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The Role of the International Patent System in the Transfer of Technology to Developing Countries with Particular Reference to Pharmaceutical Patents and Compulsory Licences.

Submitted by:

Rosie Dimopoulos

Thesis submitted to the School of Graduate Studies and Research of the University of Ottawa in partial fullfilment of the requirements for the LL.M. degree in Law.

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ACRONYMS AND ABBREVIATIONS

ALIFAR	Latin America Pharmaceutical Industry Association
ARCT	African Regional Centre for Technology
ASEAN	Association of South-East Asian Nations
BIRPI	Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle
CARICOM	Central American Common Market and Caribbean Market
CDMA	Canadian Drug Manufacturers' Association
CEAO	West African Economic Community
COPPTECs	Regional Cooperative Production and Technology Centres
C.P.C.	Community Patent Convention
CTC	Commission on Transnational Corporations
E.E.C.	European Economic Community
E.P.C.	European Patent Convention
ESAPIRO	Industrial Property Organization for English-Speaking Africa
GNP	Gross National Product
IDEA	The Journal of Law and Technology
IFPMA	International Federation of Pharmaceutical Manufacturers' Association
INPADOC	International Patent Documentation Centre
I.C.C.	International Chamber of Commerce
I.I.C.	International Review of Industrial Property and Copyright Law
MNCs	Multinational Corporations
NIEO	New International Economic Order
NOC	Notice of Compliance
OECD	Organization for Economic Co-operation and Development
OAPI	African Intellectual Property Organization
OMPI	Organisation Mondiale de la Propriété Intéllectuelle
PCT	Patent Cooperation Treaty
PMAC	Pharmaceutical Manufacturers' Association of Canada
RBPs	Restrictive Business Practices
R&D	Research and Development
SPECC	South Pacific Common Market for Economic Cooperation
T.I.A.S.	Treaties and Other International Act Series
TNCs	Transnational Corporations
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
U.N.T.S.	United Nations Treaty Series
U.S.T.	United States Treaties and Other International Agreements
U.S.T.S	United States Treaty Series
WHO	World Health Organization
WIPO	World Intellectual Property Organization

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ABSTRACT

This thesis deals with the role of patents in the transfer of technology and industrialization of developing countries, with a special focus on the role of pharmaceutical patents and the development of the pharmaceutical industry. In particular, this thesis examines the working of patents and the compulsory licensing system in the case of non-working as well as the compulsory licensing system for pharmaceuticals from the perspective of the Paris Convention and the national patent laws.

The following problems are addressed: 1) Whether and under what conditions patents facilitate or hinder access to technology and how they can be made to facilitate access of technology to developing countries in particular in the pharmaceutical sector. 2) Whether the obligation to work the patent and the sanctions that are provided when the patent is not being worked, i.e., compulsory licence and revocation, are adequate and effective in promoting the interests of developing countries for industrialization and 3) Whether compulsory licences can be applied in the interest of public health under different circumstances and if they would help the development of the pharmaceutical industry and the transfer of pharmaceutical technology.

These problems will be viewed from the perspective of the international system of patent protection as it is embodied in Article 5A of the Paris Convention for the Protection of Industrial Property and as it interacts with the various national patent laws of member countries.

The breakdown of the thesis into chapters is as follows: an introduction, five chapters and conclusions.

Its first chapter gives a historical background of patents. The Paris Convention would not have come to exist without preceding national patent laws. Thus it seems necessary to discuss the main landmarks in the evolution of patent law, in order to highlight the justification for early patent laws. A significant event, the antipatent movement, is then analysed. It has been traditionally accepted that patents helped the industrialization of a country. However, can a country without a patent system become industrialized? After the discussion on the antipatent movement, the events that led to the establishment of the Paris Convention for the Protection of Industrial Property are mentioned and then the Paris Convention is discussed. In particular, the principles that make the Paris Convention work are examined and the way in which it is administered.

The second chapter deals with the role of patents in developing countries in general and the third chapter with the role of patents which are relevant to pharmaceuticals in particular. The second chapter deals with the role of patents in the transfer of technology to developing countries. In order to evaluate this role the second chapter looks first upon the theories that traditionally have justified the grant of patents in developed countries. However in developing countries a different set of circumstances exists. Thus, the second chapter examines whether the same theories can apply to developing countries where different needs and interests exist or whether a different set of theories is needed in order to justify the patent grant in these countries. In order to do this an evaluation of costs and benefits associated with the patent grant is examined when the patented invention is put in production into the country and when it is not being worked. The purpose of this analysis is to analyse the impact of patents on developing countries and find out whether

patents work for or against developing countries and under what conditions they could be made to work in favour of developing countries and to help the industrialization of these countries.

