the United States, Europe, and Japan, van Zimmeren and van Overwalle agree that the scope and boundaries of research exceptions are often vague.[588] A research exception in domestic patent law may be statutory or rooted in the common law. In

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[583] Sarnoff & Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents", *supra* note 401 at 1301; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 33 [e.g. no experimental exception in Mexico].
[584] Hope, *Biobazaar*, *supra* note 21 at 60-65.
[585] *Ibid*.
[586] *Ibid* ["although in any case, perceptions and reality are likely to converge as developing countries implement their obligations under international trade agreements to protect intellectual property rights"].
[587] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 41.
[588]Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560.

Canada, the research exception was mostly made up of case law until it was codified in 2018 under section 55.3(1) of the *Patent Act*.[589] The exact scope of a research exception in common law can be uncertain because the determination of a case is tied to its facts, and its precedential effect in subsequent cases can depend on multiple factors that make up the case and the legal system.[590] In jurisdictions that have codified the research exception, the statutory language and judicial interpretation of it can vary.[591] Gold and Joly note that although it can be difficult to ascertain the boundaries of both statutory and common law research exceptions, jurisdictions with a common-law research exception struggle more with the uncertainty in scope and existence.[592]

3.7 Privatization of Biotechnology Research

Patent protection has become a common protective mechanism for life science inventions. Today, patents protect many key technologies in biotechnology, with the ownership spread across the public and private sectors.[593] Commercial organizations and public sector and private non-profit sector institutions use patents to try to generate licensing revenues, to attract research funding from businesses in exchange for first access to research results, to encourage start-ups or spinoff

[589] *Supra* note 565; Canada Bill C-86, *A second Act to implement certain provisions of the budget tabled in Parliament on February 27, 2018 and other measures*, 1st Sess, 42nd Parl, 2019, s 193 (assented to 13 December 2018).
[590] Piper, *supra* note 316 at 52-3.
[591] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 383; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 41 [i.e. "statutory experimental use exceptions are also characterized by uncertainty, since in many cases, it is unclear whether or not the exception covers experiments *with* a patented invention or if experimental acts may be done for commercial purposes."].
[592] Gold & Joly, *ibid*.
[593] Biotechnology Industry Organization, *supra* note 8 at 3, 13-15; Lemley, "Ignoring Patents", *supra* note 34 at 19; Carol Nottenburg & Carolina Roa Rodriguez, "Agrobacterium-Mediated Gene Transfer: A Lawyer's Perspective" in Tzvi Tzfira & Vitaly Citovsky, eds, Agrobacterium: From Biology to Biotechnology (New York: Springer, 2008) at 14-15, 23; [e.g. most key enabling technologies in agricultural life sciences are patented and owned by a handful of large agricultural biotechnology companies]; Robert Cook-Deegan & Christopher Heaney, "Patents in Genomic and Human Genetics" (2010) 11 Annu Rev Genomics Hum Genet 383 at 387-388.

businesses, to defend against third party ownership, and to bargain access to IP rights owned by others.[594] Many patents by academic researchers protect technologies that could be used as research tools.[595] Commentators have noted that academic researchers who seek patent protection for life science research discoveries are more likely to patent the upstream research that can enable subsequent R&D than downstream R&D outputs.[596] Scientists have expressed that patent protection for upstream research resources raises two concerns: the breakdown of the research sharing norms in the research community and patents that can deter subsequent research and downstream development.[597] The shift to increase privatization of publicly funded research can interfere with both market-based and non-market-based R&D in the life sciences because it reduces the size of the research resource commons by discouraging scientists from sharing or free revealing new discoveries.[598]

The development of patent proliferation in biotechnology also prompted scholars to consider the presence of the tragedy of the anticommons, especially in biomedicine. The tragedy of the anticommons occurs when too many fragmented rights cover a single resource; this occurrence blocks downstream development due to substantially high transaction costs to secure access to all of the fragmented rights.[599] Although empirical studies that evaluated the presence of the anticommons effect in biotechnology generally agree that patents do not block subsequent

[594] Hope, *Biobazaar*, *supra* note 21 at 273-6.
[595] *Supra* note 593; Hope, *ibid* at 31-35; Petherbridge, *supra* note 20 at 346.
[596] Heller & Eisenberg, *supra* note 298 at 700; Petherbridge, *ibid* ["[u]pstream inventions may include tools and reagents necessary for future research such as nucleic acid sequences and proteomic targets, which may serve as potential targets for chemical or small-molecule therapeutics. Other upstream inventions patented by universities may include new techniques and important materials derived from the application of new techniques, both of which may serve as important platforms for subsequent advances across a large number of life science disciplines."].
[597] McManis & Yagi, *supra* note 324 at 257; Rai, "Regulating Scientific Research", *supra* note 19 at 94-115.
[598] Nowotny, *supra* note 20 at 21.
[599] Heller & Eisenberg, *supra* note 298.

R&D,[600] patents and other property rights (e.g. MTAs and data access agreements) can adversely influence technological progress in biotechnology and reduce social benefit.

3.7.1 Propertization of Research Resources

Research tools in biotechnology can include any resources that scientists need in their labs to carry out research. For example, this can be "cell lines, drug targets, cloning tools, equipment, databases, and computer software."[601] Some of the examples of the most important biotechnology tools include oncomouse, cre-lox mouse, Cohen-Boyer's patented basic method of gene cloning, PCR technology to amplify DNA sequences, the enzyme Taq DNA polymerase, which is a key reagent in PCR, expressed sequence tags (ESTs), human embryonic stem cells, and gene patents associated with genetic diagnostic testing.[602] In both biomedicine and agricultural biotechnology, patents on research tools have increased exponentially in the last several decades.[603] In this biotechnology patent landscape, researchers and developers who want to develop and commercialize complex technologies may need to access an array of proprietary research tools.[604]

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[600] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 7.
[601] Carrier, *Innovation for the 21st Century*, *supra* note 525 at 254-5; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at endnote 10 citing Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts, 64 Fed. Reg. 72,090 (Dec. 23, 1999) [all "tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinational chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."].
[602] *Ibid*.
[603] Hope, *Biobazaar*, *supra* note 21 at 40-41; Nottenburg, Pardey & Wright, "Accessing other people's technology", *supra* note 51 at 392.
[604] Hope, *ibid* [e.g. approximately 70 different patented technologies were used to develop Golden Rice, a genetically engineered rice variety].

The shift to increase public-private partnerships encouraged universities and public research institutions to focus on competition and financial incentives of research.[605] These organizations created technology transfer offices (TTOs) to manage and license patents on research discoveries and to manage other research resources as property.[606] The TTOs can control access to research resources by requiring users to agree to IP licences, material transfer agreements (MTAs) for tangible physical samples,[607] confidentiality agreements to access research know-how or research notes, and database access agreements for research data.[608] IP licences, MTAs, confidentiality agreements and data access agreements permit users to use different types of research resources that are protected by one or more forms of property ownership. It is possible that research may be protected by patents as well as additional property rights that attach to different portions of research.

For example, copyright law protects original, written expressions of a researcher in research notes and research data as an original compilation.[609] Research data can be protected by database rights in EU nations.[610] Know-how or technological information may be protected as trade secrets.[611] Also, the owners of physical samples may enforce their personal property rights

[605] Rai, "Regulating Scientific Research", *supra* note 19 at 94-115; Rai & Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine", *supra* note 336.
[606] Rai, *ibid* at 111; Heller & Eisenberg, *supra* note 298 at 698; Piper, *supra* note 316.
[607] Carrier, *Innovation for the 21st Century*, *supra* note 525 at 279 ["The most common request involves biological materials such as genes, cell lines, tissues, and organisms used to create new products."].
[608] Dianne Nicol & Jane Nielsen, "Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry" (2006) Centre for Law and Genetics Occasional Paper No 6, University of Tasmania at 189; Rai, "Regulating Scientific Research", *supra* note 19 at 94-115; Bessen & Meurer, *Patent Failure*, *supra* note 418 at 13; Carrier, *ibid* at chap 13; Eisenberg, "Noncompliance", *supra* note 298 at 1061-1062.
[609] *Copyright Act*, RS C 1985, c C-42 at ss 2, 5(1); *Feist Publications Inc., v. Rural Telephone Service Co.*, 499 U.S. 340 (1991) at para 44; Vaver, *Intellectual Property Law*, *supra* note 68 at 92.
[610] *Data Protection Directive*, 95/46/EC (1995).
[611] Vaver, *Intellectual Property Law*, *supra* note 68 at 305; *Lac Minerals Ltd v International Corona Resources Ltd,* 1989 CanLII 34 (SCC), [1989] 2 SCR 574; *Cadbury Schweppes Inc. v. FBI Foods Ltd*, [1999] 1 SCR 142, [1999] SCJ No 6, 1999 CanLII 705 (SCC); Hope, *Open Source Biotechnology*, *supra* note 395 at 96-97 [In biotechnology, trade secrecy protects "peripheral information surrounding a patented invention" and information about early stage developments of an invention].

to restrict other researchers from accessing and disseminating the physical materials.[612] Moreover, research resources may contain trademarked designs, sounds or words, which cannot be used without authorization on products and services that derive from subsequent R&D.[613] IP licences, MTAs and data access agreements can also impose further restrictions on users, such as obligations to assign or license any downstream development back to the upstream licensor, publication restrictions, or restrictions on sharing the licensed resource or its derivatives with others.[614] Hence, these additional property rights can be used alone or in conjunction with patent rights to block access to upstream research, restricting subsequent R&D.[615] Herder and Gold note that it is artificial to separate patent rights and other property protection that can cover different pieces of upstream research; it is better to see these property protections as interacting together and reinforcing one another.[616] Therefore, the proliferation of patents and other property rights protecting upstream research resources can impose access barriers for downstream researchers and developers in biotechnology.

Since patents became available for biotechnology inventions, some expressed that more focus on propertizing research in the research community can shift research sharing practices in the life sciences.[617] As discussed above, scientific competitions within the research community can negatively affect scientists' willingness to make research available to others. Moreover, it has been suggested that increased patenting in academic research can delay the disclosure of new

[612]Hope, *Biobazaar*, *supra* note 21 at 144, 160-164.
[613] *Ibid*; Vaver, *Intellectual Property Law*, *supra* note 68 at 428-430.
[614] Heller & Eisenberg, *supra* note 298 at 699; Rai, "Regulating Scientific Research", *supra* note 19 at 111 citing Report of the NIH Working Group on Research Tools (1999) at 4.
[615] Carrier, *Innovation for the 21st Century*, *supra* note 525 at 284; Hope, *Biobazaar*, *supra* note 21 at 101, 160-164.
[616] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 15 ["MTAs, as a general rule, attach confidentiality obligations and use restrictions, in large part, for the purpose of safeguarding the ability of material providers… to file subsequent patent applications."].
[617] Joseph Straus, "Intellectual Property Rights and Bioeconomy" (2017) 12:7 J IP L & Prac 576 at 581; Welsh, "Close Enough but not too Far", *supra* note 48 at 1854-1855.; Rai, "Regulating Scientific Research", *supra* note 19 at 95, 111 citing US Congress, "House Report" (1980) No. 96-1307, part 1 at 3; Eisenberg, "Public Research and Private Development", *supra* note 321 at 1664.

scientific discoveries. Patents can discourage researchers from openly sharing upstream research that could be preliminary discoveries or a precursor or early versions of patentable inventions until they have made sufficient progress to obtain a patent grant.[618] Academic researchers who are participating in public-private partnerships may be required to delay reporting the research in publication for more than six months in order to file a patent application.[619] This delay may be necessary to preserve the novelty of patentable research discoveries.[620]

Furthermore, patents and other property rights that protect upstream biotechnology research resources can increase the overall cost of research by creating access costs (e.g. licensing fees) and transaction costs (e.g. negotiation and search costs).[621] Moreover, these property rights can create research delays by forcing researchers to enter into licensing negotiations before they can use protected research resources. Reduced research sharing, increased research costs, and possible research delays are more likely to negatively impact researchers and developers who have limited resources to experiment with biotechnology, such as scientists in developing or least developed nations, amateur scientists or DIYers, entrepreneurs, open innovation communities, and small-to-medium-sized firms.

When research tools with broad use are tightly controlled with patents and other property rights, innovation can be stifled.[622] Research tools in biotechnology and molecular biology are also important tools in other disciplines that work with biotechnology, such as "chemistry,

[618]Rebecca S Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research" (1987) 97:2 Yale Law Journal 177 at 206-207, 216-217.
[619] Rai, "Regulating Scientific Research", *supra* note 19 at 111 citing David Blumenthal et al, "Withholding research results in academic life sciences: evidence from a national survey of faculty" (1997) 1224 JAMA 227 at 371.
[620] Asay, "Enabling Patentless Innovation", *supra* note 81 at 434-6.
[621] Lemley, "Ignoring Patents", *supra* note 34 at 26 [Inventors are expected to clear patents by carrying out a patent search to identify relevant patents and to license them so as to avoid infringement]; Petherbridge, *supra* note 20 at 354-355.
[622]Bubela, FitzGerald & Gold, "Recalibrating Intellectual Property Rights", *supra* note 426 at 3.

engineering, materials science, ecology, evolution and computer science."[623] Research tools such as fundamental or unique discoveries that cannot be invented around or substituted (e.g. DNA sequences and genes for diagnostic testing) require wide access to enable subsequent R&D.[624] Patenting enabling technologies is particularly problematic because scientists in one or more disciplines may need to access them routinely to solve research problems.[625] Lemley notes that broad patents on enabling inventions are particularly problematic because such patents can block others from experimenting with wider and diverse applications of enabling technologies.[626]

The patent landscape in biotechnology is considered to be highly complex and dynamic.[627] It is difficult to gain a clear understanding of the patent coverage in a research area due to dynamic changes in the status of patents and patent applications in multiple jurisdictions, such as when patent applications are filed, subsequent changes in the status of patent applications, and expired or abandoned patents.[628] It can take years after a patent application is filed for a patent to be granted, and each year, thousands of biotechnology patent applications are filed and are granted in different jurisdictions.[629] An invention may also fall in the public domain earlier

[623] Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283.
[624] Matthew Herder, "Proprietary Interests and Collaboration in Stem Cell Science: Avoiding Anticommons, Countering Canalyzation" in Kristina Hug & Goran Mermeren, eds, *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo* (NJ: Humana Press, 2011); Gert Matthijs, "Gene Patenting and Licensing on and Beyond the BRCA Case" (2004) 10 Eur Soc'y Hum Genetics 13 cited in Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 390; Piper, *supra* note 316 at 46-50.
[625]Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283 at 29; Petherbridge, *supra* note 20 at 360- 361; Rai, "Regulating Scientific Research", *supra* note 19. [e.g. Platform technologies, such as molecular systems, cell lines and transgenic animals, which can be used in various research to generate different discoveries. Also, research equipment that is used in multiple research areas, such as PCR machines].
[626] Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 743.
[627] Biotechnology Industry Organization, "BIO 2005-2006: Guide to Biotechnology", *supra* note 283 at 5; Van Beuzekom & Arundel, *supra* note 313 at 70-75; Hope, *Biobazaar*, *supra* note 21 at 44-45, 63-66; Walsh et al, "Effects of Research Tool Patents", *supra* note 51; Nottenburg & Roa-Rodriguez, *supra* note 593; Petherbridge, *supra* note 20; Murray & Stern, *supra* note 124 at.4.
[628] Also, see John P Walsh, Charlene Cho & Wesley M Cohen, "View from the Bench: Patents and Material Transfers" (2005) 309 Science 2002 at 2002.
[629] According to the "Canadian Intellectual Property Office Annual Report 2017-2018", the time between the request for examination of a patent application and the moment of patent grant is an average of 33.6 months in 2017-2018.

than at the end of the patent term if a patent application is withdrawn after publication,[630] an application is deemed abandoned,[631] or a patent lapsed for non-payment of maintenance fees.[632] Even after a patent is granted, patent claims may be challenged and invalidated in litigation or through post-grant opposition procedures (where available).[633] The patent coverage of the same invention can vary by nation and may be issued at different times.[634] Therefore, patents can expire at different times in different jurisdictions. Some argue that patenting an invention solely for a defensive purpose may also further complicate the patent landscape in biotechnology.[635] All of these dynamic actions in the patent databases can make it difficult for scientists in different jurisdictions to navigate the patent landscape to ascertain which technologies are free of patent protection at a given moment in time. Scientists can experience difficulty avoiding patent infringement or organizing R&D collaboration across multiple jurisdictions.

Even after identifying relevant patents, access to patented research tools may not be available at all to users because key patents protecting a research tool are exclusively licensed to a commercial licensee, users cannot find information about subsequent patent assignments, or patentees refuse to license to people outside of their research or industry network.[636] When university-invented research tools are patented and sold or exclusively licensed to commercial entities, they can strategically use their rights to influence scientific progress towards a direction that can benefit private interests rather than allow public assets to benefit public interests (e.g.

CIPO received 34,718 patent applications in 2017-2018 and granted 24,204 patents. See online: CIPO < http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr04468.html>.

[630] MOPOP, *supra* note 309 at s 20.01 ["An application which is withdrawn after being opened to public inspection will remain publicly accessible."].

[631] *Patent Act*, *supra* note 303, ss 73(1)&(2); MOPOP, *ibid* at s 20.01 [Abandonment "could result from failure to reply in regards to the application or to pay necessary fees when due."].

[632] MOPOP, *ibid* at s 20.04 ["A lapsed patent cannot be revived"].

[633] Hope, *Biobazaar*, *supra* note 21 at 44-45.

[634] *Ibid*.

[635] Bubela, FitzGerald & Gold, "Recalibrating Intellectual Property Rights", *supra* note 426 at 3; Shapiro, "Navigating the patent thicket", *supra* note 513 at 121.

[636] Hope, *Biobazaar*, *supra* note 21 at 46.

towards increasing innovation and improving access to knowledge).[637] For example, it caused an outrage from the mouse research community when Harvard University's patents on oncomouse and cre-lox mice were exclusively licensed to DuPont, which then began offering to license the transgenic mice to the academic community with stringent conditions and a fee.[638] The licence included restrictions on sharing and breeding, annual research disclosure to DuPont, and a grant-back clause on the rights of any discoveries made with the mice.

Moreover, when Myriad Genetic granted an exclusive licence of its patents on the BRCA 1&2 genes and diagnostic tests for breast cancer to a commercial test provider, the licensee tried to force public laboratories in Canada to conduct genetic diagnostic testing through the test provider rather than carry out their own testing.[639] Myriad had obtained the BRCA 1&2 gene patents from multiple patent offices, including the United States, Europe, Canada, Australia and Japan.[640] Government health agencies, diagnostic test providers and research organizations criticized Myriad's enforcement of these patents to control the marketing of the BRCA tests as interfering with the provision of healthcare services as well as improvements and further advances in the area by restricting the number of labs that can work with a particular test.[641]

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[637] Boettiger & Burk, *supra* note 68 at 221-225; Hope, *Biobazaar*, *supra* note 21 at 61[One type of strategic patent use is a submarine patent, which is "a patent that is not issued or enforced until after the relevant [invention] has been widely adopted, leaving users in a weak bargaining position with respect to the patent owner"].

[638]Murray et al, "Of Mice and Academics", *supra* note 525; Fiona Murray, "The Oncomouse that Roared: Hybrid Exchange Strategies as a Source of Distinction at the Boundary of Overlapping Institutions" (2010) 116:2 Am J Soc 341 at 361-364.

[639] Piper, *supra* note 316 at 46-50[Piper also discusses Warnex Inc.'s enforcement of its exclusive licence for a diagnostic test for the JAK2 gene and Myeloproliferative disorders].

[640] *Ibid*; "Bioethics and Patent Law: The Case of Myriad", *WIPO Magazine* 4/2006 (August 2006), online: WIPO <https://www.wipo.int/wipo_magazine/en/2006/04/article_0003.html>; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (London: Nuffield Council on Bioethics, 2002) at 39-40; E. Richard Gold & Julia Carbone, "Myriad Genetics: In the eye of the policy" (2010) 12 Genet Med S39, online: National Center for Biotechnology Information <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037261/>.

[641] *Ibid* [The Ontario Provincial Government ignored the patents by not responding to Myriad's cease-and-desist letter to stop public laboratories from administering its own tests. Subsequently, the Canadian Biotechnology Advisory Committee (CBAC) recommended amending the *Patent Act* to adopt a broad research exception, to allow the public healthcare system to use health-related patents, and to include provisions to discourage high pricing to access these patents. Several research institutions in European nations, including three French organizations, the Belgian Society of Human Genetics, and the Danish Society for Medical Genetics, filed opposition procedures

3.7.2 Adverse Effects of the Proliferation of Rights in Biotechnology

Since the development of patent proliferation in biotechnology, scholars have debated whether patents on research resources block subsequent R&D efforts by barring researchers' access to them. Heller and Eisenberg devised the anticommons hypothesis in 1998 upon observing that the patent landscape in biomedical research suffered from the preconditions of an anticommons: "the existence of a large number of patents [with sometimes overlapping patent claims], owned by different parties with different agendas".[642] The anticommons theory rests on the view that the development of too many fragmented upstream IP rights will stifle downstream innovation because there will be substantially high transaction costs to secure access to all upstream rights.[643] The risk of bargaining failure increases when multiple fragmented rights cover a single technology. The "tragedy of the anticommons" is based on Garrett Hardin's theory of the tragedy of the commons.[644] The tragedy of the commons provides a strong justification for privatizing commons property to avoid overuse because otherwise, people will act on self-interest and will have no incentive to preserve the commons. Conversely, the tragedy of the anticommons occurs when there are too many owners of a scarce resource, and each owner has the right to exclude others' use of the resource. In this situation, all rights holders must coordinate the use of the

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against Myriad Genetics to challenge these patents' validity for lack of novelty, inventiveness, utility or industrial application and sufficient disclosure. They also raised the two policy issues noted above. The oppositions resulted in Myriad's patents being limited in scope at the EPO].

[642] Heller & Eisenberg, *supra* note 298 at 698-701; Eisenberg, "Noncompliance", *supra* note 298 at 1060, 1072-1075.

[643] Heller & Eisenberg, *ibid*; Eisenberg, "Noncompliance", *ibid* at 1060, 1075.

[644] Heller & Eisenberg, *ibid*; Garrett Hardin, "Tragedy of the Commons" (1968) 162 Science 1243; and "Extensions of 'The Tragedy of the Commons'" (1998) 280 *Science* 682.

resource. If it is difficult for users to negotiate with multiple owners to collect all of the rights covering the resource, it will suffer from underuse.[645]

Heller and Eisenberg suggested that the tragedy of the anticommons would likely occur in biomedical research and block downstream development because it is difficult to standardize the use of diverse upstream patented research resources; there are heterogeneous rights holders including both academic and private sector researchers who operate with different motives, resources and constraints; and licensing negotiations might be difficult due to cognitive bias in patentees who are likely to overestimate the value of their patents.[646] The problem of allocating the value of a licensed technology is common in biotechnology because participants are made up of a heterogeneous group, the value of patented upstream research or research tools depends on undiscovered downstream inventions, and there is an asymmetry of knowledge between licensors and licensees.[647]

The tragedy of the anticommons can form horizontally or vertically.[648] A horizontal anticommons can occur when separate IP rights encumber different parts of a resource. For example, fragmented patent rights on human gene sequences can interfere with or holdup drug discovery or the development of therapeutic treatments by barring researchers' access to gene sequences.[649] A vertical anticommons occurs when multiple patents cover a cumulative process.[650] This occurs when there is a stacking of reach-through rights of multiple upstream

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[645] *Ibid*; Robert P Merges, "A New Dynamism in the Public Domain" (2004) 71 U Chicago L Rev 1 at 4.
[646] Heller & Eisenberg, *ibid*.
[647] Hope, *Biobazaar*, *supra* note 21 at 48 ["the biotechnology and related industries are made up of many different kinds of institutions, each with its own mission, resources, and constraints. In fact, all institutional types - universities, hospitals, private non-profit research institutions, government agencies, small biotechnology firms, and major pharmaceutical firms or agribusiness concerns – recognize that such differences might sometimes justify asymmetrical terms of exchange."].
[648] Burk & Lemley, *The Patent Crisis, supra* note 453 at 86; Heller & Eisenberg, *supra* note 298 at 699-700.
[649] Merges, "A New Dynamism in the Public Domain", *supra* note 645 at 5; Burk & Lemley, *The Patent Crisis*, *ibid* at 89.
[650] Burk & Lemley, *ibid* at 86; Heller & Eisenberg, *supra* note 298 at 699.

researchers, such as an obligation to receive a royalty payment from the sale of downstream products.[651] In that case, a downstream developer can face large access costs for multiple upstream patents in order to engage in cumulative development downstream. Reach-through agreements can make it possible for upstream patentees to control downstream developments that fall outside of their patent claims, for example, by staking their rights to seek benefit from downstream products or improvements that fall outside of the upstream patent claims.[652]

After Heller and Eisenberg's anticommons theory was published, several empirical studies considered the presence of the tragedy of the anticommons in biomedicine within and outside of the United States.[653] These empirical studies generally agreed that the evidence of the tragedy of the anticommons is not present in biotechnology, where patents impede biotechnology R&D (except for research on genes and genetic testing services).[654] That is, despite a significant increase in patenting, patent rights have not blocked research and development activities in biotechnology. The empirical studies found that there is very little evidence of bargaining failure for academic researchers.[655] Moreover, in most cases, patents did not completely block firms

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[651] *Ibid* [Reach-through conditions may also require downstream developers to assign or license, exclusively or non-exclusively, subsequent discoveries using the upstream patent].

[652] Murray, "The Oncomouse that Roared", *supra* note 638 at 361-364; Eisenberg, "Noncompliance", *supra* note 298 at 1072-1075 [e.g. DuPont's non-commercial use licence for mice patents included terms that "require licensees to return to DuPont for further approval before any new discoveries or materials resulting from the use of licensed mice are passed along to others or used for commercial purpose. DuPont thereby gains the right to participate in future negotiations to develop commercial products that fall outside the scope of their patent claims."].

[653] Walsh et al, "Effects of Research Tool Patents", *supra* note 51; Walsh, Cho & Cohen, "Patents, Materials Transfers", *supra* note 628; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608; Mildred K Cho et al, "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services" (2003) 5 J Molecular Diag 3; John P Walsh, Wesley M Cohen & Charlene Cho, "Where excludability matters: Material versus intellectual property in academic biomedical research" (2007) 36 Research Policy 1184; Zhen Lei, Rakhi Juneja& Brian D Wright, "Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research" (2009) 27:1 Nat Biotech 36; OECD*, Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (Paris, OECD, 2002); Walsh et al, "View from the Bench", *supra* note 628; Stephen M Maurer, "Inside the Anticommons: Academic Scientists' Struggle to build a Commercially self-supporting Human Mutations Database (2006) 35 Res Policy 839.

[654] Cho et al, *ibid*; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608 at 83; Walsh et al, "Effects of Research Tool Patents", *ibid* at 317-19.

[655] OECD, *Genetic Inventions*, *supra* note 653 at 45-48 and Walsh et al, "View from the Bench", *supra* note 628 at 2002 [e.g. These surveys show that very few academic researchers experienced research delay due to patented

from pursuing downstream R&D; firms were able to gain access to relevant technology or to find an alternative project to pursue that did not suffer from extensive upstream patent coverage.[656]

Nonetheless, commentators note that the development of patent proliferation in biomedicine can still be detrimental to scientific progress and the provision of healthcare because patents can affect who can contribute to R&D and what types of R&D are pursued.[657] They argue that more evidence is needed to understand how patents influence progress in biotechnology.[658] It is difficult to perform rigorous empirical studies of the anticommons effect in biotechnology because institutions may not have records of abandoned projects or keep such records as confidential information, a researcher's decision not to pursue a project is not always clear, and researchers themselves may not be fully aware of how much patents may have affected their decision to start a project.[659]

Furthermore, patents on research resources can still burden researchers and developers by adding costs to R&D and affect their decisions.[660] When researchers try to avoid patent thickets by pursuing another research, society foregoes R&D opportunities that could have generated considerable value.[661] Murray and Stern suggest that there is evidence that patents interfere with scientists' ability to build on prior research. They observed that patents do appear to have a mild anticommons effect in scientific research and adversely affect the dissemination of scientific knowledge because the citation rate of published scientific articles declined after the patent grant

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research tools (approx. 1%) and no one had to abandon a project specifically due to patent barriers to research inputs]; Timothy Caulfield et al, "Evidence and anecdotes: an analysis of human gene patenting controversies" (2006) 24 Nature Biotech 1091 at 1092.

[656] Walsh et al, "Effects of Research Tool Patents", *supra* note 51 at 1189; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608 at 88-89.

[657] Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 7.

[658] Hope, *Biobazaar*, *supra* note 21 at 52.

[659] *Ibid*.

[660] *Ibid* at 67.

[661] Walsh et al, "Where Excludability Matters", *supra* note 653; Eisenberg, "Noncompliance", *supra* note 298 at 1066; Hope, *ibid* at 60-65.

of the underlying discovery.[662] Scholars also note that the proliferation of patents and proprietary management of biotechnology inputs and outputs, which raise transaction costs, are indeed detrimental to open and collaborative research.[663]

The anticommons theory also does not consider preventative or avoidance strategies that researchers practice to lower transaction costs or to avoid patent access barriers when a research area appears to suffer from too many patents.[664] These measures help researchers avoid the tragedy of the anticommons. Many of these measures to avoid patent interference in R&D (i.e. patent access barriers on upstream research tools and the anticommons problems such as holdup and royalty stacking) can impose additional costs on researchers and cause them to waste time, which could be used on R&D. Hence, patent proliferation in biotechnology can still be detrimental to technological progress.

These strategies include trying to invent around patents where possible; carrying out the offending portion of research in jurisdictions where the patent is not issued; and pursuing a different research project.[665] As noted above, researchers can also challenge the validity of patents in litigation or through post-grant opposition procedures to avoid infringement. Researchers can also prevent future patent access barriers to research resources by defensively publishing or releasing research results into the public domain, implementing private ordering (e.g. open source licensing), and creating cooperative rights management (e.g. patent pooling and patent clearinghouses).[666] In some instances, the research community was able to successfully apply pressure on public and private sector patentees to open up access to proprietary research

[662] Murray & Stern, *supra* note 124.
[663] Hope, *Biobazaar*, *supra* note 21 at 60-63; Caulfield et al, "Open Science Versus Commercialization", *supra* note 44 at 6; Piper, *supra* note 316 at 47.
[664] Hope, *ibid* at 52; Caulfield et al, "Evidence and anecdotes", *supra* note 655.
[665]Carrier, *Innovation for the 21st Century*, *supra* note 525 at 264-267; Walsh et al, "Effects of Research Tool Patents", *supra* note 51; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608.
[666] Delfanti, *supra* note 1 at 76; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560; Boettiger & Burk, *supra* note 68 at 230; Hope, *Biobazaar*, *supra* note 21 at 52.

resources to prevent the tragedy of the anticommons.[667] Even in these situations, the research community can still incur high transaction costs to negotiate access in these situations.

Researchers may be able to avoid patent access barriers under a research exception in patent law or by ignoring patents and wait to see if patents are enforced against them.[668] A research or experimental use exception[669] in patent law can be an important defence for academic researchers and in open science as it permits some free, unauthorized use of patents for research or experimental purposes.[670] On the other hand, as noted above, it may be risky to rely on a research exception in patent law because it does not always excuse unauthorized patent use in research (i.e. unauthorized use of research tool patents and research use in commercial activities are not excused). Also, the exception's scope can be uncertain and varies in nations, with some nations not offering a general research exception in patent law.[671]

Some studies suggest that academic researchers have not been impeded by the development of patent proliferation in biotechnology because many have been able to ignore patents without experiencing patent enforcement.[672] Patentees bear the costs to locate infringers and enforce patents, which can deter patentees from enforcing their rights against some

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[667] Delfanti, *ibid*; Nielsen, *Reinventing Discovery, supra* note 1 at 6-7; Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76; Rai, "Regulating Scientific Research", *supra* note 19 at 112—115; Hope, *ibid* at 40; Boettiger & Burk, *ibid* at 222.

[668] Walsh et al, "Effects of Research Tool Patents", *supra* note 51 at 1189; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608 at 88-89; Lemley, "Ignoring Patents", *supra* note 34; Walsh et al, "View from the Bench", *supra* note 628 at 2002 [A U.S. survey of 414 biomedical researchers in the public sector shows that only 5% of respondents regularly checked patents on research tools even after *Madey v. Duke University,* 307 F.3d 1531 (Fed. Cir. 2002)].

[669]Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560at 384 ["The terms 'research exception.' 'research exception,' 'experimental use exception,' and 'experimental use defense' are often used as synonyms."].

[670] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 46; Bently, "Introduction", *supra* note 330 at 36-39; Panel Report *Canada-Patent Protection of Pharmaceutical Products* (2000), *supra* note 569.

[671] Sarnoff & Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents", *supra* note 401 at 1301; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 33; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560.

[672] *Supra* note 668; Nicol & Nielsen, "Patents and Medical Biotechnology", *supra* note 608 at 178; Eisenberg, "Noncompliance", *supra* note 298 at 1080; Katherine J Strandburg, "Sharing Research Tools and Materials: Homo Scientificus and User Innovation Community Norms" (2008) [unpublished achieved at SSNR], online: SSNR < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1136606>.

infringers.[673] The possibility of avoiding the tragedy of the anticommons by ignoring patents is likely to be effective when research does not have a commercial purpose or is not associated with a profit-generating entity that can pay patentees settlement fees or damages (see Chapter Four for discussions on the ignoring norms in research). Nonetheless, instead of pursuing individual university researchers for infringement, some patentees may choose to pursue actions against their universities and cause them to incur high transaction costs for the faculty members' unauthorized patent use.[674]

Even if patent rights do not impede academic research, as noted above, research can be deterred or delayed when researchers have difficulty accessing complementary upstream research resources protected with other IP rights, MTAs and data access agreements. These property rights can be enforced alone or in conjunction with patents to regulate access to upstream research. Empirical studies found that scientists did have more problems gaining access to physical materials and data from other scientists because physical materials and research data are difficult to replicate.[675] When researchers are able to replicate a patented research tool in their lab without contacting its owner, researchers can ignore the patent and practice it without incurring transaction costs or experiencing bargaining failure. However, users are more likely to need to contact the property owner(s) and incur transaction costs before they can use research resources that are difficult to reproduce, such as physical materials and data. Empirical studies found that academics refused to fulfill other researchers' requests to access research materials for three main reasons: to avoid the cost or effort to supply the requested research input, to protect

[673] Eisenberg, *ibid* at 1063 – 1071, 1085-6.
[674] Eisenberg, *ibid* at 1081-2.
[675] See *supra* note 653; Walsh et al, "View from the Bench", *supra* note 628 at 2002 [According to a survey, 75% of survey respondents in academia made the average 7 requests for materials to other academics and 2 requests to industry labs in the past 2 years. 19% of the respondents reported that their most recent request was denied. The authors note that this trend seems to be growing].

research publications from academic competitors, and to protect the commercial value of research.[676] More scientists (in academia and private industry) reported that the use of MTAs on research samples and database access agreements causes more impediments for follow-on research.[677] For example, complex MTA negotiations can cause significant research delays of months and years. Hence, the tragedy of the anticommons can occur in biotechnology because the shift to increase proprietary management of research has yielded the proliferation of property rights that can restrict access to upstream research resources.

Eisenberg refined the original anticommons hypothesis by adding a new qualifier to the original anticommons theory after these findings: the practical difficulties of restricting user access to research resources are also an important consideration when evaluating whether the proliferation of rights will actually cause resources to be underused.[678] Hence, if the property owner bears the burden of inertia (which is likely in the case of easily replicated patents), it is less likely that the property will suffer from underuse despite the proliferation of rights. That is, patentees will not enforce their rights against all infringers because patentees bear the costs to locate infringers and enforce patents. However, if users bear the burden of inertia (which is likely for physical materials and data), it is more likely that the tragedy of the anticommons will occur, causing protected resources to be underused. Therefore, the development of the proliferation of property rights in biotechnology can impede subsequent R&D by blocking access to upstream research resources.

[676] Walsh et al, "View from the Bench", *ibid* at 2003; Walsh et al, "Patents, Material Transfers", *supra* note 359 at 27-28, confirming the result of an earlier survey study by Eric G Campbell et al, "Data Withholding in Academic Genetics" (2002) *JAMA* 287 at 473-480.
[677] Walsh et al, *ibid*; Eisenberg, "Noncompliance", *supra* note 298 at 1082.
[678] Eisenberg, *ibid* at 1063 – 1071, 1085-6.

3.8 Patent Failures in Downstream Development of Biotechnology

While biotechnology is applied in several sectors, the two most prominent industries that engage in biotechnology R&D are healthcare and agricultural industries.[679] Scholars have argued that the utilitarian justification of patent law is challenged when life science patents protect technologies that are fundamentally important to ensure people's welfare, such as healthcare and agriculture.[680] They have argued that the upward harmonization of patent law, which establishes strong and uniform patent rights in nations, does not guarantee the global population's welfare. Patents can threaten public welfare by creating inequitable access to essential technologies and blocking downstream uses in developing nations. Patent failures can occur in biotechnology when patent law interferes with or discourages R&D efforts for socially valuable inventions in nations. And patent failures can be detrimental to citizens' welfare when patent law disrupts healthcare delivery and agricultural practices in nations.

Healthcare biotechnology is used for drug development, medical devices and diagnostics.[681] Hope notes that with the explosion of life science patents on upstream research tools, increasingly more patents are involved in a medical invention that is close to commercialization.[682] Moreover, studies show that patents do not provide positive incentives for R&D to solve healthcare problems in developing nations, and patents can hamper efforts to modify existing drugs to meet healthcare needs in these nations.[683] Patent rights can create

[679] Hope, *Biobazaar*, *supra* note 21 at 54.
[680] Taubman, *supra* note 283 at 220-222; Helfer & Austin, *Human Rights and Intellectual Property*, *supra* note 283 at 31-42; *ibid* at 97-102.
[681] Hope, *ibid* at 54.
[682] Hope, *ibid* at 40.
[683] Hope, *ibid* at 97-99 citing Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, Final Report of the Commission on Intellectual Property Rights (London, 2002), online: Commission on IPR <http://www.iprcommission.org/graphic/documents/final_report.htm>; Gold et al, "Are Patents Impeding Medical Care and Innovation?", *supra* note 446 at 2; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 12 [There is not enough market incentive to adapt existing therapies "for example, fixed-dose combinations of HIV/AIDS antiretrovirals or formulations suitable for children – for use by afflicted

inequitable access to medical treatments by increasing their costs, and the patent system encourages R&D efforts to concentrate on producing treatments for diseases that are prevalent in developed nations.[684] Businesses are unwilling to make the large R&D expenditures necessary to develop a new drug unless they can return a profit; consequently, businesses are neglecting developing nations' healthcare needs as these markets are not large enough to generate profit.[685] Businesses also do not want to jeopardize their market in developed nations by selling the same drug cheaper in developing nations.[686]

Public sector researchers, on the other hand, primarily focus research efforts on domestic illnesses of developed nations and lack funding to fully engage in pharmaceutical R&D.[687] The incentive to create profits from the publicly funded research by transferring it to the private sector may encourage university researchers to selectively choose projects that interest private sector organizations and yield profits rather than pursuing research projects that can maximize public benefit.[688] Meanwhile, not many developing nations possess the capacity for R&D in biotechnology.[689] Developed nations' researchers conducting R&D for medical needs in developing nations may experience access restrictions on proprietary research tools due to patents owned by the patentees rooted in developed nations. Hence, scholars have argued that

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populations in the developing world."]; Amy Kapczynski et al, "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations" (2005) 20 Berkeley Tech LJ 1031 at 1042-1057.

[684] Kapczynski, *ibid*; Hope, *ibid*.

[685] Kapczynski, *ibid* at 1038; Hope, *ibid*; Gold et al, "Are Patents Impeding Medical Care and Innovation?", *supra* note 446 at 3.

[686] Hope, *ibid*.

[687] *Ibid* citing Thomas Pogge, "Could Globalization be Good for World Health?" (2007) 1 Global Justice 1 and Lorenzo Savioli et al, "Response from Savioli and Colleagues from the Department of Neglected Tropical Diseases, World Health Organization" (2006), online: PLoS Medicine < https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0030283>
["Currently, malaria, pneumonia, diarrhea, and tuberculosis, which together account for 21% of the global disease burden, receive 0.31% of all public and private funds devoted to health research. More than 1 billion people – the overwhelming majority of whom are in the developing world – suffer from neglected tropical diseases, those for which there are inadequate or nonexistent treatments and a paucity of research and development."].

[688] Eisenberg, "Public Research and Private Development", *supra* note 321 at 1714-5.