Chapter three examines the role of patents which are relevant to pharmaceuticals in developing countries. Developing countries want to have access to safe and reasonably priced drugs. However access to pharmaceuticals may be prevented by constraints within this industry. Patents may be one kind of these constraints. Thus, a brief overview of the pharmaceutical industry seems necessary in order to highlight the main features of this industry and examine how patents work and why they are important to this industry. Then the third chapter discusses the kinds of patents that are available for pharmaceuticals. Each category creates different results and has a different impact on a country. Patents' role on the transfer of technology to the pharmaceutical sector of developing countries is analysed and the status of present developments in this area is mentioned. Many countries exclude from the patent system certain sectors when they consider them vital to their economic development, public health or national security. For example, pharmaceuticals is one of these sectors that in some countries may be limited or excluded from patent protection in the public interest, as are nuclear and atomic energy inventions in other countries.

The fourth chapter deals with the working of patents and the sanctions in the case of non-working. Working is a very important aspect of the patent grant that may decide the access to new technology. The patent grant makes sense if the patent is worked in the country that granted it, in which case technology may be transferred given that restrictions are not attached to the agreement. As a matter of fact the patent right is granted to the patentee and in exchange he has the obligation to disclose his patent so that

society would benefit and technology would be diffused. A second obligation that society puts on the patentee is the obligation to work his invention in order that technology is effectively transferred. When the patentee does not properly use his right but instead he abuses it, then safeguards are called for in order to protect the public interest. Thus, this chapter analyses the working of patents and the sanctions that are provided in cases when the patent is not being worked, i.e., the compulsory licence and revocation of the patent grant. As was mentioned above, national patent laws may be constrained by the Paris Convention. Thus the evolution of the working and compulsory licensing provisions in the Paris Convention are examined and the strong opposition that was raised towards these provisions is seen as well as the support by countries which considered that public interest necessitates such provisions in their patent laws. The fourth chapter analyses the question of interpretation that arises with the provisions on compulsory licence and revocation as are embodied in Article 5A of the Paris Convention, and the national measures that were taken with regard to these provisions. The purpose is to decide whether these provisions that refer to the working of the patent, revocation, and the compulsory licence in the case of non-working are effective and can really safeguard the public interest of developing countries or whether there are limitations and delays that reduce their potential and the developing countries' freedom to take necessary measures.

Furthermore in the fifth chapter the question that arises is whether such provision, i.e., compulsory licence, can effectively safeguard the public interest. Could this kind of compulsory licence be imposed on specific sectors when overriding reasons of public interest require it? Could compulsory licences be granted under the Paris Convention for pharmaceuticals on different terms, i.e., without the delays and the limitations that are attached to the compulsory licences which are granted in the case of

abuse, for example, non-working? Would such licences be in accordance with or in violation of the Paris Convention? It is with these questions that the fifth chapter deals. First it examines the developments that have taken place on an international level and how different legislations have regulated the issue. Then one specific country, Canada, is reviewed because of the very recent developments that have taken place in Canada in the field of pharmaceutical patents and because the research and analysis of this thesis was conducted in Canada; therefore it is interesting to examine the Canadian perspective and see if there are any models that can be followed by developing countries. The fifth chapter examines where the Paris Convention stands on the issue of compulsory licences for pharmaceuticals and discusses the steps and actions that developing countries have been taking with the Paris Convention and their attempts to revise compulsory licence provisions.

This thesis concludes that on the national level developing countries should take full advantage of the opportunities allowed by the Paris Convention and legislate on these areas that are left free to legislate. Developing countries should allow for pharmaceutical processes while eliminating pharmaceutical products from patent protection and provide a compulsory licence for pharmaceuticals in the interest of public health where the constraints set by the Paris Convention do not apply. On the international level efforts should be continued towards revising the Paris Convention as far as compulsory working and compulsory licencing are concerned. The latest draft text, the Nairobi text, is a step in the right direction.

INTRODUCTION

The end of the devastating World War II brought hopes for peace and constructive development in the world. These hopes were materialized in such activities as the reconstruction of Europe, the establishment of the United Nations Organization and the foundation of the European Community. Soon after the end of the war, however, a new reality emerged in the world arena with its leading actors the two superpowers, the USA and the USSR, and the two alliances that they formally established, NATO and the Warsaw Pact. For most of the latter half of the twentieth century, conflicts between these two power blocks dominated world affairs. Only recently has there been any diminution of tension between Eastern Europe and the West.

Parallel to this sequence of events, other circumstances shaped the world political scene. After a long and unprecedented struggle for freedom most countries achieved their political independence from colonial rule. All these new nations joined the United Nations Organization. However, the dissimilarity between developing countries and the developed world gradually became apparent. Colonialism had left its scars on the Third World. All the newly independent countries were at a comparatively low level of development[1]. The era of political colonialism for many nations had ended, only to be replaced by a period of North-South disparity.

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[1]The reasons for their state of underdevelopment are found in political, economic, historic, sociological and demographic factors. Colonialism is considered to be one reason for underdevelopment while existing institutions and conventions are thought by developing countries to perpetuate this situation.

A common characteristic of all developing countries is a lack of technological development. In developing countries, where 3/4 of the world population lives,[2] the per capita income is less than 10 percent than that of the developed countries and the GNP is $660, whereas in developed countries it is $10,050[3].

In many sectors the developing countries face a range of complex problems. They face the reality of an infrastructure which is characterized by unequal distribution of income, high illiteracy rates, unemployment, undernourishment, absence of primary health care facilities and high prevalence of diseases. Moreover governments which are often unstable because of a combination of internal and external factors, lagging in technology and non-existent or quasi-existent industry are the main parameters of underdevelopment. The existing economic and technological gap between developing countries and the developed world is widening.

Since the achievement of political independence the primary objective of all developing countries has been to promote industrialization through economic development[4] The necessary prerequisite for economic advancement is the development of a strong technological base. Technological development is considered the key element in the industrialization process and can be considered as synonymous with economic development.[5]

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[2] George Thomas Kurian, The Encyclopedia of the Third World, 3rd ed. (New York: Facts on File, 1987) Vol III at p. 2241, Appendix V, Table 1.

[3] Id., at p. 2242, Appendix V, Table 2.

[4] See for example the strategies followed in India towards this purpose in A. Ramachandran, "Self Reliance in Technology and Patent System" in The Importance of the Patent System to Developing Countries: Collection of Lectures Given at the World Symposium organized by WIPO at Colombo, Sri Lanka in February 1977, (Geneva: WIPO, 1977) at p. 294 (hereinafter WIPO Colombo Symposium).

[5] Trends and Problems in World Trade and Development, UN Doc. UNCTAD/TT/28 Suppl. (1987), at p. 6.

The development of a technological base would gradually shrink the technological gap between the developing countries and the developed world and thus help materialize the New International Economic Order aspirations and goals of the developing countries of equality and industrialization.[6]

Technology however is not for free. It is not humanitarian aid but a commodity bought and sold in international markets[7]. This fact has a consequence of great magnitude. The owner of such technology, or in other words the supplier of such technology makes it available and in return asks for payment. The supplier of technology in a market economy country may be either a multinational corporation (hereinafter MNC) or a medium or small size enterprise or a government, usually a socialist government in a centrally planned economy country[8]. As will be seen, in the pharmaceutical sector a few MNCs from developed market economy countries dominate the production, trade and technology in the pharmaceutical industry throughout the world; developing countries rely almost

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[6]Declaration on the Establishment of a New International Economic Order, G.A. Res. 3201 (S-VII) (1 May 1974), para. 4(p); (1974), 13 Int'l Legal Materials 715, Programme of Action on the Establishment of a New International Economic Order, G.A. Res. 3202 (S-VI) (1 May 1974), sec. IV(B) and (d); (1974), 13 Int'l Legal Materials 720.

[7]See Guidelines for the Study of the Transfer of Technology to Developing Countries, UN Doc. TD/B/AC. 11/9 (1972), at p. 5 para. 17, (hereinafter Guidelines), which states: Technology is considered to be an essential input to production, it is a commodity subject to international transactions in various forms such as "... capital goods and sometimes intermediary goods ... human labour usually skilled and sometimes highly skilled and specialized manpower ... [and] ... information whether of a technical or a commercial nature, which is either readily available in markets or subject to proprietary rights and sold under restrictive conditions"; See also, Licensing Guide for Developing Countries (Geneva: WIPO, 1977) at p. 28. For the components of technology see The Channels and Mechanisms for the Transfer of Technology from Developed to Developing Countries, UN Doc. TD/B/AC.11/5 (1971) at p. 6 para. 19, (hereinafter Channels).

[8]The Role of Small and Medium-sized Enterprises in the International Transfer of Technology: Issues for Research, UN Doc. TD/B/C.6/64 (1980); see also Promotion of Transfer of Technology by Small and Medium-sized Enterprises to Developing Countries: Public Policy Implications and Applicable Instruments. UN Doc. TD/B/C.6/79 (1982).

exclusively on the MNCs for such technology.[9]

An important matter related to the dependency of developing countries on developed countries is the appropriateness of technology. Appropriate technology is a crucial developmental concern since some products are inappropriate for the special needs and circumstances of developing countries[10].

On the one hand, the reasons for such inappropriate technology may be that developing countries do not possess the necessary skills and knowledge to disseminate and adapt the technology transferred into their country or even to make the right initial choice when there may exist the same or better technology on terms more advantageous for them. On the other hand, the reasons for such inappropriate flow of technology may be either because it has been designed for consumers' needs in developed countries and therefore does not necessarily fit the priorities of developing countries or in the case of the pharmaceutical sector because pharmaceutical research is concentrated in Western type diseases and only a minimal amount of research is focused on tropical diseases. In other cases the essential drugs needed in developing countries are not a profitable market, given the strict controls imposed on these essential drugs.