[689] Hope, *Biobazaar*, *supra* note 21 at 97-99.

patents raise a public policy concern in healthcare biotechnology: patents should not exist to benefit only one section of the national or global population while failing to benefit or causing detriment to others.[690]

Biotechnology allows agricultural businesses to develop an entirely new type of product, such as genetically modified seeds. Scholars note that the upward harmonization of patent law benefits developed nations' agricultural businesses while interfering with traditional agricultural practices and global food security.[691] Although most agricultural R&D had been publicly funded in the past, the decline in public funding in recent years allowed the private sector to evolve.[692] Less than ten multinational agricultural corporations rooted in developed nations, such as Monsanto and Dupont, control the global agricultural biotechnology market.[693] Agricultural businesses focus their R&D efforts on the development of crops and products with large markets rather than aiming to serve the many citizens who suffer from poverty.[694] Patents (and plant variety rights) on genetically modified seeds can also interfere with traditional agricultural practices (e.g. seed saving) and create hardships for farmers in developing nations.[695] Agricultural businesses create revenues by forcing farmers in developing nations to repurchase patent-protected genetically engineered seeds each year and continuing to charge high prices for the off-patent pesticides or herbicides, which are supposed to work with a genetically engineered

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[690] Gold et al, "Are Patents Impeding Medical Care and Innovation?", *supra* note 446 at 3.
[691] Hope, *Biobazaar*, *supra* note 21 at 98-102 [i.e. biotechnology is applied to solve "problems of soil management, crop production, and environmental sustainability in poor rural areas"]; Nancy Podevin et al, "Transgenic or not? No simple answer!: New biotechnology-based plant breeding techniques and the regulatory landscape" (2012) 13 EMBO Rep 1057 at 1057 citing Clive James, *Global Status of Commercialized Biotech/GM Crops: 2011*, Brief No 43 (New York: ISAAA, 2011); Blair D Siegfried & Richard L Hellmich, "Understanding successful resistance management: the European corn borer and Bt corn in the United States" (2012) 3 GM Crops Food 184; Jerry M Green, "The Benefits of Herbicide-Resistant Crops" (2012) 68 Pest Manag Sci 1323; Helfer & Austin, *Human Rights and Intellectual Property*, *supra* note 283 at chap 6.
[692] Alan B Bennett & Sara Boettiger, "Case 5. The Public Intellectual Property Resource for Agriculture (PIPRA)" in van Overwalle, *Gene Patents and Collaborative Licensing Models*, *supra* note 85 at 135-8; Hope, *ibid*.
[693] "Six multinational companies dominate the agricultural input market" (11 June 2011), online: Gas&Oil < http://www.gasandoil.com/oilaround/2011/06/six-multinational-companies-dominate-the-agricultural-input-market>.
[694] Hope, *Biobazaar*, *supra* note 21 at 98-102.
[695] *Ibid*; Helfer & Austin, *Human Rights and Intellectual Property*, *supra* note 283 at 364-394.

crop.[696] Also, agricultural companies can enforce patents to remove other businesses from marketing the same genetically modified seeds or crops.[697]

Moreover, it has been observed that research tools in agricultural biotechnology are close to suffering the tragedy of the anticommons due to many overlapping proprietary rights.[698] Agricultural businesses and public-sector research institutions patent-protect their research tools that can be used to generate agricultural products. Researchers and developers may need access to dozens of propertized research tools in agricultural biotechnology to create genetically engineered seeds or crops.[699] The development of overlapping upstream rights can interfere with public sector researchers' R&D in both developed and developing nations by restricting their access to research tools.

As discussed in the previous chapter, patent failures in these biotechnology industries have motivated some DIYers to explore real-life problems that are overlooked by researchers developers in patent-based R&D. These non-traditional scientists may think of ways of applying science and technology that scientists working in the private sector, public research institutions or universities may not be able or hesitant to pursue due to their funding source, research partnerships, employers, or the culture and hierarchical structure of professional research labs. The DIY bio movement also encourages participants to broadly and openly disseminate biotechnology inventions for cumulative development and public benefit. Nonetheless, patent law can also fail society when existing patents in biotechnology discourage and interrupt alternative open R&D and rob society of the opportunities to benefit from them (see below in Chapter Four).

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[696] Hope, *ibid*.
[697] Hope, *ibid*.
[698] Hope, *ibid* at 40-1, 275-6; Nottenburg, Pardey & Wright, "Accessing other people's technology", *supra* note 51 at 392.
[699] *Ibid.*

3.9 Conclusion

This chapter examined potential problems in patent law: trade-focused upward IP harmonization that promotes stronger uniform IP law in nations, fragmented and overlapping patent rights in biotechnology, improvident and poor quality patents in cumulative industries, aggressive and strategic patent enforcement, and outdated patent exceptions. The U.S.-led patent law developments since the 80s encouraged the development of patent proliferation and propertization of upstream research resources from public and private sector research in biotechnology. The proliferation of biotechnology patents with fragmented and overlapping rights and increasing uses of other property rights to protect upstream research in biotechnology can increase inadvertent patent infringement and reduce access to research tools and equipment for researchers and developers. Society can maximize public benefit when both open and closed systems of innovation contribute to the overall scientific and technological progress. However, developments in patent law since the 80s can increase patent risks for researchers and developers in biotechnology, where third party patents in a research area create hardships and discourage contribution to science and technology. The following chapter explores how the existing biotechnology patent landscape can create patent risks for DIYers and potentially discourage R&D.

Chapter 4: Conflicts between Patents and Social Production in Biotechnology

4.1 Introduction

A highly complex and dynamic patent landscape in biotechnology can also create hardships in socially produced biotechnology, such as DIY bio. DIYers experimenting with biotechnology today may try to avoid patent infringement and patent access barriers to upstream research resources by building on off-patent technologies and inventing around patents. Nonetheless, contributors and users of such social production projects can inadvertently infringe patents when fragmented and overlapping patents cover significant upstream technologies. This chapter considers possible patent risks for contributors and users of socially produced biotechnology.

Patents can also interfere with the use of socially produced biotechnology inventions when subsequent third party patents block its use, follow-on development and commercialization. Open innovation communities stimulate modifications and improvements as well as non-commercial and commercial uses of open innovation by openly disseminating the innovation. When patent use is prevalent in a field of endeavour, open innovation communities may consider actively protecting open inventions from third party patent interference to safeguard the inventions for future R&D and commercial use. Freely revealing an invention to the world or defensive publishing may not establish prior art that can always defeat subsequent attempts of patenting the same invention.

Social production in biotechnology is at a nascent stage of development.[700] Hence, at this time, many activities may not engage patent law as they are trivial, minor and obvious.[701] Nonetheless, as discussed in Chapter Two and below, there are publicized DIY bio and citizen science projects that demonstrate the substantial innovation potential in this innovation

[700] Grushkin, Kuiken & Millet, *supra* note 7 at 6 at 4; Golinelli & Ruivenkamp, *supra* note 3 at 153.
[701] Grushkin, Kuiken & Millet, *ibid* at 10; Delfanti, *supra* note 1; Golinelli & Ruivenkamp, *ibid*.

environment. I did not observe patent disputes relating to these activities during my research. However, patent conflicts may become visible when there is active participation from more commercially motivated contributors and users who are better targets of patentees. The presence of more patent trolls in biotechnology can also increase patent risks for social production participants. The discussions in this chapter incorporate a small selection of DIY projects that I have come across in my research; these are used to illustrate some of the ways that patent conflicts can arise from DIY bio.

As discussed in the previous chapter, patent law in many nations extend a research exception to non-commercial patent users but not for the use of research tool patents and commercially motivated patent infringement. The cost-benefit account of patent risks in open innovation and the norms-based information exchange in scientific research are examined to assess possible patent risks for different types of social production participants. According to the cost-benefit account, non-commercially motivated patent infringers and foundations or non-profit organizations that represent or assist an open innovation community will likely face negligible patent risks from commercial patentees and patent trolls because the cost of pursuing these types of infringers outweigh the benefit for patentees and the infringing use is likely ignored. Nonetheless, the development of patent thickets in a research area can still be detrimental to open innovation because non-commercial contributors and users may be discouraged from participating in such a research area to avoid creating patent conflicts. Open innovation participants with commercial or mixed non-commercial and commercial motivations will likely face actual or legitimate patent risks when they infringe patents controlled by commercial patentees or patent trolls. Yet, commercial patentees who can benefit from commercial infringers' activities may be discouraged from bringing actions against such

infringers (e.g. commercial contributors that increase open source tools for commercial patentees' products).

According to the norms-based account of information exchange in scientific research, academic researchers benefit from academic and commercial patentees who ignore unauthorized patent use in academic research. Some suggest that there might be an ignoring patent norm in academic research. The norms in research and the cost-benefit evaluation influence patent ignorance in academic research. Academic patentees may ignore patent infringement in DIY bio, which follows the open science tradition. However, academic researchers will likely not ignore patent use that resembles a commercial endeavour more than open science because there are signs that the sharing norm in academic research is weakening, and the patentees' benefit may outweigh the costs of enforcing patents. Commercial patentees in biotechnology will likely not ignore commercially motivated patent infringement of DIYers and subsequent users unless their infringing activities also benefit the patentees. Academic patentees who can support a DIY-business without a conflict of interest may ignore the commercially motivated patent use if the patentees consider the infringing activity to benefit society or scientific progress.

Some open science and open innovation communities depend on alternative knowledge management using private ordering and central control to protect the open and cooperative development from IP threats.[702] The OSS development community's use of open source licensing is a famous example that has been followed in other commons-based communities (see Chapter Five below). Before moving on to consider different types of alternative knowledge management for DIY bio, this chapter briefly reviews the role of non-profit organizations that

[702] Mariateresa Maggiolino & Maria Lilla Montagnani, "Standardized Terms and Conditions for Open Patenting" (2013) 14:2 Minn J L Sci& Tech 785 at 811-814; Clark D Asay, "The General Public License Version 3.0: Making or Breaking the FOSS Movement?" (2008) 14 Mich Telecomm L Rev 265; Vikrant Narayan Vasudeva, *Open Source Software and Intellectual Property Rights* (Alphen aan den Rijn, The Netherlands: Wolters Kluwer Law & Business, 2014). Also, see Chapter Five below.

support commons-based communities because they can enhance the communities' knowledge management and open and cumulative development. Organizations can carry out various functions to protect commons-based development from internal and external interference. As a neutral intermediary, organizations can provide top-down control and centralized decision-making in bottom-up and loose-knit open R&D. Organizations can define and enforce community rules, norms and law, resolve disputes between volunteer participants, transact with external entities on behalf of project members, and centrally manage access to shared resources and community properties.

4.2 Possible Patent Interferences in Open Innovation

Open innovation communities traditionally operated outside of the patent system, without obtaining patent protection for their inventions.[703] Unlike patent-incentivized innovation that depends on the right to exclude unauthorized use, Open innovation communities that follow the open science tradition and hacker culture depend on the free flow of R&D and broad access to research tools to stimulate cumulative development. Open innovation communities encourage both non-commercially and commercially motivated uses of open innovation. Therefore, these activities can replenish the commons and encourage entrepreneurship.

As discussed in the previous chapter, patentees are granted the right to control "making, constructing, and using the invention and selling it to others to be used" and patent law applies strictly against unauthorized users who unknowingly or inadvertently infringe patents.[704] Patent law encourages improvements by awarding separate patents on downstream inventions, which

[703] Asay, "Enabling Patentless Innovation", *supra* note 81 at 436.
[704] *Patent Act, supra* note 303, s 42.

leads to multiple fragmented and possibly overlapping rights for cumulative technologies.[705] Asay notes that when significant technologies are involved (i.e. fields of endeavours with high competition and patent practice), open innovation communities are vulnerable to patent infringement claims without intending to infringe third party patents.[706]

Contributors in open innovation or DIY bio (e.g. DIYers and their research partners) can infringe one or more patents by inadvertently or knowingly incorporating third party patents or using patented research tools in their contribution without patentees' permission. Using a patented machine or process (or a patented cell or gene in biotechnology) to produce an unpatented output is infringement.[707] In that instance, the use of a patent must be a significant or important aspect of the output production.[708] Where output is produced by applying multiple patented processes, each patent owner of these processes can sue for infringement if their patented process was important to the production of the output.[709] In cumulative technology, it is possible that a commercial product or an open innovation output can infringe several upstream patents.[710]

Moreover, patent infringement occurs when unauthorized users sell a patent-protected product, and selling the product in pieces to be assembled by users is also an infringement.[711] This type of infringement can occur when a business builds and sells open source inventions or

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[705] Severine Dusollier, "Sharing Access to Intellectual Property through Private Ordering" (2007) 82:3 Chicago-Kent L Rev 1391at 1402.
[706] Asay, "Enabling Patentless Innovation", *supra* note 81 at 434.
[707] Vaver, *Intellectual Property Law*, *supra* note 68 at 377-8 [e.g. "a patent that covers a zipper-making machine or method extends to zippers made by the machine or method. Each zipper sold without authority infringes the patent, even if the zippers themselves are unpatented." See *Colonial Fastener Co Ltd v Lightning Fastener Co Ltd*, [1937] SCR 36; *Hoffmann-La Roche & Co Ltd v Commissioner of Patents*, [1955] SCR 414; *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902 at para 41-42].
[708] *Ibid*; *Patent Act*, *supra* note 303, s 55.1 [The logic here is that if a manufacturing process produced the same product as one can get from a patented process, it is presumed that the product was made from using the patented process. It is up to the infringer to show that they did not use the patented process to produce the product].
[709] Vaver, *ibid* at 381.
[710] Shapiro, "Navigating the patent thicket", *supra* note 513 at 121.
[711] Vaver, *Intellectual Property Law*, *supra* note 68 at 378-9.

research tools protected by third party patents, which are not part of the open source project. However, selling services for a patented machine is not an infringement.[712] Selling parts of a patented machine is not an infringement unless the seller deliberately induces a buyer to infringe a patent (i.e. by using the patented machine).[713] Patents also apply to sales and imports of the infringing product made within the jurisdiction that issued the patent.[714]

In a collaborative or crowdsourced project, it is possible that although participants' contributions may not always engage patent law for being trivial, minor, obvious, or patent-ineligible, collaborative outputs may be inventive and patent-eligible to engage patent law.[715] For example, if public participation occurs during an initial stage of collaborative research, patent issues will not arise from public contributions such as gathering preliminary data for citizen science because participants' action does not produce a patent-eligible subject matter.[716] The following types of public contributions are also patent-ineligible: classifying images or sounds, transcribing information, and gathering data in nature.[717] On the other hand, a participant's contribution to a collaborative project may be patent-eligible when it is not trivial. For example, when a participant solves a significant problem, provides an inventive concept or develops a working prototype in open collaboration.[718] In a citizen science project known as Foldit, public participants were asked to identify several possible protein folding structures that could be used by the project managers to develop new and innovative biological inventions, for

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[712] *Ibid*.
[713] *Ibid* citing *Dominion Chain Co v McKinnon Chain Co* (1919), 58 SCR 121; *Axcan Pharma Inc v Pharmascience Inc*, 2005 FC 1231 at 51, 54.
[714] *Ibid*.
[715] Teresa Scassa & Haewon Chung, "Typology of Citizen Science Projects from an Intellectual Property Perspective: Invention and Authorship Between Researchers and Participants" (2015) Policy Memo Series, Vol. 5, Commons Lab, Wilson Center for International Scholars, online: Wilson Center <http://www.wilsoncenter.org/publication/typology-citizen-science-projects-intellectual-property-perspective> at 10 (see Table II).
[716] *Ibid*.
[717] *Ibid*.
[718] Scassa & Chung, "Managing IP Rights", *supra* note 151 at 4.

instance, in healthcare.[719] Although the individual contribution of identifying the protein folding structure is not patent-eligible, the final output can engage patent law.

If a new and non-obvious open invention is not defensively patented for use in open innovation communities, despite the rapid development of patents and high competition, those who use the invention can be vulnerable to third party patentees who own overlapping or downstream patents. Popular open source licences like the GNU General Public License (GPL) protect open source developers from liability by generally including broad disclaimer of warranty and limitation of liability clauses, which declare no warranty for the distributed technology and no liabilities from the use of it.[720] These prevent users of open source technology disseminated under such licences from suing the developer(s) when third party IP owners threaten IP infringement lawsuit.

Even when an open innovation project is organized in an unpatented R&D area, third party patents may develop over time, interfering with subsequent use of the project, downstream developments and commercialization.[721] Open innovation may become appropriated by a third party that subsequently patent the same invention. Publicly released open inventions do not always create prior art to defeat all subsequent attempts to patent the inventions (see Section 4.4.1 below). Furthermore, downstream patents may develop over time, which enclose access to the upstream open innovation and disrupt open innovation communities' downstream activities.

[719] Wiggins & Crowston, "Typology of Citizen Science", *supra* note 249. [For example, participants in Foldit identified several possible protein folding structures that could be used to develop biological inventions within three weeks, which was a problem that scientists were trying to solve for more than a decade before this experiment].
[720] E.g. ss 15 & 16 of GNU GPL, online: FSF < https://www.gnu.org/licenses/gpl-3.0.html>.
[721] Lemley, "The Myth of the Sole Inventor", *supra* note 450; Peter Andrey Smith, "A Do-It-Yourself Revolution in Diabetes Care", *The New York Times* (22 February 2016), online: NYTimes <https://www.nytimes.com/2016/02/23/health/a-do-it-yourself-revolution-in-diabetes-care.html>.

4.3 Navigating Biotechnology Patents in Biotechnology Social Production

DIYers can experience difficulty navigating the existing patent landscape, inventing around patents, and avoiding inadvertent patent infringement in biotechnology research areas that suffer from fragmented and overlapping patent rights. As discussed in Chapter Three, it can be difficult and costly to access upstream research tools when multiple patents and other property rights protect them. Patent access barriers to research tools also raise concerns in the social production of biotechnology because they can discourage participants and slow the speed of progress in this non-traditional R&D environment. Moreover, commercial activities and entrepreneurship will not grow around DIY bio projects that do not clear patent risks.

For instance, commentators have noted that while synthetic biology, which combines information technology, engineering and biotechnology, enables increased participation of DIYers in biotechnology, inadequacies in patent law when it comes to dealing with cumulative technologies can increase the risk of patent conflicts for participants.[722] Cumulative technologies can suffer from fragmented and overlapping patent rights, as discussed above in Chapter Three. Kahl and Endy note that an application in synthetic biology is likely to consist of multiple patented parts.[723] Furthermore, Rai and Boyle note that patent law's inadequacies for dealing with cumulative technology can cause patent holdup and patent thickets that interfere with progress in synthetic biology.[724]

Some DIYers try to build on off-patent technologies to solve a problem in society. However, DIYers and subsequent users of a DIY bio project may not be safe from patent infringement when a research area suffers from the proliferation of rights that protect upstream

[722] Rai & Boyle, *supra* note 174; Herder & Gold, "Intellectual Property Issues in Biotechnology", *supra* note 17 at 32.
[723] Kahl & Endy, *supra* note 224 at 2.
[724] Rai & Boyle, *supra* note 174.

research resources. This proliferation of upstream rights is a problem that DIYers and community labs can encounter when working with complex technologies in biotechnology. For example, Open Insulin[725] is a project that was started by biohackers in a community lab in Oakland, California, to create an open source protocol for producing insulin to encourage generic insulin manufacturing.[726] This initiative gained multiple international collaborating partners from community labs in multiple jurisdictions, such as ReaGent in Ghent, Belgium, BioFoundry in Sydney, Australia and other community labs in Senegal, Cameroon and Zimbabwe.[727] Insulin was discovered in 1921; however, continued increases in the drug's cost still limit the patient's access to it.[728] Human insulin is not patented, but insulin manufacturers had been protecting their products using patented genetically modified insulin analogues that contain improved properties such as fast-acting or long-acting effect.[729] Many patents on these analogues have recently expired in the United States, enabling generic insulin manufacturing.[730]

Nevertheless, it is still challenging to manufacture generic insulin because insulin is a biologic drug that cannot be replicated exactly,[731] and incumbent manufacturers continue to rely

[725]Online: Open Insulin <http://openinsulin.org/>; Alexandra Ossola, "These biohackers are creating open source insulin", *Popular Science* (15 November 2015), online: Popular Science <https://www.popsci.com/these-biohackers-are-making-open-source-insulin>.
[726] Anne Manning, "Open Insulin, 'DIY bio' and the future of pharma" (13 September 2018), online: Colorado State University <https://engr.source.colostate.edu/open-insulin-diy-bio-and-the-future-of-pharma/>; Gallegos et al, *supra* note 244; "Clinical Trial Protocol Development" (10 March 2017), online: Univ of Cal SF, Clinical Research Resource Hub <https://hub.ucsf.edu/protocol-development> ["A research protocol is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project."].
[727] Gallegos et al, *ibid* at 2.
[728] *Ibid* citing X Hua et al, "Expenditures and prices of antihyperglycemic medications in the United States: 2002–2013" (2016) 315 JAMA 1400 [Between 2002 to 2013, the cost of insulin tripled in the United States] and JA Greene and KR Riggs, "Why is there no generic insulin? Historical origins of a modern problem" (2015) 372 N Engl J Med 1171 [According to this article, the cost to receive this life saving drug treatment is $400 per month for an uninsured diabetic patient in the United States].
[729] Gallegos et al, *ibid* at 3 citing L Heinemann & M Hompesch, "Biosimilar Insulins" (2014) 8 J Diabetes Sci Tech 6.
[730] *Ibid*.
[731] Ellis, "Supporting innovation in next-generation medicines", *supra* note 415; Matthews, "Exclusivity for Biologics", *supra* note 456 at 104 [i.e. Biologic drugs are produced from living organisms. Biologic drugs have much larger molecular structures than traditional small-molecule drugs. These new drugs "contain proteins from

on patents and trade secrets to protect their manufacturing process.[732] Gallegos et al. note that although some of the genetically modified molecules are no longer protected in patent law, there are patents protecting the production methods of insulin, and the pharmaceutical companies are the only ones who know the manufacturing protocol for producing patented biologics as it is kept as a trade secret.[733] Pharmaceutical companies also have patents and patent applications on the next-generation "insulin analogs, methods of making them, and methods of using them."[734] Open Insulin's collaborating partners face the difficult task of navigating around the manufacturers' patents and figuring out a way to produce an open source protocol for off-patent insulin analogues. Moreover, when the project successfully produces and publishes an open source protocol for manufacturing generic insulin, it is possible that a generic drug manufacturer who

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living plant and animal cells, bacteria and viruses". Examples include "hormones such as insulin, enzymes to speed up chemical reactions, blood factors to regulate blood clotting, antibodies to support the immune system, and vaccines and advanced therapies including cell, gene and tissue therapy products." Since biologics have complex structures, it is not possible to create an exact copy of an original biologic. Nonetheless, just as traditional pharmaceutical drug manufacturers experienced competition from generic drug manufacturers, biologic drug manufacturers face competition from the manufacturers of biosimilar pharmaceutical drugs (i.e. "a product that is similar in structure and effect."].

[732] Gallegos et al, *supra* note 244 at 3-4; Ellis, *ibid*; Matthews, *ibid* at 110-3 [Businesses can protect commercially valuable data with trade secrecy. Biologic drugs are also protected by the regulatory data protection in the data from clinical trials, which can demonstrate the safety and effectiveness of the drugs. Pharmaceutical companies must report the data to regulators for market entry, and genetic companies can also rely on their clinical trial data for the regulatory approval of generic drugs. The market exclusivity protection period can vary by nation; it is currently 8 years in Canada, 10 years in the EU, while 12 years in the United States from the date the original biologic drug was approved by the government. During that time, the government cannot approve a biosimilar product. See TRIPS, *supra* note 306, art 39.3; C.08.004.1 of the Canadian *Food and Drug Regulations*, CRC, c 870; *Community Code Relating to Medicinal Products for Human Use*, Directive 2004/27/EC, art 10; U.S. *Biologics Price Competition and Innovation Act*, ss 7002(7)(a)&(b)].

[733] Gallegos et al, *ibid*; Ellis, *ibid*.

[734] Gallegos et al, *ibid* citing WA Kaplan & RF Beal, "The global intellectual property ecosystem for insulin and its public health implications: an observational study" (2017) 10 J Pharm Poli Pract 3; Vaver, *Intellectual Property Law*, *supra* note 68 at 296; Christopher M Holman, "Inside Views: Why Follow-on Pharmaceutical Innovations should be Eligible for Patent Protection" (21 September 2018), online: IP Watch < https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> [Some criticize pharmaceutical companies for engaging in evergreening by filing for following patents that cover different forms of a compound that is already patented to extend the patent protection in the compound beyond 20 years. On the other hand, others have refuted such an assumption noting that in a well-functioning pharmaceutical market, patents on an improved drug formulation "is limited to that improvement and does not extend patent protection for the original formulation." Evergreening is still a concern when there is a pharmaceutical market where patients are forced to pay high monopoly pricing for the next version of drugs that offer little improvement over the original drug. These commentators argue that this is patent misuse rather than a flaw in the patent system itself].

uses the protocol can still risk infringing the incumbent manufacturers' patents.[735] Hence, upstream patents and other property rights that protect complex technology can still pose a threat to subsequent developments in the DIY bio network and downstream commercial uses.

Another example to illustrate this point is the patent protection of the CRISPR gene-editing technology, which is an important tool in genetic research that "works as a molecular scissor that can trim away unwanted pieces of genetic material and replace them with new ones".[736] Upon its discovery by university researchers, it quickly replaced older techniques and became a popular tool for genetic modifications in research labs.[737] This technology is changing science in a significant way by making it easier for researchers, including DIYers, to explore DNA technology.[738] Some DIYers have experimented with CRISPR. For example, there were widely reported controversial DIY attempts to create gene therapies to treat or prevent diseases, such as HIV and herpes.[739] The CRISPR gene-editing tool's core technology and various improvements are protected by many overlapping patents and patent applications of various companies and universities in the United States, including the CRISPR pioneers at UC Berkeley

[735] Gallegos et al, *ibid*; Lauren Schweizer, Ralph Minderop & Natalie Kirchhofer, "Patent pools in the life sciences: a potential facilitator of CRISPR commercialization", IAM (13 June 2017) online: IAM Media < https://www.iam-media.com/patent-pools-life-sciences-potential-facilitator-crispr-commercialisation> [The same problem exists for developing personalized medicine. "[C]ompanies must secure licences on various gene segments, mutations, pathways and diagnostic tools, as well as production and formulation technology – which place a large burden on newcomers."].

[736] Annie Sneed, "Mail-order CRISPR Kits allow absolutely anyone to hack DNA", *Scientific American* (2 November 2017) online: Scientific American <https://www.scientificamerican.com/article/mail-order-crispr-kits-allow-absolutely-anyone-to-hack-dna/>; Brendan Pierson, "University of California to be granted pioneering CRISPR patent", *Reuters* (8 February 2019) online: Reuters <https://www.reuters.com/article/us-ucberkeley-ip-crispr/university-of-california-to-be-granted-pioneering-crispr-patent-idUSKCN1PX25K>.

[737] *Ibid.*

[738] Sneed, *ibid*.

[739] Sarah Zhang, "A biohacker regrets publicly injecting himself with CRISPR", *The Atlantic* (20 February 2018) online: The Atlantic <https://www.theatlantic.com/science/archive/2018/02/biohacking-stunts-crispr/553511/>; Angela Chen, "A biohacker injected himself with a DIY herpes treatment in front of a live audience", *The Verge* (5 February 2018) online: The Verge < https://www.theverge.com/2018/2/5/16973432/biohacking-aaron-traywick-ascendance-biomedical-health-diy-gene-therapy>; *Ibid*.

and Harvard and MIT's Broad Institute.[740] Commentators note that since CRISPR significantly lowers the cost of experimenting with gene editing, it is possible that non-institutional scientists may be able to discover new ways of using the technology that can benefit society in ways that may not occur to institutional scientists.[741] Since the discovery of the CRISPR technology, several start-up biotech companies have been trying to create various commercial applications of the technology, and some have entered into exclusive licensing agreements with the university researchers who pioneered the technology.[742] Commentators noted that subsequent commercial users of the technology would likely need to negotiate with multiple patentees holding CRISPR patents to gain access to relevant patents in relevant jurisdictions to produce commercial applications and operate freely despite overlapping patents and patent applications.[743] CRISPR offers biotechnology researchers and DIY scientists a cheap, easy, faster and reliable method of editing DNA without having access to expensive tools that professional researchers previously used for gene editing. Nonetheless, overlapping patents surrounding CRISPR create patent risks for downstream DIY bio uses of CRISPR and commercial ventures.

Another area in which DIYers make active contributions is the development of open source research tools and equipment. DIYers and open science communities can enter the

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[740] Schweizer, Minderop & Kirchhofer,, *supra* note 735; Fiona Mischel, "With the recent patent news, who owns CRISPR now?", *SynBioBeta* (19 March 2019) online: SynBioBeta < https://synbiobeta.com/with-the-recent-patent-news-who-owns-crispr-now/>; Megan Molteni, "CRISPR's epic patent fight changed the course of biology", *Wired* (9 November 2018) online: Wired <https://www.wired.com/story/crisprs-epic-patent-fight-changed-the-course-of-biology/>; Pierson, *supra* note 736; Broad Communications, "For journalists: Statement and background on the CRISPR patent process" (25 June 2019), online: Broad Institute <https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process>; *The Broad Institute, Inc. v. The Regents of the University of California*, Patent Interference No. 106,048 (DK), 2017, affirmed in *Regents of University of California v. Broad Institute, Inc*., No 17-1907 (Fed. Cir. 2018) [The Patent, Trial and Appeal Board ruled in 2017 that UC Berkeley's CRISPR 2012 patent applications, which do not restrict the CRISPR-Cas9 to any particular environment, and the Broad Institute's CRISPR patents, which limit the technology application to a new environment, are different inventions and affirmed their patent eligibility].

[741] Sneed, *supra* note 736.

[742] *Ibid.*

[743] Mischel, *supra* note 740; Sharon Begley, "Disputed CRISPR patents stay with Broad Institute, U.S., patent rules", *Scientific American* (15 February 2017) online: Scientific American <https://www.scientificamerican.com/article/disputed-crispr-patents-stay-with-broad-institute-u-s-panel-rules/>.

commercial realm by developing, manufacturing and selling open source research tools and equipment online.[744] Nonetheless, these activities require DIYers to navigate patents to avoid infringing those that protect the proprietary versions of research tools and equipment. Patent users can secure access to patent-protected cumulative technology by incurring the costs to search for and license all key patents protecting the technology. These costs may be too high for many DIYers who have limited funds. As noted above in Chapter Two, most contributors in the DIY bio network (i.e. young scientists, hobbyists or bioartists, and programmers) depend on self-funding and creative workarounds to replace expensive research tools and equipment.[745] Many use cheap and accessible materials to build their own laboratories and DIY lab equipment.[746] Some of them try to avoid patent infringement by waiting until the core patents expire before developing open source versions of proprietary research tools and equipment.

The OpenPCR project, for example, is responsible for creating and selling an open source version of a PCR (polymerase chain reaction) machine.[747] The PCR technology, one of the most

[744]Golinelli & Ruivenkamp, *supra* note 3 at 155; Gallegos et al, *supra* note 244 at 2 [e.g. OpenTrons and Bento Bioworks sell lab instruments such as robots for biologists and tools for molecular biology, and Amino Labs and the ODIN work on creating molecular biology kits that can be used for "various applications from DNA extraction to genome editing"].

[745] Delfanti, *supra* note 1 at 115; Golinelli & Ruivenkamp, *ibid*; Ikemoto, *supra* note 10 at 546.

[746] Meyer, "Domesticating and Democratizing Science", *supra* note 227 at 124-6; Joe Alper, "Biotech in the Basement" (2009) 27 Nature Biotech 1077 at 1077 [For example, members of a DIYbio lab, BiologiGaragen, have experimented with hacking lab equipment, "such as transforming a webcam into a microscope, building one's own centrifuges, stirring plates, incubators and sterile hoods." Also, Kay Aull, a student in bioinformatics at the University of California, San Francisco, built a private lab using cheap materials to build a hemochromatosis test that can identify whether a person carries the mutation for this genetic disease. It cost approximately $1000 for Aull to set up her homelab.]; Delfanti, *supra* note 1 at 115 ["such as DNA extraction or bacteria isolation with household tools and products (you basically need a kitchen centrifuge, dish soap and a few other easily available chemicals to create a buffer solution and extract DNA from strawberries)"].

[747]Kahl & Endy, *supra* note 224 at 9; Tusi Ram Damase et al, "Application of the Open qPCR Instrument for the in Vitro Selection of DNA Aptamers against Epidermal Growth Factor Receptor and Drosophila C Virus" (2018) 20:2 ACS Comb Sci 45, online: ACS Publications <https://pubs.acs.org/doi/abs/10.1021/acscombsci.7b00138?src=recsys&> [Other examples of open source research tools, devices and equipment include open source centrifuges used in biological, chemical, and medical research to isolate and separate liquids (e.g. polyfuge and Dremelfuge), open source laboratory sample rotator mixer and shaker, an open microscope from the OpenLabTools, a DIY BioPrinter that can print/replicate biological materials, and open source infusion pumps. See Joshua M Pearce "Building research equipment with free, open-source

important research tools in biotechnology, allows researchers to replicate a segment of DNA and has numerous uses in molecular biology, including genetic sequencing, genetic diagnosis and DNA cloning.[748] The OpenPCR project openly distributes the open source research equipment online under the GNU GPLv3 open source licence, allowing anyone to build their own PCR machine using the project's designs, instructions and open source software. The project also sells the assembled version of the OpenPCR machine for a low cost of $499USD. A PCR machine costs thousands of dollars to purchase from an industrial manufacturer.[749] The OpenPCR project significantly lowers the cost of working and experimenting with DNA technology. Open source research tools and equipment benefit open scientists and professional researchers around the globe who cannot afford expensive proprietary versions.

A modern PCR machine that is manufactured and sold to professional research labs is still protected by hundreds of patents that cover modern improvements.[750] The OpenPCR project can build and sell a simple open source PCR machine without fearing patent infringement because the patent on the basic PCR process expired many years ago.[751] The project reproduces the off-patent PCR technology in its hardware design. However, the project and subsequent users cannot reproduce or sell patent-protected modern functions that improve the operation of a basic

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hardware"(2012) 337 Science 1303 at1303-4; Karankumar C Dhankani & Joshua M Pearce, "Open source laboratory sample rotator mixer and shaker" (2016) 1 HardwareX 1, online: ScienceDirect <https://www.sciencedirect.com/science/article/pii/S2468067216300049?via%3Dihub#b0165>; Gerrit Niezen, Parisa Eslambolchilar & Harold Thimbleby, "Open-source hardware for medical devices" (2016) 2 BMJ Innov 78 at 80-1].

[748]Peter Carroll & David Casimir, "PCR Patent Issues" in John MS Bartlett & David Stirling, eds, *PCR Protocols*, 2nd (NJ: Humana Press, 2003).

[749]*Ibid*.

[750] *Ibid* at 7; "What is PCR" (29 June 2017), online: Science Learning Hub <https://www.sciencelearn.org.nz/resources/2347-what-is-pcr> [e.g. "In qPCR, the amplification of DNA is monitored in real time, allowing the quantification of target DNA throughout the process. dPCR is a new, more refined approach that breaks the PCR process up into many smaller steps. It offers increased precision, more reliable measurements and absolute quantification from very small or mixed samples."].

[751] Canadian patent No. 1237685; US patent No. 4,683,202; Delfanti, *supra* note 1 at 122; Kahl & Endy, *supra* note 224 at 9 ["elements of PCR technology have entered the public domain or will do so shortly. Specifically, foundational patents covering amplication methods…, thermal cycling instructions…, and thermostable DNA polymerases… have now expired."].

PCR machine without patent infringement. DIYers can add functional improvements to the open source version as patents expire or become abandoned on the improvements. To do so promptly, DIYers need to find all relevant patents and patent applications for making different enhancements, identify their scopes, and monitor the patent database of the relevant jurisdiction(s) to see when patents expire or become abandoned. As discussed above in Chapter Two, scientists typically do not monitor patents or possess extensive knowledge about the patent coverage in their research areas. Identifying the overall patent coverage in research is a difficult task; it may take a while even for a patent-expert to discover the patent coverage in highly competitive R&D areas. The proliferation of fragmented and overlapping patents and patent applications in a research area can delay open R&D by making it difficult for DIY scientists to access patented research tools and equipment and work around patents. Also, if there are open source versions of proprietary research tools and equipment that suffer from multiple patent rights, open source users can infringe patents on the proprietary improvements by making modifications and improvements and redistributing and selling the open source project.

4.4 Possible Interferences from Third Party Patents

Open science and open innovation communities practice non-proprietary development; they create open access to available shared resources, such as research tools and previous open R&D discoveries, to encourage modifications, improvements and even commercialization.[752] They may depend on the open norms, laws and central management to create access to shared resources. This section will consider possible ways that third party patents can interfere with the use of publicly released inventions in the social production of biotechnology.

[752] Jyh-An Lee, "Organizing the Unorganized: the Role of Nonprofit Organizations in the Commons Communities" (2010) 50 Jurimetrics 275 at 296-309; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 21-25.

Openly sharing scientific research increases efficiency in science because other researchers can reuse, modify, improve and review or verify the research. User innovators also frequently freely reveal their discoveries, allowing wide dissemination without incurring high costs. Despite the development of patent-dominant biotechnology, some professional scientists in universities, public research institutions and the private sector also freely share research tools in biotechnology.[753] Creating broad access to a biotechnology invention is particularly important when the invention is needed as an input in various future R&D efforts and could be used to produce many commercial products or services.[754] Following this tradition, DIYers and local community labs also support and practice free access to information and the freedom to tinker with science.[755] The DIY bio movement was founded on open science principles to encourage coordination and contributions of DIY scientists around the globe.[756] DIY bio improves access to science and research tools, which encourage R&D outside of institutional science.[757]

Publicly released socially produced biotechnology inventions can stimulate both non-commercial and commercial activities. For instance, a group of hackathon participants can extend their collaborative project after the event to launch a startup company, and DIYers can start a business based on open source biotechnology projects.[758] However, publicly released inventions are not entirely protected from coming under the control of third parties. While

[753]Weigelt, *supra* note 135 at 943; OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31-2; Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76; Delfanti, *supra* note 1 at chaps 4&5.
[754] Rai, "Regulating Scientific Research", *supra* note 19 at 112- 113, 144 [Rai notes that U.S. research universities balance the open norms of traditional academic research and the goal of promoting development based on university research by adopting policies that encourage privatization of discoveries when it is likely that these will have specific commercial uses].
[755] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 52; Delfanti, *supra* note 1 at 12-13; Levy, *supra* note 60; Nielsen, *Reinventing Discovery, supra* note 1 at 187.
[756] Delfanti, *ibid* at 121.
[757] Poncelet, *supra* note 140.
[758] Tim Stephens, "Biology grad wins seed funding for biotech startup company", NewsCenter (8 June 2016) online: UC Santa Cruz <https://news.ucsc.edu/2016/06/antonio-lamb.html> [Some DIY scientists started a business based on their DIY experiments with funding from venture capitalist firms, such as Rebelbio and Indiebio, which offer to fund startup companies in life sciences]; Gallegos et al, *supra* note 244 at 2.

releasing a patentable invention into the public domain is cheap and practical, this method of disseminating discoveries into the world may not always be appropriate due to increased propertization and patenting in biotechnology. Biotechnology inventors cannot control subsequent uses of publicly shared inventions and cannot guarantee ongoing free and open access for subsequent open development. It may be necessary to retain the right to control subsequent uses also for humanitarian purposes. For example, when the golden rice genome was released into the public domain, which was discovered by a publicly funded research project to improve vitamin A deficiency in developing nations, it allowed private companies to develop and patent various downstream applications and products which impede developing nations' access to the research.[759] The patent thicket on downstream inventions can prevent the upstream invention from being used for its intended purpose of providing aid in developing nations.

Freely releasing a new and non-obvious invention into the public domain does not always prevent a third party from patenting the same invention. Also, it may not always establish prior art to defeat subsequent patent applications. Hope notes that third parties are more likely to assert ownership of publicly released innovation in a field that suffers from too many overlapping IP rights or a field that is highly competitive and litigious.[760] Moreover, access to the upstream open invention can be barred by the development of downstream patents. Publicly released upstream inventions can come under third party control due to broad patent claims on subsequent modifications and improvements or third party patents on proprietary products that incorporate the upstream invention.[761] Third party patents that capture and propertize publicly released inventions can discourage open innovation communities from engaging in downstream

[759] Dusollier, *supra* note 705 at 1402; Online: Golden Rice Project <http://www.goldenrice.org/> [i.e. patents on downstream inventions "such as genetic markers, specific genotypes related to nutrition, new quality of fibers, or targets for herbicides"].
[760]Hope, *Biobazaar*, *supra* note 21 at 161-4.
[761] Poncelet, *supra* note 140; Feldman, "Intellectual Property Wrongs", *supra* note 496 at 292.

development and commercialization. Third party patents that threaten non-proprietary development and subsequent use can discourage contributors from continuing to be part of open R&D and cause open scientists and open innovators to stop sharing future discoveries.