The development of the much-needed technological base (including the pharmaceutical technology), can be achieved through local production and development of the indigenous capabilities of the country and/or through the acquisition of technology from abroad in order to complement the local industry.

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[9]Sanjaya Lall, Major Issues in Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry, UN Doc. TD/B/C.6/4 (1975), at p. 22, (hereinafter Lall (1975)); see also Gary Gereffi, The Pharmaceutical Industry and Dependence in the Third World (Princeton: Princeton University Press, 1983), (hereinafter Gereffi).

[10]Gereffi, supra note 9 at p. 198.

Developing countries can acquire technology through a variety of ways. The various mechanisms of transfer may be classified into two categories according to whether several or one supplier is used to acquire the technology, i.e. the unpackaged transfer and the packaged transfer.[11]

In the unpackaged form of transfer outright sales of goods and services take place, such as consultancy agreements, management contracts, etc. Unpackaged form of transfer occurs mainly in developed countries which possess the experience to operate such technology.

In the packaged form of transfer Foreign Direct Investment or Joint Ventures and licensing agreements are usually involved. The recipient of the technology does not usually possess the experience and skills to operate the technology, a situation that often occurs in developing countries. Thus the supplier has control over the technical and managerial part of production of the project, a consideration that carries a lot of weight for MNCs.

In practice, a package form of transfer usually involving a Foreign Direct Investment is the MNC's classic way of transferring technology to the developing countries. Foreign Direct Investment comprises various elements of technology, capital and management and exerts a considerable degree of control.[12]

Another mechanism of transfer is through a Joint Venture, where the recipient has more control over the imported technology. This is more prevalent in the more advanced of the developing countries.[13]

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[11] Guidelines, supra note 7 at p. 8, para 35.

[12] Channels, supra note 7 at p. 25, para. 61; See also Major Issues Arising from the Transfer of Technology to Developing Countries, UN. Doc. TD/B/AC.11/10 (1973) at p. 11, (hereinafter Major issues).

[13] Suresh B. Pradham, International Pharmaceutical Marketing (Westport Connecticut: Quorum Books, 1983) at p. 32, (hereinafter Pradham); See also Guidelines, supra, note 7 at p. 11 para. 54.

An alternative method by which technology may be transferred is the licence agreement. The licence agreement is a contract that may transfer technology which is protected by an industrial property right such as a patent, a trade name, a design or a copyright. The industrial property rights confer the exclusive right to the holder of the property to prevent unlawful use, production, importation or sale by others. They permit the holder to use, produce, import, sell or licence articles covered by industrial property rights for a monetary consideration called royalties. In the licence agreement the recipient has a greater degree of control over the imported technology than he has via the Foreign Direct Investment mechanism, unless restricted clauses are inserted in the licence agreement in which case the control shifts to the supplier of the technology.

Highly sophisticated and complex technology that has been patented, such as pharmaceuticals, is usually transferred in a packaged form. Thus, especially when the technology is complex and new and beyond the capabilities of the local infrastructure, such as is the case in developing countries, the classic way to transfer it is by way of licence agreement within the framework of a Foreign Direct Investment or joint Venture scheme with equity participation.

Particularly for pharmaceuticals, even when the techniques involved are simple (such as packaging and formulating of pharmaceuticals), the usual way of transfer is by licence agreement and/or Foreign Direct Investment with majority owned or wholly Foreign owned enterprises, i.e., enterprises which are owned and controlled by MNCs.

Thus, one of the ways in which technology can be transferred to developing countries is by way of technology embodied in a patent which is part of a package transfer involving a licence agreement within a Foreign Direct Investment or Joint Venture scheme.

Developing countries need technology in order to promote industrialization. Among the various institutions that govern access to new technology are patents. A patent confers the exclusive right to the inventor, i.e., the patentee, to use, produce, sell and import his patented invention for a limited period of time. Thus, with the patent the patentee has a monopoly over use, production, sale and importation of the invention to the exclusion of any unauthorized party.

Society confers such an exclusive right to the patentee as a reward for his contribution, efforts and expenses and as an incentive for further inventive activity. Thus a portion of competition is relinquished and a monopoly is instead legally created for a limited period of time. This monopoly however is balanced against the benefits that society expects to gain through the required disclosure of the invention and through the industrial use of the invention. Hence, a patent is granted in order to encourage industrial use of the patented invention and foster technological and economic development.

Patents constitute one of many instruments for transfer of technology to developing countries. Patents may facilitate access to technology through the exclusive rights accorded to the patentee by creating a favourable climate for investment and through the benefits that flow when the patented invention is locally used in production, i.e., employment, knowledge and technical skills, foreign exchange savings, improvement in the balance of payments etc.

However, patents may hinder access to technology because the exclusive rights accorded to foreigners may involve onerous restrictive clauses for the country, or they may be used to prevent the importation of cheaper products, or they may prevent a national firm from producing similar products, even when the patentee does not start local development.