Moreover, open innovation or DIY bio projects that create improvements, add-ons or subsequent versions of proprietary products can experience patent conflicts when commercial manufacturers subsequently patent the improvements, add-ons or follow-on versions. For example, a DIY engineer tweeted in 2012 that he was able to modify the software component of a medical device, a continuous glucose monitor (CGM), to enable data transmission from the device to an online spreadsheet, making the device's real-time data remotely accessible via web browsers and smart devices.[762] This improvement allowed him to monitor his young son's glucose level from anywhere.[763] The tweet eventually led to an open source project called Nightscout, which allowed anyone to modify existing CGMs manufactured by Dexcom and Medtronic.[764] The DIY project also gave way to a DIY bio-based business in Spain that sells products based on Nightscout.[765] After the engineer's initial tweet, existing manufacturers, including Dexcom, rushed to patent and market the improvement (i.e. a remote CGM that automatically transmits glucose data via wireless transmission).[766]

This scenario illustrates multiple downstream developments that can occur from openly shared DIY works. The manufacturers' improvement patent based on a DIY project can help incumbent manufacturers to maintain and strengthen their market presence. As discussed below

[762] Smith, *supra* note 721; [While the device manufacturers may rely on the anti-circumvention provisions in copyright law to block DIYers from accessing the device to make software modifications, this is outside the scope of this research. This scenario can also occur when DIYers publicly release improvements, add-ons or subsequent versions of existing goods that are not copyright or patent protected].
[763] *Ibid*.
[764] Online: The Nightscout Project <http://www.nightscout.info/>.
[765] Online: GlucoAngel Instead <http://glucoangel.instead-technologies.com/>.
[766] One of Dexcom's patents in the United States is titled "Distributed system architecture for continuous glucose monitoring", which claims wireless transmission of and automatic forwarding of glucose data to a display device. US Pat no 10085640, filed on May 11, 2016, and patented on October 2, 2018.

in Section 4.5, although rationale commercial patentees may not enforce their patents against non-commercially motivated infringers in open innovation (i.e. contributors and open innovation users) since the cost will be high and patentees may benefit from their technological contributions, overlapping patents in a field of endeavour can still pose a threat to open innovation and discourage participation. Everyone can benefit from openly accessible DIY science and technology contributions. Patents that interfere with open R&D are detrimental to society. Moreover, in a scenario like above, existing manufacturers can use the improvement patent to block other businesses from using and commercializing DIY improvements, thereby reducing competition in society. If the manufacturer's patent contribution is trivial and obvious because the manufacturer did not sufficiently add to the upstream DIY science, the improvement patent should not be granted. If the manufacturer's contribution is significant and non-obvious, the patent should still not be broad enough to discourage open development and downstream activities from existing alongside the manufacturer's proprietary development.

4.4.1 Free Revealing and Prior Art

A publicly released new and non-obvious invention can establish prior art in patent law, which prevents future patenting of the same invention. Prior art can bar subsequent attempts to patent the invention because an invention known to everyone cannot satisfy the statutory requirement of novelty in patent law, and it is no longer patent-eligible.[767] For this reason, some inventors

[767]Asay, "Enabling Patentless Innovation", *supra* note 81 at 447; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1471; Vaver, *Intellectual Property Law*, *supra* note 68 at 322-3; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 23-24. [Public disclosure of an invention may not bar subsequent patenting if a grace period is provided under national patent law. For example, s.28.2(1)(a) of the Canadian *Patent Act*, *supra* note 303, states that a patentable invention must not have been disclosed "more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such manner that the subject-matter became available to the public in Canada or elsewhere"]; *Canwell Enviro-Industries Ltd. v Baker Petrolite Corp.* (2002), 2002 FCA 158 (CanLII), 17 CPR (4th) 478 at 497-500 [A chemical product sold to the public

defensively publish new and non-obvious inventions to discourage subsequent patenting attempts (e.g. academic researchers publishing technical information in scientific journals).[768] However, releasing an invention into the public domain does not always establish prior art. What constitutes prior art varies by jurisdiction. In Canada, the publication of an invention must contain sufficient information or all relevant steps to allow a person skilled in the art to perform or make the invention without undue burden.[769] Also, the prior art must be self-contained in a document; the inventive steps of an invention should not be scattered over multiple documents (i.e. an invention cannot be described over multiple discussion threads or multiple user posts).[770] Prior art should be easily accessible to patent examiners, judges and juries in multiple jurisdictions. While openly sharing information nowadays costs little to no cost with access to the computer and the Internet, it can cost a significant amount of effort, money and time to publish sufficient information to establish prior art.

A new and non-obvious invention released into the public domain does not bar subsequent patent applications on the same invention if patent examiners ignore it due to insufficient information, human error or strategic drafting of patent claims. Schultz and Urban note that when open innovation communities organize information, they tend to organize it in a manner that speaks to other potential contributors working in the same field.[771] They do not typically organize information to be accessible to "patent examiners, judges, or juries" who may

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is disclosed to the public under s. 28.2(1)(a) of the Canadian *Patent Act*, if a person skilled in the art can discover its composition through analysis or reverse engineering.]; *Bayer Inc v Apotex Inc,* 2014 FC 436 at paras 119 -122 [In this case, the court held that conducting clinical studies of a drug more than a year before the filing date does not constitute anticipation under s. 28.2(1)(a) as experimental use does not constitute public use].

[768] Hope, *Biobazaar*, *supra* note 21 at 162 [As for professional researchers, "[m]ainstream scientific journals are one avenue for defensive disclosure. There also exist journals devoted to defensive publishing, some of which are respected sources of technical information that are included as part of the Patent Cooperation Treaty minimum documentation for International Search Authorities. In addition, some large corporations rely on their own technical disclosure bulletins"].

[769] *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at para 33; *Free World Trust v Électro Santé Inc*, *supra* note 503 at 25-27; *Eli Lilly Canada Inc v Apotex Inc*, 2010 FC 1065 at 63.

[770] Vaver, *Intellectual Property Law*, *supra* note 68 at 322-3.

[771] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 28.

not understand necessary technical information in a field of endeavour.[772] When the published information lacks an adequate explanation for "patent examiners, judges, or juries" who have no technical or expert knowledge in a field of endeavour, they may need additional information to help them assess patent claims against the published information to invalidate or reject patent claims.[773] Patent examiners have a limited number of hours to examine a patent application, and prior art that is difficult to read or locate may be ignored.[774] Nonetheless, prior art that is discovered after the patent grant can still invalidate a patent.[775] Even if a domestic patent office overlooked an open invention, the publication of information exchanged between its collaborators may be used in the future by commercial competitors to invalidate a patent.[776]

Furthermore, some patent attorneys draft patent claims using words that are not traditionally used in a field of endeavour and use made-up words to prevent defensively published prior art from blocking their client's patent application.[777] Even if open innovation communities spend time and money to create a publicly accessible database of open innovation projects to improve external access to them, it may not be easy to locate relevant prior art when database contents are compared to strategically-drafted patent claims.[778] Therefore, even when open innovation communities defensively publish to establish prior art, their prior art may not defeat all subsequent patent applications.

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[772] *Ibid*.
[773] *Ibid*.
[774] Hope, *Biobazaar*, *supra* note 21 at 162 citing Esteban Burrone, "New Product Launch: Evaluating Your Freedom to Operate", online: World Intellectual Property Organization <http://www.wipo.int/sme/en/documents/freedom_to_operate.html> [Defensively publishing an invention to gain better attention of patent examiners can also create costs and delays for researchers].
[775] Vaver, *Intellectual Property Law*, *supra* note 68 at 320 citing *Woven Plastic Products Ltd. v. British Ropes Ltd*., [1970] F.S.R. 47 at 58 (CA).
[776] Asay, "Enabling Patentless Innovation", *supra* note 81 at 465.
[777] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 28-29; Lemley, "The Myth of the Sole Inventor", *supra* note 450 at 745-6.
[778] Schultz & Urban, *ibid*.

4.5 Patent Risks in Social Production

A patent infringer can receive patent infringement litigation threats from patent patentees, who may demand a large settlement payment, pursue litigation to collect damages or obtain an injunction to shut down any infringing commercial activities.[779] In open innovation, Asay notes that the actual patent risks may vary depending on the type of participant.[780] The social production of biotechnology is also open innovation. Patentees can sustain different amounts of costs and benefits from pursuing different types of infringers.[781] According to a cost-benefit analysis, if the overall cost outweighs the benefit, a patentee is discouraged from pursuing actions against an infringer.

The norms of information exchange also influence the patent risk for researchers.[782] The norms can describe how patented research is used within the research community. According to Eisenberg, the norms account and the cost-benefit account of access to patented technology in biotechnology research are not wholly distinct; both play a role in the patterns of information exchange between researchers.[783]

4.5.1 Patent Risk in Open Innovation based on Cost-Benefit Analysis

Asay examined the actual patent risks using cost-benefit analyses for different types of open innovation participants in the context of OSS development and high-tech patents.[784] This overview can inform DIY bio participants' patent risks from infringing third party patents. The

[779]Lemley, "Ignoring Patents", *supra* note 34 at 20; Feldman, "Intellectual Property Wrongs", *supra* note 496 at 281-284.
[780] Asay, "Enabling Patentless Innovation", *supra* note 81.
[781] *Ibid.*
[782] Sarnoff & Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents", *supra* note 401 at 1329; Eisenberg, "Noncompliance", *supra* note 298 at 1084.
[783] Eisenberg, *ibid*.
[784] Asay, "Enabling Patentless Innovation", *supra* note 81.

OSS movement has evolved into a mature open innovation community compared to the emerging social production of biotechnology; there are successful OSS projects which compete with commercially produced software, and OSS is widely used in both non-commercial and commercial situations.[785] In the software industry, there have been attempts by large businesses, such as Microsoft, using patents to threaten commercial users of an OSS project, such as Linux OS.[786] In response to increased patenting of software-related inventions and patent enforcement that can threaten OSS development, some OSS projects defensively patent and buy up relevant patents to build a large patent portfolio to protect their activities.[787]

Asay notes that patent infringement in open innovation can be experienced by non-commercial contributors, non-commercial users, foundations or non-profit organizations working with open innovation communities, commercial contributors and commercial users.[788] Non-commercial motivated contributors and users of an open innovation project (i.e. those who do not have economic incentives) will likely experience negligible patent risks from commercial patentees and patent trolls, while commercial contributors and users will likely face actual patent risks.

Non-commercially motivated infringers will be excused in jurisdictions with a private and non-commercial use exception or a research exception in patent law. In jurisdictions where non-commercial infringers cannot rely on patent exceptions, their patent risk still likely remains negligible because the cost of enforcing a patent against non-commercial users who generate no revenues from patent use can discourage rationale patentees from pursuing actions against them.

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[785] Vasudeva, *supra* note 702; Raymond, *supra* note 4.
[786] Debra Brubaker Burns, "Titans and Trolls Enter the Open-Source Arena*"* (2013) 5 Hastings Sci & Tech LJ 33 at 58–61; Graham Bassett & Nic Suzor, "Recent Developments" in Brian Fitzgerald & Graham Bassett, eds, *Legal Issues Relating to Free and Open Source Software* (Brisbane, QLD: Queensland Univ of Tech, 2005) at 124.
[787] E.g. Open Invention Network; "Red Hat's Patent Promise" (21 September 2017), online: Red Hat < https://www.redhat.com/en/about/patent-promise>.
[788] Asay, "Enabling Patentless Innovation", *supra* note 81.

Non-commercial infringers do not create revenue with their patent use and have little or no resources to pay a settlement fee or to defend against legal actions.[789] It may also be challenging for patentees to locate non-commercial infringers to enforce patents, and it may be difficult to ascertain whether infringement actually occurred based on any openly shared contents in open innovation projects. Asay acknowledges that patent trolls can threaten non-commercial users in order to collect licensing fees and subject those who submit to such demands to a non-disclosure agreement to avoid publicizing their actions.[790] However, Asay also argues that the chances of this occurrence are low as it is not cost-efficient for patent trolls to engage in this type of activity.

It was observed in OSS development that commercial patentees are generally not known to pursue actions against non-commercial contributors because businesses can benefit from encouraging open R&D contributions in the same field of endeavour.[791] For example, Google, Red Hat, IBM and Microsoft have pledged their patent portfolio to the Open Invention Network's patent pool for Linux development.[792] Businesses can use open innovation contributions to enhance their products and services and benefit from increased use of their products when open innovation communities produce related tools and interoperable technologies.[793] Businesses also benefit from maintaining good relations with open innovation communities as having ties to open innovation communities can generate good publicity and attract potential employees from open innovation contributors.[794] These positive benefits can

[789] *Ibid* at 450-3; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 8.
[790] Asay, *ibid*.
[791] *Ibid* citing Burns, "Titans and Trolls Enter the Open-Source Arena", *supra* note 786 at 56–72.
[792] Red Hat's Patent Promise", *supra* note 787; Mitch Wagner, "Microsoft: We 'Pledge Our Entire Patent Portfolio' to Linux", Light Reading (10 November 2018), online: Light Reading < https://www.lightreading.com/enterprise-cloud/microsoft-we-pledge-our-entire-patent-portfolio-to-linux/d/d-id/746766>.
[793] Benkler, *Wealth of Networks*, *supra* note 2 at 44-46, 63-4; Asay, "Enabling Patentless Innovation", *supra* note 81 at 452-3.
[794] Asay, *ibid*.

discourage commercial patentees from disrupting open innovation projects by enforcing their patents.

Although non-commercial infringers (both contributors and users) in open innovation communities are unlikely to experience patent threats or litigation from commercial patentees and patent trolls based on the cost-benefit analysis, the presence of potentially conflicting patents can discourage open innovation activities by deterring participation. As noted above in Chapter Three, academic researchers' research direction or project choice may be influenced by the perceived risk of patent access barriers to research resources when patent proliferation occurs in a research area. Asay suggests that although non-commercial patent infringers in open innovation will likely experience little to no actual patent risk from commercial patentees and patent trolls, the participants' perceived patent risk from the presence of patent thickets can discourage their participation.[795]

Asay notes that foundations or non-profit organizations that represent and aid open innovation projects also experience negligible actual patent risks from patentees and patent trolls.[796] Non-profit organizations can infringe third party patents by using, managing or distributing infringing open innovation outputs. Nonetheless, non-profit organizations in open innovation are poor targets of commercial patentees and patent trolls because the organizations also likely have few resources to pay the patentees' demands. Furthermore, the patentees may be discouraged from pursuing these organizations that have considerable resources and industry backing because the organizations can use their resources to engage in patent litigation, which can lead to the patent being invalidated.[797] Wealthy organizations that support open innovation communities may be more willing to fight patent threats to protect the alternative innovation

[795] *Ibid*.
[796] *Ibid* at 455-456.
[797] *Ibid*.

environment and open innovation ideology. Also, commercial patentees may be less likely to pursue these organizations for patent infringement to avoid attracting bad publicity.

In comparison, commercial patent infringers (i.e. commercial contributors and users of open innovation) are more likely to experience actual patent risks because they can create returns from their infringement and are likely to have the resources to pay patentees.[798] Potential commercial infringers in open innovation are businesses that contribute to open innovation projects, businesses that commercialize open innovation, improvements and derivatives, and businesses that use open innovation tools to create unrelated products.

Commercial patentees can target competing open innovation-based businesses that contribute to and make use of infringing open innovation technologies, but this does not seem a routine practice in the high-tech industries.[799] Rather than disrupting commercial contributors in open innovation, it may be possible for patentees to benefit from their openly shared contributions to improve their business. Different industry participants can still react differently than high-tech businesses. On the other hand, patent trolls have targeted open innovation businesses like Red Hat that contribute to and commercialize OSS.[800]

Moreover, instead of reacting to non-commercial contributors' patent infringement, it is more strategic for patent trolls and commercial patentees to pursue actions against downstream commercial users of open innovation.[801] Asay notes that it is possible that entering into a licensing agreement with an upstream contributor in open innovation may foreclose actions

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[798] *Ibid* at 457-472; Hope, *Biobazaar supra* note 21 at 63.
[799] Asay, *ibid* at 459; Thomas Dysart, *Systems within Systems – Free and Open Source Software Licenses under German and United States Law* (PhD Thesis, St Peter's College, University of Oxford, 2017) [There are few lawsuits and not enough public data to assess the actual patent risk of businesses that commercialize open innovation technologies].
[800] Asay, *ibid* at 457; Burns, "Titans and Trolls Enter the Open-Source Arena", *supra* note 786 at 55-56; Josh Taylor, "Rackspace targets patent troll to stop the lawsuits", ZDNet (5 April 2013), online: ZDNet <https://www.zdnet.com/article/rackspace-targets-patent-troll-to-stop-the-lawsuits/>.
[801] Asay, *ibid* at 452-3; Feldman, "Intellectual Property Wrongs", *supra* note 496 at 254.

against downstream commercial users due to the terms of the upstream licence or the doctrine of exhaustion (in the U.S.).[802] Commercial open innovation users are also vulnerable to third party patentees because, as discussed above, standard open source licences disclaim third party liabilities in the case that any open source contributions infringe third party IP rights. The commercial users of open innovation and their customers who buy the infringing products can be pursued for patent infringement.[803] Even if an open innovation technology is defensively patented by the open innovation community or subsequent commercial users, third party patents can still pose a threat in industries that suffer from overlapping patents or patent thickets.[804]

Patent trolls can target both small and large businesses that use infringing open innovation; however, the larger business-infringers are more likely to be targeted by patent trolls for their resources.[805] Commercial users who have accumulated an extensive patent portfolio of their own may defend themselves better against patent infringement claims from patent trolls or commercial patentees.[806] However, these users must still incur large opportunity costs to defend against such claims. Also, users that commercialize open innovation technologies (rather than using them to produce unrelated products) are disadvantaged because it may be easier for patent trolls to identify patent infringement against publicly available information.

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[802] Asay, *ibid*; Feldman, *ibid*; Vaver, *Intellectual Property Law*, *supra* note 68 at 378-9 [i.e. Upon purchasing a patented product, the doctrine of exhaustion allows the purchaser to exercise the right to resell or "do whatever it likes with the product or process" unless restrictions on use or resale are imposed on the purchaser with notice at the time of sale. Vaver notes that Commonwealth courts have enforced such restrictions. See *Motion Picture Patents Co v Universal Film Co,* 243 U.S. 502 (1917) at 502; *Quanta Computer Inc v. LG Electronics Inc*, 553 U.S. 617 (2008); *Thomas v Hunt* (1865), 17 CB 183 (NS)].

[803] Asay, *ibid* at 469; Feldman, *ibid* [Patentees strategically go after small companies who are consumers of patented equipment – targeting them instead of the manufacturers - because patentees can "approach people who have little information about patents and little ability or incentive to do anything but pay"].

[804] Asay, *ibid* at 461.

[805] *Ibid* at 468-9; Mark A Lemley & A Douglas Melamed, "Missing the Forest for the Trolls" (2013) 113 Colum L Rev 2117 at 2164.

[806] Lemley & Melamed, *ibid* at 2129–39.

4.5.2 Information Exchange Norms in Scientific Research and Patent Risk

Aside from commercial patentees and patent trolls, academic researchers also own and control biotechnology patents. The open science model described above in Chapter Two encourages academic scientists to share new research discoveries within the research community. This research sharing practice still influences academic scientists today to openly share upstream research resources that enable subsequent R&D. Academics have shifted from discouraging patents on upstream research to allowing the research community to patent their research to preserve their freedom to operate; nonetheless, they seem to encourage academic patentees to ignore patent infringement in academic research.[807] Some scholars opine that the open sharing norm in academic research also encourages academic patentees to ignore when their patent is used for academic research without permission; therefore, scholars argue that an "ignoring patent" norm also exists in academic research.[808]

Academic patentees who support patent use in academic research may also allow the ignoring patent norm to be extended to the DIY bio movement, which also follows the tradition of open science, allowing DIY scientists to use patents in biotechnology experiments.[809] Moreover, the DIY bio movement was started by academic scientists, and many DIYers also work as professional scientists in academic, corporate or government labs.[810] Thus, DIY bio's

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[807] Eisenberg, "Noncompliance", *supra* note 298 at 1093; Strandburg, "Sharing Research Tools and Materials", *supra* note 672 at 8-9; Carrier, *Innovation for the 21st Century*, *supra* note 525 at 264-267; Sarnoff & Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents", *supra* note 401 at 1329 [According to *Madey v. Duke University, supra* note 668 at 1362, the U.S. research exception only allows a person to fulfill his/her "amusement, satisfy idle curiosity, or for strictly philosophical inquiry". Post-*Madey* in the Unites States, Holman notes that he was unable to find any patent infringement litigation brought against a university researcher who conducted "basic research of a purely noncommercial nature."].
[808] Strandburg, *ibid* at 8-12; Carrier, *ibid* at 265.
[809] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 52; Delfanti, *supra* note 1 at 12-13; Levy, *supra* note 60; Nielsen, *Reinventing Discovery, supra* note 1 at 187.
[810] Grushkin, Kuiken & Millet, *supra* note 7 at 6-7.

connection to open science and the research community in biotechnology can also encourage academic patentees to ignore their patents used in DIY bio.

The cost-benefit calculation can also reinforce this normative action from academic patentees when there is a non-commercial infringement or non-commercial use of patented research tools in DIY bio. As discussed in Chapter Three, research exceptions in patent law in many nations excuse non-commercial infringement but do not excuse unauthorized users of research tool patents and unauthorized users with commercial or mixed non-commercial and commercial purposes. According to the cost-benefit account, non-commercial motivated DIYers' unauthorized use of patented research tools for social production will also likely attract little or no threat of patent infringement lawsuit from academic patentees, commercial patentees and patent trolls because it may be difficult to identify patent infringement based on what is publicly made available in DIY bio. Moreover, non-commercially motivated DIYers who self-fund their small projects may not have the funds to pay patentees, and attacking these open scientists may generate a public backlash against patentees.

On the other hand, it may be risky to expect academic patentees to generally ignore patent use in academic research (and DIY science) based on the ignoring norm. Eisenberg argues that it is difficult to conclude that a strong ignoring norm exists or that it will persist over time in academic research because the ignoring norm depends on the practice of the sharing norm.[811] Norms can shift and change over time in a community.[812] As discussed above in Chapter Three, the fact that academic researchers are increasingly withholding access to research materials and data shows that the research community's sharing norm has weakened.[813] Furthermore, it is

[811]Eisenberg, "Noncompliance", *supra* note 298 at 1097-8.
[812] *Ibid*.
[813] Ibid citing Wesley M Cohen & John P Walsh, "Real Impediments to Academic Biomedical Research" (2008) 8 Innov Pol'y & Econ 1 at 17-18.

argued that when there is an innovation landscape where a group of innovators are successfully and consistently ignoring patents, this divergence between the normative practice and patent law can threaten the integrity of patent law and weaken the patent incentive for patentees.[814] Patent law can seem arbitrary and unfair when it is actually applied against patent infringers who are following a normative practice that is not consistent with patent law.

Weak sharing norms and increased propertization of academic research in biotechnology and the cost-benefit of patent enforcement can work together to create patent risks for commercially motivated DIYers and subsequent users who infringe academic patents. As noted above, commercially motivated contributors and users in open innovation face actual patent risks from commercial patentees and patent trolls. It was described above in Chapter Two that many DIYers are user innovators who are excellent downstream developers. They have explored DIY research tools and equipment (e.g. OpenPCR, open cell printers, open microscope, open source centrifuges, DIY bioprinters, and open source environmental chamber) and healthcare inventions (e.g. Open Insulin, DIY blood pressure monitor and improved glucose monitor). DIY bio projects can produce discoveries that are closer to commercialization than academic scientists who tend to work on upstream, basic, theoretical research. When commercially motivated DIYers infringe upstream academic patents or research tool patents, relying on the ignoring norm may be risky. Academic patentees can take actions against these DIYers as well as other businesses that commercialize infringing DIY bio projects or use infringing DIY research tools, which allow academic patentees to share in their profits.

Scholars note that the increasingly multidisciplinary nature of scientific problems also weakens ignoring norms that might be present in biotechnology research.[815] Norms operate well

[814] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1056; Eisenberg, *ibid*.
[815] Eisenberg, *ibid*; Strandburg, "Sharing Research Tools and Materials", *supra* note 672 at 10-11.

within small, close-knit communities.[816] However, a biomedical researcher can face negative consequences when patents are held by patentees outside the biomedical research community with different patent practices.[817] Interdisciplinary biotechnology fields, such as bioinformatics and synthetic biotechnology, make it easier for DIYers to contribute to biotechnology. However, these DIYers can also be exposed to different patent practices in high-tech industries, which may increase DIYers' patent risks from infringing third party patents.

When commercial entities control patented research tools, Walsh et al. note that, except for the use of diagnostic patents in clinical research, commercial patentees generally tolerate unauthorized use of patented research tools by academic researchers because the costs of patent enforcement outweigh the benefits: "such use could increase the value of the technology and as legal fees, risks of having the patent narrowed or found invalid, and bad publicity from using universities typically outweighed the potential benefits from such lawsuits."[818] Thus, commercial patentees generally ignored patent infringement when they can benefit from academic research to improve their patented research tools.[819] Moreover, academic researchers may have been able to use industry-owned patents in biotechnology because the ignoring norm may be reinforced by the existing symbiotic and cooperative relationship that universities have built with industry.[820]

Although commercial patentees tend not to aggressively enforce their patents against academic researchers, largely excusing non-commercial research uses, patent infringement

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[816] C Ellickson, *Order Without Law: How Neighbors Settle Disputes* (MA: Harvard Univ. Press, 1991) cited in Heller & Eisenberg, *supra* note 298 at 698; Burk & Lemley, *The Patent Crisis, supra* note 453 at 86; O'Rourke, *supra* note 338 at 1199.
[817] Eisenberg, "Noncompliance", *supra* note 298 at 1095; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1458-1460.
[818] Sarnoff & Holman, "Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents", *supra* note 401 at 1323 citing John P Walsh, Ashish Arora & Wesley M Cohen, "Working Through the Patent Problem" (2003) 299 Science 1021.
[819] Sarnoff & Holman, *ibid* at 1329.
[820] Carrier, *Innovation for the 21st Century*, *supra* note 525 at 266.

actions can be brought against universities for commercially motivated patent uses.[821] Some commentators note that the high profile patent infringement cases against university researchers can also weaken the ignoring patent norm.[822] Hope suggests that the risk of a patent infringement lawsuit within the research community "is likely to increase as public and non-profit institutions form closer relationships with industry."[823]

One cannot assume that a cooperative relationship exists between the biotechnology industry and the DIY bio community; it is unclear what relationship exists between industry and socially produced science at this time. As noted above, OSS contributors and users have been targeted by high-tech industry patentees and patent trolls; commercially motivated contributors and users in open innovation likely face actual patent risks from existing patentees. Social production in biotechnology can generate downstream works closer to commercialization and stimulates DIY bio-based businesses. Commercial patentees and patent trolls can take on a wait-and-see approach, where they can observe any potential infringing uses of patented research tools and wait to enforce their patents against commercially motivated DIYers and DIY bio-based businesses when they become profitable.

On the other hand, commercial patentees may ignore commercially-motivated infringement from DIY bio if the infringing activity benefits commercial patentees. Academic patentees may also refrain from enforcing patents against commercially motivated contributors' and users' in DIY bio if the infringing activity somehow benefits the patentees. Unlike commercial patentees who are motivated by gaining commercial benefits from infringing

[821] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1056; Carrier, *ibid* [Carrier also notes that commercial entities are more likely to sue for unauthorized commercial research use in universities because "the amount of damages increases and harm to reputation decreases." However, Carrier notes that this assessment is still observed in a single field: gene patent use in clinical diagnostic testing].
[822] *Ibid*.
[823] Hope, *Biobazaar*, *supra* note 21 at 63.

activities, academic patentees may perceive benefit from a DIY bio project that increases the science commons or public benefit. Moreover, academic patentees may ignore commercially motivated DIYer's patent use when they do not have a conflict of interest, such as preexisting agreements with business research partners and funders.

For example, it is possible that commercial contributors in DIY bio collaboration or community projects, such as Open Insulin, can infringe third party patents while developing upstream open source tools for essential healthcare products in society. Some commercial patentees may ignore this type of patent infringement if the bad publicity from blocking the project can cause more harm to its business than allowing unauthorized patent use. Moreover, DIY bio businesses that develop, distribute, and sell open source biotechnology research tools and equipment at low prices can infringe existing research tool patents. However, academic patentees may allow such infringement because these businesses stimulate scientific progress by improving access to research tools and equipment for researchers everywhere.

4.6 Organizations in Open and Cooperative Development

Early discussions about commons-based projects organized over decentralized networks emphasized the open norms and technology, such as message boards, forums, hosting services and OSS tools, for making it possible to organize peer production or social production in loose-knit groups.[824] Many small commons-based projects start with informal decision-making between collaborating partners and a bottom-up structure. However, commentators note that when grassroots or bottom-up, loose-knit and cooperative open development projects grow in size and prominence, they will likely also need legal rules and organizations to safeguard the

[824] Lee, *supra* note 752 at 276.

open and cumulative development process and shared resources from both internal and external IP interference.[825] It is important to protect the open development process and its outputs when open development operates alongside proprietary development in a field of endeavour. The remainder of this section will examine neutral organizations' functions in commons-based development.

For example, the OSS community creates a protected commons of copyright-protected OSS with open source copyright licences, which impose legal obligations on software owners and users to protect OSS development.[826] The protection of OSS development can also be attributed to funding and support from high-tech businesses and non-profit organizations. For instance, the Free Software Foundation (FSF) and the Open Source Initiative (OSI) are prominent non-profit organizations in OSS development.[827] These organizations facilitate software sharing and distribution by publishing voluntary open source licensing standards and open source licences that reflect essential community values, and they enforce open source licences on behalf of the community.

Non-profit organizations that assist loose-knit open innovation communities as neutral and trusted intermediaries create better infrastructure for open and cumulative development. They can implement top-down control and centralized decision-making in loose-knit collaboration. Establishing supportive organizations in open innovation can increase the cost of sustaining an open innovation environment.[828] However, their presence can encourage more

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[825] *Ibid*.
[826] Maggiolino & Montagnani, *supra* note 702 at 811-814; Asay, "The General Public License Version 3.0", *supra* note 702; Vasudeva, *supra* note 702.
[827] Richard E Fontana, "Open Source License Enforcement and Compliance" (2010) 27:4 The Comp &Int Lawyer 1 at 6.
[828] Free Software Foundation, "Free Software Foundation receives $1 million donation from Pineapple Fund" (30 January 2018), online FSF <https://www.fsf.org/news/free-software-foundation-receives-1-million-donation-from-pineapple-fund>; "Membership", online: Biocurious <http://biocurious.org/faq/>.

individuals, governments and other private and public sector organizations to join and support these activities.

Organizations can encourage cooperation and safeguard open development by defining and enforcing acceptable community practice. In academic research, universities and research organizations influence research sharing within the scientific research community by observing individual researchers' research sharing practices and creating guidelines and principles that can improve those practices.[829] Organizations in open innovation can also improve resource sharing practices by creating information exchange guidelines that identify and encourage efficient practices and discourage inefficient or harmful practices.[830] Moreover, as observed in OSS development, organizations can enforce resource sharing rules within and outside the community via private ordering using IP licences and contracts. In projects which use open source licensing or user agreements to protect the commons, organizations can be established to monitor the use of its contents and to enforce open source licences and user agreements. For example, the FSF established the GPL Compliance Lab in 2003 to enforce OSS licences and to encourage settlement in the OSS community.[831] And Harald Welte founded a non-profit project known as *gpl-violations.org* to enforce OSS compliance via a mailing list and a website to collect information about non-compliant users of the GPL licence.[832] The group has successfully brought court actions against non-compliant commercial users in Europe.[833] Thus, organizations play an important role in growing open development communities and projects: they can shape

[829] Rai, "Regulating Scientific Research", *supra* note 19 at 81; Tenopir et al, *supra* note 48; Delfanti, *supra* note 1 at 22; Nielsen, *Reinventing Discovery, supra* note 1 at 6-7.
[830] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31-32.
[831] Fontana, "Open Source License Enforcement and Compliance", *supra* note 827 at 6.
[832] *Ibid*; Online: <gpl-violations.org>.
[833] *Ibid*.

community norms and enforce legal obligations in a society based on these norms to protect open development.[834]

Moreover, non-profit organizations can act as a neutral intermediary for a group of collaborators who may have conflicting interests outside of the collaboration. A neutral intermediary can force collaborating partners to cooperate by enforcing the community rules via membership contracts. For example, the Open Invention Network (OIN) was established by a group of businesses to free Linux development from patent interference.[835] As a neutral intermediary, the OIN works to achieve this common goal, which may be difficult if left to the participating businesses which compete in the marketplace. The OIN works with numerous companies that grant patent access and use for the Linux development community.[836] By 2018, approximately 2400 companies around the world had joined the OIN's patent pool for Linux.[837]

As loose-knit collaboration projects become prominent and operate for a long time, formal dispute settlement and governing rules may replace informal rule-making and informal dispute settlement between participants because the conflict between project members can threaten to disrupt the collaborative process.[838] A neutral intermediary can offer mediation to smooth out conflicts between participants, which is critical in some cases to ensure ongoing collaboration and success.[839] For example, Wikipedia is one of the longest volunteer-sustained crowdsourced projects on the Internet. Although this project is mostly sustained and administered by its contributors, the Wikimedia Foundation, a non-profit organization that

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[834] Rai, "Regulating Scientific Research", *supra* note 19.
[835] "The OIN Community", online: Open Invention Network <https://www.openinventionnetwork.com/community-of-licensees/>.
[836] *Ibid*.
[837] Peter Bright, "Microsoft promises to defend – not attack – Linux with its 60,000 patents" (10 October 2018), online: Ars Technica <https://arstechnica.com/gadgets/2018/10/microsoft-promises-to-defend-not-attack-linux-with-its-60000-patents/>.
[838] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1605.
[839] *Ibid*.

supports the project, has been offering conflict resolution for contributors to protect the website's cooperative development.[840]

Non-profit organizations representing open innovation projects can also interact with entities outside of the projects for collaborating partners.[841] As an intermediary, organizations can also represent a group's interest in society. For example, organizations that aid open innovation projects can hire patent experts to perform prior art searches to help participants avoid infringement. They can also hire businesses to perform some R&D in an open science project, such as clinical testing, which requires central control and is difficult to perform efficiently within a decentralized environment.[842] Contracting out some R&D requirements allows open innovation communities to mix open and proprietary R&D while remaining in control of its outputs. Open innovation organizations can also hire or partner with businesses to influence the commercial distribution of open innovation outputs; this approach reduces the possibility of third party appropriation and market failures.[843] For instance, organizations representing community research projects like Open Insulin can enter into an agreement with a generic drug manufacturer to produce open source drugs and to protect equitable access to drugs.

Organizations can also centrally manage resources for open R&D. For example, clearinghouses manage and create central access to information, patents and other resources on behalf of the resource owners (see Chapter Six below). Organizations can also administer shared tools and resources in open development, such as websites, databases, research equipment, rental

[840] Lee, *supra* note 752 at 290.
[841] *Ibid* at 293.
[842] Kapczynski, "Order without Intellectual Property Law", *supra* note 22; OSDD license, s 4.3, online: Open Source Drug Discovery < http://www.osdd.net/about-us/osdd-policies/access-policy>.
[843] *Ibid* [Another example of a licensing scheme that mixes up open and closed development is the Tropical Disease Initiative (TDI). It was proposed to create a mixed drug discovery process (i.e. open source development for upstream research and proprietary development for downstream product development) to meet the R&D needs for tropical diseases. See Stephen M Maurer, Arti Rai & Andrej Sali, "Finding Cures for Tropical Diseases: Is Open Source an Answer?" (2004) 1 PLoS Medicine 183].

properties for meeting spaces, and patents. And organizations can help loose-knit communities practice knowledge management strategies, which may require central-decision making and considerable resources, such as defensive patenting, open source patent licensing and defensive publishing. Organizations can help community members gather resources by soliciting donations, organizing crowdfunding, collecting membership fees from participants, and seeking funding from governments and public and private sector organizations.

Although many user-directed volunteer-initiatives in science like DIY bio and community projects may begin as small, informal grassroots or bottom-up commons-based projects, larger projects may need an infrastructure to deal with the complexities of coordinating open collaboration between a large group of volunteer contributors and managing large resources that accumulate over time in a project.[844] Supporting organizations in open science and open innovation communities can offer many functions and services to improve alternative innovation environments' infrastructure. Moreover, they can assist bottom-up, loose-knit projects that operate alongside private sector organizations that pursue proprietary development in society without compromising non-proprietary development and open norms.

4.7 Conclusion

Patent proliferation in biotechnology with fragmented and overlapping patents can cause social production participants to experience patent access barriers to upstream research and inadvertent patent infringement. In this patent landscape, it can be challenging to build on off-patent technologies and invent around patents. It is also possible that participants will need to prepare

[844]Hope, *Biobazaar*, *supra* note 21 at 131; Golinelli & Ruivenkamp, *supra* note 3 at 154.

against the development of third party patent rights that can control DIY bio inventions and their downstream uses.

The research exceptions in many nations do not excuse unauthorized use of research tool patents and commercially motivated patent use in research. According to the cost-benefit and the norms-based assessments of patent risks in biotechnology, even without the patent exception, non-commercial contributors and users in DIY bio will likely face little to no patent actions from academic patentees, commercial patentees and patent trolls in biotechnology for infringing upstream patents or patented research tools. However, non-commercially motivated DIYers and downstream users may be discouraged from participating in social production when the research area suffers from overlapping patents, and they perceive this patent development as a potential risk (i.e. perceived patent risk). Commercially motivated contributors and users (e.g. DIY bio-based businesses) in social production will likely experience actual or legitimate patent risks from academic and commercial patentees and patent trolls in biotechnology. However, academic and commercial patentees might ignore commercially motivated patent infringement from DIY bio if the unauthorized patent use also benefits them. Patentees in other industries can also target DIY bio contributors and users if they infringe patents in interdisciplinary DIY bio projects.

When an invention is freely released into the public domain or defensively published by open innovation communities, those who invented it cannot control its subsequent use. Publicly released inventions do not always create prior art that can block third parties from patenting the same invention. To avoid creating an unprotected commons of patentable inventions, some open scientists and open innovation communities practice defensive patenting and open source licensing to build a protected commons. Open source licensing is a knowledge management strategy used in non-proprietary development. It was created in OSS development to protect OSS

development and the OSS commons against IP interference. Open source-inspired licences and contracts have been used in other commons-based development as well as in biotechnology research (see the next chapter).

Chapter 5: Open Source Licensing in the Social Production of Biotechnology

5.1 Introduction

The rapid increase in biotechnology patents with fragmented and overlapping rights can expose participants in the social production of biotechnology to patent access barriers to upstream research resources or research, inadvertent patent infringement and the development of overlapping third party patents. This chapter considers whether creating a protected commons of patented resources with open source licensing will promote open and cumulative development in DIY bio while protecting this innovation environment from patentees in biotechnology.

Open source licensing was originally developed for OSS development. [845] It was designed to protect open source access to copyright-protected software. This licensing scheme is based on important community values in OSS development, such as openness, transparency, cooperation and trust.[846] It allows the OSS community to self-regulate the use of OSS with standardized licences. Open source licences travel with the protected subject matter (i.e. software source code) as it is passed on between users. The licensing scheme is automatic and self-perpetuating: OSS can be distributed to an unlimited number of users without negotiations between users or requiring an administrative structure. The OSS licences offer royalty-free access to software source code to encourage use, modification, improvement and redistribution, and it does not discriminate on the purpose of use. This scheme also encourages more contribution to the OSS commons by requiring users to practice copyleft licensing; hence, software users must use the same open source licence as the original OSS when they distribute any modifications and improvements. The copyright protection of the OSS source code allows this community to

[845] The open source software development community uses the term "free and open source software" (FOSS) and "open source software" (OSS) interchangeably to refer to their activities. See Vasudeva, *supra* note 702 at 24.
[846] "Open Standards Requirements for Software Rationale" (19 September 2006), online: Open Source Initiative <https://opensource.org/osr-rationale>.

effectively enforce this licensing scheme.[847] The success of OSS development attracted many open science and open development communities to use this automated, copyleft or viral licensing strategy with different subject matters, such as artistic and literary works, open source hardware, and biotechnology inventions.[848]

There have been some efforts from open science and innovation communities to create a protected commons of patentable inventions with open source licensing. In the social production of biotechnology, this licensing scheme may be used to increase the pool of patented research resources, which can reduce DIYers' inadvertent infringement and patent access barriers to research resources. Nonetheless, existing patentees in public and private sectors of biotechnology will need to cooperate and agree to open source license upstream patents. Some patentees have been willing to allow their life science patents to be used in open R&D. Open source licensing may be suggested when patentees have nearly expired patents, patents that do not generate profits for them, and defensive patents in biotechnology. Although open source licensing may benefit their business, it may be challenging to convince private-sector biotechnology patentees to join open source licensing because of the unwillingness to adopt a different business model. Moreover, the open source licensing pool may also include defensive patented new DIY bio inventions, although DIY biologists may experience practical, legal and ideological obstacles accessing patent-protection.

Open source patent licences will need to be carefully drafted to consider the different scope of protection guaranteed in patent law and copyright law. However, some patent problems in biotechnology are difficult to avoid. Open source users' rights to use, modify and improve under patent law will be limited by the scope and the boundaries of the licensed patent claims.

[847] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1072; Vasudeva, *supra* note 702 at 30-31.
[848] Vasudeva, *ibid* at 6.

When there are overlapping patents in a research area, open source licensees can risk infringing overlapping third party patents. This licensing strategy may be inappropriate with some biotechnology inventions, such as complex technologies that require access to additional rights and services and living matters. Furthermore, one of the problems of using open source licences to create a protected commons is that it can lead to licence proliferation, causing licence incompatibility and technology incompatibility within open development. Although participants are encouraged to exchange different types of resources in open biotechnology R&D, it may not be easy to standardize access to various forms of patented biotechnology inventions.

5.2 A Review of Open Source Licensing

Open source licensing is a knowledge management strategy for creating a protected commons with private ordering. It was originally designed for OSS development, where standardized copyright licences were used to protect free and open access to software source code. Open source licensing encourages software users to replenish the protected commons, and it prevents subsequent users from commoditizing OSS.[849] The licence creates obligations for software developers and users. Software developers who publicly share copyright-protected software source code (i.e. licensors) must voluntarily agree not to enforce their copyright against all subsequent users who follow the open source licensing conditions.[850] Open source licences grant broad permissions for software users (i.e. licensees), including the right to study, use, distribute, modify, and distribute the modified or improved source code. Open source licences are self-perpetuating or viral licences that automatically grant royalty-free access to all subsequent

[849] Niva Elkin-Koren, "What Contracts Cannot Do: The Limits of Private Ordering in Facilitating a Creative Commons" (2005) 74:2 Fordham L Rev 375 at 375-6 [Open source licensing is "a way to bypass the increasingly protectionist global intellectual property regime" which threatens access to resources and people's ability to create new things with them].
[850] *Ibid*.

users.[851] It is an economically efficient knowledge management strategy since there is little or no administration cost, and it does not require a central administrating body.[852] This licensing scheme is ideal in low-cost open and cumulative development of IP works because it significantly lowers the cost of accessing and using copyrighted works within the innovation environment by removing the costs of individual negotiations and licensing.[853] Thus, it significantly lowers the transaction costs compared to proprietary licensing.[854]

Open source licensing has been used successfully for many years within OSS development with very little litigation, and it is generally accepted within software development that OSS licences are legally enforceable.[855] This general acceptance discourages disputes and encourages dispute settlement.[856] This section will begin by reviewing voluntary open source licensing standards created by the OSS movement, which define how open source licences should operate in order to protect open and cumulative development. It goes on to examine how the core open source licensing conditions function and encourage OSS development, the enforceability of open source licences in copyright law and contract law, and how this licensing strategy has been applied outside of OSS development.

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[851] Janet Hope, "Open Source Genetics Conceptual Framework", in van Overwalle, *Gene Patents and Collaborative Licensing Models*, *supra* note 85 at 185; *Ibid*.
[852] Maggiolino & Montagnani, *supra* note 702 at 811-814; Joly, "Open Source Approaches in Biotechnology", *supra* note 56 at 393-4.
[853] Joly, *ibid* at 401-2.
[854] Hope, *Biobazaar*, *supra* note 21 at 159.
[855]Fontana, "Open Source License Enforcement and Compliance", *supra* note 827 at 5-6 [Many disputes under open source software licences end by settling out of court]; Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 420; Dysart, *supra* note 799 at 159, 168.
[856] *Ibid*.

5.2.1 Open Source Licensing Standards

The two influential authorities that published the voluntary open source licensing standards are the Free Software Foundation (FSF)[857] and the Open Source Initiative (OSI).[858] These standards describe the necessary functions of an open source licence in OSS development. The voluntary standards do not define how each OSS licensing condition must be implemented within a licence, allowing some flexibility for drafting. There is a significant overlap between the two definitions with minor differences, which stem from the organizations' ideological stances.[859] The standards overlap because they reflect the OSS community's goals and values, such as safeguarding and encouraging non-proprietary, incremental, open and collaborative development software and making software widely available for reuse and modification.[860] They describe what kinds of rights and obligations should be recognized in an open source licence. Hence, it is not difficult for open source licences to comply with both standards. These organizations also independently review and certify open source licence templates that comply with the voluntary open source licensing standards of the organization. The OSS community has published numerous OSS licence templates over the years, which allow software developers to freely use and modify them for disseminating OSS source code. Most OSS licences comply with the voluntary open source

[857]The Free Software Foundation is a non-profit organization organized by Richard Stallman, a programmer from MIT, who was committed to promoting the free software ideology; Vasudeva, *supra* note 702 at 23; Raymond, *supra* note 4 at 69.

[858]The Open Source Initiative is a non-profit organization that promotes open source software development. It was established by programmers Eric Raymond and Bruce Perens. See "About the Open Source Imitative", online: OSI <https://opensource.org/about>; Hope, *Open Source Biotechnology*, *supra* note 395 at 67-71; Vasudeva, *ibid*; Raymond, *ibid*.

[859] Asay, "The General Public License Version 3.0", *supra* note 702 at 271-3[While both organizations have certified many open source licences, it appears more difficult to qualify under the FSD than the OSD. All of the FSF-qualified licences are also qualified by the OSI but not the other way around. For example, the FSF rejected the Original Artistic Licence because it was too vague and may allow developers to impose restrictions that interfere with OSS users' freedoms]; Rosen, *supra* note 60 at 9-11.

[860] *Ibid*.

licensing standards, and many have been approved and certified by both organizations.[861] Both organizations have certified more than 60 open source licences.[862]

The FSF began as a social movement to promote free software as a necessary component of a free society; it argues that software ought to be free in society in order to promote individual liberty.[863] This is the general philosophy behind the Free Software Definition (FSD). The FSF has sponsored OSS development and the hacker culture since the 1980s, and it is also responsible for publishing one of the most popular OSS licence templates: the GPLs ("GNU Public License").[864] According to the FSD, all software users should enjoy the four essential freedoms:

1) freedom to run the program for any purpose;
2) freedom to access the source code to study it and modify it;
3) freedom to redistribute the software, and
4) freedom to distribute modified copies.[865]

The FSF certifies software licences that guarantee these four freedoms.

On the other hand, the OSI's Open Source Definition (OSD) was published after the FSD to increase private sector participation in the OSS movement.[866] The OSI was established to promote private sector involvement without advocating the philosophical and political viewpoints of the FSF because the free software ideology discouraged business participants who considered OSS development as a charitable activity.[867] The FSF promotes free software as an ethical norm in society, whereas the OSI takes a more pragmatic view that OSS should be more

[861] Asay, *ibid*.
[862] *Ibid*; "The Licence Proliferation Project", online: OSI <https://opensource.org/proliferation>.
[863] Online: FSF <http://www.fsf.org/about/>; Raymond, *supra* note 4 at 69.
[864] *Ibid*.
[865] "The Free Software Definition", online: FSF <http://www.gnu.org/philosophy/free-sw.html>.
[866] Vasudeva, *supra* note 702 at 23 [The OSI sought to remove the perception that an open source approach must produce free software and that open source is not for businesses].
[867] "About the Open Source Initiative", online: OSI <https://opensource.org/about>; Hope, *Open Source Biotechnology*, *supra* note 395 at 67-71; Vasudeva, *supra* note 702 at 23-24.

business-friendly.[868] Thus, instead of using the term "free software", the OSI chose to be associated with the term "open source software" to emphasize that software source code ought to be openly shared to all, including commercial entities.[869] The OSD consists of ten criteria as the requisite conditions of an open source licence:

1. Free Redistribution;
2. Source Code;
3. Derivative Works [i.e. copyleft];
4. The integrity of the Author's Source Code;[870]
5. No Discrimination Against Persons or Groups;
6. No Discrimination Against Fields of Endeavour;
7. Distribution of License [i.e. OSS licence is extended automatically to all users];
8. License Must Not Be Specific to a Product; [871]
9. License Must Not Restrict Other Software;[872] and
10. License Must Be Technology Neutral.[873]

The OSD expresses more detailed requirements than the FSD, but the additional conditions are also implied under the FSD.[874] The OSD is also followed in other open innovation communities that use open source licensing (see below). For example, the FSF has stated that imposing the obligation of reciprocity or copyleft sharing of derivative works on users protects all of the four freedoms in the FSD.[875] Non-discrimination, interoperability and technology neutrality under the OSD can be considered as being implied by the FSD's "freedom to run the program for any purpose". To achieve software interoperability, open-source licences must also

[868]Asay, "The General Public License Version 3.0", *supra* note 702 at 267-270.
[869]Vasudeva, *supra* note 702 at 23-24.
[870] I.e. "The license may restrict source-code from being distributed in modified form only if the license allows the distribution of "patch files" with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software." See "The Open Source Definition" (last updated 22 March 2007), online: OSI <https://opensource.org/osd>.
[871] I.e. The licence must not attach a program for being part of a particular software distribution. *Ibid*.
[872] I.e. The licence must not insist that other software distributed with OSS must also be distributed with the same licence. Thus, OSS can be distributed with proprietary software in the same medium. *Ibid*.
[873] *Ibid*; Vasudeva, *supra* note 702 at 23.
[874] Dysart, *supra* note 799 at 44; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 23-24.
[875]"The Free Software Definition", *supra* note 865; Vasudeva, *supra* note 702 at 23.

be compatible to allow multiple OSS to be combined or used together. And with the assurance of technology neutrality, all technologies are available under the same licensing strategy to allow users to combine various technologies.[876] While the FSF's free software ideology may have led some businesses to avoid using OSS in their products and services in the past, the FSF has since clarified their position and stated that they do not oppose commercial uses of OSS.[877]

Therefore, it is generally accepted that an open source licence grants royalty-free, non-exclusive access to the "source" information of the licensed work that enables anyone to exercise the freedom to use the work for any purpose, and these licensing conditions also attach to downstream derivatives.[878]

5.2.2 Open Source Licensing Conditions in Open and Cumulative Development

This section will examine how open source licensing conditions are relevant to open and cumulative development. As noted above, an open source licence guarantees royalty-free and open access, source sharing, non-discrimination of users and the purpose of use, and copyleft obligations for downstream developers. These conditions facilitate OSS development by encouraging volunteer contributions in the commons, and they promote important community values in open innovation, such as openness, transparency, cooperation and trust.[879]

First, an open source licence must grant royalty-free, open access to the protected subject matter. Free and open access encourages the public to study, use and disseminate the licensed technology.[880] Moreover, it encourages subsequent users to invest in it by engaging in further development and even commercialization. Free access to open-source tools allows more people

[876] Schultz & Urban, "Protecting Open Innovation", *supra* note 459.
[877] Asay, "The General Public License Version 3.0", *supra* note 702 at 269.
[878] Pearce, *Open-Source Lab*, *supra* note 153 at 45.
[879] Hope, *Biobazaar*, *supra* note 21 at 154-5; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 22-3; Benkler, *Wealth of Networks*, *supra* note 2 at chap 8.
[880] Hope, *ibid*; Schultz & Urban, *ibid*.

to try to solve real-world problems using these tools.[881] Unlike proprietary development, open innovation communities create royalty-free access to the common pool resources to encourage R&D, and the royalty-free access must be irrevocable to protect resource users' incentive to adopt, invest in and develop them.[882] The text of an open source licence is also available for free and open access and is open source licensed, allowing anyone to read and understand the licensing conditions. This legal instrument governs important relationships within open and cumulative development; therefore, the freedom to examine the licences increases transparency, trust-building, and accountability in open development.[883]

It has been noted that while open source licensors cannot charge users a licensing fee to access and use the licensed technology, they may charge other fees to recover costs that they may incur from creating free access to the technology. [884] For instance, the FSF and OSI agree that licensors can charge a one-time fee to cover a reasonable reproduction cost.[885] The cost of copying and disseminating digital information is zero or minuscule. However, if the underlying subject matter has tangible components (e.g. hardware tools or genetic materials) or requires additional processing to enable subsequent use (e.g. data), open source users may be responsible for the reasonable costs of duplicating and delivering the tangible portions to them. This one-time fee accommodates the use of open source licensing where open source developers must incur additional costs to freely disseminate IPs.

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[881]Katherine M A Reilly & Matthew L Smith, "The Emergency of Open Development in a Network Society" in Matthew L Smith & Katherine M A Reilly, eds, *Open Development: Networked Innovations in International Development* (Cambridge, MA: The MIT Press, 2013) at 30.
[882] E.g. GPLv3, s 2 "Basic Permissions", online: FSF <https://www.gnu.org/licenses/gpl-3.0.en.html> ["All rights granted under this License are granted for the term of copyright on the Program, and are irrevocable provided the stated conditions are met. All rights granted under this License are granted for the term of copyright on the Program, and are irrevocable provided the stated conditions are met."].
[883] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 23.
[884]"The Open Source Definition (Annotated)", ver 1.9, at "2. Source Code", online: OSI < https://opensource.org/osd-annotated>.
[885]*Ibid*.

Secondly, it is important to give users sufficient information that will allow them to use the licensed subject matter. In OSS development, the software is disseminated in the source code format in order to allow users to exercise their broad rights under an OSS licence, including the right to study, copy, use, modify and improve the software.[886] Users' freedom in OSS development is meaningless if the source information is unavailable.[887] If an open source licence is used to create access to a different technology, the licensor must provide the licensees with the source code equivalent information that allows the licensees to study how the technology functions, to put it to use, and to develop modifications and improvements without wasteful reverse engineering.[888] This "source" sharing makes open source projects transparent to users, promoting public confidence and trust.[889]

Third, a true open source approach does not discriminate as to who open source users are and what their purpose of use might be. The nondiscrimination requirements encourage more volunteers and organizations to participate in and contribute to open source projects.[890] Open source licensing can encourage both commercial and non-commercial uses of OSS.[891] In OSS development, many businesses, including IBM, Hewlett Packard, Google and Red Hat, support and use OSS in business.[892] Businesses can lower the cost of developing commercial products and services by using free and open source components instead of self-produced or proprietary

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[886] *Ibid* at 21-22; Beat Fluri, Michael Wursch & Harald C Gall, "Do Code and Comments Co-Evolve? On the Relation Between Source Code and Comment Changes" (Proceedings from 14th Working Conference on Reverse Engineering, 2007) at 1.
[887] Schultz & Urban, *ibid*.
[888] Hope, *Biobazaar*, *supra* note 21 at 171; Pearce, *Open-Source Lab*, *supra* note 153 at 51.
[889] Hope, *ibid* at 155; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 22.
[890] Reilly & Smith, "The Emergency of Open Development in a Network Society", *supra* note 881.
[891] Pearce, *Open-Source Lab*, *supra* note 153 at 45.
[892] Peter Bright, "Microsoft promises to defend – not attack – Linux with its 60,000 patents" (10 October 2018), online: ARS Technica < https://arstechnica.com/gadgets/2018/10/microsoft-promises-to-defend-not-attack-linux-with-its-60000-patents>; "The OIN Community", online: Open Invention Network <https://www.openinventionnetwork.com/community-of-licensees/>; Benkler, *Wealth of Networks*, *supra* note 2 at 46, 64.

components.[893] Companies that have stakes in OSS projects have sponsored their employees to contribute to OSS projects.[894] Society benefits from commercial activities that build around open development because they increase competition and products and services available in the market.[895]

Fourth, one of the most discussed and controversial open source licensing conditions is the copyleft or reciprocity provision.[896] An open source licence must require modifications and derivative works to be distributed under the same licence as the original upstream work.[897] The copyleft condition removes the possibility that downstream users block access to the upstream open source work. This provision prevents proprietary downstream developments and products from capturing and blocking access to upstream open source technologies or open source tools. A copyleft licence also incentivizes innovation sharing by protecting the upstream innovator's right to benefit from downstream developments that are contributed back to the open source commons.[898]

It has been argued that a copyleft licence discourages commercial uses of OSS, where a commercial product is a derivative of the open source technology. Open source copyleft licences require licensees to publish the "source information" for commercial derivatives, which businesses are reluctant to do, given their desire to protect their proprietary contributions from

[893] Hope, *Open Source Biotechnology*, *supra* note 395 at 211-214.
[894] Sharon Belenzon & Mark Schankerman, "Motivation and Sorting in Open Source Software Innovation" (November 2008) No 019, Discussion Paper Series, EDS Innovation Research Programme at 2; Benkler, *Wealth of Networks*, *supra* note 2 at 46, 64.
[895] Hope, *Open Source Biotechnology*, *supra* note 395 at 211-214.
[896]Hope, *Biobazaar*, *supra* note 21 at 161.
[897] As reflected in this language, the OSI permits open source licences that do not prohibit the use of copyleft conditions. It has certified weak copyleft licences and licences without copyleft conditions (i.e. permissive licences).
[898]Hope, *Biobazaar*, *supra* note 21 at 178 [In proprietary licences, upstream innovators can use reach-through licences, which impose "royalty payments on the use or sale of follow-on innovation". However, this causes royalty stacking for downstream developers who have to pay royalty fees to all licensors upstream. Open source copyleft licences provide incentives for upstream contribution (e.g. freedom to use downstream OSS) without creating royalty stacking].

other businesses and to remain competitive in the marketplace.[899] To overcome this dilemma, the OSS community has developed OSS licences with different strengths of the copyleft obligation on downstream developers.[900] Thus, some OSS licences (e.g. GNU GPL) require downstream users to exercise copyleft licensing strictly regardless of the purpose of use, while some licences (e.g. GNU Lesser General Public Licence (LGPL), Mozilla Public License and Eclipse Public License) impose weaker copyleft obligations to encourage open source software code to be incorporated into commercial projects. Also, some OSS licences, such as the MIT licence and the Berkeley Software Distribution (BSD) licences, do not have a copyleft condition (also called permissive licences).[901] Strict copyleft licences do not allow users to incorporate OSS into proprietary software because all downstream works must be available under the same licence.[902] For example, under the GPL, the copyleft condition attaches to any work that is based on an earlier GPL licensed work, and downstream works must be available under the same licence "as a whole" and "regardless of how [the parts] are packaged."[903] Under the strict copyleft licence, subsequent users must disseminate the original software source code and any new source code that they have added (i.e. the derivative work in entirety under the same GPL).

On the other hand, in weak copyleft licences, the copyleft obligation only attaches to the portions of the downstream work that contain the OSS and its derivatives, but not to the entire software program.[904] The LGPL, a weak copyleft licence, is often used for OSS libraries that

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[899]Boettiger & Burk, *supra* note 68 at 224; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1473; Hope, *ibid* at 185-6 [Thus, strict reciprocity can encourage non-compliant commercial use of OSS where commercial modifications and improvements are marketed without acknowledging the open source resources that are incorporated in commercial products].

[900]Vasudeva, *supra* note 702 at 23; Fontana, "Open Source License Enforcement and Compliance", *supra* note 827 at 2-4.

[901] Vasudeva, *ibid* [The FSF has not certified permissive licences while the OSI accepts permissive licences as open source licences].

[902] Vasudeva, *ibid*; Fontana, "Open Source License Enforcement and Compliance", *supra* note 827 at 2-4.

[903] Fontana, *ibid*.

[904] *Ibid*.

many programmers include in their program to create common functions. These libraries may be compared to common research resources or enabling technologies (e.g. DNA sequences) in scientific research, which allow scientists to develop various application-level results (e.g. vaccines). For example, under the LGPL, the copyleft requirement attaches to software libraries and their modifications and derivatives; it does not attach to the portions of a software program that was implemented by commercial users.[905] The LGPL does not require commercial users to publicly disclose their proprietary components. As long as the final software is not a derivative of the open source library, the final software application can be distributed as a proprietary product without source sharing.[906] Therefore, the weak copyleft obligation allows common tools or upstream enabling technologies to be open source licensed and used in proprietary applications.

Lastly, there are OSS licensing conditions that are included to protect open source contributors' incentives. As discussed above in Section 2.2, reputational gains can incentivize software developers' participation in OSS development. OSS licences have two features, which allow programmers to be credited for their work: attribution and version control. OSS users must maintain the contributing programmers' attributions and OSS version history in the source code because these allow credit to be given to the people who are responsible for specific additions, modifications and improvements in the software.[907] Furthermore, as discussed above in Chapter Three, popular open source licences typically contain provisions that limit software developers' liabilities and disclaim OSS warranties.[908] These provisions protect the contributors' interest in

[905] "GNU Lesser General Public License", online: FSF <www.gnu.org/copyleft/lesser.html>.
[906] *Ibid*.
[907] E.g. GPLv3, s 5(a), *supra* note 882; "The Open Source Definition", *supra* note 870 at s 4.
[908] E.g. GPLv3, *ibid* at ss 15-16,

participating in open development by preventing OSS users from bringing lawsuits against them for losses incurred from using OSS.

5.2.3 Legal Enforceability of Open Source Licences and Agreements

Copyright and patent law stimulate R&D by granting IP owners the right to exclude unauthorized users' access to and use of IP-protected assets subject to limitations in the law; this allows IP owners to avoid free-riding. On the other hand, open source technologies are stimulated by allowing these technologies to be widely available, free of charge to anyone for use and downstream activities. Nonetheless, IP protection in open source licensed resources is important to effectively enforce open source licensing and to protect open and cumulative development. The operation of the open source licensing scheme in OSS development depends on the software source code's copyright protection.[909] It is generally accepted within software development that OSS licences are legally enforceable, even though OSS licences were not litigated until the 2000s, and there are still not many fully litigated cases involving open source licences.[910]

An IP licence is permission from an IP owner to use the IP protected asset according to the licence conditions. The IP owner-licensor can bring an IP infringement lawsuit against licensees who act outside the licence scope and violate the licensor's IP rights.[911] IP rights can

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[909] Eben Moglen, "Enforcing the GNU GPL" (10 September 2001), online: FSF < https://www.gnu.org/philosophy/enforcing-gpl.en.html>; Dreyfuss, "Does IP Need IP", *supra* note 31.

[910] Fontana, "Open Source License Enforcement and Compliance", *supra* note 827 at 5-6; *Versata Software Inc. v. Ameriprise Financial Services Inc. et al*., Case No. 1:14-cv-12 (W.D. Tex. District of Texas 2014); *XimpleWare Corp. v. Versata Software Inc. et al.,* Case No 5:13cv5161-PSG (N.D. Cal. 2014); *Artifex Software Inc., v. Hancom Inc*., Case No.16-cv-06982-JSC (ND Cali, 2017); Sylvia F Jakob, "Versata saga settled with prejudice" (19 March 2015), online: Institute for Legal Questions on Free and Open Source Software <http://www.ifross.org/en/artikel/versata-saga-settled-prejudice-1>; Dysart, *supra* note 799 at 159, 168.

[911] Vaver, *Intellectual Property Law*, *supra* note 68 at 575; Rosen, *supra* note 60 at 52-3; *Jacobsen v. Katzer*, *supra* note 923 citing *S.O.S., Inc. v. Payday, Inc*., 886 F.2d 1081 (9th Cir. 1989) and Nimmer on Copyright, §1015[A] (1999).

be enforced against the world. Hence, open source licences for IP-protected assets can be enforced against all asset users (subject to limitations in law), including open source licensees (if they act outside of the licence scope) and other unauthorized users. Any user who copies or uses open source licensed assets must follow the open source licensing conditions to avoid IP infringement. As noted in Chapter Three, while copyright law has an independent creation defence, patent law does not. Hence, patent rights can be enforced against independent inventors who arrive at and practice a patented invention without knowing the patent.

When contracts regulate the use of a group of resources, a contract must exist between a resource provider/owner and a resource user. For instance, a contract can be used to regulate the use of biotechnology research resources, provided that a contract exists between resource owners and users. A binding legal agreement exists between contracting parties when there is contract formation in law (i.e. offer, acceptance and consideration), and contract law governs the parties' relationship under the contract.[912] An IP licence can also be a contract when the formalities of contract formation are satisfied between a licensor and a licensee. The formalities may be weakened when standard form contracts are used; U.S. and Canadian courts have affirmed that there is a binding contract between an offeror and offerees who assent to the agreement (e.g. by signature or by conduct) having received reasonable notice of its terms and the parties exchange consideration.[913]

Early U.S. scholarship on the enforceability of OSS licences debated whether OSS licences are mere contracts or copyright licences because OSS licences create positive duties on software users that are not rooted in copyright law (i.e. the obligation to share the source code

[912] Wacha, *supra* note 914 at 473-5; Stephanie Ben Ishai & David R Percy, *Contracts: Cases and Commentaries*, 9th ed (Toronto, ON: Carswell, 2014) at chap 1.
[913] *ProCD Inc v. Zeidenberg*, 86 F.3d 1447 (7th Cir. 1996); *L'Estrange v F Graucob Ltd* [1934] 2 KB 394; *Parker v South Eastern Railway* [1877] 2 CPD 416; *Tilden* Rent-A-Car Co. *v Clendenning* (1978), 18 OR (2d) 601, 4 BLR 50; Rosen, *supra* note 60 at 53; Dysart, *supra* note 799 at 148-9.

upon redistribution, to maintain the notice of licence and attribution, and to practice copyleft).[914] As described above, these open source licensing conditions are essential to encourage voluntary contributions in open and cumulative development and to prevent subsequent users from using property rights to hinder open development. Scholars also debated whether the formalities of contract formation exist in open source licences, which must be present in order to create a binding agreement between licensors and licensees.[915] Therefore, there was uncertainty about whether such positive obligations of users can be enforced in law and whether copyright law or contract law is applied when users breach those obligations.

The advantage of enforcing key open source licensing conditions in IP law rather than contract law is that IP rights owners can access broader rights and remedies in IP law. As noted above, IP rights are property rights, which can be enforced against the world (subject to limitations in law).[916] Contracts, on the other hand, bind two or more parties, not the world at large, and only when there is a binding contract between the parties.[917] Also, IP licensors can access the equitable remedy of injunction in IP law when there is an IP infringement.[918]

In OSS development, the open source licensing scheme was designed to allow an indefinite number of software users, and each user can pass along the software and its modifications and improvements to an indefinite number of users.[919] Open source users maintain a notice of licence on the software to allow the OSS licence to travel with the software as it is

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[914] Jason B Wacha, "Taking the Case: Is the GPL Enforceable?" (2004) 21 Santa Clara Computer & High Tech LJ 451 at 482; Rosen, *supra* note 60 at 53, 55-56; Dysart, *ibid* at 146, 158 citing Rahmatian, *Copyright and Creativity: the Making of Property Rights in Creative Works* (Edward Elgar, 2011) at 23

[915] *Supra* note 910.

[916] Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 407-9 [Property rights are negative obligations; these restrict others' access to a particular resource rather than impose positive obligations on people. Property rights are a bundle of rights that are applied to everyone in society].

[917] Elkin-Koren, *ibid* at 405 citing Thomas W Merrill & Henry E Smith, "The Property/Contract Interface" (2001) 101 Colum L Rev 773 at 788-89.

[918] Dysart, *supra* note 799 at 147; Robert W Gomulkiewicz, "Conditions and Covenants in License Contracts: Tales from a Test of the Artistic License" (2009) 17 Texas IP L J 335 at 345.

[919] Dysart, *ibid* at 73-6.

passed between people. The licensor does not directly transact with each software user. This scheme creates a challenge in contract law because there is no interaction between the parties to a licensing agreement. Nonetheless, drafting techniques and the relaxed requirements of contract formation for standard form contracts make it possible for the OSS community to avoid challenges under contract law.

For example, the GPLv3 expressly states that the agreement shall be between the original licensor and each recipient of the open source software rather than between a distributor and their recipients.[920] Open source licensor grants all open source users the permission to run, modify and propagate the software. The GPL stipulates that the agreement shall exist between the original licensor and each recipient of the software, and the recipients can assent by their conduct in using the software to establish contract formation upon receiving the notice of terms with the software.[921] Reasonable notice of terms is necessary to create a binding contract with standardized open source licensing agreements, and each user must maintain the licensing notice on the source code to provide this notice to the next user who receives the software. Consideration is also exchanged between the contracting parties. Software users receive broad permission to use the software, and the software developer receives consideration from all users promising reciprocal obligations to benefit the developer (i.e. the obligation to share the source code upon redistribution, to maintain the notice of licence and attribution and to practice copyleft); these promises are not given to the benefit of the one who distributes the software.[922]

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[920] GPLv3, ss 10-11, *supra* note 882; Dysart, *ibid* at 161-163; Gomulkiewicz, *supra* note 918 at 335; Rosen, *supra* note 60 at 53; Wacha, *supra* note 914.

[921] E.g. In regards to a user's right to propagate or modify the licensed work, s. 9 of the GPLv3 states that "by modifying or propagating a covered work, you indicate your acceptance of this License to do so."

[922] I.e. users agree to keep all copyright notices intact, to insert certain required notices, to distribute in source code format and to practice copyleft. Wacha, *supra* note 914 at 473-5; *Jacobsen v. Katzer*, *supra* note 923 at 1379, 1382 [The OSS licence examined in the case was the Artistic Licence. Although OSS licences charge no royalty fee, the court held that consideration was exchanged in an OSS licence. "The lack of money changing hands in open source licensing should not be presumed to mean that there is no economic consideration, however. There are substantial

The Court of Appeal for the Federal Circuit (CAFC) in *Jacobsen v. Katzer* (2008)[923], a landmark decision, considered the enforceability of OSS licensing conditions not rooted in copyright law. Before *Jacobsen*, there were arguments that these open source conditions could not be enforced in copyright law because that would allow IP owners to increase the set of rights that attach to this property.[924] The CAFC stated that an open source licensor is capable of explicitly restricting the scope of the licence with a set of conditions, such as the obligation to maintain the attributions, notice of licence and version control. The court also recognized that although OSS licences charge no licensing fee, such conditions are vital to the licensor's economic benefit from open source licensing (i.e. reputational benefits that can translate into pecuniary benefits such as job opportunities).[925] The court held that the copyright permission to modify and distribute the software (i.e. licensor's rights rooted in copyright law) was granted subject to these restrictions limiting the scope of the licence; thus, the licensor can bring a copyright infringement claim when licensees fail to operate within the scope of the licence.[926] The access to copyright or patent law gives open source licensors a significant advantage over a mere contractual approach to enforce the open source licensing scheme, such as being able to seek an injunction against infringers rather than damages, which would not adequately compensate licensors who distribute software for free. Post-*Jacobsen* in the United States,

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benefits, including economic benefits, to the creation and distribution of copyrighted works under public licences that range beyond traditional licence royalties." These economic benefits include the possibility of programmers increasing their market share by freely releasing some components, improving their reputation, and gaining access to improvements from downstream open source users.]; Asay, "The General Public License Version 3.0", *supra* note 702 at 285 [even if there is no exchange of consideration, a licence-contract may be still enforced by a licensee in contract law under an equitable, reliance-based defence such as promissory estoppel]; Gomulkiewicz, *supra* note 918 at 346.

[923] *Jacobsen v. Katzer*, 535 F.3d 1373 (Fed. Cir. 2008).

[924] Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 407-9 [Before *Jacobsen*, some viewed contract law as a more appropriate vehicle when IP licences attach additional positive duties on users because contracts only bind the parties to a contract, not third parties who did not have an opportunity to negotiate the terms of use. It is argued that a set of rights that attach to a property needs to be standardized in order to lower everyone's cost of processing those rights, especially third parties who seek to avoid inadvertently infringing IP rights].

[925] *Jacobsen v. Katzer*, *supra* note 923.

[926] *Ibid*.

inconsistences are still observed in lower courts on the enforceability of open source conditions not rooted in copyright law, which can confuse people.[927]

The GPL, for example, deals with any uncertainties about the enforceability of the positive open source licensing duties by including a catch-all termination clause. The copyright licence automatically terminates when open source users do not comply with the conditions for distributing and modifying the licensed work (e.g. sharing in source code format, maintaining licence notice and attribution, and practicing copyleft).[928] Thus, when copyright users do not carry out these positive duties upon distribution and modification, their copyright licence terminates, giving rise to a copyright infringement claim.[929]

Sometimes contracts are used to regulate access to shared resources, which are not IP-protected (i.e. User Agreements). Since contracts bind two or more people who are parties to a contract,[930] a contract must be executed with each user. Otherwise, a person has no obligation to abide by the terms of use. The offeror cannot enforce the terms of use when there is no contract with a person using the shared resources, which could occur when a person independently reproduces them or receives them from a third party without contacting the offeror.[931] When these users exist, it is hard to regulate how a resource is used and disseminated in society since there are users who are not bound by its terms of use. A contract-based strategy without IP-protection may be appropriate when a group shares information or technology that is not easy to

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[927] Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 407-9 [This debate is still unsettled in U.S. case law post-*Jacobson*. For example, the District Court in *Versata Software Inc. v. Ameriprise Financial Services Inc. et al*., *supra* note 910, interpreted the copyleft condition as contractual, which possibly contradicts *Jacobsen*'s interpretation of licence restrictions as licensing conditions].
[928] GPLv3, s 8 "Termination", *supra* note 882.
[929] *Versata Software Inc. v. Ameriprise Financial Services Inc. et al*. *supra* note 910; Dysart, *supra* note 799 at 173-4.
[930] *London Drugs Ltd v Kuehne & Nagel*, [1992] 2 SCR 299, 97 DLR (4th) 261; *Fraser River Pile & Dredge Ltd v Can-Dive Services Ltd*, [1999] 2 SCR 108, 176 DLR (4th) 257; Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 405 citing Merrill & Smith, *supra* note 917 at 788-89.
[931] Boettiger & Burk, *supra* note 68 at 225-227; Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614.

reproduce, which minimizes third party copying and unauthorized sharing. To avoid this dilemma, open innovation communities try to control how their resources are disseminated, for example, by making them available only through a single access location and force all users to obtain a user agreement before accessing them. This approach also allows open innovation communities to track users and control dissemination in society, unlike viral licensing agreements, which are hard to track since they travel with the asset to an unlimited number of people.[932]

A click-wrap or browse-wrap agreement is typically used to create user agreements between individuals operating online.[933] These are typically used to bind a website user to the terms and conditions of a website. A click-wrap agreement, which is often incorporated into a website's registration process, requires a user to click a spot on a computer screen to manifest assent to the terms.[934] Users must also be shown the terms of the agreement or given easy access to them, such as through a weblink.[935] On the other hand, a browse-wrap agreement binds users when they use the protected work, such as using a website by browsing past its initial page, to manifest assent.[936] The browse-wrap agreements are typically made accessible to users through a link on the website. Click-wrap agreements are typically enforced by courts, whereas the enforceability of browse-wrap agreements is less certain.[937]

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[932] *Ibid*.
[933] *Rudder v Microsoft Corp* (1999), 2 CPR (4th) 474*; Century 21 Canada Limited Partnership v Rogers Communications Inc*, 2011 BCSC 1196; *Trader Corporation v. CarGurus, Inc*., 2017 ONSC 184; *Douez v Facebook Inc*, 2017 SCC 33, [2017] 1 SCR 751; Rosen, *supra* note 60 at 60.
[934] *Ibid*.
[935] *Ibid*.
[936]*Century 21 v Rogers Communications, ibid*.
[937] Boettiger & Burk, *supra* note 68 at 228 [Unilateral viral licences are "troubling but the general trend appears to favour them valid and enforceable except where the circumstances of formation are especially outrageous or where the terms of the contract are noticeably overreaching"]; *Rudder v Microsoft*, *supra* note 933; *Ibid*.

5.2.4 Open Source Licensing outside of Software Development

Since open source licensing was developed for OSS development, other communities, such as the DIY maker community and open biotechnologists, have adopted open source licensing and other open source-inspired IP licences and contracts to create a protected commons. A copyleft or viral licensing scheme is popular in loose-knit, bottom-up, commons-based collaboration. This knowledge management strategy allows collaborating partners to freely and widely disseminate information, knowledge and innovation that are protected from subsequent appropriation. Moreover, they can create a protected commons without incurring large costs from ongoing administration and user negotiations and usually without centralized management.

The GPL is a popular open source licence outside of software development as well to create open access to copyright-protected works, such as literary and artistic works, datasets, and audio and visual files. The Open Source Hardware Association (OSHWA), a non-profit organization that supports open source hardware development, recommends the GPL as one of the licences that hardware designers can use to openly disseminate the copyright-protected components of a hardware tool, such as open source software, hardware design and documentation.[938] DIY projects published in blogs and websites, such as *instructables.com*, commonly attach the Creative Commons (CC) licences or the GPL.[939] Moreover, OSHWA publishes the voluntary open source licensing standards for the DIY hardware maker community that match the OSD.[940] The "Open Source Hardware Statement of Principles" (OSHWver1.0) lists the standard licensing conditions for disseminating open source designs of "tangible artifacts"

[938]David Mellis, "Open-Source Hardware FAQ", online: Open Source Hardware Association <https://www.oshwa.org/faq/>.
[939] Also, the OpenDrop project is published under the CC-attribution-sharealike 2.5 licence. See online: OpenDrop <http://www.gaudi.ch/OpenDrop/?p=17>.
[940] "OSHW", online: Definition of Free Culture Works <https://freedomdefined.org/OSHW>; "Open Source Hardware (OSHW) Definition 1.0", online: OSHWA <https://www.oshwa.org/definition/>.

such as machines, devices, or other physical things.[941] OSHWA also certifies open source hardware licences based on these criteria.

Open scientists have also tried to create a protected commons in biotechnology to improve access to upstream research resources using licences and contracts that are based on OSS licences. For example, there was a proposal for a GPL-equivalent licence for plant germplasm (GPLPG) in 1999, which suggested standardized open access to plant germplasm.[942] The HapMap project created a copyleft database access agreement to allow subsequent access to the project's haplotype mapping information (see below in Section 5.4).[943] Cambia's BIOS patent licences were designed to encourage biotechnology researchers' access to patented plant enabling technologies and genetic resources indexing technologies (see Section 5.3.3.2 below).[944] The BioBricks Foundation's biobrick database agreement creates unrestricted access to biobricks, which researchers voluntarily deposited in its database for synthetic biology (see Chapter Six below). Open Source Drug Discovery (OSDD) License is used for patented research resources available to all members of the OSDD consortium (see Chapter Six below).

These attempts to implement a protected commons in biotechnology or life sciences have had mixed results. Unlike software development, biotechnology researchers and developers use a variety of inputs and outputs in cumulative development. Patentable research resources in biotechnology can come in many different forms. Copyleft licences and agreements may not adequately protect certain resources while ensuring users' freedoms in an open and cumulative R&D environment. As discussed below, DIY biotechnologists can experience further

[941]Mellis, *supra* note 938.
[942]Hope, *Biobazaar*, *supra* note 21 at 304-308.
[943] *Ibid*.
[944] *Ibid* at 316-7.

complications and difficulties when they try to create a protected commons of patentable research resources with an automated copyleft licensing scheme.

5.3 Open Source Licensing of Patentable Inventions in DIY Bio

DIYers in the social production of biotechnology are often self-funded, and many depend on access to cheap and easy to access research tools and other materials to experiment with biotechnology. Navigating the patent landscape in biotechnology to avoid patent conflicts in competitive, litigious fields with fragmented and overlapping patents is challenging for typical DIYers, who cooperate and loosely collaborate in the DIY bio network.

Open source licensing or viral licensing allows a group to establish a protected commons to stimulate open and cumulative development and downstream developments. As discussed in the previous chapter, participants in DIY bio can face inadvertent infringement, patent access barriers to upstream research tools and third party patents that subsequently develop around open innovation. Creating access to a large pool of upstream research resources in DIY bio can stimulate these activities while reducing patent access barriers to upstream research tools in biotechnology and inadvertent infringement. Existing patentees in public and private sectors of biotechnology may be encouraged to contribute to the open source patent commons. Also, creating a protected commons for DIY biotechnology inventions may allow DIYers and DIY-based businesses to avoid third-party patent interference. Nevertheless, accessing patent protection may be harder in loose-knit, open and cumulative collaboration.

5.3.1 Accessing Existing Patents in Biotechnology

Public and private sector researchers both seek patent-protection for research tools and upstream research resources in biotechnology, which contribute to problems for downstream development. These patent activities expose participants in the social production of biotechnology to patent access barriers to upstream research tools and inadvertent patent infringement. It may be possible to reduce such patent issues and increase shared resources available for DIY bio by encouraging existing patentees to open source license their patents.

Hope notes that when existing patentees decide to practice open source licensing after they have already made a substantial investment in order to obtain and maintain patents, these costs are sunken costs and should not be considered as costs of open source licensing since the decision to practice open source licensing is an afterthought.[945] Moreover, since open source licensing is an automated viral licensing scheme, existing patentees who control biotechnology or life science patents will incur little to no ongoing knowledge management costs by open source licensing their patents.

Burk notes that the greatest obstacle to institutional scientists' use of open source licences to disseminate patentable research resources is "the social disparity between open source and scientific research settings."[946] There are more variables to consider in the context of scientific research that involves professional researchers, which can influence open source sharing, such as the expectations of private sector funders, different standards, norms or practices in different fields of research on research sharing, and competition for funding opportunities or research partnerships.[947] Large academic research projects that can lead to significant discoveries in biotechnology may have multiple funders who have rights to the final research output. Upstream

[945] Hope, *Biobazaar*, *supra* note 21 at 161.
[946] Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614-5.
[947] *Ibid*.

university research discoveries with private funding have been exclusively licensed to the funder or other commercial entities, such as the mice patents discussed above in Chapter Two. While research sharing is encouraged, academic researchers can struggle to practice it due to fierce competition for funding.[948] It was also discussed in Chapter Two that scientists operate under a particular institutional reward system that includes recognized peer-reviewed publications and awards, which can discourage and delay researchers from sharing early research discoveries prematurely before they had an opportunity to publish or share them via scholarly journals or other desired venues or filing patent applications. Highly valuable patented research resources with a known commercial application are likely unavailable for open source licensing. Van Zimmeren notes that most genetic inventions require long-term R&D and high investment, which leaves most inventors likely choosing to recover their R&D costs over considering a non-proprietary open access regime that makes their inventions freely accessible to subsequent researchers.[949] Also, as discussed below, some patentees may not practice open source licensing because the cost of publicly disclosing biotechnology inventions may be too burdensome in some cases, such as complex technology, which may require technology owners to give training and ongoing troubleshooting and support services to users.