Thus, the patentee may not work his patent in the country but instead, he may license it and put onerous terms in the licensing agreement. Alternatively the patentee may choose to import the product covered by his patent instead of producing it, since importation is among the rights conferred to him by the patent. In this way he can use his patent rights either to exclude all other importers from importing the invention or he can prevent all other producers from producing the invention in the country. Thus he can charge high import prices and secure for himself a monopoly position in the market. Consequently the country will not be able to shop around to find alternative sources of supply at more competitive prices. Hence the patent may become an obstacle to import from cheaper sources of supply and may result in an absolute and exclusive permit. Furthermore, the patent may become an obstacle for local production of the invention. As a matter of fact, as will be seen, in developing countries 80-85% of patents are owned by foreigners and 95% of them are never used in production but instead are used to secure a monopoly on imports.

The question that arises, within this context, is whether patents facilitate the transfer of technology to developing countries and assist them in their industrialization process or whether they hinder such access to technology and industrialization. Therefore in order to assess the role of patents it seems necessary to compare the costs and the benefits associated with patents and weigh them, in order to see if the patents work in favour or against developing countries. In the latter case, i.e., if they work against developing countries it will be necessary to examine the conditions, if any, under which patents can be made to work in favour of developing countries.

The pharmaceutical industry serves as a good case study to examine the role of patents in developing countries because developing countries want to promote industrialization in this sector and have access to safe and reasonably priced drugs. Furthermore, patents are very important to this industry. The pharmaceutical industry incurs heavy expenses during the research and development for a new drug. Production costs on the other hand are not equally high. Pharmaceuticals can be easily imitated by scientists with the necessary skills. Patents however erect a shield against imitation and against competition and thus they determine this industry's profitability.

On one hand developing countries want to have access to safe and reasonably priced drugs and to promote industrialization in the pharmaceutical sector. On the other hand, the pharmaceutical industry wants to recuperate its costs and to make profits. Patents provide this means with the monopoly they create against competitors. Thus a confrontation of interests takes place. Will developing countries' interests be protected without harming the industry's interests?

There exist two main categories of patents that are relevant for pharmaceuticals: the product patent and the process patent. Each has a different impact on developing countries. Thus, for example, when a country grants a patent that protects a pharmaceutical product then it cannot procure the raw materials needed to produce the pharmaceutical nor can it start or build upon a production of a pharmaceutical industry. Furthermore, it cannot import the pharmaceutical product from other suppliers but it will be obligated to rely on the patentee who enjoys an absolute import monopoly and exclusive distributorship. This results in high prices of the pharmaceutical. The question arises: what are the alternatives that exist for a developing country in order to procure good and reasonably priced drugs and/or start building up a pharmaceutical industry? In order to evaluate this problem we

will examine the kinds of patents that exist for drugs and we will analyse the role that each kind plays on developing countries' access to pharmaceuticals. We will further discuss what form of patent protection seems more appropriate for developing countries taking into account the legitimate interests of the industry.

As was mentioned above, a patent is granted in order to encourage industrial exploitation of the patented invention and foster technological development. A means to achieve this purpose is the working of the patent and, as will be seen, when the patent is worked in the country that granted it, the technology may be transferred; otherwise, when the patent is not worked, then the flow of technology may be hindered.

Thus, when the patentee does not properly use his patent but instead he abuses it by not working the patented invention in the country (for example when he uses the patent as an import permit) then safeguards are called for in order to protect the divergent interests that are involved in the granting of a patent, i.e., those of the patentee and those of the country that granted the patent. These safeguards are compulsory licences and/or revocation of the patent grant. A compulsory licence authorizes a person to do acts which would not have been possible for him to do without this licence, i.e., he can produce or import the patented invention without the patentee's authorization. Revocation is a sanction that terminates the patent grant.

The patent right is governed by the national law of the country that issues the patent. However, on the international level patents are regulated by the Paris Convention for the Protection of Industrial Property. The Paris Convention is the most important multilateral agreement for the regulation of industrial property rights. The international system of patent protection, as embodied in the Paris Convention establishes certain legal

standards that member countries should follow. These legal rules however may limit the freedom of a member country from legislating and taking all the appropriate measures to prevent abuses that may result from the patent grant.

The question that arises within this context is whether the Paris Convention, and in particular the "common rules" that establishes when the patent grant is abused, takes into account and promotes the interests of developing countries or not. In other words does the Paris Convention help or hinder developing countries in acquiring technology and their efforts towards industrialization in particular in the pharmaceutical sector? And what could developing countries do in order to have access to technology and promote their economic development in the pharmaceutical sector?

It is with such questions and problems that this thesis is concerned.

CHAPTER I

THE INTERNATIONAL PATENT SYSTEM

This chapter provides a historical background of patents and a review of the Paris Convention. First, the most significant milestones in the history of patents will be discussed in order to highlight the rationale of these early patent laws. Then the anti-patent movement and its effects will be examined. Finally, the Paris Convention, which constitutes the main instrument of the international system of patent protection and regulates international transactions involving industrial property rights, will be discussed focusing on the principles that make the Paris Convention work.