There are some instances where patentees in public and private sectors voluntarily created access to patented and unpatented biotechnology inventions. As discussed in Chapter Two, public and private sector researchers have combined efforts to publicly disseminate patentable upstream research resources, such as DNA fragments and biobricks, to avoid the development of severely fragmented patent rights on important upstream research tools.[950]

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[948] Picard, *supra* note 1133.
[949] Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 76.
[950] E.g. the Human Genome Project, the Single Nucleotide Polymorphism (SNP) Consortium, the Structural Genomics Consortium (SGC) and the Biobricks Foundation. See Chapter Six below; Van Zimmeren,

Genomic researchers publicly released unpatented upstream research resources and relied on peer pressure to prevent the formation of fragmented rights on upstream technologies in their research area. Public and private sector researchers are sometimes willing to cooperate and publicly share significant upstream technology when doing so benefits all researchers in a field of research. Moreover, in Open Source Drug Discovery (open and cumulative research collaboration funded by the Indian government, see Chapter Six), consortium members share patents to encourage the discovery of affordable drugs in developing nations.[951] This project uses open source-inspired patent licences with practice restrictions (i.e. royalty-free patent use to carry out open source drug discovery) to create a pool of shared research resources. Research groups may adjust the original open source licensing scheme by adding or removing licensing conditions, which may be necessary in a research environment to protect patentees' economic interests or to impose fewer restrictions on users.[952] Academic and government researchers managing citizen science projects can also make patentable research resources available to public participants.

Commentators note that there are situations where patentees should be encouraged to practice open source licensing to create access to existing patents for subsequent use. Open source licensing may be appropriate when life science businesses own patents that are close to expiring, do not have commercial value, or do not generate licensing revenue.[953] Commentators

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"Clearinghouse Mechanisms", *supra* note 189 at 75-6; Rai, "Regulating Scientific Research", *supra* note 19 at 112—115; Ester van Zimmeren et al, "A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?" (May 2006) 84:5 Bulletin of the World Health Organization 352 at 354.

[951] Hassan Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies" in Matthew L Smith & Katherine M A Reilly, eds, *Open Development: Networked Innovations in International Development* (Cambridge, MA: The MIT Press, 2013).

[952] E.g. Eco-Patent Commons and the Pool for Open Innovation against Neglected Tropical Diseases – see OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 27-8; Kapczynski et al, "Addressing Global Health Inequities", *supra* note 683; Maurer, Rai &Sali, "Finding Cures for Tropical Diseases: Is Open Source an Answer?", *supra* note 843; Hope, *Biobazaar supra* note 21 at 319-320.

[953] Hope, *ibid* at 161.

note that universities and academics continue to engage in patenting upstream research discoveries even when most academic patents do not generate revenues.[954] Most university TTOs across the globe have not been able to generate profits with patents, and some are not even able to afford the costs of maintaining the patents.[955] It has also been suggested that academic life science patents that do not generate profit for researchers should be open source licensed or at least licensed for use in developing nations to encourage follow-on development.[956] Patentees who follow these suggestions can stimulate social production and commercial activities in biotechnology by giving participants more upstream resources to explore. DIYers can experiment with patented inventions as soon as they are open source licensed rather than wait until participants become aware of expired or abandoned patents. It would reduce wasted time.

Moreover, some businesses, academic researchers and non-profit organizations patent scientific discoveries and research tools purely for defensive purposes, and open source licensing should be used in such cases to create access to these patents and stimulate development.[957] For example, Hope suggests that multinational pharmaceutical corporations should be encouraged to open source license patented research tools in drug development.[958] Hope argues that these corporations commonly patent these research tools for defensive reasons, and open source licensing the research tools will not affect their business profits. A copyleft licensing would be

[954] Baldini, *supra* note 956.
[955] Hope, *Biobazaar supra* note 21 at 273 citing Drahos & Braithwaite, *Information Feudalism, supra* note 333 at 163.
[956] Kapczynski et al, "Addressing Global Health Inequities", *supra* note 683; Nichola Baldini, "Negative Effects of University Patenting: Myths and Grounded Evidence" (2008) 75 Scientometrics 289 [Only a few blockbuster patents have been profitable, like Carnegie Mellon University's patent on the Lycos Internet search engine and Stanford University's recombinant DNA gene-splicing patent]; Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 605 citing Arti Rai "Addressing the patent gold rush: The role of deference to PTO patent denials" (2000) 2 Washington U J Law & Poli 199; Bubela, FitzGerald & Gold, "Recalibrating Intellectual Property Rights", *supra* note 426.
[957] Asay, "Enabling Patentless Innovation", *supra* note 81 at 434-5, 476.
[958] Hope, *Biobazaar supra* note 21 at 268-272.

appropriate in this situation because these pharmaceutical patentees are mostly concerned about third parties claiming ownership of these research tools to prevent their access to them.

Many small biotechnology companies that were created around a single proprietary platform technology do not have the flexibility of large pharmaceutical corporations to pursue open source licensing with their patents.[959] For these biotechnology businesses, their only assets are patents that protect the platform technologies, and they try to create profit by licensing patents to larger firms that can use the platform technology in drug development. Hope notes that this business model in biomedicine led to fierce patent litigation in this industry.[960] Nonetheless, Hope suggests that most biotechnology businesses are not profitable, and they would not lose any money by inserting their technology into open source development and stimulate development. It may allow them to commercialize complementary technologies. Furthermore, as discussed below in Section 5.3.3.4, some biotechnology patentees may consider dual licensing where their patent is available with a proprietary licence and an open source licence. Dual licensing may be an attractive option for some commercial patentees because licensors can profit from commercial licensees who pay for patent use, and licensors also benefit from open source users' follow-on contributions in the commons, which may be used to improve the licensor's business.

On the other hand, convincing private sector patentees in biotechnology to join open source licensing may be challenging even when patents do not create business profits. The DIY bio movement may not be able to easily convince private-sector patentees to switch their business practice by open source licensing their patents, and it may be difficult to establish a patent pool when there are private sector patentees in multiple industries. For instance, the

[959] *Ibid.*
[960] *Ibid*

Science Commons once partnered with several businesses, including Nike, to launch GreenXchange, a project that was aimed at facilitating businesses to make their defensive patents available for free to researchers or for a fee to non-competing companies in order to encourage innovation from these patents.[961] The project had planned to create a patent commons where business patentees would commit their patents for other companies to exploit, and patent users would be required to grant-back the use of any improvements to the patentee.[962] The project was never realized.[963] The project organizers acknowledged that it was difficult to draft a standard patent licence that would meet all of the private sector patent licensors' needs due to the wide disparities between the commercial operations in different industries.[964] Furthermore, businesses that usually engage in proprietary IP management will not easily give up their IP rights.[965] For instance, private sector patentees may not commit to open source sharing even for dual licensing unless there is a large community of open innovation contributors who are willing to use their patents to yield open results that can benefit patentees' business.

Patent sharing can stimulate biotechnology R&D from traditional scientists as well as non-traditional scientists in the DIY bio movement. DIYers can examine and build on publicly accessible research resources released by public and private sector researchers. Some patentees should be encouraged to open source license patents, such as biotechnology patentees who have nearly expired patents, patents that do not generate profits, or purely defensive patents. On the other hand, it is likely difficult to convince business patentees to switch their business model and start open source licensing patents.

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[961] Don Tapscott, "Nike and partners launch the GreenXchange" (27 January 2017), online: The Globe and Mail <https://www.theglobeandmail.com/report-on-business/nike-and-partners-launch-the-greenxchange/article1364510/>; "Model Patent License" (19 October 2010), online: Creative Commons <https://wiki.creativecommons.org/wiki/Model_Patent_License>.
[962] *Ibid*.
[963] *Ibid*.
[964] *Ibid*.
[965] Lee, *supra* note 752 at 284-5.

5.3.2 Defensive Patenting DIY Bio Inventions

As social production activities in biotechnology become more popular and sophisticated, free revealing new inventions may not create perpetual open access to these inventions, especially if a field of research is characterized by overlapping patent rights and high competition and patent litigation. As noted above in Chapter Four, the actual and perceived patent risks in biotechnology can discourage DIY bio and subsequent commercial development. Some argue that open science and open innovation communities should increase defensive patents to protect against third party patent threats in light of the growing patent thickets in information technology and biotechnology.[966] Patent applications and patents are also more effective as prior art than defensive publishing because patent examiners search for prior art in patent databases.[967] Patents can bar subsequent patent applications on the same open invention and are effective bargaining tools when there are overlapping patents.

For instance, when there are overlapping patents in cumulative industries, each patentee can infringe on other overlapping patent rights by practicing in the area. Patentees with potentially overlapping patents have small incentives to bring a lawsuit against the other patentee as doing so may risk their patent being invalidated. Patentees who own overlapping and fragmented patents can benefit from cooperating and cross-licensing patents to gain access to and use the overall development in a field of endeavour.[968] Thus, open innovation communities can use defensive patents as a protective measure to discourage subsequent third party patent development and a bargaining tool to leverage access to overlapping and fragmented third party

[966] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 2, 5.
[967] Schultz& Urban, *ibid* at 48.
[968]Hope, *Biobazaar*, *supra* note 21 at 182.

patents in a field of R&D.[969] Furthermore, as noted above, the open source licensing scheme depends on the underlying IP right to effectively enforce the licensing scheme against the world. By defensive patenting new inventions from social production activities in biotechnology, DIYers and open scientists can enforce the licensing scheme more effectively against unauthorized users.

When patent trolls (i.e. non-practicing entities) threaten open innovation, defensive patents are not useful as a bargaining tool because patent trolls do not need to bargain for access to other patents in the area.[970] Nonetheless, open innovation communities with defensive patents can try to defend against a troll in litigation by attacking the validity of its patent. However, in this situation, open innovation communities incur litigation costs.

However, defensive patenting is expensive because of the high costs of obtaining and maintaining patents. Moreover, participants in open and collaborative biotechnology projects may experience difficulty establishing their inventions' patent eligibility because, as discussed in Chapter Three, patent law is designed to protect new and non-obvious inventions from a closed R&D environment. There may also be confusion and resistance to adopting patent-based knowledge management in open development.

5.3.2.1 Patent Costs

Different types of participants in the social production of science have different capacities to participate in the patent system due to high patent costs. The costs of obtaining, maintaining and enforcing a patent can become a significant financial burden for social production participants,

[969] Asay, "Enabling Patentless Innovation", *supra* note 81 at 448, 461 [Business patentees can strike cross-licensing agreements to gain access to patents owned by other businesses]; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1438.
[970] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 7.

leaving some unable to access this protection.[971] In a copyright-protected open source commons where copyright protection arises automatically,[972] the cost to practice open source licensing can arise from creating and updating standardized open source licences.[973] However, individual contributors do not need to incur these costs as they can use and modify many of the existing free open source copyright licence templates (e.g. GNU GPL, MIT License and Apache License, drafted and updated by various organizations that support OSS development), which are also available as open source licensed works. As noted above, the general acceptance of the OSS licensing scheme in software development also discourages disputes and encourages dispute settlement. Patent costs significantly increase the transaction costs of open source licensing patentable inventions. Recall from Chapter Two that most of the DIY bio contributions come from young scientists, hobbyists or bioartists, and programmers who want to experiment with biology. These DIYers (who most likely do not have access to large funds),volunteer-sustained community labs and entrepreneurs with limited resources may not be able to afford to patent their inventions in addition to funding their biotechnology experiments.[974]

Unlike copyrights, inventors can only exercise patents if they have filed a patent application and obtained a patent grant from a domestic patent office in relevant jurisdictions.

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[971]Von Hippel, *Democratizing Innovation*, *supra* note 4 at 77 [Patents are impractical for user innovators and small to medium sized firms of limited means because it is costly]; Schultz & Urban, *ibid* at 3; Tony Wilson, "When do patent something and how to do it" (8 June 2010), online: The Globe and Mail <https://www.theglobeandmail.com/report-on-business/small-business/sb-growth/when-to-patent-something-and-how-to-do-it/article626823/>; Canadian Intellectual Property Office, "Standard Fees for Patents", online: CIPO, Government of Canada <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00142.html>; Hope, *Biobazaar*, *supra* note 21 at 50 citing J T Ellis, "Distortion of Patent Economics by Litigation Costs" (In *Proceedings of the 1999 Summit Conference on Intellectual Property, University of Washington, Seattle,* CASRIP Symposium, 2000).

[972]*Copyright Act*, *supra* note 609, s 3(1); TRIPS, *supra* note 306, art 9(2); *CCH Canadian Ltd v Law Society of Upper Canada*, 2004 SCC 13, [2004] 1 SCR 339*; Delrina Corp v Triolet Systems Inc* (2002), 58 OR (3d) 339 at 36; Vaver, *Intellectual Property Law*, *supra* note 68 at 217-218.

[973] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 32.

[974] Delfanti, *supra* note 1 at 115; Hope, *Biobazaar*, *supra* note 21 at 159; von Hippel, *Democratizing Innovation*, *supra* note 4 at 112; Asay, "Enabling Patentless Innovation", *supra* note 81 at 434, 448 citing James Boyle, *"The Second Enclosure Movement and the Construction of the Public Domain"* (2003) 66 Law & Contemp Probs 33 at 32–33; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 8.

OSS licences are designed to regulate access to copyright-protected software; copyright protection automatically arises when an original expression is fixed in a tangible medium.[975] A copyright-protected work in Canada is automatically protected internationally without registration or formalities.[976] On the other hand, patent rights can exist if a patent application of an invention is filed with a patent office, goes through a rigorous examination process, and the patent is granted afterwards. An open source licence is enforceable in patent law only if a patent is granted on an invention.

Patent applicants must be able to finance the process of filing a patent application, which can cost thousands of dollars, and to pay the patent maintenance fees during the patent term. For example, depending on the complexity of an invention, it can cost between $8,000 to $15,000 or more to have a patent application prepared and filed by a registered patent agent in Canada.[977] In Canada, fees paid during the patent application process to the patent office include a filing fee of $400, a fee of $800 to request for an examination, and a final fee of $300 before the patent grant.[978] The maintenance fees start at $100 and increase up to $450 over the course of the patent term.[979] If a patent applicant is a small entity (employs 50 employees or less) or a university, the applicant may qualify to pay half of the rate for application and maintenance.[980] Patent law reduces fees for these applicants to encourage wider use of the patent system.[981]

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[975] *Supra* note 972.
[976] *Berne Convention for the Protection of Literary and Artistic Works*, 9 September 1886, 828 UNTS 221, Art 5; *WIPO Copyright Treaty*, Dec. 20, 1996, S Treaty Doc. No. 105-17 (1997); 2186 UNTS 121; 36 ILM 65 (1997), Art 3; TRIPS, *supra* note 306, art 9.1.
[977] Matt Kwong, "How to get a patent in Canada and protect your business idea" (22 May 2018), online: CBC <https://www.cbc.ca/dragonsden/blog/patents-in-canada-when-do-you-own-your-idea>.
[978] Canadian Intellectual Property Office, "Standard Fees for Patents", *supra* note 971 [A patent applicant can pay $500 to request an advanced examination].
[979] *Ibid*.
[980] *Ibid*; *Patent Rules*, SOR/96-423, s 3.01(3).
[981] Vaver, *Intellectual Property Law*, *supra* note 68 at 276.

Additionally, the cost of hiring a registered patent agent increases if the application is prosecuted in order to deal with refusals and objections from the patent office. The cost of patenting and maintaining an invention will increase when applications are filed in multiple jurisdictions. If a patent applicant wants to apply for a foreign patent under the *Patent Cooperation Treaty*,[982] which provides a standard international filing procedure for 142 member nations, it can cost approximately another $5,000.[983] Furthermore, enforcing a patent against commercial entities or patent trolls who have the resources to engage in patent litigation is also expensive; pursuing patent litigation is an often lengthy process that can take years and cost hundreds of thousands of dollars.

Available resources will vary depending on the size and popularity of a project in the social production of biotechnology. University researchers, research institutions and large open science projects that can gather large donations and external funding likely have the option of defensive patenting. For example, Foldit, a citizen science project organized by the University of Washington, has multiple public and private funders according to its website.[984] Foldit's Terms of Service and Consent state that the scientific discoveries from the project will be made publicly available, with the project hosts managing the IP ownership, including the responsibility of filing patent applications for the discoveries.[985] Without the financial support of wealthy research institutions, governments, universities or other sponsors, defensive patenting coupled with open

[982] *Patent Cooperation Treaty*, 19 June 1970, TIAS 8733, 28 UST 7645, 9 ILM 978.
[983] Canadian Intellectual Property Office, "PCT Schedule of Fees", online: CIPO, Government of Canada <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04515.html>.
[984] These include the National Science Foundation (NSF), Defense Advanced Research Project Agency (DARPA), National Institutes of Health (NIH), Howard Hughes Medical Institute, Microsoft Corporation, Adobe and RosettaCommons. See online: Foldit Credits https://fold.it/portal/info/credits. The project received more than $200K funding from the National Science Foundation, Award Abstract #1629879, <https://www.nsf.gov/awardsearch/showAward?AWD_ID=1629879>.
[985] "Foldit Terms of Service and Consent", online: Foldit <https://fold.it/portal/legal>.

source licensing may not be accessible generally as a knowledge management option in social production.[986]

5.3.2.2 Statutory Requirements in Patent Law

The structure of patent law can also reduce open innovation communities' access to patent protection. Asay notes that the statutory requirements of novelty and non-obviousness in patent law may be more difficult to establish in open innovation when public participants engage in cumulative open development with multiple individuals working on the same general inventive concept while sharing their progress publicly.[987] For example, patent applicants must demonstrate that their invention has not been publicly disclosed anywhere in the world before filing a patent application to satisfy the novelty requirement in Canada.[988] As discussed in Chapter Four, an invention lacks novelty if it was publicly disclosed in a self-contained prior art[989] that provides sufficient information about the invention to allow a person skilled in the art to practice the invention.[990] That can include disclosures made in patent applications, by publishing on the Internet or in conference presentations.[991]

For example, it is possible that publishing hackathon submissions online after the event to show prototypes or preliminary solutions from hackathon participants may threaten the

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[986] Von Hippel, *Democratizing Innovation*, *supra* note 4 at 77; Boettiger & Burk, *supra* note 68 at 231; Asay, "Enabling Patentless Innovation", *supra* note 81 at 434; Hope, *Biobazaar*, *supra* note 21 at 50.
[987] Asay, *ibid* at 436.
[988] *Patent Act*, *supra* note 303, ss 2 "Invention", 28(1)(b); *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265.
[989] Canadian Intellectual Property Office, "What is prior art?", online: CIPO, Government of Canada <https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04009.html#what-is-prior-art>; Vaver, *Intellectual Property Law*, *supra* note 68 at 321-3.
[990] Vaver, *ibid* citing *Research In Motion UK Ltd v Motorola Inc*, [2010] EWHC 118 at 181 (Pat Ct), *Canwell Enviro-Industries Ltd v. Baker Petrolite Corp*, 2002 FCA 158 at 42, and *Eli Lilly Canada Inc v Apotex Inc*, 2010 FC 1065 at 63.
[991] *Ibid*; Dreyfuss, "Does IP Need IP", *supra* note 31 at 1471 ["If information that is tightly held and available only to those who join the project is not considered 'public,' then it would be possible for participants in a non-IP project to discover that another inventor could patent their work. To eliminate that possibility, it should be made clear that information that is in a commons is nonetheless 'public' enough to be considered prior art."].

participants' ability to patent their invention at a later time. Furthermore, some DIY bio projects can publicly disclose an invention by using wikis, blogs and user forums, which allow public participants to share ideas, discussions and solutions publicly. Some public disclosures are excused in jurisdictions that provide a grace period.[992] Nations may not provide a grace period, and if they do, the rules can vary.[993] Vaver notes that publicly disclosing an invention prior to filing a patent application by relying on a grace period in patent law is risky because there is no harmonization of grace periods in patent law at the international level.[994] When DIYers and groups publish their R&D experiments and results over the Internet, they risk removing the novelty of a patentable discovery and being unable to obtain patent protection.

Novelty can be difficult for open innovation communities to overcome in patent law because participants are encouraged to openly share valuable resources with other contributors, and openly exchanging valuable information can lead to the group being able to arrive at a solution.[995] Burk notes that the novelty standard clashes with the norms of scientific research that encourage open exchanges of knowledge and information.[996] Open collaboration increases the efficiency of the knowledge discovery process by allowing large-scale public participation and open exchanges of knowledge and information, but this cumulative development process can sacrifice the cumulative invention's patentability, possibly by publicly disclosing too much about

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[992] E.g. s. 28.2(1)(a) of Canadian *Patent Act*, *supra* note 303, states that a patentable invention must not have been disclosed "more than one year before the filing date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant, in such manner that the subject-matter became available to the public in Canada or elsewhere". Australia, Brazil, the U.S. and Mexico also offer a patent grace period.

[993] Vaver, *Intellectual Property Law*, *supra* note 68 at 320 citing EPC, Arts 54(2) & 55, *Chiropedic Bedding Pty Ltd. v. Radburg Pty Ltd*, [2008] FCA 142 at 26 &51-55 ["The United States and Australia have [grace periods] but Europe allows only six months' grace, and then only for inventions shown at officially recognized international exhibitions or for disclosure that are an 'evident abuse' of the inventor (e.g. breaking a confidentiality agreement)"].

[994] *Ibid*.

[995] Dan L Burk, "Intellectual Property Issues in Electronic Collaborations" (2000) Minnesota Legal Studies Research Paper No. 06-66, online: SSRN < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=938448> at 12; Asay, "Enabling Patentless Innovation", *supra* note 81 at 436 [Patenting subsequent improvements of an open invention may also be difficult for lack of novelty because of the possibility of more than one member of the open project pursuing the downstream invention and having invented them before the patent applicant].

[996] Burk, *ibid*.

the invention before filing a patent application. Public exchanges of knowledge and information in this open and cumulative development also allow more people to learn about the project and contribute to the process. Limiting public exchanges of knowledge and information in this R&D setting can reduce both the value and the effectiveness of open collaboration.

It may still be possible for open innovation communities to patent a collaborative invention despite organizing their activities publicly. As discussed in the previous chapter, freely revealing a patentable invention with the world over the Internet may not always guarantee that it will stop subsequent patent applications on the invention. If the patent examiner does not consider an activity to provide sufficient information to establish prior art, it will not bar subsequent patent applications.[997] The patent examiner may consider that the activities in open development did not disclose an invention adequately per the patent standards (e.g. all inventive steps are not self-contained in a single document).

Another statutory requirement in patent law is that an invention must be non-obvious or display inventive ingenuity to be patentable.[998] The non-obviousness of an invention is determined in light of the combined publicly available prior arts before the claim date, and the invention must not be obvious to a person skilled in the art.[999] Minor advances may be deemed trite, obvious and unworthy of a patent grant.[1000] One of the advantages of organizing open collaboration is that difficult problems can be solved quickly and easily between many public participants working together and sharing knowledge and resources. This process allows for a

[997] Asay, "Enabling Patentless Innovation", *supra* note 81 at 483; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 27-9 ["open innovation communities often do a poor job of making their ideas available in a manner that patent examiners are likely to come across them or, even if they do, understand what they are looking at"].
[998] *Apotex v Sanofi-Synthelabo Canada Inc*, 2008 SCC 61, [2008] 3 SCR 265 at para 51.
[999] Vaver, *Intellectual Property Law*, *supra* note 68 at 331-2; *Apotex*, *ibid* at 67; *KSR v Teleflex, supra* note 397.
[1000] Vaver *ibid* at 335 ["Verifying results that the prior art already predicts, motivates, and shows how to achieve is just routine uninventive work, even if the tests produce other benefits."] citing *Hallen Co v. Brahantia (UK) Ltd (No 1),* [1991] RPC 195 (CA); *Ratiopharm Inc v Pfizer Ltd*, 2009 FC 711 at 167 to 171, aff'd 2010 FCA 204.

significant load of information to be gathered quickly from many different sources. Asay notes that when innovation results from many incremental steps, individual contributions at each step may seem trite and obvious compared to the overall achievement of the group that accumulated over time.[1001] Therefore, individual incremental contributions in open collaboration may not be patentable as they are seen as obvious or trite.[1002]

However, the inventive ingenuity or non-obviousness of the overall collaborative output may be easier to establish unless there are several similar projects within the broader open innovation community, and there is a significant amount of publicly accessible information on the topic.[1003] For instance, projects like Open Insulin, where multiple community labs across several jurisdictions work on the same research problem and publicize progress, can rapidly accumulate publicly accessible information in the project, which may increase the non-obviousness threshold in the research area. On the other hand, due to inadequate resources for examining patent applications at patent offices, patent examiners may not adequately consider prior art in open innovation, allowing a not new and obvious patent application to receive a patent grant.[1004]

Lastly, patents may be difficult to obtain and manage in open innovation because patents are awarded to an individual inventor or a small number of joint inventors, not to a large group where each takes on small responsibilities in cumulative development. In large community lab projects, it may be difficult to determine who is responsible for the inventive concept or to identify joint inventors who have contributed significantly to the overall inventive concept of an

[1001] Asay, "Enabling Patentless Innovation", *supra* note 81 at 436.
[1002] *Ibid*.
[1003] *Ibid*.
[1004] *Ibid* at 465; Lemley, "Rational Ignorance at the Patent Office", *supra* note 491.

invention.[1005] This may occur in large collaborative research projects such as citizen science, where each person makes a trivial, minuscule and not patent-eligible contribution. Even after joint inventors are identified, decentralized loose-knit groups can struggle to obtain a consensus within the larger group about how to manage the group's collaborative invention or coordinate resources for patent management.[1006]

5.3.2.3 Non-Proprietary Preference in Open Innovation

There are several reasons why open innovation participants may not consider defensive patenting. It has been observed that academic researchers sometimes do not share their research findings in the research community because they do not believe that the output has any value, and this assumption can also discourage them from seeking patent protection.[1007] Participants in social production can also misjudge, mischaracterize or undervalue potentially patentable contributions, especially since many DIYers experiment with biotechnology for amusement and try to solve day-to-day issues they have encountered in life. Hence, they may continue to openly disseminate their contributions, which is also practical and may generate immediate non-pecuniary benefits. Furthermore, they can confuse copyright and patent protection. Many DIYers appear to be comfortable attaching open source licence notices on their online projects with popular copyright licences, but these licences do not protect the functional aspects of an invention, such as hardware research tools. DIYers, entrepreneurs and community labs with small R&D funds may consider patent-based knowledge management as also a luxury and dismiss its importance early on.

[1005] Asay, *ibid* at 462-3.
[1006] *Ibid* at 435-6.
[1007] Tenopir et al, *supra* note 48.

Open innovation communities have traditionally operated outside of the patent system, without seeking patents to protect their inventions and mostly ignoring existing patents.[1008] Open innovation communities support open science and hacker ethos, which encourage the free flow of information and knowledge in society.[1009] Some open scientists and open innovators may resist a formal knowledge management strategy involving patent rights because they strongly believe that science and technology should be released into the public domain to remove transaction costs.[1010] Increased use of IP licences and contracts to regulate scientific discoveries and resources can also emphasize the view that science is property.[1011] As noted in Chapter Two, open innovation communities traditionally viewed patent rights as imposing taxes and causing unnecessary hardships for open innovation. As discussed in Chapter Three, defensive patents in academic research and the private sector can also change ownership and become monetizers under the control of patent trolls. When defensive patents become monetizers, open innovation communities and downstream commercial developers are disadvantaged. Defensive patenting new inventions in DIY bio to avoid third party patent interruption can further complicate the already complex and rapidly growing patent landscape in biotechnology.[1012] Therefore, open scientists and open developers may choose to opt-out of the patent system because they associate

[1008] Asay, "Enabling Patentless Innovation", *supra* note 81 at 442.
[1009] *Ibid* at 484; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560.
[1010] Hope, *Biobazaar*, *supra* note 21 at 160; OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31-2; Delfanti, *supra* note 1 at chap 4 [e.g. The Human Genome Project, Single Nucleotide Polymorphism (SNP) Consortium and the Structural Genomics Consortium (SGC) released their research into the public domain rather than patenting them because researchers agreed that the sequence of the human genome should not belong to anyone].
[1011] Dusollier, *supra* note 705; Elkin-Koren, "What Contracts Cannot Do", *supra* note 849 at 398-9.
[1012] Hope, *Biobazaar*, *supra* note 21 at 159.

patents with patent trolling, hardship in open innovation communities, and reduced competition and innovation.[1013]

5.3.3 Drafting Open Source Licensing Conditions for Patentable Inventions

There are differences in the protection offered by copyright law and patent law and the nature of the underlying inventions in biotechnology.[1014] Open source patent licences can be implemented to replicate most functions of copyright-based open source licences. Certain open source licensing conditions under patent law may not operate as well as they do under copyright law. Moreover, viral patent licensing in biotechnology may not be appropriate for some inventions.

Patent rights in open source patent licences expire much earlier than copyrights in OSS licences, but open source patent licences in biotechnology can still stimulate non-commercial and commercial activities before patents enter the public domain. As a patentable knowledge management strategy, open source licensing may be more expensive under patent law if there are additional costs to create open source access to complex technologies. The protection against third party patents may not be as robust as open source licensing in copyright law. Third party patents can exist outside of open innovation in areas suffering from patent thickets; licensees can infringe overlapping patents when they use open source patents. And the copyleft obligation will need to be implemented carefully under patent law as follow-on developments (modifications and improvements) can create downstream patent thickets, which interfere with open source users' activities. Also, viral open source licensing may be inappropriate in biotechnology because it interrupts subsequent development.

[1013] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 3; Asay, "Enabling Patentless Innovation", *supra* note 81 [Historically, open innovation communities struggled to determine what role patents should play in their communities and often declaring "none at all"].

[1014] Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614-5; Opderbeck, "The Penguin's Genome", *supra* note 48 at 195-200.

5.3.3.1 The Length of Licensing Term

One significant difference between patent protection and copyright protection is that patents expire much earlier than copyrights. Under the Berne Convention, the minimum copyright term is the author's life plus 50 years.[1015] However, more nations are increasingly extending the copyright term to the author's life plus 70 years.[1016] The length of the patent term is twenty years from the patent application filing date, which is significantly shorter than the copyright term.[1017] When a patent expires, the invention falls into the public domain, and the public is free to use the invention. Thus, the public will gain access to patented inventions much earlier than copyrighted works. A patent licence cannot be enforced in patent law after the underlying patent protection expires. Some may argue that open source patent licences are not as useful as open source copyright licences due to the shorter patent term. However, open source patent licensing can create access to biotechnology patents without forcing patentees to give up their rights and to lose protection against third parties. Thus, open source licensing can reduce the patent access barriers that have formed over upstream research tools. As discussed above, open source licensing can create user access to patents near the end of the patent term, patents that do not create profits, and defensive patents, which can stimulate open R&D before patent expiration.

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[1015] *Berne Convention*, Art 7, *supra* note 976.
[1016] The *United States-Mexico-Canada Agreement* (USMCA), which completed negotiations in 2018 and will replace the North American Free Trade Agreement (NAFTA) once ratified, increases the minimum duration of copyright protection to life plus 70 years. See *Agreement between the United States of America, the United Mexican States, and Canada*, 05/30/19 Text (30 November 2018), online: Office of the United States Trade Representative <https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between>.
[1017] TRIPS, *supra* note 306, art 33.

5.3.3.2 Source Sharing

As noted above, open source licensors must provide sufficient information to allow open source licensees-users to exercise broad rights under the licence without wasteful reverse engineering. For this reason, OSS licences require licensors and subsequent users to disclose software source code when disseminating OSS. In the life science R&D, the type of scientific invention that is disseminated with open source patent licences will dictate what source information must be disclosed to allow subsequent users to study, practice and modify the invention. If a patentable invention can be described and shared in a digital file (in words or images), source sharing is relatively easy as in OSS. Other times, users may need access to additional information and related property rights to be able to practice and modify a biotechnology invention.[1018] For example, open source licensors may need to provide access to a database, biological materials, and supplementary information, such as know-how or trade secrets, as source information for a biotechnology invention.[1019]

Some suggest that researchers and developers in open biotechnology should practice the standard of patent disclosure in patent law to satisfy the source sharing obligation under open source licensing.[1020] Patent law requires patent applicants to disclose their invention by correctly and fully describing the invention so as to enable a person skilled in the art to use it.[1021] Patent law may also require patent applicants to disclose their invention using the best mode to share that information with the public.[1022] Upon publication of a patent application, the public can access the disclosure via patent databases of patent offices. In some instances, if an invention is

[1018] E.g. copyright-protected texts, original trademarks, personal property rights and/or plant rights on biological materials, and database protection rights on research data.
[1019]Hope, *Biobazaar*, *supra* note 21 at 144-145; Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 356.
[1020]*Ibid*.
[1021] *Patent Act*, *supra* note 303, s 27(3); Vaver, *Intellectual Property Law*, *supra* note 68 at 343.
[1022]Vaver, *ibid* [In Canada, an inventor of a machine invention must describe the best mode of how to practice the machine. As for processes, an inventor must explain all of the necessary steps in the process].

difficult to describe in words or images, patent law requires additional disclosure of information.[1023] For example, for sufficient disclosure of biological inventions, such as new strains of bacteria, cells, tissues or recombinant proteins, the inventor must deposit a sample of the biological material as part of the patent disclosure requirement to enable the public to recreate the invention.[1024] The deposit of biological materials is made with an international depositary authority that is accredited under the Budapest Treaty (for treaty nations) before the filing date.[1025]

The standard of patent disclosure may offer a guideline on how much disclosure is necessary to publish patentable inventions to enable subsequent use. But this may not always be enough to enable practice in open innovation. As discussed in Chapter Three, patentees try to maximize benefit from patents by using broad and ambiguous claim language, and they avoid disclosing too much detail about their invention in patent applications. Social production encourages the participation of individuals with different levels of expertise, education, and research experience in biotechnology. The standard of patent disclosure in patent law may be too high, confusing, and is likely not promoting a user-friendly environment.

Instead, open source hardware developers abide by more specific source sharing rules for open source hardware tools to minimize confusion within the community and to promote adequate disclosure of hardware tools to encourage use and adoption. OSHWver1.0 states that an

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[1023]Boettiger & Burk, *supra* note 68 at 225 [Biological inventions frequently fall into this category because the organisms or biological starting materials may be unique or irreproducible].

[1024]Vaver, *Intellectual Property Law*, *supra* note 68 at 342; Hope, *Biobazaar*, *supra* note 21 at 173 ["The *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* was established in 1977 and became operational in 1981. The Treaty requires signatory countries to recognize a deposit with any depository which has been approved by the World Intellectual Property Organization (WIPO)."]; *United States Manual of Patent Examining Procedure,* 8th ed., August 2001 (latest revision October 2005), s 2402, online: USPTO <http://www.uspto.gov/web/offices/pac/mpep/documents/2400_2402.htm#sect2402>.

[1025] *Patent Rules*, ss 103-4, *supra* note 980; WIPO, "Section E: Requirements of Industrial Property Offices of States Party to the Budapest Treaty and of Intergovernmental Industrial Property Organizations", online: WIPO <https://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/section_e.pdf>.

open source hardware project must share documentation, design files and open source software to enable the use and modification of a hardware tool. It also suggests acceptable file formats that should be used by developers and how to make the files available to others to avoid any unnecessary costs users can incur from practicing open source hardware. These guidelines can also evolve with the community and reflect changes in technology.

A one-size-fits-all approach to open source sharing biotechnology should not be expected because there are various types of biotechnology inventions, and some will be more difficult to share with other users.[1026] Then, the cost of creating access to the source information can be an important factor in biotechnology when patentees consider open source licensing. Open source licensing complex technologies in biotechnology will be more challenging and costly because users may need to access a set of additional rights and services (e.g. supplementary information, documentation and technical support). When the cost of open source sharing is high, this may discourage some inventors from joining open source licensing. If licensees are responsible for paying these fees individually (i.e. as a reasonable reproduction cost), the cost of accessing and using a complex technology under open source licensing is a burden that not all users may be able to afford, creating inequitable access to certain technologies.

For example, the Cambia research organization's open source-inspired BIOS (Biological Innovation for Open Society) licences are designed to create a commons of enabling technology for biotechnology R&D.[1027] Cambia also offers access to the organization's patents with these licences. Cambia developed several BIOS licences: for exchanging plant-molecular enabling technology, another for health technologies, and a generic agreement for patented technologies

[1026] Burk, "Intellectual Property in the Context of e-Science", *supra* note 32.
[1027] Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951 at 115.

that can be used with any type of patent.[1028] The BIOS 2.0 generic agreement does not allow the dissemination of the licensed technology to indefinite users; instead, it creates a common pool of resources for a group of researchers who sign the licensing agreement and are willing to share enabling technologies. Each participant in the pool cross-licenses the right to use other patents in the pool; therefore, the licensing scheme is used to establish a patent pool for the group.[1029]

The BIOS generic agreement is accompanied by the BIOS Technology Support and Materials Transfer Agreement, which helps licensees access additional information needed to practice the cross-licensed technology. This supplementary agreement ensures that researchers are able to use the licensed technology. It states that licensors will provide technical support, know-how, physical materials and future improvements to licensees who register with the licensor and that licensors should be willing to discuss the licensed technologies, including safety and regulatory requirements.[1030] The additional support to for-profit companies is to provide for an annual payment for technology support, which starts at $5,000 for small commercial entities having fewer than five employees and $150,000 for large commercial entities with more than 500 employees.[1031] Registered non-profit institutions are exempt from the payment.[1032]

Masum et al. note that the BIOS licensing scheme may be too expensive for small-sized organizations to pursue and that the complexities of sharing biotechnology need to be smoothed out further in the licensing scheme.[1033] In fact, although some firms showed interest in BIOS licences initially for the first few years when they launched in 2005, the licensing scheme never

[1028] *Ibid*.
[1029] Boettiger & Burk, *supra* note 68 at 230.
[1030] "Material Transfer and Technology Support" of Cambia Draft PME BiOS 2.0 Agreement and BIOS Technology Support and Materials Transfer Agreement, s 5.
[1031] BIOS Technology Support and Materials Transfer Agreement, Annex C.
[1032] *Ibid*.
[1033] Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 952 at 117.

caught on as OSS licences did.[1034] The additional costs and individual negotiations to access supplementary information and technical support to practice a complex technology can bar some people's access to it.

As noted above, one of the advantages of open source licensing is that it lowers the transaction costs since licensors do not need to negotiate each transaction with licensees, and there is no central administration. However, even under an open source licensing scheme, users may be significantly burdened with transaction costs and access costs from requiring access to supplementary rights and services to practice a patented invention. Moreover, viral licensing where technology is transferred between users[1035] is inappropriate when users do not have all source information or cannot transfer all source information to enable subsequent users to practice licensed technology.

5.3.3.3 Freedom to Use, Modify and Improve Open Source Patents

OSS copyright licences grant broad permissions to users: users can study, copy, use, distribute, modify and improve OSS. Copyright owners can effectively regulate downstream uses of open source software because they have broad rights over the use of original literary and artistic works under copyright law, such as reproduction and the creation of derivative works (e.g. translations, adaptations, abridgements and sound and video recordings).[1036] On the other hand, as discussed in Chapter Three, the scope of a patentee's rights is rooted in the patent claims. Thus, the scope of an open source patent licence is also defined by the licensed patent claims, and they define subsequent users' right to use, modify and improve the licensed patent.

[1034] *Ibid*.
[1035] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 32.
[1036] *Berne Convention*, Art 2(3), *supra* note 976, incorporated into TRIPS, Art 9; *Copyright Act*, *supra* note 609, ss 2, 3(1), 5(10), 64(1)(d); *CCH, supra* note 972; *Delrina Corp v Triolet*, *supra* note 972 at 39. [A copyright owner can also control how a work is presented (*Copyright Act*, ss 14.1(1) & 28.2(1)), public performance (*Copyright Act*, s 26) and Broadcasting (*Copyright Act*, ss 21(1) and 27(2)-(4))].

Compared to copyright owners, patentees sometimes have broader rights and narrow rights to control follow-on development in patent law. Patentees have a broader right to control the follow-on developments in patent law because patentees can control subsequent inventions that fall within the scope of their patent claims whether or not they are derived from the patented invention.[1037] However, patentees do not have the right to control derivatives or subsequent developments if they fall outside of the original patent claims. As described in Chapter Three, the patent grant on subsequent improvements can be awarded separately to the downstream inventor responsible for them. When upstream and downstream patents belong to different patentees, the upstream patentee needs permission from the follow-on inventor to use the patented improvements and vice versa.[1038] Both upstream and downstream patentees need each other's permission to use the whole technology. It is noted that this structure of patent law encourages upstream and downstream inventors to cooperate, although patentees can refuse to cooperate and resist fair cross-licensing depending on the type of invention involved and the bargaining power of inventors.[1039] This structure of patent law can also expose open source patent licensees to patent infringement claims from downstream patentees who own patents on follow-on improvements because there could be an overlapping coverage between the upstream and downstream patents.[1040]

The GPLv3, for example, addresses overlapping follow-on patents within open innovation projects by creating open source access to patents that belong to all participants in an open innovation project as long as those patents can interfere with the use of the project. Thus, everyone who is part of an open source project is safe from patent infringement lawsuits from

[1037]Hope, *Biobazaar*, *supra* note 21 at 182.
[1038]*Ibid*.
[1039]*Ibid*.
[1040] Boettiger & Burk, *supra* note 68.

other members of the project to the extent that patent infringement arises from using the project. GPLv3 patent licensees have the permission to use project contributors' patent(s) that covers the contribution that was added to the open source project. Because open source users are prohibited from bringing patent infringement lawsuits against other open source users, the GPLv3 creates access to patents owned by other open source licensees.[1041] This provision prevents open source users from subsequently obtaining patents that cover the open source project without licensing its use to other open source users. However, if a contributor or a third party owns patents that cover subsequent modifications or improvements not injected into the open source project, GPLv3 licensees cannot use these subsequent modifications or improvements.[1042]

Moreover, as discussed in Chapter Three, if a field of technology suffers from the development of fragmented and overlapping patents covering a resource, it will be challenging to create access to the resource because users need to secure access to a bundle of patent rights. Users need to secure access to key patents that cover the resource since minor patents may be invented around. Hence, all key patentees must agree to open source licensing to create open source access to this resource, which will be challenging. Persuading a group of patentees to

[1041] GPLv3, ss 8, 10, *supra* note 882 [S. 10 of the GPLv3 states that in reference to a user who conveys a covered work, "you may not initiate litigation (including a cross-claim or counterclaim in a lawsuit) alleging that any patent claim is infringed by making, using, selling, offering for sale, or importing the Program or any portion of it." And s. 8 states that the license can terminate when a licensee does not "propagates or modifies a covered work except as expressly provided under this License… including any patent licences granted" under the GPLv3's patent provision. Thus, an open source user who brings a patent infringement lawsuit against other open source users will experience the consequence of their open source licence being terminated]; Asay, *ibid* at 289; The TAPR Open Hardware License" version 1.0 (May 25, 2007), online: TAPR <https://www.tapr.org/TAPR_Open_Hardware_License_v1.0.pdf >, s 2 "Patents" [The TAPR OHL also applies the same approach to open source patent licensing by prohibiting contributors/licensors and users from bringing patent or other IP infringement lawsuit against other open source hardware licensors and users to the extent that there was infringement for using the open source hardware (but not for infringement that results from modifications subsequently made by others).]; "Frequently asked questions about the GPL licences", online: FSF <https://www.gnu.org/licences/gpl-faq.html#v3PatentRetaliation>.