1.1 Historical Background

1.1.1 Early Patent Laws

i. The Venetian Patent of 1474

The first patent in a form of a statutory instituted patent law originated in the city-state of Venice.[14] The Venetian law of 1474 is considered to be the precedent for

[14] Long before the Venetian patent, in the 3rd century B.C., in the ancient Greek city of Syvaris there existed a provision that referred to a kitchenware item that could be considered the forerunner of contemporary law of patents. In the Middle Ages, the invention was considered a property of the guilds which dominated the whole economy. In the Renaissance the princesses and lords of the various guilds had absolute power to arbitrarily grant monopoly privileges over production and sale of certain products.

contemporary patent law. According to this law, "the first and true inventor" was given a monopoly but obligated to exploit his patent, otherwise it was revoked. The main rationale behind the Venetian patent law was the promotion of the interests of society. In the Venetian patent law, which "provided for patents as a matter of right and general principle, not merely of royal favour,"[15] we find the same elements that prevail in modern patent laws. It should be mentioned here that the Venetian patent law was instituted when Venice was already at the peak of its development; Venice was "the dominating sea power of the world from the year 100 to 1500. About 1400 she largely monopolized the trade between Europe and the rest of the then-known world."[16]

ii The Statute of Monopolies of 1623

In England, the scheme of royal grants to individuals was the practice until 1603 when there was an organized reaction against such an activity. In Darcy v. Allin, the Case of Monopolies, the royal grants were severely criticized.[17] It was held that these exclusive monopolies were against "the liberty and benefit of the subjects" and against the common law. It was suggested that for "the public weal" a monopoly should be granted for only 14 years for the sole purpose of exploiting the patent and making the product. This proposition formed the basis of the Statute of Monopolies enacted in 1623. With this

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[15] G. Mandich, "Venetian Patents from 1450 to 1550" (1948), 30 J. Pat. Off. Soc. 162 at p. 177, (hereinafter Mandich).

[16] F. D. Prager, "A History of Intellectual Property from 1545 to 1787" (1944), 26 J. Pat. Off. Soc. 711 at p. 712, (hereinafter Prager).

[17] Darcy v. Allin (1602), 11 Co. Rep. 84. In Darcy v. Allin, a monopoly on playing cards was declared void by the court. See H. G. Fox, The Law and Practice of Letters Patent of Inventions in Canada (Toronto: Carswell, 1926) at p. 223.

Statute the system of royal favours was finally abolished when the Parliament compelled King James I to sign the famous statute which had been called the Magna Carta of Patent Law. Similar to the Venetian patent law, in the Statute of Monopolies, the working of inventions was perceived as obligatory and its rationale was centred on the economic interest of society.[18] The Statue of Monopolies, however, went a step further than the Venetian patent in that it not only granted a patent to "the first and true inventor" but to those who introduced a foreign technology aiming at urging the British citizens to introduce a foreign invention for the benefit of the national economy.[19]

iii The French Patent Law of 1791

The next landmark in the evolution of the patent law was the French Revolution of 1789 that abolished the guilds which had existed since the Middle Ages. The French Revolution led to the Declaration of the Freedom of Trade and the establishment of a comprehensive patent law in 1791.[20] The French patent law of 1791 was influenced by the ideas of the Revolution and the Declaration of the Rights of Man and consequently the inventor's right was perceived as a right of man and as a property right.[21] Parallel to the

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[18] Edith Penrose, The Economics of the International Patent System (Baltimore: The John Hopkins University, 1971) at p. 3, (hereinafter Penrose).

[19] Ulf Anderfelt, The International Patent Legislation and Developing Countries (The Hague: Martinus Nijhoff, 1971) at p. 44, (hereinafter Anderfelt).

[20] Id. at p. 14; see also Penrose, supra note 18 at p. 8.

[21] From France the patent institution spread to other countries such as Belgium (1817), the Netherlands (1817), Spain (1820), Mexico (1832), Sweden (1834), Portugal (1837), Austria (1810) and Venezuela (1878). The Austrian patent law took a diametrically opposite view from the French law by rejecting the inventor's natural right concept and accepting rather the natural right to imitate an inventor's idea.

French patent law, the United States Constitution empowered Congress "to promote the Progress of Science and useful Arts by securing for limited times to Authors and Inventors the exclusive rights to their Writings and Discoveries,"[22] and thus the first Federal Patent law was passed by Congress and signed into law by George Washington.

1.1.2 The Antipatent Movement

A milestone in the evolution of the patent law was the large scale anti-patent movement from 1850-1873. This serious crisis was a result of the free trade ideas that prevailed at that time.

In Britain, royal commissions and various committees held inquiries about the deficiencies and abuses of the patent law that led to a patent reform in 1872.[23] In Germany, pressures were created by trade associations and chambers of commerce and with the support of Bismark, patent laws, deemed as "injurious to common welfare"[24] were abolished. In the Netherlands, the patent law was repealed in 1869 because "a good law is an impossibility."[25] In Switzerland, proposals for a patent system were rejected in 1849, 1851, 1854 and 1863. All proposals were rejected on the basis that patent protection seemed to be harmful and unjustifiable.[26]

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[22] Art. I, sec. 8 of the United States Constitution of 1789.

[23] It provided, inter alia for compulsory licenses and a minimum 7 year term.

[24] See Penrose, supra note 18 at p. 14.

[25] Fritz Machlup, An Economic Review of the Patent System, Study of the Subcommittee on Patents, Trade Marks and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No. 15 (Washington: Government Printing Office, 1958) at p. 14, (hereinafter Machlup).

[26] See Penrose, supra note 18 at p. 16.

The conflict over the patent law system had a great impact on the evolution of patent law and on the above-mentioned countries, especially the Netherlands and Switzerland.

1.1.2.1 The Case of the Netherlands

The 1870-1914 period is regarded as the period in which the Netherlands became an industrialized country. This period coincides with the absence of patent protection in the country. This patentless period was beneficial to the Dutch economy.[27] During this period, two great industries were founded and achieved an impressive level of development.

In 1871, the first margarine factory was founded in the Netherlands, using an invention patented in France. The absence of a monopoly secured through a patent did not deter the margarine industry from getting established and maintaining a leading position in the market.[28]

Similarly, the first incandescent lamp factory was set up by G. Philips and during the patentless period achieved its spectacular growth and became a world concern.[29] Incandescent lamps were already known and established in the world market; there was competition mainly from "Compagnie Continentale Edison" in France and AEG in Germany.[30] The fact, however, that there was not a patent system in the Netherlands gave

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[27] E. Schiff, Industrialization Without Patents (Princeton: Princeton University Press, 1971) at p. 56, (hereinafter Schiff).

[28] The invention was made in 1869 by Mèje Mouriès. The margarine industry was founded by Jurgens and Van den Bergh and became the greatest industry in the Netherlands.

[29] It was founded at Eindhoven by G. Philips in 1891.

[30] The Edison company had patented the Edison's carbon filament lamp. E. Rathenay was its licensee who established AEG in Germany.

Philips an advantage over AEG and Edison. The absence of patents meant that foreign firms, such as AEG and Edison, would not get a patent in the Netherlands and thus could not secure a monopoly position in the market, a situation that would have delayed production for Philips and would have obligated the company to sign a licence agreement with the patentee (Edison) accepting all his onerous restrictions and high royalties. As a matter of fact, this is what happened with AEG in Germany[31]. Philips, however, avoided all these impediments in its development as the result of the absence of a Dutch patent and succeeded in growing into a company of global proportions.

Hence, the lack of a patent law did not stifle industrialization; indeed, these two particular industries benefited from its absence.[32]

1.1.2.2 The Case of Switzerland

The same can be said for Switzerland. The absence of patent protection has not hampered industrialization.[33] In Switzerland, as is mentioned above, several proposals to introduce a patent law were rejected, as the prevailing climate toward the patent institution was hostile. Typical is the attitude among industrialists and businessmen as is expressed in a memorandum characterizing the patent system as a "cup of sorrows".[34] The

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[31] AEG was confronted with considerable obstacles and a series of restrictions imposed by the patentee (Edison Company). In 1887 AEG succeeded in getting rid of the "satellite position vis-à-vis the original Edison Group." See Schiff, supra note 27 at p. 62.

[32] Id., at p. 67.

[33] Id., at p. 103.

[34] "In the interest of the general prosperity of industry and trade patent protection, that cup of sorrows may pass from us" See Schiff, supra note 27 at p. 87.

same anti-patent attitude prevailed in the Zurich Chamber of Commerce and resulted in a strong debate between the proponents and the opponents of a future patent law.[35]

It should be mentioned within this context that two Swiss industries, the textile industry and the chemical industry, strongly opposed a prospective patent law as they were persuaded that the costs were considerable and would outweigh the benefits."[36] The chemical industry in particular opposed and debated on all fronts any Swiss patent law. This industry insisted that in the event of enactment of a patent law it should be left outside the scope of the patent law. In the 1883 Zurich Congress Resolution, which was in favour of a patent system, the chemical industry was recommended to be excluded from the patent law.[37]

Notwithstanding the absence of patent protection and the opponents' argument that the absence of patent protection would result in deterring the stimulation of industrial progress, inventive activity was vigorous. Many inventions took place and many companies were established and achieved a spectacular growth during this period. In 1859, Alexander Clave founded a silk dying factory in Basel. From this small factory emerged the Chemische Industrie in Basel (CIBA) in 1884, which grew into a giant world concern.[38]

In addition, the textile industry became very successful despite its English competitors. Parallel to the textile industry, the electro-technical industry achieved an

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[35] A report was published in 1886 based on a survey containing the position of institutionalists and businessmen: "The majority of the big industrialists of Zurich are not in favour of the granting of patents". See Penrose, supra note 18 at p. 122.