[1042] Asay, "The General Public License Version 3.0", *supra* note 702 at 286-8 [i.e. Even if the contributor owns patents on improvements, if the contributor chose not to open source license the improvement patents, open source licensees cannot use the improvements without infringing those patents. The GPLv3 patent licence was drafted in this way to encourage corporate patentees with a large patent portfolio in a research area to join and contribute to open source projects without having to share their entire patent portfolio].

agree to open source licensing will be difficult also when patent trolls own key patents.[1043] Open source licensing some of the fragmented and overlapping patents that cover a technology does not allow licensees to practice the whole technology. Creating access to some of the less significant patents out of hundreds covering a research tool via open source licensing will not guarantee access to it or help users avoid patent infringement from using the research tool.[1044]

5.3.3.4 Copyleft

The copyleft obligation in an OSS licence requires OSS users to make subsequent versions of software (i.e. "all modified and extended version of the program")[1045] publicly available using the same licence as the upstream OSS. This condition prevents downstream developments from blocking access to OSS and encourages subsequent developers to contribute back to the OSS commons.

The copyleft condition in a patent licence can be implemented in two ways: by discouraging subsequent patents or allowing subsequent patents but requiring open source licensing of the follow-on patents with a reverse grant-back condition.[1046] The first option creates access to subsequent inventions by forcing downstream developers to place them in the public domain, which may not be desirable to commercial participants in open development as this can restrict their business strategies. The second option ensures that even if downstream patents develop, downstream patentees must license their patents to all open source users. As discussed above, patentees can only control modifications and improvements that fall within the patent

[1043] Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 356.
[1044]Hope, *Biobazaar*, *supra* note 21 at 39-41.
[1045] Free Software Foundation, "What is Copyleft?", online: FSF < https://www.gnu.org/licenses/copyleft.en.html>.
[1046]Boettiger & Burk, *supra* note 68 at 228; Hope, *Biobazaar*, *supra* note 21 at 308.

claims. A grant-back condition in a patent licence allows upstream patentees to assert control over downstream inventions whether or not they fall within the scope of the upstream patent.

If a copyleft patent licence prohibits open source licensees from obtaining follow-on patents, it removes the risk of follow-on patent thickets.[1047] Some suggest that this copyleft approach still encourages commercial activities on unpatented modifications and improvements because open source businesses can still benefit from the first-mover advantage.[1048] The approval and the support of the open source communities can also discourage the strategic use of third party patents that can interfere with open source businesses that commercialize unpatented modifications and improvements.[1049] It is also suggested that open source businesses may be able to combat competition with strong branding and fair practice.[1050] On the other hand, when subsequent patents are barred, inadequate control of subsequent inventions can discourage commercial participants' contributions in the upstream technology and discourage commercial downstream uses.[1051] This is avoided by allowing follow-on patents in a copyleft patent licence.

Boettiger and Burk note that when a copyleft patent licence is implemented through the use of a grant-back condition, a better term for this is a "reverse grant-back" condition because subsequent inventors not only grant back the use of follow-on patents to upstream patentees but also grant back the use to every open source users.[1052] Others have also characterized this type of copyleft condition as "passing it forward" because it benefits all users, not just those who

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[1047] Free Software Foundation, "What is Copyleft?", *supra* note 1045.
[1048] "Open Source Hardware FAQ", online: OSHWA <https://www.oshwa.org/faq/>.
[1049] *Ibid*.
[1050] *Ibid*.
[1051] Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614 [Burk notes that this type of copyleft patent licence can be seen as contradicting or frustrating the general policy of the patent system to encourage follow-on developments by allowing separate patents to be granted to the person who invents the improvements. Burk also notes that this argument is strong in the United States, which constitutionally recognizes patent rights to promote science and useful arts (Article 1, Section 8, Clause 8 of US Constitution). Thus, patent licences prohibiting a follow-on inventor from patenting their improvement may be pre-empted as contrary to the U.S. Constitution].
[1052] Boettiger & Burk, *supra* note 68 at 228. [e.g. Open Source Drug Discovery, see Chapter Six below].

contributed to open source development.[1053] The GPLv3, the Tucson Amateur Packet Radio Open Hardware License (TAPR OHL), and BIOS 2.0 Agreement have implemented the copyleft obligation with a reverse grant-back condition.

Using a grant-back licensing condition in proprietary patent licences can be anti-competitive because it allows upstream patentees to assert control over the use of downstream development.[1054] Some may suggest that a reverse grant-back condition in open source licensing is also anti-competitive since it can restrict downstream inventors' use of their patents, who are forced to grant-back their patent to certain users.[1055] Open source copyleft licensing also does not allow downstream patentees to recoup their R&D and patent costs by licensing the invention to others.

However, a reverse grant-back open source condition is not anti-competitive because it does not offer any privilege to the upstream open source licensor.[1056] Copyleft licences grant all open source users the same rights to use the downstream invention non-exclusively as the upstream open source invention. Moreover, copyleft licences do not bar commercial activities. Follow-on inventors who contribute their patents to the open source commons can still engage in commercial activities with their invention.[1057] As discussed in Chapter Two, open source licensing encourages commercial activities to build around open source technology because businesses can commercialize the technology or complementary products and services and use

[1053]Hope, *Biobazaar*, *supra* note 21 at 179.
[1054] Hope, "Open Source Genetics Conceptual Framework", *supra* note 851 at 182-3; Boettiger & Burk, *supra* note 68 at 228.
[1055] *Ibid*.
[1056] Hope, *ibid*.
[1057] Benkler, *Wealth of Networks*, *supra* note 2; Hope, *Biobazaar*, *supra* note 21 at 179 ["copyleft- style terms restrict licensees' freedom in order to create a competitive market in which the licensor retains no advantage relative to other prospective users or distributors of downstream technologies."].

the technology to improve their business.[1058] Businesses can also profit from an open invention because wide adoption of it in society creates positive network effects, which can increase the sale of complementary products, related services, and improved versions.[1059] This open source-based business model is also possible in biotechnology. For example, Diverse Arrays Technologies (DArT) is a for-profit company based in Canberra, Australia, that exploits its patents[1060] by making them broadly available with non-exclusive patent licences and offering research biodata handling service modelled after Red Hat.[1061]

The copyleft condition is necessary to allow some businesses to practice dual licensing, where the same software is offered under a proprietary licence and an OSS copyleft licence.[1062] Businesses can benefit from offering two versions of their software because they can improve their proprietary software with open source users' copyleft contributions of derivative software in the commons. The public also benefits from this licensing scheme because they gain free access to the open source version. Commercial software users who are not willing to open source their derivative works under the copyleft obligation of the open source licence can license the proprietary version of the software. The copyleft condition is critical to this business strategy as this restrictive condition encourages downstream commercial users to pay for the proprietary version to avoid open source licensing their contributions, thus allowing the licensor to maximize

[1058] *Ibid*. Also, see Mikko Mustonen, "When does a Firm support substitute Open Source Programming?" (2005) 14 J Econ & Manag Strategy 121.
[1059] Mustonen, *ibid* at 123-4.
[1060] E.g."Genotyping by hybridisation", US Patent No. 6713258 B2.
[1061] "About US", online: Diversity Arrays Technology <https://www.diversityarrays.com/about-us/>.
[1062] *Artifex v. Hancom, supra* note 910; Stefano Comino & Fabio M Manenti, "Dual licensing in open source software markets" (2011) 23 Info Econ & Poly 234 at 235-6, 239 [e.g. Sun Microsystems dual licenses the MySQL server. Comino notes that dual licensing is optimal if there is a large open source community willing to contribute improvements].

profit.[1063] The dual licensor also gains access to open source users' derivative works for free, which the licensor can use towards improving the proprietary version.

5.3.3.5 Automatic and Self-Perpetuating Licensing Scheme

As discussed above, an automatic and self-perpetuating licensing scheme is implemented with standardized open source licences that travel with the protected subject matter. To protect the software commons, OSS developers must attach a notice of open source licence on OSS, and all subsequent licensees must maintain this notice when they redistribute the software. The notice of open source licence allows subsequent users to know that the software source code is subject to an open source licence, and the software is not a public domain work.[1064] The notice is typically attached to a place where users should reasonably be able to find it. In OSS, users must maintain a notice of licence as well as attribution and software version control information in the software source code, and this information travels with the source code as it is passed between users. The licence notice and a web address for the licensing texts are also typically included at the start of each file containing the source code, and the licence notice may also be included on the program's user interface and displayed to users when it starts.[1065] The notice of open source licence is easy to attach on many copyright-protected works that can be disseminated over the Internet in readable digital files (e.g. software, images and written instructions). Self-perpetuating or viral licensing is not difficult when a patentable subject matter can be distributed over the Internet. For example, open source hardware projects like OpenPCR are also disseminated over the Internet in a bundle of files, which includes information to allow users to

[1063] *Ibid* [These authors argue that a dual licensor can charge more for a proprietary version if there is a large OSS community making derivative contributions.].
[1064] E.g. GPVv3, s 4, 5, *supra* note 882.
[1065] "The license notices", online: FSF <https://www.gnu.org/licenses/gpl-howto.html>.

build and use the tool (i.e. building instructions, software source code, circuit designs and a list of materials needed to build the tool). The TAPR OHL requires open source hardware developers to include the licence notice in the hardware's documentation package, each documentation file, the printed circuit board artwork and the product itself, if there is one.[1066] Thus, viral licensing is possible in some open source projects for patentable inventions, and the notice of licence can be maintained as these projects pass between users.

On the other hand, it can be challenging to establish a self-perpetuating open source-based licensing scheme for some biotechnology inventions, such as genetically modified life forms. Living organisms grow, multiply and spread; humans can struggle to control how this type of invention spreads even with patent rights. Patents of a seed's genetically modified genes or cells have been used to control its use.[1067] The Open Source Seed Initiative, for example, abandoned an open source-based strategy to protect open source seeds because patenting the seeds can discourage plant breeding, and it was not easy to ensure that open-source seeds are subsequently disseminated in society per the user agreement after the initial purchase.[1068] Seeds grow into plants that produce new seeds after a cycle of growth. Some of those new seeds may be saved and reused by a farmer or distributed to others. Seeds do not need to exchange human hands to spread; they can spread over time naturally to nearby lands. It is also possible for open source plants to evolve by mixing with other crops in plant breeding and local adaptation.[1069] Hence, using open source-based licensing or contracts to protect some inventions from private ownership or control may not be effective, and this knowledge management strategy may be too

[1066] "The TAPR Open Hardware License" version 1.0 (May 25, 2007), online: TAPR <https://www.tapr.org/TAPR_Open_Hardware_License_v1.0.pdf >, preamble, ss 1.4, 4.1, 5.1.
[1067] *Monsanto Canada Inc v Schmeiser*, 2004 SCC 34, [2004] 1 SCR 902.
[1068] Lisa M Hamilton, "Linux for Lettuce" (14 May 2014), 90 VQR, online: VQP <http://www.vqronline.org/reporting-articles/2014/05/linux-lettuce>.
[1069] *Ibid*.

restrictive for downstream users, disrupting existing traditional practices in a field of endeavour.[1070]

5.3.4 Interoperability of Open Source Technologies and Licence Compatibility

Licence proliferation and licence incompatibility are potential obstacles in open source development communities that use open source licences to create a protected commons because these problems can lead to poor interoperability of open source technologies.[1071] Open source development is efficient when participants are able to combine and reuse the commons resources to create something else. Licence proliferation can occur when there are many IP owners of upstream components, and each owner uses an IP licence that imposes different obligations on users.[1072] Too many open source-inspired licences in a field of endeavour can create a licence thicket.[1073] When open source-based licences cannot be combined, the underlying technologies likewise cannot be combined by subsequent users. Thus, the interoperability of open source technologies and licence compatibility must occur together. Licence proliferation and licence incompatibility may be more serious in cumulative and interdisciplinary R&D environments, where various types of open source tools, information and technologies in multiple research fields are shared with multiple open source-inspired licences and contracts. Social production in interdisciplinary biotechnology fields, such as bioinformatics and synthetic biotechnology, are possibly more vulnerable to these licence issues.

In the OSS community, developers generally accept and use the voluntary open source licensing standards, which promote licence compatibility between different open source software

[1070] Hamilton, *supra* note 1068.
[1071] "The Licence Proliferation Project", online: OSI <https://opensource.org/proliferation>; Rosen, *supra* note 60.
[1072] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 23.
[1073] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 32.

licences.[1074] As described above, open innovation communities outside of OSS development, such as open source hardware makers, have also adopted the OSI's licensing standards. This can promote license compatibility between open innovation communities. It is suggested that a serious interoperability problem may be avoided if licensors do not impose restrictive conditions on users that go beyond the FSD or OSD criteria. For example, a CC licence that imposes fewer obligations on licensees (i.e. the CC-Attribution or CC0) than the GPL is still compatible with the GPL because a user does not violate a CC licence by practicing additional obligations under the GPL, such as open source or copyleft conditions.[1075] However, more restrictive licences, such as the CC-NC (non-commercial use) or CC-ND (no derivative), are incompatible with the GPL because these CC licences explicitly prohibit open source conditions that must be present under the GPL.[1076]

Nonetheless, some licence incompatibility still occurs even under these rules, which have prompted non-profit organizations like the OSI to study open source licence compatibility and use.[1077] The open source licensing standards do not specify how licensing conditions should be drafted in an open source licence. These standards allow flexibility for drafting open source licences as needed, as a one-size-fits-all approach cannot adequately facilitate different projects' goals even in software development. For example, even though software developers largely adhere to the voluntary licensing standards, there are different OSS licences with different strengths of copyleft obligations, which can confuse downstream users who want to combine OSS projects with different copyleft requirements.

[1074] For instance, the OSI has been studying license incompatibility of OSS licences since 2004. They make their research public on their website and offer recommendations to improve interoperability of OSS. See "The Licence Proliferation Project", *supra* note 1071.
[1075] "Why is the original BSD license incompatible with the GPL?", online: FSF <https://www.gnu.org/licences/gpl-faq.html#OrigBSD>.
[1076] *Ibid*.
[1077] "The Licence Proliferation Project", *supra* note 1071.

In biotechnology, it may not be practical or possible in some circumstances to force patentees to practice open source licensing based on the FSF and OSI's licensing standards, for example, because patentees want to improve patent access but protect the ability to generate revenues with their patent. It is possible that patentees may want to allow free and open source access to patents within specific jurisdictions or for specific practices (e.g. right to exercise non-commercial use or use for teaching purposes).[1078] Creating access to important upstream patents in biotechnology for narrower subsequent uses can benefit some researchers and developers and the society at large (e.g. allow drug discovery in developing nations or improve access to upstream enabling technologies).

On the other hand, individualized open source-inspired licences and contracts should not be encouraged since they can lead to licence thickets and licence incompatibility and disrupt technology interoperability. Licence proliferation can hinder research freedom in biotechnology.[1079] Also, such licences and contracts impose information costs on users because users will need to study each open source-inspired licence or contract before using the underlying tool or technology in order to avoid IP infringement or breach of contract.[1080] More work is needed to identify appropriate open source licensing standards and necessary licensing flexibilities for exchanging biotechnology.

[1078] E.g. The European Mouse Mutant Archive. See OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 26-7 [These permissions can benefit researchers in jurisdictions like the United States which has a narrow research exception in patent law].
[1079] OECD, *ibid* at 32.
[1080] Elkin-Koren, "What Contracts Cannot Do", *supra* note 849.

5.4 Discussion

Open source licensing can create open access to patented inventions without requiring biotechnology patentees to giving up their patent rights. While private sector patentees may be reluctant to switch from proprietary IP management to participate in open source licensing, some public and private sector biotechnology patentees already participated in open source-based knowledge management to increase access to upstream patents. Patentees should be encouraged to open source license patents if patents are nearly expired, no longer generate revenues for patentees, or they are purely defensive patents. Open source licensing existing patents will increase the pool of resources that can stimulate the social production of biotechnology and entrepreneurship in society. Access to more upstream resources can also reduce potential patent conflicts in the open and cooperative development of biotechnology. Since open source licensing is automatic and self-perpetuating, which does not require individual licensing negotiations or administration, biotechnology patentees and users are not burdened with large costs to create a protected commons of patented research resources.

The original open source licensing scheme in OSS development relies on the underlying copyright protection in the licensed asset to effectively enforce the licensing strategy against all unauthorized users. When DIYers and open scientists publicly release unpatented inventions, new and non-obvious patentable aspects of the inventions belong in the public domain. However, as discussed in Chapter Four, publicly released inventions can still be captured by subsequent third party patents.[1081] Defensive patenting DIY bio inventions may avoid the risk of third party control. Patent applications also create more effective prior art than defensive publishing. And

[1081]Mellis, *supra* note 938.

defensive patents are good bargaining tools to gain access to other patents in the same field of endeavour.

Nonetheless, open source licensing with defensive patenting is expensive compared to OSS copyright licensing due to the costs for obtaining and maintaining patent protection. It may have limited use in the DIY bio network because many DIYers currently self-fund and self-sustain their biotechnology experiments. They rely on easily accessible materials and research resources, such as DIY research tools and equipment.

When biotechnology software research tools are open source licensed by DIY scientists, which may receive dual protection under copyright and patent law,[1082] the copyright protection in these tools can be relied on to force subsequent users to comply with the open source licensing obligations. This may be adequate in some circumstances, but it still does not remove the possible development of third party patents that can cover open source research tools. DIYers, local community research projects and entrepreneurs participating in social production with little resources for R&D protection are vulnerable when there is a conflict with third party patentees because these participants likely do not have defensive patents on DIY inventions to bargain with third party patentees. Such patent conflicts can also create the perception of a larger patent threat in the DIY bio network, which can discourage participation and contribution in these activities.

Encouraging professional collaboration and sponsorship from larger research institutions in the DIY bio network can increase knowledge management options in the innovation environment. However, defensive patenting may not be available in open and cumulative development because it may be difficult to prove the open and collaborative inventions' patent

[1082] I.e. software source code can be protected under copyright law as original expression, and software tools may also receive patent protection if, for instance, it embodies functions that may be patent-eligible in a larger invention. Vaver, *Intellectual Property Law*, *supra* note 68 at 313-315; *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *Canada (Attorney General) v Amazon.com, supra* note 392.

eligibility. Some patent confusion and reluctance within open science and open innovation can also discourage patent-based knowledge management in such communities.

On the other hand, open source-inspired contracts may be relied on to create a shared pool of unpatented biotechnology. Scientists have tried to create a contractually-regulated commons using open source licensing rules to regulate the use of unpatented inventions in biotechnology. Contract-based management of shared resources may effectively regulate subsequent users when the regulated resources or tools are difficult to replicate independently by third parties (e.g. MTAs, data access agreements). Hence, users are forced to contact the resource owner and agree to the owner's terms of use before accessing necessary resources. When it is easy to self-produce biotechnology resources and tools, users can ignore the user agreement or patent licence imposed by the initial owner. If access to technology or information is regulated through a central access point and a user agreement, there are also costs to set-up and maintain the database and a web portal.[1083]

For example, the HapMap project[1084] used a click-wrap agreement to bind users who downloaded the project's data from its website.[1085] The project's click-wrap agreement does not bind anyone who does not use the web portal to access the data (e.g. users who obtained data from another data user). To remedy this weakness and to control downstream uses of their data, the project imposed more user restrictions. For instance, the project tried to protect the data's open access status by initially restricting users from filing patent applications on the inventions

[1083] Rai & Boyle, "Synthetic Biology", *supra* note 174 at 392; Boettiger & Burk, *supra* note 68 at 228; *Ibid*.
[1084] Hope, *Biobazaar*, *supra* note 21 at 308 [An international consortium of private-public collaboration for creating a haplotype map of the human genome. "A haplotype is a set of closely linked alleles – for example, genes or DNA polymorphisms, such as SNPs – that tend to be inherited together as a unit."].
[1085] Robin Feldman, "The Open Source Biotechnology Movement: Is It Patent Misuse?" (2004) 6 Minn J L Sci& Tech 117 at 125; Hope, *ibid* [This project began in 2002, and they stopped using the database access agreement in 2004].

that enclose the HapMap project's data.[1086] The project also prohibited users from sharing data with anyone who had not signed the HapMap's data agreement.[1087] Researchers criticized this contract as restricting research sharing in academic research because the data agreement limited users' disclosure of data outside of the project, such as reporting them in peer-reviewed journal articles and presenting them in professional conferences.[1088] The agreement prevented how academic research is commonly presented to the rest of the scientific community. It also reduces opportunities for peer reviews on subsequent scientific discoveries.[1089]

Open source copyright licensing in software development is generally considered a success and legally enforceable. It has generated fewer threats from high-tech industries. While it is possible to implement open source licensing in patent law to create a protected commons of patented research resources, this licensing strategy under patent law does have some limitations. Under OSS licensing, the software is digitally disseminated between users in the source code format to enable subsequent users. This user-to-user transfer of technology over a decentralized network may not be appropriate for complex biotechnology inventions because it may be expensive and impossible to transfer complementary rights and support services between users. Open source licences are also difficult to enforce and may be ignored when the licensed subject matter (e.g. living matters) is difficult to control and the licence disrupts downstream activities.

Moreover, open source licences do not provide an efficient solution to deal with patent law's poor treatment of cumulative technologies. Since patent law grants separate patents on downstream improvements, which can create possible overlaps between upstream and

[1086] Boettiger & Burk, *supra* note 68 at 222; Dusollier, *supra* note 705 at 1403; Hope, *ibid* at 308-9; Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1071.
[1087] Rai & Boyle, "Synthetic Biology", *supra* note 174 at 392; Boettiger & Burk, *ibid* at 228; Hope, *ibid* at 308 citing Rebecca Eisenberg, "Patents and Data Sharing in Public Science" (2006) 15:6 Industrial & Corp Change1013 at 1015.
[1088] Hope, *ibid*.
[1089] *Ibid*.

downstream patents, these overlapping patents can weaken the open source users' freedom to deal with patented inventions. When an upstream patent is open source licensed, the licensee can still infringe overlapping downstream patents. The licensees' exposure to possible third party patent infringement in patent law can threaten their incentive to contribute back to the open source commons. The patent proliferation with fragmented and overlapping rights in biotechnology also poses a problem because open innovation communities must find a way to gain patentees' consent to bundle key patent rights protecting a cumulative technology to create open source access to the whole technology.

Open source licensing in biotechnology may also impede the free flow of information and knowledge and interfere with open and cumulative development when too many open source licences and contracts are used. Licence compatibility is a problem that can occur in open innovation communities using open source licensing. However, licence thickets and incompatibility may be more serious when open source licensing is encouraged in biotechnology because biotechnology supports several industries, and biotechnology inventions can have various forms and complexities. Creating standardized open source access for all biotechnology inventions may not accommodate different R&D practices in biotechnology.

5.5 Conclusion

This chapter examined the design and operation of the open source licensing scheme and how to extend this licensing scheme to reduce patent risks and protect the social production of biotechnology. Encouraging biotechnology patentees in the public and private sectors to join open source licensing can increase the pool of shared resources in social production, stimulating more innovation and entrepreneurship. On the other hand, most DIYers in social production

activities in biotechnology will likely forego defensive patenting due to the costs of patent protection, the inadequate handling of open innovation outputs in patent law, and the non-proprietary preference in open innovation communities. A protected commons can be created with contracts, which may be another way for DIYers to regulate access to unpatented DIY inventions. However, it is still difficult to control the dissemination of trivial and easy-replicable resources with contracts.

When open source licensing is used with patented inventions, licensors and licensees should know how open science licences might operate differently under patent law. Open source licensing under patent law can still leave licensees vulnerable to third party patentees who own downstream overlapping patents. Moreover, open source licensing may not always be appropriate in biotechnology. The automated viral licensing may be inappropriate for complex inventions and living matters. The licensing scheme does not adequately deal with the patent access barrier problem from fragmented and overlapping patents in biotechnology. Social production communities should also discourage the development of licence proliferation in this environment, which can disrupt the free flow of information and knowledge and technology interoperability. The following chapter will examine knowledge management strategies that use centralized management of resources to improve patent navigation.

Chapter 6: Other Strategies to Stimulate Social Production in Biotechnology

6.1 Introduction

Clearinghouses and compensatory liability regimes can provide alternative knowledge management for patented and unpatented inventions in open biotechnology. Unlike viral open source licensing that allows open source research resources to be disseminated between users, these strategies provide central access to shared research resources. Thus, they require administrative structures and costs.

This chapter considers two types of clearinghouses and examines their use in open biotechnology. An information clearinghouse is a database containing information about patents in one or more research areas. Advanced information clearinghouses with information processing and visualization tools improve downstream inventors' access to the patent-related information in relevant research areas. Researchers and developers, including DIYers, can use the information to navigate around biotechnology patents, to identify publicly accessible and off-patent technologies, and to try to avoid patent infringement. Information clearinghouses do not remove the risk of inadvertent patent infringement, which may be difficult to avoid in research areas with fragmented and overlapping patents and opportunistic patentees and patent trolls.

Alternatively, a patent clearinghouse can centrally administer access to a group of research resources, including patents, unpatented inventions and related information, as a neutral intermediary between resource owners and users. Patent clearinghouses eliminate individual negotiations between upstream and downstream inventors and standardize and streamline access to patents and other research resources. This mechanism can benefit scientists in a research area that need access to a bundle of upstream rights and related information to conduct downstream R&D. Open access patent clearinghouses can use open source licences, contracts, defensive

publishing, informal rules and norms to regulate subsequent use and dissemination of open R&D. The challenge of organizing patent clearinghouses is convincing a significant portion of patentees in a field of research to agree to collective management and to use standardized licensing conditions.

Compensatory liability regimes use a liability rule (an entitlement to be compensated) instead of a property rule (a right to exclude) to regulate access to information and knowledge. This chapter considers a contract-based compensatory liability regime for biotechnology, which makes upstream inventions available for any purpose of use, provided that downstream users agree to equitably compensate upstream resource owners when they make a profit. The liability rule enforced with contracts removes the need for individual licensing, and it creates free access to upstream research resources for non-commercially motivated DIYers. However, the possibility of third party ownership of open R&D inventions by patenting in biotechnology can interfere with this strategy.

Alternative knowledge management strategies for open and cooperative R&D in biotechnology, such as defensive publishing, open source patent licensing, clearinghouses and compensatory liability regimes, do not address existing issues in patent law, such as poor treatment of cumulative technologies, opportunistic and strategic patent practices, and patent intrusion in open innovation environments. Governments can encourage science and innovation in society by designing and administering IP law. Governments can reduce possible third party patent interferences and threats in DIY bio by amending patent law. This chapter will close by exploring the possibility of expanding patent exceptions, which many argue as the appropriate vehicle to adjust the patent incentives in light of new developments in society, such as cumulative technologies, patent trolls and open innovation environments.

6.2 Clearinghouses

Clearinghouses are cooperative knowledge management mechanisms for improving access to patents and patent-related information.[1090] This scheme centrally manages a group of resources to facilitate knowledge dissemination and use. It can be organized and used by industry actors,[1091] academic scientists,[1092] public-private partnerships,[1093] open science or open innovation communities,[1094] or a mixture of various stakeholders from all of these groups. This section explores two types of clearinghouses that can support non-proprietary open biotechnology initiatives. An information clearinghouse is an information portal that provides information related to patents, and sometimes it can show research activities and available technologies in research areas.[1095] Information clearinghouses can help downstream inventors perform patent searches and plan a course of R&D around the existing patent landscape.[1096]

[1090] Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 353-4; Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 69 -70 [Van Zimmeren identified five types of patent clearinghouses in this article. 1. Information clearinghouse provides information about technical knowledge and/or information about IP status; 2. Technology exchange clearinghouse lists patented inventions available for licensing; 3. Open access clearinghouse provides information about unpatented inventions and makes free and open access to them using a standardized agreement; 4. Standardized licence clearinghouse uses a standard patent licence to create access to a group of patents; and 5. Royalty collection clearinghouse is an institution that facilitates patent licensing and collects royalty payments for patentees. The first two types provide information about patented technologies (i.e. information clearinghouse and technology exchange clearinghouse), and the other three types provide information and standardized access to a group of patents (i.e. open access clearinghouse, standard licence clearinghouse and royalty-collection clearinghouse). Since there are limited examples of patent clearinghouses in non-proprietary open biotechnology which can aid DIY bio and other social production activities, I will use the term "information clearinghouse" to reference the types that only offer patent-related information to potential patent users and the term "patent intermediary" to refer to clearinghouses which facilitate access to and enable the use of a group of patents and patentable inventions.]; OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 29-30; Bennett & Boettiger, *supra* note 692 at 135.

[1091] E.g. Eco-Patent Commons was established by four companies (IBM, Nokia, Pitney Bowes and Sony) to facilitate the development of environmentally beneficial technologies – see OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 26.

[1092] E.g. The European Mouse Mutant Archive is a clearinghouse to archive and distribute mouse mutant lines for non-commercial research and teaching purposes, *ibid*.

[1093] E.g. The SGC, *ibid* at 31.

[1094] OECD, *ibid* at 29-30.

[1095] Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 353-4; OECD, *ibid*; Bennett & Boettiger, *supra* note 692 at 135.

[1096] Van Zimmeren, *ibid* at 356; Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 69 -70.

Information clearinghouses offer information that can help users navigate around patents and license patents.

Another type of clearinghouse can centrally administer the use of a group of patents, unpatented inventions and other research information[1097] on behalf of their owners.[1098] Hence, a patent clearinghouse functions as a neutral intermediary between licensors and licensees, removing direct negotiations and interactions between them.[1099] In non-proprietary R&D, such as DIY bio, this type of clearinghouse can use open source licences, contracts, defensive publishing and informal rules to regulate and protect access to a group of patented and unpatented inventions in the commons.[1100]

6.2.1 Information Clearinghouses

An information clearinghouse is a database of patent-related information, such as existing patents and published patent applications in one or more research areas. It can also provide information such as previous and ongoing research efforts and available research tools and technologies-in a field of research.[1101] Some may even provide licensing information for patents and information about publicly accessible technologies.[1102] Researchers can use information clearinghouses to assess previous R&D activities and patent developments in research areas to plan a research project and avoid patent infringement.[1103] Information clearinghouses do not remove patent infringement risks for researchers and developers in biotechnology, especially in

[1097] *Ibid*.
[1098] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 29-32.
[1099] *Ibid* at 25; Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 352.
[1100] *Ibid*.
[1101] Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 69 -70.
[1102] Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 353.
[1103] *Ibid* at 356.

research areas suffering from fragmented and overlapping rights. Information clearinghouses also benefit existing patentees by making patents more visible to potential licensees, increasing licensing revenues. The costs of operating an information clearinghouse will vary and likely depend on database contents and any additional database tools to improve user access.[1104]

National and regional patent databases maintained by patent offices are examples of information clearinghouses. These databases offer public access to published patent applications, patents, and other patent-specific documents.[1105] Patent offices maintain them as a means of providing public notice of patents and patent applications. However, database users need advanced search skills and technological knowledge of the relevant R&D area and understand patent drafting techniques to use the databases to discover the patent developments in a field of endeavour.[1106] It is generally recommended that inventors hire a professional to carry out patent searches to find prior art.[1107] These databases are not adequate patent search tools for non-patent experts like ordinary scientists and DIYers.

An example of a user-friendly information clearinghouse is the Cambia organization's Patent Lens project, a free and open biotechnology patent and information platform.[1108] Patent Lens offers information about agricultural and life science patents,[1109] related research publications, and patent-related documents and data obtained from multiple patent offices.[1110] Patent Lens also provides information about millions of DNA and protein sequences that are

[1104] *Ibid* at 353.
[1105] For example, Canadian Patent Database publishes patent-specific documents, such as the prosecution history of patent applications and granted patents. See "Improved Canadian Patents Database" (29 October 2018), online: Government of Canada <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03928.html>; *Ibid*.
[1106] Gene Quinn, "Patent Searching 101: A Patent Search Tutorial" (11 July 2015), online IPwatchdog <https://www.ipwatchdog.com/2015/07/11/patent-searching-101-a-patent-search-tutorial-2/id=59308/>.
[1107] *Ibid*.
[1108]Berthels, *supra* note 510 at 196 [Patent Lens is a free and open patent information platform in biotechnology research unlike commercial versions such as Derwent, Delphion and MicroPatent. Other free patent search services include Google Patent Search and Free Patents Online]; Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951.
[1109]Berthels, *ibid*.
[1110]*Ibid*; "About the Lens", online: Lens.org <https://about.lens.org/>.

disclosed in patents.[1111] It has user-friendly search functions to help users find relevant patents and patent applications and scholarly literature linked to patents and patented products and services. Linking the related information helps non-patent experts learn about patent developments and patent-related R&D activities in a research area.[1112] Patent Lens also provides visualization tools to help users view collaboration networks and map how scholarly publications have influenced subsequent research and industrial developments.[1113] Users can also find "tutorials on IP, information on patent policies and practices", and patent-related news.[1114] Therefore, this information clearinghouse helps biotechnology researchers and developers understand "who does what, when and where to inform decision making."[1115] Masum et al. note that Cambia researchers used Patent Lens to avoid patent infringement and to develop around third party patents protecting an agricultural research tool for making transgenic plants (agrobacterium).[1116] Unlike patent databases maintained by patent offices, Patent Lens makes patent-related information more accessible to ordinary scientists by combining a variety of publicly accessible information and multiple information processing tools.

Such an information clearinghouse provides free access to patent information that can otherwise be difficult and expensive to obtain, especially for scientists and DIYers who have limited access to funding and do not have IP advisors. Advanced information clearinghouses encourage innovation by reducing the follow-on inventors' burdensome costs of navigating the

[1111] "About the Lens", *ibid*; Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951 at 118.
[1112] "About the Lens", *ibid*.
[1113] *Ibid*.
[1114] Berthels, *supra* note 510 at 196.
[1115] Online: Lens.org <https://www.lens.org/>.
[1116] Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951 at 118-9.

biotechnology patent landscape.[1117] Furthermore, they can make the patent coverage in a research area more transparent to more patent users.[1118] Hence, it helps researchers, DIYers, entrepreneurs, and smaller businesses plan a course of R&D in biotechnology and reduce the risk of third party patent conflicts.[1119] Moreover, they can direct DIYers, academic researchers, entrepreneurs and businesses to research, innovate and commercialize in underexplored research areas by helping scientists and innovators locate R&D areas that do not suffer from patent thickets. These information platforms can also encourage DIY bio by helping DIYers expeditiously locate off-patent technologies and tools as they come off patent protection. Moreover, advanced information clearinghouses can stimulate DIY bio by linking and displaying information for DIY scientists with varying degrees of scientific education and experiences, such as instructions, tutorials and educational materials in a field of research. Therefore, information clearinghouses can stimulate R&D from traditional and non-traditional R&D environments in biotechnology.

An information clearinghouse's utility will depend on the quality and the scope of the information it holds and the users' ability to find and process relevant information in the database. As discussed in Chapter Three, only courts can give a conclusive determination of the scope and boundaries of patent claims. Broad, ambiguous and strategic patent claims can still confuse and mislead information clearinghouse users about the patent coverage in a research area. On the other hand, information clearinghouses can make broad, poor quality and improvident patents and patent applications more visible to the public by linking them to the related research activities. Information clearinghouses are designed to help scientists and innovators work around

[1117] Berthels, *supra* note 510 at 196-7; Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951 at 118.
[1118] Berthels, *ibid*.
[1119] *Ibid*.

patents and avoid inadvertent patent infringement. They do not address patent problems such as fragmented and overlapping patents in cumulative industries and abusive and strategic patent enforcement. As discussed above, the risk of patent infringement is difficult to avoid in highly competitive and litigious research areas suffering from fragmented and overlapping patents.

6.2.2 Collective Patent Management

Patent clearinghouses can also provide central access to patents, patent pools, unpatented inventions and related information, acting as intermediaries between resource owners and users. This strategy reduces transaction costs and avoids negotiation delays for downstream inventors since they do not have to contact and negotiate with each upstream patentee or resource owner to obtain permission.[1120] Van Zimmeren notes that patent clearinghouses can streamline and standardize access to patented inventions, make patents and other research resources visible to users, and reduce royalty stacking in fields suffering from fragmented patents.[1121] Furthermore, patent clearinghouses that manage a significant number of patents and unpatented inventions can prevent licence and contract proliferation in a research area. Whereas viral or open source licensing without an administrative structure cannot easily transfer complex biotechnology with multiple rights holders and complementary resources, patent clearinghouses may create access to such technologies. Patent clearinghouses can also enforce patent rights on behalf of patentees and offer dispute resolution.[1122] Van Zimmeren suggests that patent clearinghouses can be set up at the national or regional level "to identify, match, negotiate, collect royalties, monitor

[1120] Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 352-356; OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 25.
[1121] Van Zimmeren, *ibid*.
[1122] *Ibid*.

infringements and assist in dispute resolution."[1123] Moreover, standard licences used in national clearinghouses can be written with national patent law in mind since patents operate at the national level, and an umbrella organization at the global level can coordinate national clearinghouses.[1124] A patent clearinghouse can charge royalties to clearinghouse users, which is not appropriate in open science and open innovation communities that promote free and open access to community resources.[1125] The remainder of this section will consider open access or open source clearinghouses that organize broad access to shared research resources in biotechnology. It will review three examples in open biotechnology, which were created by a large research consortium, a non-profit organization, and a government-funded R&D project. As noted in Chapter Five, these clearinghouses can stimulate DIY bio by increasing openly accessible research resources in a research area. Moreover, patent clearinghouses like the Biobricks database allow scientists, including DIYers, to freely disseminate patented and unpatented research outputs.

A patent clearinghouse that supports open R&D can create open access to voluntarily pledged patents and unpatented inventions.[1126] It can use open source patent licences to create royalty-free access to patents and contracts, informal rules and norms to manage user access to

[1123] *Ibid* at 353-5.
[1124] *Ibid*.
[1125] *Ibid* [van Zimmeren defines royalty collecting patent clearinghouses as providing the following services: "[a]ccess and use on the basis of standardized licences, royalty collection, monitoring of the patent rights transferred to the clearing house, [and] independent dispute resolution mechanism"]; Jorge L Contreras, "Considerations Regarding a Canadian Patent Collective"(2018) CIGI Paper No. 172, Centre for International Governance Innovation at 6-7 citing Ryan Davis, "Buying patents to thwart 'trolls' is a tricky strategy", Law360 (3 November 2014); Allied Security Trust (AST), "The AST membership advantage", online: AST <https://www.ast.com/about-us/be-a-member/> [For example, RPX Corporation, a for-profit organization that collectively manages purchased information technology patents, charges annual members fees between $85,000 to $7millionUSD (as reported in 2014). Allied Security Trust (AST), a non-profit version, charges annual membership fees from $100,000 to $200,000USD to cover operating costs].
[1126] Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 33.

unpatented research resources.[1127] It can also prevent third party patentees from interrupting access to unpatented open inventions with defensive patenting, defensive publishing, and encouraging scientists to practice open sharing in a research area. A patent clearinghouse can be organized to create open access to a group of patents for a specific purpose of use, such as non-commercial research, teaching[1128] and drug discovery in developing nations. There are costs to operate patent clearinghouses, which may be subsidized from funding and donations from those who support open biotechnology.[1129] Although some patent clearinghouses are considered anti-competitive for centrally managing the use of a group of patents, dictating licensing conditions, and bundling patents into patent pools, this issue is irrelevant in open access patent clearinghouses that offer royalty-free access to patents, allowing anyone to access and use them.[1130]

For example, the Single Nucleotide Polymorphism (SNP) Consortium created a web-accessible public database in 1999 to release the research group's unpatented SNPs.[1131] The SNP Consortium resulted from the joint efforts of public and private sector researchers and research organizations that wanted to prevent the development of severely fragmented patent rights on

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[1127]OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 26-9.

[1128] E.g. The European Mouse Mutant Archive – OECD, *ibid* at 26-7 [It archives and distributes mouse mutant lines in biomedical research for research with non-commercial purposes or teaching purposes. This type of arrangement could benefit researchers in jurisdictions like the United States, which has a narrow research exception in patent law, and it is not always certain if patent use in non-commercial research or teaching would be exempted in patent law].

[1129]Contreras, *supra* note 1222; Schultz & Urban, "Protecting Open Innovation", *supra* note 459 at 9; Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950.

[1130]Burk, "Intellectual Property in the Context of e-Science", *supra* note 32 at 614; Van Zimmeren, *ibid* at 354 [A royalty charging patent clearinghouse can be anti-competitive because it bundles patent pools and sets the rate of royalty to license patents in a field of endeavour].

[1131] Rai, "Regulating Scientific Research", *supra* note 19 at 112-5; Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 75-6; Gudmundur Thorisson and Lincoln D Stein, "The SNP ConsortiumWebsite: Past, Present and Future" (2003) 31 Nucleic Acids Research 124 at 124, online: NCBI <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC165499/pdf/gkg052.pdf> [The SNP consortium released 1.4 million SNPs into the public domain at the end of 2001. The SNP consortium's website is not currently operational]; Another example of an open access clearinghouse is the Structural Genomics Consortium (SGC) – see OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31-32.

SNPs, which can seriously impede genomic research.[1132] As discussed in Chapter Five, the HapMap project once enforced a restrictive database agreement to protect its data from third parties, which restricted database users' subsequent patenting and data sharing, but this strategy was heavily criticized for interfering with academic research. The SNP Consortium did not impose formal restrictions on follow-on use.[1133] Instead of requiring users to enter into contracts that restrict subsequent patenting and dissemination, the Consortium, which had the support of a significant number of genomic researchers, informally regulated subsequent use and dissemination by urging genomic researchers not to pursue patents on SNPs.[1134] Moreover, the Consortium used defensive publishing to protect the unpatented SNPs from subsequent third party patents; it established strong prior art by filing patent applications on newly discovered SNPs and waiting until the applications were published before abandoning the examination process.[1135]

Another open access example is the Biobricks Foundation's public database of patented and unpatented standard biobricks (i.e. free genetic functions). The biobricks are pledged and added to the database by volunteer contributors. The Foundation notes that while patents are the predominant form of IP rights in biotechnology, it does not expect most people to have IP rights

[1132] Van Zimmeren, *ibid*; Rai, *ibid*; Van Zimmeren et al, "A clearing house for diagnostic testing", *supra* note 950 at 354 ["[t]he goal of the non-profit SNP Consortium is to identify and collect single nucleotide polymorphisms (SNPs) and to make the SNP map of the human genome publicly available, without any proprietary rights, in order to enable further drug discovery."].

[1133] A similar example is the Neuro, a Canadian open science initiative at Mcgill University, which will publicly release all of its discoveries freely without patenting. See Andre Picard, "In Montreal, a wee opening in the closed world of science research" (20 December 2016), online: The Globe and Mail < https://www.theglobeandmail.com/opinion/in-montreal-a-wee-opening-in-the-closed-world-of-science-research/article33372907/>; "Open Science at The Neuro", online: Mcgill University < https://www.mcgill.ca/neuro/open-science>.

[1134] OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 31-2 [The Structural Genomics Consortium (SGC) adopted an "open access policy", in which the Consortium agrees that it "will not seek, nor permit its affiliated scientists or collaborators (including from industry) to seek, patents that would grant exclusive rights over its research outputs." Moreover, the SGC agreed to work with its funders to discourage subsequent users from patenting follow-on inventions].

[1135] Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 75.

in genetic engineering.[1136] Therefore, some contributions deposited into the Foundation's database will be patent protected while some will not. Anyone, including DIYers, experimenting with synthetic biology can use the biological parts in the database to create functional biological systems.[1137]

The Foundation uses two click-wrap agreements to create this database: the BioBrick User Agreement and the BioBrick Contributor Agreement.[1138] The User Agreement grants Biobrick users royalty-free, open access to the biobricks, including the right to use, improve, distribute, patent follow-on developments, and commercialize the genetic material(s) and its modified forms.[1139] It does not enforce the copyleft practice, allowing for broad downstream possibilities and wider use of the Foundation's standards instead. Thus, users are not obligated to contribute any follow-on developments back to the database but are encouraged to do so.[1140] They must also comply with additional conditions that encourage research safety and other norms in academic research: to refrain from harmful uses and to comply with applicable laws and regulations;[1141] the permission to distribute and commercialize the material in its original or modified forms (including in publications, products and other public displays of these forms) is granted subject to the condition that users make reasonable efforts to attribute the contributor (if requested) and the Foundation in their works;[1142] and do not remove any BioBrick identification tag or data included in the materials they access.[1143] According to the Contributor Agreement, contributors who deposit refined and standardized genetic material(s) must irrevocably agree not

[1136] "Frequently asked questions", online: BioBricks Foundation <https://biobricks.org/bpa/faq/>.
[1137] Kahl & Endy, *supra* note 224.
[1138] "The Biobrick Public Agreement", online: Biobricks Foundation <https://biobricks.org/bpa/>.
[1139] "The BioBrick User Agreement", ss 2(4), 3(2), online: Biobricks Foundation < https://biobricks.org/bpa/users/agreement/>; Drew Endy, "Open Technology and the BioBrick Public Agreement", presentation slides at 19.
[1140]OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science*, *supra* note 19 at 30.
[1141] "The BioBrick User Agreement", ss 4-5, *supra* note 1139; "Frequently asked questions", *supra* note 1136.
[1142] "The BioBrick User Agreement", *ibid* at s 3.
[1143] *Ibid*.

to assert any patents, other related IP rights, or any future rights against the Foundation or BioBrick users.[1144]

The Foundation acknowledges that not restricting subsequent patenting can lead to possible patent threats in the future for database users. However, the Foundation believes that such conflicts are practically unlikely to materialize because it is expensive to obtain patents, and the growing community of Biobrick users and contributors will leave fewer opportunities for patent trolling.[1145] Moreover, it encourages biobrick contributors to create prior art by disclosing known and possible future uses that can be imagined in their database submissions.[1146] Thus, the Foundation tries to supplement and protect the database using informal and formal means: encouraging synthetic biologists to openly share biobricks and defensively publish them through the database while contractually binding contributor-synthetic biologists not to enforce IP rights against other synthetic biologists using the database.

Open Source Drug Discovery (OSDD) is a research consortium in India that invites the participation of global researchers to discover drug treatments for neglected diseases through the incremental and cumulative open source development or peer production process. It administers access to a group of patents (and other research information) for this purpose. The consortium owns some of these patents, and some patents are pledged to the consortium for open source

[1144] "The BioBrick Contributor Agreement, version 1" (Jan 2010), s 3, online: Biobricks Foundation < https://biobricks.org/wp-content/themes/bbf2016/bpa-sample.php>; "Frequently asked questions", *supra* note 1136 [This includes "a user's manufacturers, distributors, customers, or anyone acting under User's authority or control". Contributors do not have to deposit genetic materials with the Foundation. The Foundation keeps a record of completed, time-stamped contributor agreements. Contributors provide the Foundation with the information about the contributed DNA sequence information to enables use. If access to physical material is necessary to re-synthesize the DNA sequence, the Foundation encourages the contributors to use public depository create public access to materials].
[1145] Endy, *supra* note 1139 at 22.
[1146] *Ibid*.

drug R&D.[1147] OSDD uses an open source-inspired patent licence (i.e. the patent permission is limited to carrying out the consortium's objectives) with the patents, which are accessible via a web portal.[1148] The OSDD Licence grants non-exclusive, royalty-free, and open access to patents and requires attribution and copyleft sharing.[1149] The patentees retain their ownership and grant licensees the right to use the patents to carry out the consortium's mandate.[1150] Any licensee is free to develop additions, modifications and improvements and to use the provided resources commercially and non-commercially, but a licensee must add any additions, modifications, and improvements back to OSDD via the web portal, supplementing the group's shared pool of resources.[1151]

These examples demonstrate that patent clearinghouses can be structured to support and stimulate open biotechnology. Open access clearinghouses can engage in open source licensing, contract-based management, defensive publishing, and informal regulation to secure open access to commons resources and protect the open and cumulative R&D process. The SNP Consortium demonstrates that sometimes public and private sector researchers are willing to cooperate to avoid the tragedy of the anticommons resulting from the development of fragmented patent rights in biotechnology. However, it is usually difficult to convince a large number of patentees in a research area to agree to collective management.[1152] Furthermore, whether a clearinghouse mechanism can improve access to a research tool protected by numerous fragmented and overlapping patents will depend on whether patentees who own the key patents of the technology

[1147] "OSDD License", ss 2.1, 3.5, 4.3, online: Open Source Drug Discovery < http://www.osdd.net/about-us/osdd-policies/access-policy>.
[1148]Masum et al, "Open Source Biotechnology Platforms for Global Health and Development: Two Case Studies", *supra* note 951 at 119; "OSDD License", *ibid*.
[1149]"OSDD License", *ibid* at ss 3.2-3.7, 4.
[1150] "OSDD License", *ibid* at s. 4.3.
[1151] "OSDD License", *ibid* at s 4.2.
[1152] Kapczynski, "Order without Intellectual Property Law", *supra* note 22 at 1077; Bennett & Boettiger, *supra* note 692 at 138.

will agree to collective patent management, which is harder when patent ownership is spread out in the public and private sectors.

6.3 Compensatory Liability Regimes

Whereas a property rule creates a right to exclude users, a liability rule creates an entitlement to be compensated upon use. A liability rule can be observed in an international treaty and some IP systems.[1153] A liability regime can also be constructed with private ordering.[1154] For example, patent pools are constructed with liability rules; a group of patentees agree to non-enforcement of their rights, and the right to use the patent pool is granted to users for a reasonable term.[1155] A liability rule was used to create access to the Cohen-Boyer patent (a critical patent on DNA manipulation techniques); it is available to any scientists who pay specified royalties.[1156] Central knowledge management with a liability rule can be organized in open biotechnology with contracts and an intermediary. It can incentivize some patentees to make their patents available for DIY bio and allow DIYers to benefit from downstream commercial users. However, the availability of patent protection for biotechnology inventions can diminish the use of a liability-

[1153] Arti Rai et al, "Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery" in van Overwalle, *Gene Patents and Collaborative Licensing Models*, *supra* note 85 at 272-3 citing Robert Merges, "Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations" (1996) 84 Cal L Rev 1293 at 1308-9, 17 USC § 115 ["a liability regime for sound recordings of copyrighted musical works"] and *International Treaty on Plant Genetic Resources for Food and Agriculture*, 3 November 2001, Res 3/2001 ["imposing a compensatory liability regime on those who make commercial applications derived from public-domain seeds"].
[1154] Rai et al, *ibid*; Jerome H Reichman, "A Compensatory Liability Regime to Promote the Exchange of Microbial Genetic Resources for Research and Benefit Sharing" in Paul F. Uhlir, ed, *Designing the Microbial Research Commons*: *Proceedings of an International Workshop* (DC: The National Academies Press, 2011) at 45; Jerome H Reichman, "Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation" (2000) 53 Vand L Rev 1743 at 1791 [Compensatory liability regimes can be implemented in legislation or through contractual regulation of resources to promote industrial applications].
[1155] *Ibid*.
[1156] *Ibid*.

based scheme in open biotechnology. A contractually-regulated liability regime works best in a field of endeavour with no patent protection or if it can replace patent protection.[1157]

Reichman proposes a compensatory liability regime to incentivize small-incremental subpatentable innovations[1158] without discouraging follow-on development. These minor inventions do not qualify for patent protection as they are below the non-obviousness threshold in patent law, but they are significant in the post-modern economy that is driven by small incremental developments in cumulative industries.[1159] Reichman notes that such small-scale inventions suffer from market failure and provide the inventors little lead time advantage because the invention's technical know-how is difficult to keep from competitors once the know-how is applied in market products since competitors can duplicate the know-how by reverse engineering with minimal costs.[1160]

Because small-incremental subpatentable inventions are important to sustain cumulative industries, these industries have pressured nations to lower the non-obviousness standard in patent law to patent these inventions despite the development of patent thickets that raise the cost of follow-on R&D.[1161] In some instances, nations tried to protect small-scale innovations from free riding by legislating sui generis property regimes, which grant legal monopolies for "integrated circuit designs, plant breeders' varieties, boat hull designs, and … computer

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[1157] *Ibid*.
[1158] Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1762 [Reichman defines subpatentable inventions as "a small grain-sized innovation, based on cumulative and sequential know-how, that falls below the prevalent standard of nonobviousness applicable under relevant domestic patent laws."].
[1159] Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1749; Reichman, "A Compensatory Liability Regime, *supra* note 1154 [e.g. "Computer programs, integrated circuit designs, biogenetically engineered organisms, new plant varieties, and… electronically generated databases"].
[1160] Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1750.
[1161] *Ibid* at 1797; Roger Collier, "Drug Patents: The Evergreening Problem" (2013) 185 CMAJ E385, online: NCBI <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/> [in drug discovery, some pharmaceutical companies try to recoup their R&D costs with evergreening where "companies patent 'new inventions' that are really just slight modifications of old drugs."].

generated databases".[1162] Reichman suspects that adding these sui generis property interests to IP law will not increase the incentives to invest and develop these inventions; the sui generis regimes will instead diminish the public domain, reducing opportunities to build incremental developments and causing innovation losses in society.[1163]

Unlike patents and copyrights, Reichman notes that different economic calculation applies to subpatentable inventions. [1164] If these inventions are within reach of a person skilled in the art, it is questionable why powerful property rights like patents should be available to incentivize their development.[1165] Reichman argues that property-based rules do a poor job of protecting the upstream inventor's incentive to invest and develop subpatentable inventions.[1166] Reichman provides three scenarios to support this argument. First, if there is no protection available for subpatentable inventions against free riding (as in a free market economy), it is risky for an inventor to develop subpatentable inventions since subsequent developers can take them without owing any obligations to the original inventor.[1167] Thus, free riding can discourage the initial investment in R&D.

Second, if there is weak protection for subpatentable inventions against free riding (which only protects against literal or near-literal copying), all follow-on developers who add value to subpatentable inventions will be free to pursue their activities.[1168] Reichman notes that this property solution does not leave the original inventor much better off than the first scenario

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[1162] Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1749-53 citing *Vessel Hull Design Protection Act*, Pub. L. No. 105—304, 112 Stat. 2905 (1998), *Data Protection Directive*, 95/46/EC, *Directive on the Legal Protection of Designs*, 98/71/EC, *International Convention for the Protection of New Varieties of Plants*, 2 December 1961, 33 UST 2703, 815 UNTS 89.
[1163] Reichman, *ibid*; Rai, "Regulating Scientific Research", *supra* note 19 at 142-3 [Rai also notes that "[t]he possibility of interest group influence in a legislative scheme of such specialized application [and the additional administration cost] would be quite significant"].
[1164] Reichman, *ibid* at 1756.
[1165] *Ibid*.
[1166] *Ibid* at 1763-71.
[1167] *Ibid*.
[1168] *Ibid*.

with no protection for free riding.[1169] Follow-on developers can use upstream subpatentable inventions for free without owing royalties as long as they add value to them; upstream inventors may be undercompensated as they cannot share in downstream commercial successes. Thus, this property solution may not create sufficient incentive to develop upstream inventions in cumulative technology.

In the third scenario, the original inventor of a subpatentable invention is granted a strong monopoly right to exclude unauthorized free riding in downstream inventions.[1170] Unlike the above, this strong, patent-like protection can discourage investment in downstream development because downstream commercial developers need to expand licensing and transaction costs or defend their infringement against the upstream inventor. If they choose to license before commercializing downstream inventions, downstream developers incur licensing and transaction costs. They also risk exposing any know-how and business secrets to the upstream inventor during licensing negotiations, who might be a business competitor. If they do not license, they risk incurring settlement costs or the cost of patent litigation and damages. Attracting a patent infringement lawsuit can also harm the downstream developer's business reputation. The risk of patent infringement can encourage inventors to invest in a novel invention rather than improving someone else's invention. The underdevelopment in the downstream market may be avoided if downstream developers can generally disregard property rights in a field of endeavour, but this practice threatens the integrity of this property regime and weakens the incentive for upstream inventors. Reichman notes that even if an independent discovery is excused, downstream developers are not much better off because they will need to incur the wasteful cost of repeating the upstream R&D in addition to the costs of downstream development and commercialization.

[1169] *Ibid*.
[1170] *Ibid*.

Reichman states that all three scenarios offer unsatisfactory and flawed economic outcomes for subpatentable inventions and do not maximize social benefit. Reichman notes that property rules are unsatisfactory because they focus on rewarding individual achievements while ignoring the community members who have added to the collective knowledge available to future developers.[1171] Property rules work well only if the value of the property exchanged is known in advance but they fail when no one knows the true value of the exchanged technology or information.[1172]

Thus, Reichman proposes a compensatory liability regime for subpatentable inventions, which relies on contractual regulation and a trusted intermediary to oversee information exchange. Upstream inventors deposit their inventions with the intermediary allowing downstream inventors to use them freely for any purpose without requiring individual permission, and in exchange, upstream inventors are entitled to share in the commercial successes of the downstream inventors (e.g. based on a fixed set of modest percentage royalties).[1173] The liability rule creates an automatic licence to use the deposited inventions for any purpose and a right of compensation for upstream depositors, but it does not include a right to exclude follow-on users like a property regime.[1174]

The trusted intermediary is responsible for enforcing the benefit-sharing contracts and providing infrastructure and services for resource sharing, such as maintaining a registry of commons resources, defining governance rules, and offering mediation and dispute resolution to

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[1171] *Ibid* at 1773.
[1172] *Ibid*; Reichman, "A Compensatory Liability Regime", *supra* note 1154 at 47 citing T Lewis & Jerome H Reichman, "Using liability rules to stimulate local innovation in developing countries: application to traditional knowledge" in KE Maskus & JH Reichman, eds, *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (Cambridge U Press, 2005).
[1173] Reichman, "A Compensatory Liability Regime", *ibid* at 45; Reichman, "Of Green Tulips and Legal Kudzu", *supra* note 1154 at 1777.
[1174] Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1794.

smooth out disputes that can arise between upstream and downstream inventors.[1175] This proposal requires downstream developers to pay for the intermediary's costs.[1176] If used in biotechnology, this proposed scheme can include attribution requirements and additional controls to oversee the use of upstream inventors' physical samples.[1177]

Reichman suggests setting a time limitation on the downstream developers' equitable sharing responsibility to avoid over-compensating upstream inventors.[1178] A time limitation would be like a natural lead time advantage an upstream inventor would have over competitors in the marketplace but does not actually exist when the invention is easily reverse-engineered. While the compensatory liability rule is in effect, the upstream inventor is entitled to be compensated for downstream commercial uses, but when it expires, the upstream invention will fall into the public domain.

The economic rationale for compensatory liability regimes is that upstream inventors would be motivated to deposit their invention into the semi-commons because they can encourage multiple downstream developments and commercialization and share in downstream commercial successes.[1179] This approach can yield more benefit for upstream inventors than when they work alone.[1180] Reichman notes that if upstream inventors already know the commercial value and potential uses of their invention, they will likely not join the contractually-regulated semi-commons because they can try to maximize their gain by holding out for higher royalties.[1181] The proposed compensatory liability regime promotes technology interoperability better than open source licensing because the contractual semi-commons only requires benefit-

[1175] Reichman, "A Compensatory Liability Regime", *supra* note 1154 at 45, 47; Reichman, "Of Green Tulips and Legal Kudzu", *ibid* at 1781
[1176] Reichman, "A Compensatory Liability Regime", *ibid* at 47.
[1177] *Ibid* at 45-6.
[1178] Reichman, "Of Green Tulips and Legal Kudzu", *supra* note 1154 at 1780-1.
[1179] Reichman, "A Compensatory Liability Regime", *supra* note 1154 at 46.
[1180] *Ibid*.
[1181] *Ibid* at 45.

sharing rather than multiple open source standards, which can lead to licence proliferation and incompatibility.[1182] The proposed strategy can remove the pressures in nations to lower the non-obviousness standard in patent law to extend patent protection to small-scale subpatentable inventions or create sui generis IP protection.[1183]

Central management of upstream research resources that contractually enforce benefit-sharing can aid open biotechnology by increasing available upstream research resources and removing individual licensing. Existing biotechnology patentees with defensive patents or patents that do not generate revenues can join a compensatory liability regime to stimulate downstream uses of their patents. Like patent clearinghouses, this strategy benefits patentees by making their patents more visible to potential users. The liability rule benefits both non-commercially and commercially motivated participants in social production: both can use the deposited upstream resources for free without incurring transaction and licensing costs. Only commercially motivated participants would be responsible for equitably compensating upstream inventors when there is a profit. Moreover, DIY scientists and community projects can publish and create access to privately funded, unpatented discoveries through a contractual compensatory liability regime, which allows them to benefit from downstream commercial users.

However, the availability of patent protection for biotechnology inventions can disrupt a contractual liability-based regime in biotechnology because a third party can patent and control unpatented open inventions. Reichman's compensatory liability regime can replace property rules and be used in situations where property rules do not exist.[1184] Open exchanges of innovative ideas and R&D outputs in DIY bio allow anyone to observe these activities and learn from them. As discussed in Chapter Five, open innovation communities can struggle to patent

[1182] Reichman, "Of Green Tulips and Legal Kudzu", *supra* note 1154 at 1796-7.
[1183] *Ibid*.
[1184] *Ibid.*

their inventions from open and cumulative development. Nonetheless, third parties can develop, patent and commercialize innovative ideas and unprotected inventions from open projects before anyone else without agreeing to equitable compensation, and they can also use patents to block competitors from practicing these inventions. Such opportunistic patentees interfere with open R&D and the operation of contractual compensatory liability regimes. Moreover, a compensatory liability regime cannot improve access to upstream research resources when a research area suffers from fragmented and overlapping patents. As discussed in the previous section, it may be difficult to convince many patentees to accept benefit sharing and agree not to enforce patents to improve access to patented inventions.

6.4 Discussion: Patent Exceptions

Patent law offers protection for biotechnology inventions.[1185] However, patent law poorly deals with cumulative technologies.[1186] The development of patent proliferation in biotechnology creates access barriers to upstream research and the risk of inadvertent patent infringement for researchers. DIYers can also experience difficulty inventing around patents, adding to off-patent technologies, accessing significant upstream research tools and equipment, and exploring downstream commercial opportunities. To avoid patent conflicts, open scientists and open innovation communities have practiced alternative knowledge management.

This thesis considered alternative knowledge management strategies that can improve access to patentable research resources and reduce patent risks for DIY bio participants. Alternative knowledge management strategies can combine defensive publishing and patenting, private ordering, central resource management and informal regulation to facilitate the free

[1185]Bessen & Meurer, *Patent Failure*, *supra* note 418; Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403 at 1243; O'Rourke, *supra* note 338 at 1237; Heller & Eisenberg, *supra* note 298 at 699-700.
[1186] Rai, "Regulating Scientific Research", *supra* note 19 at 79.

exchange of information and knowledge. Nonetheless, these protection measures can add costs to open R&D and still expose open scientists to patent conflicts in biotechnology. Defensive publishing to establish prior art may not always bar subsequent patent applications of the same invention. While defensive patents are good bargaining tools to use against third party patentees, as discussed in Chapter Five, defensive patenting is expensive, and it may be difficult to establish the patent eligibility of open and collaborative inventions.

Furthermore, open source patent licensees can infringe overlapping, follow-on third party patents. Open source licensing is designed to transmit the licensed subject matter between users; it may not be appropriate for complex biotechnology inventions or living organisms. A contract-based regulation of unpatented inventions may be inadequate when people can easily replicate the inventions. Alternative knowledge management strategies, such as open source licensing, patent clearinghouses and compensatory liability regimes, also need the consent and cooperation of existing patentees to improve access to patented research resources and to avoid fragmented and overlapping patent rights. Although alternative knowledge management may improve access to upstream patents and help DIY bio participants avoid patent conflicts, these solutions do not remove possible patent interferences in DIY bio.

Governments have broad powers to encourage public goods and to deal with market failures.[1187] Governments can design and administer IP law to incentivize innovation and to deter free riding.[1188] Scholars agree that a broader patent exception is needed to balance the patent incentives in light of new developments and theories in patent law, such as licensing failures due to strategic uses of patent rights in cumulative technology and the development of the anticommons, inadvertent infringement by inventors in concurrent development, and the

[1187] Lee, *supra* note 752 at 284-5 citing Burton A Weisbrod, *The Nonprofit Economy* (Cambridge, MA: Harvard University Press, 1988) and Henry B Hansmann, "The Role of Nonprofit Enterpreise" (1980) 89 Yale LJ 835.
[1188] *Ibid*.

presence of an alternative innovation paradigm.[1189] Broader research or experimental use exceptions in domestic patent law can reduce the strength of patent rights, which will discourage unnecessary patenting and reduce the complexity of the biotechnology patent landscape. Broader research exceptions may also encourage patentees to cooperate and reach licensing agreements with patent users rather than hold out unreasonably.[1190] Although legislative actions can take time,[1191] legislative reform "has the advantage of being highly authoritative, clear, and universally enforceable".[1192]

In recent years, there have been more discussions about expanding research or experimental use exceptions in patent law to improve access to upstream patents and stimulate improvements and progress.[1193] As discussed in Chapter Three, research exceptions in patent law improve access to patents by excusing some infringing patent use in research. Many jurisdictions use the following criteria to define the breadth of research exceptions in domestic patent law: whether the exception extends to research *on* a patent and *with* a patent and whether it is available for non-commercial or commercial research purposes.[1194] Research or experimental use

[1189] O'Rourke, *supra* note 338 at 1193, 1204; Strandburg, "Patent Fair Use 2.0", *supra* note 281 at 293-299; Asay, "Enabling Patentless Innovation", *supra* note 81.
[1190] O'Rourke, *ibid* at 1238.
[1191] Piper, *supra* note 316 at 51-2; Dan L Burk & Tarleton Gillespie, "Autonomy and Morality in DRM and Anti-Circumvention Law" (2006) 4(2) TripleC 239 ["While we have mechanisms for making such changes, through legislation by our political representatives, we know this system often suffers from calcified unresponsiveness, bureaucratic inertia, and the powerful bias of moneyed interests."].
[1192] Piper, *ibid*.
[1193] Piper, *ibid* at 49 citing Canadian Biotechnology Advisory Committee, "Patenting of higher life forms and related issues: report to the Government of Canada Biotechnology Ministerial Coordinating Committee (2002), online: Government of Canada < http://www.ic.gc/eic/site/cbac-cccb.nsflvwapj/E980 IC IntelProp e.pdf/$FILE/E980 IC IntelProp e.pdf> at 15; Ontario Ministry of Health, "Genetics, Testing & Gene Patenting: Charting new Territory in Healthcare" (2002), online: Government of Canada <http://www.health.gov.on.ca/english/public/pub/ministry reports/geneticsrep02/genetics.html> at 88; Rai & Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine", *supra* note 336 at 299 citing Janice M Mueller, "No 'Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools" (2009) 76 Wash L Rev 1; O'Rourke, *supra* note 338; Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403; Short, "A Research Exemption for the 21st Century", *supra* note 579; Dreyfuss, "Varying the Course", *supra* note 465; Strandburg, "Patent Fair Use 2.0", *supra* note 281.
[1194] Short, *ibid* at 16; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 39-40.

exceptions in patent law are not always present in domestic patent law, and the scope of the exception can vary from nation to nation.[1195] The research exception in many nations often does not extend to patented research tools.[1196] Also, there is no agreement between nations on excusing commercially motivated research use.[1197]

Before the latest legislative amendment, Canadian researchers enjoyed unauthorized patent use for regulatory use[1198] and an experimental use exception in common law for non-commercial patent use.[1199] In *Smith Kline & French Inter-American Corp. v. Micro Chemicals Ltd.*, the Supreme Court of Canada held that exempted uses are for *bona fide* experiments and include making improvements of a patented invention and experiments to see if improvements can be made.[1200] The experiment ceases to be a *bona fide* experimentation when "experimenting is no longer 'reasonable and necessary' or the main purpose of the activity changes from experimental."[1201] Also, research "on" a patent, such as testing the patent claims and verifying the adequacy of the patent disclosure, is not an infringement,[1202] which is consistent with public

[1195] Van Zimmeren, "Clearinghouse Mechanisms", *supra* note 85 at 64; Gold & Joly, *ibid*; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 412 [For instance, European nations have similar research exceptions but national courts have given divergent interpretations. Also, there is no consensus in European nations over whether research exception should only apply for non-commercial research].
[1196] Van Zimmeren, "Clearinghouse Mechanisms", *ibid*; Gold & Joly, *ibid* at 30, 39-40 citing Belgian *Patent Act*, art 28(1)(b) (enacted on April 25, 2005) and *Dablehv v Ontario Hydro,* [1996] FC 751, 781-2; *Micro Chemicals* v *Smith Kline, supra* note 565 at 519-20.
[1197] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 412.
[1198] *Patent Act, supra* note 303, s 55.2(1) ["It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."]
[1199] *Micro Chemicals* v *Smith Kline, supra* note 565 at 518 - 520; *Cochlear Corp. v Cosem Neurostim Ltée* (1995), 64 C.P.R. (3d) 10 at 44; *Merck & Co Inc v Apotex Inc*, 282 FTR 161; 53 CPR (4th) 1; [2006] FCJ No 671 (QL), 2006 FC 524 (CanLII) at paras 159-163; *Merck & Co v Apotex Inc*, [2007] 3 F.C.A. 588 at para 109.
[1200] *Micro Chemicals*, *ibid* at 519 citing *Frearson v Loe* (1878), 9 Ch D 48 and *Proctor v Bayley & Son*, (1889), 6 RPC 106 at 109; *Merck & Co Inc v Apotex Inc*, *ibid* at 161.
[1201] Vaver, *Intellectual Property Law*, *supra* note 68 at 327 citing *Canadian Patent Scaffolding Co Ltd v Delzotto Enterprises Ltd*. (1978), 42 CPR (2d) 7, *Longworth v Emerton* (1951), 83 CLR 539 at 549-51 (Austl HC).
[1202] *Merck & Co Inc v Apotex Inc*, *supra* note 1199 at 161; Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1074-5 citing *Whittemore v Cutter*, 29 F Cases 1120 (CC D Mass 1813).

policy that this type of research use should be permitted so that patents are not awarded to fraudulent or erroneous claims.[1203]

The Canadian government recently added a statutory research exception under section 55.3(1) of the Canadian *Patent Act*.[1204] The new section exempts "[a]n act committed for the purpose of experimentation relating to the subject matter of a patent".[1205] The expression "relating to the subject matter" is also used in the German and the UK patent legislation, and the expression indicates research use "on" a patent rather than 'with' a patent.[1206] Only in rare cases does a research exception in national patent law permits the use of patented research tools or research "with" a patent (e.g. Belgium) even though some suggest that there are reasons to excuse the use of patented research tools.[1207]

Short notes that although it is generally accepted that patents are important in pharmaceutical industries due to the significant private investment needed to produce drugs, companies pursuing drug discovery also enjoy a broad research exception in the United States.[1208] Short argues that a broad research exception should not be denied in other industries

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[1203]Eisenberg, "Patents and the Progress of Science", *ibid*.

[1204] Canada Bill C-86, *supra* note 589; House of Commons Debates, 42nd Parl, 1st Sess, No 359 (27 November 2018) at 24058. [In 2018, several amendments were adopted into the Canadian *Patent Act*. The latest patent reform aims to balance patentee's economic rights and the public interest by increasing users' rights, incentivizing improvements or subsequent development, and discouraging patent trolls and abuse of patents. Other amendments include expanding the scope of prior user rights, binding licensing commitment of standard-essential patents to subsequent patentees, creating regulation to set requirements for demand letters relating to patents, and making prosecution history relevant to claim construction].

[1205] *Patent Act, supra* note 303, ss 55.3(1)&(2) [s. 55.3(2) states that the Governor in Council will make regulations for a list of factors courts can apply to determine when research use is excepted and the circumstances in which the exception should apply. These can further clarify the scope of the research exception in Canadian patent law].

[1206] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 40 citing German *Patent Act 1981*, s 11.2 and UK *1977 Patents Act*, s 60 (5) b); IPIC, "Recommendations on possible amendments to bill c-86" (27 November 2018) at 14 [IPIC notes that s. 55.3's "relating to the subject matter" would be interpreted as excluding experimental exception to research tool patents and recommended that the words be changed to "directed to the claimed subject matter"].

[1207] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 39-40; Gold & Joly, *ibid* at 30, 39 citing Belgian *Patent Act*, *supra* note 1195, art 28(1)(b).

[1208]Short, "A Research Exemption for the 21st Century", *supra* note 579 at 9-10 citing *Hatch-Waxman Act* § 271(e)(1), *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193, 202 (2005) [The SCOTUS interpreted the § 271(e)(1) - the FDA safe harbour provision which exempts patents use to perform research and tests to prepare for

where patent rights matter much less, and a broad exception has a far less significant effect on the patent incentives.[1209] Furthermore, scholars argue that the widely used criteria to limit the scope of research exceptions in patent law (i.e. research tool patents and patent use in commercially motivated research) are inappropriate, unproven, and do not adequately balance the public and private interests in patent law today.

Broader research exceptions in patent law improve access to patents, which consequently can help open science and open innovation communities contribute to the overall scientific and technological progress in society alongside proprietary R&D. Improving access to patents, including patented research tools, can encourage more participation in open R&D in biotechnology and reduce participants' perceived or actual patent risks. Protection from third party patents in open R&D can encourage more people to invest in these activities.[1210]

Some suggest that ex-post doctrines in patent law, such as patent exceptions and defences that are applied post-infringement, are better for dealing with rapid, unpredictable and constantly changing technologies, such as biotechnology, than ex-ante doctrines in patent law (i.e. doctrines that apply at the outset to determine an invention's patent eligibility).[1211] Ex-post doctrines are appropriate because courts can carefully balance competing interests and address any underlying public policy concerns raised from the infringement. When technology evolves rapidly, new problems can surface, which are not addressed through ex-ante doctrines.[1212] Adjusting the ex-ante doctrines in patent law to reduce the strength of patent rights and to avoid the excessive

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regulatory approval - broadly by holding that "reasonably related to the development and submission of information" can include "(1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA."The exception applies to exploratory research and early-stage experimentation."].

[1209] Short, *ibid* at 4, 17.

[1210] Strandburg, "Patent Fair Use 2.0", *supra* note 281 at 267.

[1211] Strandburg, *ibid* at 274; Rai, "Regulating Scientific Research", *supra* note 19 at 142.

[1212] *Ibid*.

reach of patent rights in an industry may not accommodate the needs of other industries because patent law is mostly a one-size-fits-all system that applies to all industries.[1213]

As noted above, many nations do not extend a research exception to patented research tools. It has been argued that extending the research exception to research tool patents can undermine the patent incentive to invent research tools[1214] and that broadening the exception in this way is unnecessary as patent owners will likely offer to license to research tool users to recoup the R&D costs and to benefit from the patent monopoly.[1215] However, the latter argument does not consider the possibility of market failures from the development of the anticommons or strategic patent practices, such as patent trolling.

Some argue that public benefit from creating wide access to research tools will often trump the need to protect the patent incentive to encourage the development of research tools.[1216] Patent access barriers on research tools, which can have broad uses, can significantly hinder scientific and technological progress and development. Some also argue that broader research exceptions would not undermine the patent incentive for all types of research tools.[1217] Limiting research exceptions in patent law to use *on* patents is "based on the unproven premise that allowing researchers to make or use an invention for experimentation, without penalty, would significantly undermine the incentives to develop research tools in the first place. However, this cannot be true for all types of research tools".[1218] A research tool is a type of user innovation, which means that researchers are motivated to invent it in order to carry out their own research,

[1213] Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403 at 1252; Piper, *supra* note 316 at 43; Rai, *ibid* at 142-3.
[1214] Short, "A Research Exemption for the 21st Century", *supra* note 579 at 10; Dreyfuss, "Varying the Course", *supra* note 465 at 4-5; Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 57.
[1215] Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1074.
[1216] Dreyfuss, "Does IP Need IP", *supra* note 65 at 1468.
[1217] Short, "A Research Exemption for the 21st Century", *supra* note 579 at 10.
[1218] *Ibid*.

not always from the patent incentive.[1219] Academic researchers frequently ignore patents for inexpensive research tools with small innovation costs (e.g. ESTs and SNPs), and these inventions likely do not depend on the patent incentives.[1220] If research tool patents were regularly enforced, they would impose a significant cost on scientific progress.[1221] There is insufficient evidence to presume that the presence of a research exception for easily replicable research tools would stop research institutions from commoditizing them.[1222] If some research tools or equipment do depend on the patent incentive, any diminished incentive to invent due to a broad research exception can be supplemented in other ways, such as government funding to create them.[1223]

Furthermore, some argue that a research exception is justified even for sophisticated and expensive research tools and equipment that cannot be easily replicated and have high innovation costs (e.g. laboratory machines and microscopes).[1224] The research exception does not prohibit their sale; it would only place a price ceiling for research tools and equipment in the marketplace.[1225] Sellers can still charge a price that is not higher than what it would cost individuals to reproduce them.[1226] Thus, society benefits in the long run from broader research exceptions in patent law that excuse some infringing uses of research tool patents.

Another criterion that often limits the scope of research exceptions is whether infringing research use is non-commercially or commercially motivated.[1227] Some argue that non-

[1219] Dreyfuss, "Does IP Need IP", *supra* note 65 at 1468; Hope, *Open Source Biotechnology*, *supra* note 395 at 177.
[1220] Rai, "Regulating Scientific Research", *supra* note 19 at 140.
[1221] *Ibid*.
[1222] Short, "A Research Exemption for the 21st Century", *supra* note 579 at 10-11.
[1223] *Ibid*.
[1224] *Ibid*.
[1225] *Ibid*.
[1226] *Ibid*.
[1227] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 412. [A similar debate is also made about using text and data mining tools, which enable people to turn the huge size of the content on the Internet into something useful. In reference to the non-commercial and commercial use distinction for the proposed text and

commercial or commercial motivation should not be a factor determining whether research or experimental use of a patent should be excused in patent law.[1228] As discussed in Chapter Four, social production in biotechnology encourages R&D with non-commercial, commercial and mixed goals. Academic research can also have mixed goals.[1229] A research exception that extends to both non-commercial and commercially motivated R&D can encourage non-commercially and commercially motivated individuals to collaborate together in open innovation.[1230] It would also encourage non-commercial research to be extended for commercial development.[1231]

Some suggest that a research exception should excuse research use for both non-commercial and commercial purposes, but an additional criterion can be used to determine whether patent infringement occurred under a research exception to avoid diminishing the patentees' incentives: how far the potential infringer's research is from the commercialization or the length of time before the innovation is brought to the market.[1232] This would allow both non-commercial and commercially motivated researchers to invest in and pursue early stage projects that can stimulate numerous marketable inventions, whereas inventions with narrow and specific uses are not given broad access under research exceptions. On the other hand, this approach does

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data mining exception in EU copyright law, commentators have argued that restricting commercial entities from using text and data mining tools online is an unjustified limitation as these are tools that must be available in order to create new services, information and other benefits from published contents on the Internet. Also, it contrasts with the fundamental freedom of expression and freedom to conduct a business. See European Commission, "Proposal for a Directive of the European Parliament and of the Council on copyright in the Digital Single Market", COM(2016)593 (14 September 2016), online: <https://ec.europa.eu/digital-single-market/en/news/proposal-directive-european-parliament-and-council-copyright-digital-single-market>; Thomas Margoni & Martin, "The Text and Data Mining exception in the Proposal for a Directive on Copyright in the Digital Single Market: Why is it not what EU copyright law needs" (25 April 2018), online: CREATE <https://www.create.ac.uk/blog/2018/04/25/why-tdm-exception-copyright-directive-digital-single-market-not-what-eu-copyright-needs/ >].

[1228] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 414; Rai & Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine", *supra* note 336.

[1229] Van Zimmeren & van Overwalle, *ibid*.

[1230] Van Zimmeren & van Overwalle, *ibid* at 412-4.

[1231] *Ibid*.

[1232] *Ibid*; Rai, "Regulating Scientific Research", *supra* note 19.

not excuse research tool patent use when research tools are sold in markets, which does not guarantee wide access to research tools.[1233] This approach also may not sufficiently stimulate modifications and improvements from a variety of downstream developers.

Another suggestion is that if commercial research use of a patent is sometimes excused, the patentees' incentives can be protected by incorporating a liability rule (or a compulsory licensing rule), which requires infringers to pay a reasonable royalty.[1234] Similarly, others have suggested that research tool patent use should be excused but require unauthorized users to pay a reasonable royalty to the patentees to protect the patent incentives to invent research tools.[1235] For example, a patentee may be allowed to collect a reasonable royalty from unauthorized patent users when they enter the marketplace after benefiting from unauthorized patent use, such as developing an infringing improvement, an infringing work-around, or a non-infringing product produced with the patent.[1236] It is also suggested that a reasonable royalty payment for excused patent infringement in patent law can discourage strategic patent enforcement and encourage the industries to establish private solutions (e.g. standard licensing and patent pooling) that are more efficient than going through litigation to collect a reasonable royalty payment after infringement occurs.[1237] Charging a reasonable royalty payment upon commercialization can also increase innovation because a broader research use exception allows all types of subsequent inventors to tinker with existing patents without worrying about strategic patent enforcement in the future.[1238]

[1233] Short, "A Research Exemption for the 21st Century", *supra* note 579; Van Zimmeren & van Overwalle, *ibid*.
[1234]Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1075-1078; O'Rourke, *supra* note 338 at 1203; Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception", *supra* note 1193; Short, "A Research Exemption for the 21st Century", *supra* note 579 at 11; Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560.
[1235]Mueller, *ibid*.
[1236]Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1075-1078.
[1237] *Ibid*.
[1238] *Ibid*; Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception", *supra* note 1193; Short, "A Research Exemption for the 21st Century", *supra* note 579 at 10-12.

Some note that this proposal is inappropriate because it encourages patentees to pursue expensive litigation to receive payment from patent users,[1239] and it may be difficult to determine a reasonable royalty rate in some cases.[1240] On the other hand, the litigation costs can decline as a body of precedent is created over time.[1241] Some suggest that requiring reasonable royalty upon infringement may exceed the TRIPS requirement and interfere with patentees' rights.[1242] It can diminish the patentees' incentive to innovate and their ability to exploit patents. Moreover, patentees may feel a loss of control in their right to exploit their invention in the marketplace. They cannot seek injunctions against potential competitors, and they have to accept what is deemed a reasonable royalty payment by a decision-maker.

Alternatively, some scholars advocate altogether abandoning the research exception and creating a broad and flexible patent exception that weighs multiple factors in determining patent infringement similar to the fair use or fair dealing defence in copyright law.[1243] This approach would not limit the scope of an exception in patent law by arbitrarily blocking access to research tool patents or distinguishing between non-commercial and commercial use. This approach also removes the difficult task of defining what an exempted research or experimental activity is.[1244] Rather than relying on restrictive and unproven criteria to determine the scope of an exception, possible infringement would be analyzed and excused on a case-by-case basis based on the context of patent use. Multiple factors would be used to weigh the costs and benefits of patenting. Scholars identified several factors that could be used to excuse patent infringement in circumstances where patents fail to adequately balance the patentees' incentives against public

[1239] *Ibid*.
[1240] Rai, "Regulating Scientific Research", *supra* note 19 at 142; Short, *ibid* [A possible issue with this approach is that turning patent infringement into a liability rule "would likely exacerbate, rising litigation costs that effectively tax public and private sector research."].
[1241] O'Rourke, *supra* note 338 at 1209, 1234–35, 1243-5.
[1242] *Ibid*; Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1078.
[1243] O'Rourke, *ibid*; Strandburg, "Patent Fair Use 2.0", *supra* note 281.
[1244] O'Rourke, *ibid*.

benefit from patents: whether infringing use substantially advances prior art, whether there is a market failure blocking patent licensing,[1245] whether social benefit gained from the infringing use outweighs decreased patentee's incentives,[1246] whether it was an innocent inadvertent infringement by an independent inventor,[1247] and whether an alternative innovation paradigm such as open innovation is present that reduces the need for the patent incentives.[1248] While a flexible patent exception may encourage litigation due to uncertainty at first, scholars note that litigation will likely decline as a body of precedent is created over time.[1249]

As discussed in Chapter Three, patent law exceptions in WTO nations must comply with the TRIPS requirement.[1250] That is, a patent law exception to encourage research and development must be "limited to certain uses, that it does not conflict with the normal exploitation of patents and public policies such as the advancement of science and technology".[1251] Proposals to expand research exceptions in patent law suggest different approaches for balancing the patentee's incentives and the overall public benefit gained from exempted research uses.[1252] In her proposal to create a flexible, multi-factor, fair use-like exception in patent law, O'Rourke states that Article 8 of TRIPS is in favour of allowing socially

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[1245] E.g. High transaction costs from the development of an anticommons, positive externalities, or patentee's refusal to license based on an anti-patent intent such as strategic bargaining or to deter others from verifying patent's functionality. See O'Rourke, *ibid* at 1207, 1236.

[1246] O'Rourke, *ibid* at 1193, 1204; Strandburg, "Patent fair use 2.0", *supra* note 281 at 293-299 [Strandburg notes that there are three instances where unauthorized patent use should be exempted because it is socially desirable to do so: excusable licensing failure, situations involving large improvements, and the presence of alternative, non-patent motivated innovation paradigms]; Rai, "Regulating Scientific Research", *supra* note 19 at 142 [The notion of excusing an infringer who made a very substantial change is also recognized under the U.S. reverse doctrine of equivalents].

[1247] Strandburg, *ibid* at 299-300; Asay, "Enabling Patentless Innovation", *supra* note 81.

[1248] Strandburg, *ibid*.

[1249] O'Rourke, *supra* note 338 at 1209, 1234–35, 1243-5; Eisenberg, "Patents and the Progress of Science", *supra* note 578 at 1078.

[1250] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 38-39; Panel Report, *Canada-Patent Protection of Pharmaceutical Products* (2000), *supra* note 569; Advisory Council on Intellectual Property, Australian Government, *Patents and Experimental Use* (October 2005) at 28.

[1251] TRIPS, *supra* note 306, art 30; *Ibid*; O'Rourke, *supra* note 338 at 1201-2.

[1252] *Supra* note 1193.

beneficial patent infringements to be exempted[1253] and the language of Article 30 of TRIPS is similar to Article 13, which some argue permits nations to create copyright fair use.[1254]

Inadequate and outdated patent law exceptions leave little room to conduct R&D in research areas with patent proliferation.[1255] Moreover, in the information era, a limited research or experimental use exception that varies from jurisdiction to jurisdiction in nature and scope offers limited benefit in open innovation, which encourages multiple-jurisdictional collaboration.[1256] Broader patent exceptions in nations can increase legal certainty for all types of researchers and developers.[1257]

6.5 Conclusion

After examining open source licensing in Chapter Five, this chapter examined other alternative knowledge management strategies that can be utilized in open R&D environments to facilitate access to upstream resources and stimulate downstream R&D. As a resource management solution, information clearinghouses can provide DIYers and other scientists with the information to help with patent navigation in fields of endeavour. Clearinghouses can offer central management of a group of patents and other research resources as an intermediary between their owners and users, lowering transaction costs. It also considered compensatory liability regimes that incentivize downstream developments by entitling upstream inventors to be equitably compensated by downstream users when they see a profit. Alternative knowledge

[1253] Article 8 of TRIPS, *supra* note 306, allows nations "to adopt measures necessary for public health and nutrition, and to promote the public interest in sectors of vital importance… provided that such measures are consistent with [TRIPS]" Also, the second part of the provision states that nations can adopt appropriate measures "may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affecting the international transfer of technology."
[1254] O'Rourke, *supra* note 338 at 1201-2; TRIPS, *ibid* at arts 8, 13, 30.
[1255] Dreyfuss, "Varying the Course in Patenting Genetic Material", *supra* note 465 at 2.
[1256] Van Zimmeren & van Overwalle, "False Sense of Security", *supra* note 560 at 412.
[1257] Gold & Joly, "The Patent System and Research Freedom", *supra* note 331 at 47; Osborn, Pearce & Haselhuhn, "A Case for Weakening Patent Rights", *supra* note 403.

management strategies require biotechnology patentees' cooperation to make existing patents available for DIY bio. Fragmented and overlapping patents and strategic third party patentees can still discourage and interfere with open R&D in DIY bio.

DIY bio is non-traditional, technology-enhanced open and cooperative R&D in biotechnology. These activities contribute to scientific and technological progress and encourage entrepreneurship in society. Nations can stimulate the social production of biotechnology by improving access to upstream research resources and offering protection from unnecessary patent interferences in open R&D. It has been suggested that broader exceptions in patent law can discourage unnecessary patenting and strategic use of patents and reduce inadvertent infringement in open science and open innovation. Scholars have argued that many nations continue to use questionable and outdated criteria to limit the scope of a research or experimental use exception in patent law. Nations can encourage innovation from various researchers and developers, including DIY scientists, when they modernize patent exceptions to reflect the developments in the last several decades, such as highly cumulative technologies, opportunistic and abusive patent use, and alternative innovation environments.

Concluding Remarks

DIY bio, which follows the tradition of open science, encourages participants to cooperate and share ideas, experiments and research resources in biotechnology. DIY scientists add to cumulative biotechnology R&D, working alongside public and private sector researchers who use patents to protect their research. DIY scientists need adequate access to upstream knowledge and research tools to solve real-world problems using biotechnology. When DIY scientists freely release new scientific discoveries over the Internet, they can encourage broad dissemination and reuse.

Although the DIY bio community practices open R&D, patent rights in biotechnology can interfere with their activities. It is difficult to avoid inadvertent patent infringement when there is a patent proliferation in biotechnology with fragmented and overlapping patents. DIY bio projects can also come under third party patent control when subsequent patents develop in a research area. It is challenging to control inventions in the public domain and protect ongoing access to them for subsequent open R&D. Moreover, the patent proliferation can discourage some from contributing to DIY bio and create patent risks for DIY scientists with commercial goals.

Alternative knowledge management is used in commons-based development to supplement the public domain while protecting the commons from IP owners' control. This thesis explored open source patent licensing, clearinghouses and compensatory liability regimes to improve access to upstream patents in biotechnology and to protect open access to DIY bio inventions. Biotechnology supports multiple industries, and there are various types of patentable inventions in biotechnology. Different knowledge management strategies may be appropriate in

different biotechnology research areas (e.g. complex technologies, fragmented patent rights, and access to patent protection).

DIY bio is a rapidly growing, open R&D environment. Alternative knowledge management strategies can reduce patent threats against DIY bio contributors and users. Nonetheless, they may not remove all potential patent threats in DIY bio due to patent law's treatment of cumulative biotechnology and possible strategic patent practices that encroach on DIY bio. The practical effects of an alternative knowledge management strategy in DIY bio to discourage patent threats against DIY scientists will also depend on the cooperation of other scientists and patentees in biotechnology (and their patent practices in a research area). Future research can explore DIY scientists' subsequent participation in patent law to assess the effects of biotechnology patents in DIY bio.

Bibliography

Legislation & Treaties

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 (entered into force 1 January 1995) [TRIPS].

Berne Convention for the Protection of Literary and Artistic Works, 9 September 1886, 828 UNTS 221.

Canada Bill C-86, *A second Act to implement certain provisions of the budget tabled in Parliament on February 27, 2018 and other measures*, 1st Sess, 42nd Parl, 2019, s 193 (assented to 13 December 2018).

Copyright Act, RS C 1985, c C-42.

Data Protection Directive, Directive 95/46/EC.

Patent Act, RS C 1985, c P-4.

Patent Act, 35 USC (2007).

Patent Cooperation Treaty, 19 June 1970, TIAS 8733, 28 UST 7645, 9 ILM 978.

WIPO Copyright Treaty, Dec. 20, 1996, S Treaty Doc. No. 105-17 (1997); 2186 UNTS 121; 36 ILM 65 (1997).

Case Law: Canada

Amazon.com, Inc. v Canada (Attorney General) (2010), 2010 FC 1011.

AbbVie Biotechnology Ltd v Canada (Attorney General), 2014 FC 1251.

Apotex v Sanofi-Synthelabo Canada Inc, 2008 SCC 61, [2008] 3 SCR 265.

Apotex Ltd. v Wellcome Foundation, [2002] 4 SCR 153.

Canada (Attorney General) v Amazon.com Inc, 2011 FCA 328, [2012] 2 FCR 459, 340 DLR (4th) 577.

CCH Canadian Ltd v Law Society of Upper Canada, 2004 SCC 13, [2004] 1 SCR 339.

Century 21 Canada Limited Partnership v Rogers Communications Inc, 2011 BCSC 1196.

Delrina Corp v Triolet Systems Inc (2002), 58 OR (3d) 339.

Douez v Facebook Inc, 2017 SCC 33, [2017] 1 SCR 751.

Fraser River Pile & Dredge Ltd v Can-Dive Services Ltd, [1999] 2 SCR 108, 176 DLR (4th) 257.

Free World Trust v Électro Santé Inc, 2000 SCC 66, [2000] 2 SCR 1024; *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067.

Guillot v Arvic Search Services Inc., 2001 FCT 799.

Jacobsen v Katzer, 535 F 3d 1373 (Fed Cir 2008).

London Drugs Ltd v Kuehne& Nagel International Ltd, [1992] 3 SCR 299.

Merck & Co v Apotex Inx, [2006] FCA 323.

Merck & Co v Apotex Inc, (1994) 59 CPR (3d) 133.

Micro Chemicals v *Smith Kline & French Inter-American Corp*, (1971) 2 CPR (2d) 193, [1972] SCR 506.

President and Fellows of Harvard College v Canada (Commissioner of Patents) [2002] 4 SCR 45, 2002 SCC 76.

Rudder v Microsoft Corp (1999), 2 CPR (4th) 474.

Schmeiser v Monsanto, [2004] 1 SCR 902, 2004 SCC 34.

Shell Oil Co v Commissioner of Patents, [1982] 2 SCR 536, 142 DLR (3d) 117, 44 NR 541.

Tennessee Eastman Co et al v Commissioner of Patents, [1974] SCR 11, 8 CPR (2d) 202.

Trader Corporation v CarGurus, Inc, 2017 ONSC 184.

Case Law: United States

Alice Corp. v. CLS Bank International, 573 U.S. 208, 134 S. Ct. 2347 (2014).

Artifex Software Inc. v. Hancom Inc., Case No.16-cv-06982-JSC (ND Cali, 2017).

Association for Molecular Pathology v. Myriad, 569 U.S. 576 (2013).

Diamond v. Chakrabarty, 447 U.S. 303 (1980).

Diamond v. Diehr, 450 U.S. 175 (1981).

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

Feist Publications Inc. v. Rural Telephone Service Co., 499 U.S. 340 (1991).

Gottschalk v. Benson, 409 U.S. 63 (1972).

In re Bilski, 545 F.3d 943, 88 U.S.P.Q. 2d 1385 (Fed. Cir. 2008); *Bilski v. Kappos*, 130 S. Ct.. 3218 (2010).

Jacobsen v. Katzer, 535 F.3d 1373 (Fed. Cir. 2008).

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S.Ct 1727 (2007).

Madey v. Duke University, 307 F.3d 1531 (Fed. Cir. 2002).

Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

Parker v. Flook, 437 U.S. 584 (1978).

ProCD Inc v. Zeidenberg, 86 F.3d 1447 (7th Cir. 1996).

State Street Bank & Trust Co v. Signature Financial Group, 149 F.3d 1368 (Fed. Cir. 1998).

Versata Software Inc et al. v. Ameriprise Financial Inc et al., Case No A-14-CA-12-SS (WD Tex 2014).

XimpleWare Corp. v. Versata Software et al., Case No 5:13cv5161-PSG (ND Cali, 2014).

Case Law: International

Panel Report, *Canada-Patent Protection of Pharmaceutical Products* (2000), WT/DS114/R.

Panel Report*, Australia – Tobacco Plain Packaging (Cuba)* (2018), WT/DS441/R, WT/DS441/R/Add.1, WT/DS441/R/Suppl.1.

Secondary Sources

Aaltonen, Aleksi & Giovan Francesco Lanzara. "Building Governance Capability in Online Social Production: Insights from Wikipedia" (2015) 36:12 Organization Studies 1649.

Abramowicz, Michael B. "The Danger of Underdeveloped Patent Prospects" (2007) 92 Cornell L Rev 1065.

Abramowicz, Michael B, James E Daily & F Scott Kieff, eds. *Perspectives on Patentable Subject Matter* (New York: Cambridge University Press, 2014).

Arora, Ashish, Wesley M Cohen & John P Walsh. "The Acquisition and Commercialization of Invention in American Manufacturing: Incidence and Impact" (2014), Working Paper #20264, NBER Working Paper Series.

Asay, Clark D. “Enabling Patentless Innovation” (2015) 74 Md L Rev 431.

Asay, Clark D. “The General Public License Version 3.0: Making or Breaking the FOSS Movement?” (2008) 14 Mich Telecomm L Rev 265.

Baldini, Nichola. “Negative Effects of University Patenting: Myths and Grounded Evidence” (2008) 75 Scientometrics 289.

Baldwin, Carliss & Eric von Hippel. “Modeling a Paradigm Shift: From Producer Innovation to User and Open Collaborative Innovation” (2011) 22:6 Org Sci 1399.

Belenzon, Sharon & Mark Schankerman. “Motivation and Sorting in Open Source Software Innovation” (November 2008) No 019, Discussion Paper Series, EDS Innovation Research Programme.

Ben-Ishai, Stephanie & David R Percy. *Contracts: Cases and Commentaries*, 9th ed (Toronto, ON: Carswell, 2014).

Benkler, Yochai. “Coase’s Penguin, or, Linux and The Nature of the Firm” (2002) 112 Yale LJ 369.

Benkler, Yochai. *The Wealth of Networks: How Social Production Transforms Markets and Freedom* (New Haven, Conn.: Yale University Press, 2006).

Bessen, James & Michael J Meurer. *Patent Failure: How Judges, Bureaucrats, and Lawyers put Innovation at Risk* (NJ: Princeton University Press, 2008).

Biotechnology Industry Organization, “BIO 2005-2006: Guide to Biotechnology” (2006), online: BIO-NICA < http://www.bio-nica.info/biblioteca/BIO2006BiotechGuide.pdf>.

Boettiger, Sara & Dan L Burk. “Open Source Patenting” (2004) 1 JIBL 221.

Bubela, Tania, Garret A FitzGerald & E Richard Gold. “Recalibrating Intellectual Property Rights to Enhance Translational Research Collaboration” (2012) 4:122 Science Translational Medicine.

Burk, Dan L. “Intellectual Property in the Context of e-Science” (2007) 12 J Comp-Mediated Comm 600.

Burk, Dan L. “Intellectual Property Issues in Electronic Collaborations” (2000) Minnesota Legal Studies Research Paper No. 06-66, online: SSRN < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=938448>.

Burk, Dan L & Mark A Lemley. *The Patent Crisis and How the Courts Can Solve It* (Chicago, IL: University of Chicago Press, 2009).

Canadian Intellectual Property Office, “Manual of Patent Office Practices (MOPOP)” (last revised April 2018), online: CIPO < https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html>.

Carrier, Michael. *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* (New York: Oxford University Press, 2009).

Caulfield, Timothy et al. “Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies” (2006) 24 Nature Biotech 1091.

Caulfield, Timothy, Shawn HE Harmon & Yann Joly. “Open Science Versus Commercialization: A Modern Research Conflict?” (2012) 4:17 Genome Medicine, online: Genome Medicine < http://genomemedicine.com/content/4/2/17>.

Cho, Mildred K et al. “Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services” (2003) 5 J Molecular Diag 3.

Chon, Margaret. “Intellectual Property and the Development Divide” (2006) 27 Cardozo L Rev 2821.

Cohen, Wesley M & Stephen A Merrill, eds. *Patents in the Knowledge-Based Economy* (Washington, DC: National Academies Press, 2003).

Cohn, Jeffrey P. “Citizen Science: Can Volunteers Do Real Research?” (2008) 58:3 BioScience 192.

Coleman, David J, Yola Georgiadou & Jeff Labonte. “Volunteer Geographic Information: The Nature and Motivation of Produsers” (2009) 4 Int J Spatial Data Infra R 332.

Comino, Stefano & Fabio M Manenti. “Dual licensing in Open Source Software Markets” (2011) 23 Info Econ & Poly 234.

Contreras, Jorge L. “Considerations Regarding a Canadian Patent Collective”(2018) CIGI Paper No. 172, Centre for International Governance Innovation.

Cook-Deegan, Robert & Christopher Heaney. “Patents in Genomic and Human Genetics” (2010) 11 Annu Rev Genomics Hum Genet 383.

Correa, Carlos M, ed. *Research Handbook on the Protection of Intellectual Property under WTO Rules* (Northampton, MA: Edward Elgar, 2010).

Dasgupta, Partha & Paul A David. “Toward a New Economics of Science” (1994) 23 Res Pol’y 487.

David, Paul A. “The Historical Origins of ‘Open Science’: An Essay on Patronage, Reputation and Common Agency Contracting in the Scientific Revolution” (2008) 3:2 Capitalism & Society Article 5.

Delfanti, Alessandro. *Biohackers: The Politics of Open Science* (New York: Pluto Books, 2013).

Delgado, Ana. "DIYbio: Making Things and Making Futures" (2013) 48 FUTURES 65.

Demsetz, Harold. "Towards a Theory of Property Rights" (1967) 57 Am Econ Rev 347.

Doagoo, B Courtney et al, eds. *Intellectual Property for the 21st Century: Interdisciplinary Approaches* (Toronto, ON: Irwin Law, 2014).

Drahos, Peter & John Braithwaite. *Information Feudalism* (VA: Earthscan Publications Ltd, 2002).

Dreyfuss, Rochelle C. "Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm" (2010) 31:5 Cardozo L Rev 1437.

Dreyfuss, Rochelle C. "Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course" (2003), Public Law & Legal Theory Research Paper Series No. 59, NY University.

D'Souza, Suneeta. "Gene Meets Machine: Intellectual Property Issues in Bioinformatics" (2004) 12:2 Health L Rev 34.

Dusollier, Severine. "Sharing Access to Intellectual Property through Private Ordering" (2007) 82:3 Chicago-Kent L Rev 1391.

Dysart, Thomas. *Systems within Systems – Free and Open Source Software Licenses under German and United States Law* (PhD Thesis, St Peter's College, University of Oxford, 2017).

Eisenberg, Rebecca S. "Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research" (2008) 45:4 Houston L Rev 1059.

Eisenberg, Rebecca S. "Patents and the Progress of Science: Exclusive Rights and Experimental Use" (1989) 56 U Chi L Rev 1017.

Eisenberg, Rebecca S. "Proprietary Rights and the Norms of Science in Biotechnology Research" (1987) 97:2 Yale Law Journal 177.

Eisenberg, Rebecca S. "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research" (1996) 82 Va L Rev 1663.

Elkin-Koren, Niva. "What Contracts Cannot Do: The Limits of Private Ordering in Facilitating a Creative Commons" (2005) 74:2 Fordham L Rev 375.

Ellis, Jack. "Supporting Innovation in Next-Generation Medicines" (June 2017), online: WIPO Magazine <https://www.wipo.int/wipo_magazine/en/2017/03/article_0007.html>.

Fischmann, Brett H, Michael J Madison & Katherine J Strandburg, eds. *Governing Knowledge Commons* (New York: Oxford University Press, 2014).

Feldman, Robin. “Intellectual Property Wrongs” (2013) 18 Stan J Law Bus & Fin 250.

Feldman, Robin. “The Open Source Biotechnology Movement: Is It Patent Misuse?” (2004) 6 Minn J L Sci & Tech 117.

Feldman, Robin & W Nicholson Price II. “Patent Trolling – Why Bio & Pharmaceuticals are at Risk” (2014) 17 Stan Tech L Rev 773.

Fontana, Richard E. “Open Source License Enforcement and Compliance” (2010) 27:4 The Comp & Int Lawyer 1.

Franzoni, Ciara & Henry Sauermann. “Crowd Science: The Organization of Scientific Research in Open Collaborative Projects” (2013), online: Research Policy <http://dx.doi.org/10.1016/j.respol.2013.07.005>.

Gallegos, Jenna E et al. “The Open Insulin Project: A Case Study for ‘Biohacked’ Medicines” (2018) 36 Trends in Biotech 1211, online: Cell Press Reviews <https://doi.org/10.1016/j.tibtech.2018.07.009>.

Gold, E Richard et al. “Are Patents Impeding Medical Care and Innovation?” (2009) 7 PLoS Medicine 1.

Golinelli, Stefano & Guido Ruivenkamp. “Do-It-Yourself Biology: Action Research within the Life Sciences?” (2016) 14:2 Action Research 151.

Gomulkiewicz, Robert W. “Conditions and Covenants in License Contracts: Tales from a Test of the Artistic License” (2009) 17 Texas IP L J 335.

Gonzalez, Andres Guadamuz. “Open Science: Open Source Licenses in Scientific Research” (2006) 7:2 NC J L&T 321.

Grushkin, Daniel, Todd Kuiken & Piers Millet. “Seven Myths & Realities about Do-It-Yourself Biology” (2013), online: Woodrow Wilson International Center for Scholars <https://www.wilsoncenter.org/publication/seven-myths-and-realities-about-do-it-yourself-biology-0>.

Haber, Stephen H & Seth H Werfel. “Why do Inventors Sell to Patent Trolls? Experimental Evidence for the Asymmetry Hypothesis” (2015), Working Paper Series No. 15009, Hoover Institution Working Group on Intellectual Property, Innovation, and Prosperity, Stanford University, online: HooverIP2 < http://hooverip2.org/wp-content/uploads/ip2-wp15009-paper.pdf>.

Hamilton, Lisa M. “Linux for Lettuce” (14 May 2014), 90 VQR, online: VQP <http://www.vqronline.org/reporting-articles/2014/05/linux-lettuce>.

Hardin, Garrett. “Tragedy of the Commons” (1968) 162 Science 1243; “Extensions of ‘The Tragedy of the Commons’” (1998) 280 Science 682.

Helfer, Laurence R. “Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking” (2004) 29 Yale J Int L 1.

Helfer, Laurence R & Graeme W Austin. *Human Rights and Intellectual Property: Mapping the Global Interface* (New York: Cambridge University Press, 2011).

Heller, Michael A & Rebecca S Eisenberg. “Can Patents Deter Innovation? The Anti-commons in Biomedical Research” (1998) 280 Science 698.

Herder, Matthew & E Richard Gold. “Intellectual Property Issues in Biotechnology: Health and Industry” (Paper prepared for the OECD International Futures Project on ‘The Bioeconomy to 2030: Designing a Policy Agenda’, Third Meeting of the Steering Group, Paris, 7-8 February 2008).

Hope, Janet. *Biobazaar: The Open Source Revolution and Biotechnology* (Cambridge, MA: Harvard University Press, 2008).

Hope, Janet. *Open Source Biotechnology* (PhD Thesis, The Australian National University, 2004).

Hug, Kristina & Goran Mermeren, eds. *Translational Stem Cell Research: Issues Beyond the Debate on the Moral Status of the Human Embryo* (NJ: Humana Press, 2011).

Ikemoto, Lisa C. “DIY Bio: Hacking Life in Biotech’s Backyard” (2017) 51 UC Davis L Rev 539.

Jaffe, Adam B, Josh Lerner & Scott Stern, eds. *Innovation Policy and the Economy*, Vol 2 (MA: MIT Press, 2002).

Joly, Yann. “Open Source Approaches in Biotechnology: Utopia Revisited” (2007) 59 Me L Rev 385.

Kahl, Linda J & Drew Endy. “A Survey of Enabling Technologies in Synthetic Biology” (2013) 7 J Bio Eng, online: Journal of Biological Engineering < http://www.jbioleng.org/content/7/1/13>.

Kapczynski, Amy. “Order without Intellectual Property Law: Open Science in Influenza” (2017) 102 Cornell L Rev 1539.

Kapczynski, Amy et al. “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations” (2005) 20 Berkeley Tech LJ 1031.

Kitch, Edmund W. “The Nature and Function of the Patent System” (1977) 20 J L & Econ 265.

Kittur, Aniket et al. “The Future of Crowd Work” (Proceedings from CSCW ’13: The 16th ACM Conference on Computer Supported Cooperative Work and Social Computing, 2013), online: Social Science Research Network <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2190946>.

Kuznetsov, Stacey & Eric Paulos. “Rise of the Expert Amateur: DIY Projects, Communities, and Cultures” (Proceedings from the 6th Nordic Conference on Human-Computer Interaction, 16-20 October 2010).

Landes, William M & Richard A Posner. *The Economic Structure of Intellectual Property Law* (Cambridge, MA: Belknap Press of Harvard University Press, 2003).

Landrain, Thomas et al. “Do-It-Yourself Biology: Challenges and Promises for an Open Science and Technology Movement” (2013) 7 Systems and Synthetic Biology 115.

Lee, Jyh-An. “Organizing the Unorganized: the Role of Nonprofit Organizations in the Commons Communities” (2010) 50 Jurimetrics 275.

Lei, Zhen, Rakhi Juneja & Brian D Wright. “Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research” (2009) 27:1 Nat Biotech 36.

Lemley, Mark A. “Are Universities Patent Trolls?” (2008) 18 Fordham IP Med & Ent LJ 611.

Lemley, Mark A. “Ignoring Patents” (2008) Mich St L Rev 19.

Lemley, Mark A. “Rational Ignorance at the Patent Office” (2001) 95 NW U L Rev 1495.

Lemley, Mark A. “The Economics of Improvement in Intellectual Property Law” (1997) 75 Texas L Rev 989.

Lemley, Mark A. “The Myth of the Sole Inventor” (2012) 110 Mich L Rev 709.

Lerner, Josh & Scott Stern, eds. *Innovation Policy and the Economy,* Vol 1 (Cambridge, Mass: MIT Press, 2001).

Lerner, Josh & Jean Tirole. “Some Simple Economics of Open Source” (2002) 50:2 J Indus Econ 197.

Maggiolino, Mariateresa & Maria Lilla Montagnani. “Standardized Terms and Conditions for Open Patenting” (2013) 14:2 Minn J L Sci& Tech 785.

Matthew, Duncan & Herbert Zech, eds. *Research Handbook on Intellectual Property and the Life Sciences* (UK: Edward Elgar, 2017).

Maurer, Stephen M. “Inside the Anticommons: Academic Scientists’ Struggle to build a Commercially Self-Supporting Human Mutations Database” (2006) 35 Res Policy 839.

Maurer, Stephen M. “Open Source Drug Discovery: Finding a Niche (or Maybe Several)” (2007) 76 UMKC L Rev 405.

Maurer, Stephen M, Arti Rai & Andrej Sali. “Finding Cures for Tropical Diseases: Is Open Source an Answer?” (2004) 1 PLoS Medicine 183.

Merges, Robert P. “A New Dynamism in the Public Domain” (2004) 71 U Chicago L Rev 1.

Merges, Robert P & Richard R Nelson. “On the Complex Economics of Patent Scope” (1990) 90 Colum L Rev 839.

Merton, Robert K. “Priorities in Scientific Discovery: A Chapter in the Sociology of Science” (1957) 22 Am Soc Rev 635.

Meyer, Morgan. “Domesticating and Democratizing Science: A Geography of Do-It-Yourself Biology” (2013) 18 J Material Culture 117.

Mirowski, Philip & Esther-Mirjam Sent, eds. *Science Bought and Sold: Essays in the Economics of Science* (IL: The Univ of Chicago Press, 2002).

Mueller, Janice M. “No ‘Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools” (2009) 76 Wash L Rev 1.

Munzer, Stephen R, ed. *New Essays in the Legal and Political Theory of Property* (UK: Cambridge University Press, 2001).

Murray, Fiona. “The Oncomouse that Roared: Hybrid Exchange Strategies as a Source of Distinction at the Boundary of Overlapping Institutions” (2010) 116:2 Am J Soc 341.

Murray, Fiona et al. “Of Mice and Academics: Examining the Effect of Openness on Innovation” (2006), Working Paper 14819, NBER Working Paper Series.

Murray, Fiona & Scott Stern. “Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge: An Empirical Test of the Ant-Commons Hypothesis” (2005), Working Paper 11465, NBER Working Paper Series.

Mustonen, Mikko. “When does a Firm support Substitute Open Source Programming?” (2005) 14 J Econ & Manag Strategy 121.

Nelson, R R, ed. *The Rate and Direction of Inventive Activity: Economic and Social Factors* (Princeton, NJ: Princeton University Press, 1962).

Netanel, Neil Weinstock, ed. *The Development Agenda: Global Intellectual Property and Developing Countries* (NY: Oxford University Press, 2009).

Nicol, Dianne & Jane Nielsen. “Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry” (2006), Centre for Law and Genetics Occasional Paper No 6, University of Tasmania.

Nielsen, Michael. *Reinventing Discovery: The New Era of Networked Science* (Princeton, NJ: Princeton University Press, 2012).

Nottenburg, Carol, Philip G Pardey & Brian D Wright. “Accessing other people’s technology for non-profit research” (2002) 46:3 Aust J Agri & Resource Econs 389.

Nowotny, Helga et al, eds. *The Public Nature of Science under Assault: Politics, Markets, Science and the Law* (Berlin: Springer, 2005).

OECD, *Collaborative Mechanisms for Intellectual Property Management in the Life Science* (2011), online: OECD< https://www.oecd.org/sti/biotech/48665248.pdf>.

OECD*, Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (Paris, OECD, 2002).

OECD, *OECD Principles and Guidelines for Access to Research Data from Public Funding,* OECD/LEGAL/0321 (2007), online: OECD <http://www.oecd.org/dataoecd/9/61/38500813.pdf>.

Okediji, Ruth L & Margo A Bagley, eds. *Patent Law in Global Perspective* (NY: Oxford University Press, 2014).

Opderbeck, David W. "The Penguin's Genome, or Coase and Open Source Biotechnology" (2004) 18 Harvard J L & Tech 167.

Opderbeck, David W. "The Penguin's Paradox: The Political Economy of International Intellectual Property and the Paradox of Open Intellectual Property Models" (2007) 18 Stan L & Pol'y Rev 101.

O'Rourke, Maureen A. "Toward a Doctrine of Fair Use in Patent Law" (2000) 100 Colum L Rev 1177.

Osbourn, Anne E et al. "Synthetic Biology" (2012) 196 New Phytologist 671.

Pearce, Joshua M. "Building Research Equipment with Free, Open-Source Hardware" (2012) 337:6100 Science Magazine 1303.

Pearce, Joshua M. *Open-Source Lab: How to Build your Own Hardware and Reduce Research Costs* (MA: Elsevier, 2014).

Petherbridge, Lee. "Road Map to Revolution? Patent-Based Open Science" (2007) 59 Me L Rev 339.

Piper, S Tina. "The Tools and Levers of Access to Patented Health Related Genetic Invention in Canada" (2009) 30 Wash U J L & Pol'y 43.

Purdam, Kingsley. "Citizen Social Science and Citizen Data? Methodological and Ethical Challenges for Social Research" (2014) 62:3 Current Sociology 374.

Raddick, M Jordan et al. "Galaxy Zoo: Motivations of Citizen Scientists" (2010) 9 AER 010103-1.

Rai, Arti. "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science" (1999) 94 Nw UL Rev 77.

Rai, Arti & James Boyle. “Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons” (2007) 5 PLoS Biology 389.

Rai, Arti & Rebecca S Eisenberg. “Bayh-Dole Reform and the Progress of Biomedicine” (2003) 66 L & Contemp Probs 289.

Raymond, Eric S. *The Cathedral & the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary*, 2d ed (Cambridge, MA: O’Reilly, 2001).

Reichman, Jerome H. “A Compensatory Liability Regime to Promote the Exchange of Microbial Genetic Resources for Research and Benefit Sharing” in Paul F Uhlir, ed, *Designing the Microbial Research Commons*: *Proceedings of an International Workshop* (DC: The National Academies Press, 2011).

Reichman, Jerome H. “Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation” (2000) 53 Vand L Rev 1743.

Reichman, Jerome H & Rochelle C Dreyfuss. “Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty” (2007) 57 Duke LJ 85.

Reichman, Jerome H & Ruth L Okediji. “When Copyright Law and Science Collide: Empowering Digitally Integrated Methods on a Global Scale” (2012) 96 Minn L Rev 1362.

Reichman, Jerome H & Paul F Uhlier. “A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment” (2003) L & Contemp Prob 315.

Risch, Michael. “Patent Troll Myths” (2012) 42 Seton Hall L Rev 457.

Rosen, Lawrence. *Open Source Licensing: Software Freedom and Intellectual Property Law* (NJ: Prentice Hall, 2004), online: Rosen Law < https://rosenlaw.com/open-source-licensing-software-freedom-and-intellectual-property-law/>.

Salmi, Jamil. ” Study on Open Science: Impact, Implications & Policy Options” (Aug, 2015) Research & Innovation, European Commission, online: European Union <https://ec.europa.eu/research/innovation-union/pdf/expert-groups/rise/study_on_open_science-impact_implications_and_policy_options-salmi_072015.pdf>.

Sarnoff, Joshua D & Christopher M Holman. “Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents” (2008) 23 Berkeley Tech L J 1299.

Savage, Neil. “Gaining Wisdom from Crowds” (2012) 55:3 Communication of the ACM 13.

Scassa, Teresa & Haewon Chung. “Managing Intellectual Property Rights in Citizen Science: A Guide for Researchers and Citizen Scientists” (2015), Research Series Vol 3, Commons Lab, Woodrow Wilson International Center for Scholars.

Scassa, Teresa & Haewon Chung. "Typology of Citizen Science Projects from an Intellectual Property Perspective: Invention and Authorship Between Researchers and Participants" (2015), Policy Memo Series, Vol. 5, Commons Lab, Wilson Center for International Scholars, online: Wilson Center <http://www.wilsoncenter.org/publication/typology-citizen-science-projects-intellectual-property-perspective>.

Schultz, Jason & Jennifer M Urban. "Protecting Open Innovation: The Defensive Patent License as a New Approach to Patent Threats, Transaction Costs, and Tactical Disarmament" (2012) 26 Harvard J L & Tech 1.

Short, Nicholas. "A Research Exemption for the 21st Century" (2016) 50 U Mich J L Reform Caveat 1.

Smith, Matthew L & Katherine M A Reilly, eds. *Open Development: Networked Innovations in International Development* (Cambridge, MA: The MIT Press, 2013).

Strandburg, Katherine J. "Patent Fair Use 2.0" (2011) 1 UC Irvine L Rev 265.

Straus, Joseph. "Intellectual Property Rights and Bioeconomy" (2017) 12:7 J IP L & Prac 576.

Tenopir, Carol et al. 'Changes in Data Sharing and Data Reuse Practices and Perceptions among Scientists Worldwide" (2015) 10:8 PLoS ONE, online: PLoS <https://doi.org/10.1371/journal.pone.0134826>.

Teran, Oswaldo & Jose Aguilar, eds. *Societal Benefits of Freely Accessible Technologies and Knowledge Resources* (PA: IGI Global, 2015).

Tzfira, Tzvi & Vitaly Citovsky, eds. *Agrobacterium: From Biology to Biotechnology* (New York: Springer, 2008).

Valikangas, Lisa & Michael Gibbert. *Strategic Innovation* (NJ: Pearson Education, 2015).

van Beuzekom, Brigitte & Anthony Arundel. *OECD Biotechnology Statistics 2009* (Paris: OECD, 2009).

van Overwalle, Geertrui, ed. *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regime* (New York: Cambridge University Press, 2009).

van Zimmeren, Ester et al. "A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?" (May 2006) 84:5 Bulletin of the World Health Organization 352.

Vasudeva, Vikrant Narayan. *Open Source Software and Intellectual Property Rights* (Alphen aan den Rijn, The Netherlands: Wolters Kluwer Law & Business, 2014).

Vaver, David. "Being Old and Obvious: Apotex v. Sanofi SCC" (2010) 3 Osgoode Hall Rev L & Pol'y 3.

Vaver, David. *Intellectual Property Law*, 2d ed, (Toronto, ON: Irwin Law, 2011).

von Hippel, Eric. *Democratizing Innovation* (Cambridge, MA: The MIT Press, 2005).

von Hippel, Eric & Georg von Krogh. "Open Source Software and the 'Private-Collective' Innovation Model: Issues for Organization Science" (2003) 14:2 Org Sci 209.

Wacha, Jason B. "Taking the Case: Is the GPL Enforceable?" (2004) 21 Santa Clara Computer & High Tech LJ 451.

Walsh, John P, Charlene Cho & Wesley M Cohen. "Patents, Materials Transfers and Access to Research Inputs in Biomedical Research", Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomics and Protein-Related Inventions (20 September 2005), online: Penn State <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.531.1401&rep=rep1&type=pdf>.

Walsh, John P, Charlene Cho & Wesley M Cohen. "View from the Bench: Patents and Material Transfers" (2005) 309 Science 2002.

Walsh, John P, Wesley M Cohen & Charlene Cho. "Where Excludability Matters: Material Versus Intellectual Property in Academic Biomedical Research" (2007) 36 Research Policy 1184.

Weigelt, Johan. "The Case for Open-Access Chemical Biology"(2009) 10:9 EMBO Reports 941.

Welsh, Rick. "Close Enough but not too Far: Assessing the Effects of University-Industry Research Relationships and the Rise of Academic Capitalism" (2008) 37 Research Policy 1854.

Wiggins, Andrea & Kevin Crowston. "Describing Public Participation in Scientific Research" (2011), Working Paper, Syracuse University School of Information Studies, online: Syracuse University < https://crowston.syr.edu/node/425>.

Wiggins, Andrea & Kevin Crowston. "Developing a Conceptual Model of Virtual Organizations for Citizen Science" (2010) Int J Org Design & Eng, online: <http://crowston.syr.edu/sites/crowston.syr.edu/files/WigginsCrowstonIJODE2010.pdf>.

Wiggins, Andrea & Kevin Crowston. "From Conservation to Crowdsourcing: A Typology of Citizen Science" (Proceedings of the 44th Hawaii International Conference on System Sciences – 2011).

Wilderman, Candice D. "Models of Community Science: Design Lessons from the Field" (Presentation delivered at the Citizen Science Toolkit Conference, Cornell Lab of Ornithology, 20-23 June 2007).

WIPO, Standing Committee on the Law of Patents, *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, SCP/15/3, 2 September 2010, online: WIPO <https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=141352>.