[36] See Schiff, supra note 27 at p. 92.

[37] Chemical products and processes including pharmaceuticals were left outside the Federal Patent Law on the Protection of Inventions in 1888. Under the new law of 1901, chemical and pharmaceutical products remained unpatentable and only processes were patentable.

[38] It produced a dye (mauve) invented in 1856 and patented in Great Britain by Perkin. Today CIBA is considered among the top 50 multinational pharmaceutical companies in the world.

impressive growth with a series of inventions that mechanized the textile industry. Many other industries were established during this patentless period, a fact that led Schiff to conclude that "no nation, large or small, with or without a patent system, has contributed as many basic inventions as did Switzerland during her patentless period."[39] Among the most important industries to be mentioned are the chemical industry, the chocolate industry, the soup industry, the baby food industry, and the perfume industry.[40]

1.1.2.3 Concluding Remarks

All these significant industries prove that many inventions and useful products are possible even without patents in the country of origin.[41] The chemical industry especially was helped rather than hindered by the absence of patent protection.[42]

In the case of Switzerland especially, chemical products were very popular in the world market and in straight competition with German products.[43] This situation resulted in threats originating in Germany against Switzerland and focusing on retaliatory actions such as imposing duties on imports. These threats of retaliation were coupled with the

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[39] See Schiff, supra note 27 at p. 110.

[40] Kohler (1832); Spruegli (1845); milk chocolate invented in 1875; chocolate fondant invented by R. Lindt (1879); in 1883 Julius Maggi invented the first ready-to-cook soup powder and "Maggi Cubes"; Henri Nestlé invented a baby food cereal (farine lacté) and "instant coffee" that became a big success in the USA.

[41] Not only invention, but foreign investment can flow into a patentless country as happened in patentless Switzerland with Anglo-Swiss Condensed Milk Co. See Schiff, supra note 27 at pp. 112 and 123.

[42] Id., at p. 104.

[43] The fact that chemical products were not hampered by patents resulted in very competitive prices; see Penrose, supra note 18 at p. 123.

moral and political pressure of the Paris Convention and resulted in the adoption of a patent law.[44]

In spite of the hostile attitudes and strong debates, the antipatent period came to an end after having exposed the imperfections of the institution and especially its monopolistic and restrictive feature. Many reasons have been given for this end, such as the Great Depression and the strong nationalism and protectionism that grew out of it and maybe, perhaps more importantly, the compromise solution of the compulsory licence.[45]

At any rate, the conclusion that can be drawn from these historical events and experiences is that a country can achieve economic and industrial development even without the help of a patent system.

From the strong anti-patent movement emerged the need to impose safeguards on the system. These were shaped in the form of compulsory licences which seemed to be the best method to reconcile the conflicting interests involved. Thus, compulsory licence was conceived as a compromise solution for conflicting interests.

1.2 The Paris Convention for the Protection of Industrial Property

1.2.1 Events Leading to the Paris Convention

By the end of the 19th century, as trade and industries were becoming influenced more and more by international co-operation, knowledge and commodities were crossing

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[44] In the case of Switzerland, the pressure was even more intense since the headquarters of the International Bureau were in Berne. However, the law that was enacted as a result of the pressure provided for compulsory working, compulsory licensing and excluded drugs from patent protection.

[45] See infra, text at p. 100 et seq.

borders more easily. Given the evolving international interdependence of countries, it became necessary to protect inventors' rights and to protect industrial property rights in general on an international basis.

The laws of a country relating to patents, however, were, and still are, concerned only with those acts that are performed in the country itself. Thus, the exclusive rights conferred on the patentee by the patent are prescribed and conditioned by the laws of each country, and are legally effective only within the defined territory of the country which granted the patent. The rights are not effective in other countries.[46] Consequently, the patentee of country A can exercise the rights derived by his patent in country A, but not in country B. Only acts performed in country A infringe his patent, not the ones performed in country B. This is the principle of territoriality which derives from the territorial limitation of sovereignty and which underlies the international system of patent protection.[47] The effect of the principle of territoriality is that the grant, the extinction and the consumption of the rights conferred on the patentee by the patent are limited to the territory of the country that granted the patent.

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[46] There are three exceptions: i) The European Community Patent granted pursuant to the Community Patent Convention adopted at Luxembourg in 1975 will have effect in 12 member countries of the European Community (Belgium, France, Germany, Greece, Italy, Liechtenstein, Luxembourg, the Netherlands, Ireland, Spain, Portugal and the United Kingdom); ii) The ESAPIRO Patent granted by the Patent Office of the Industrial Property Organization for English Speaking Africa in Harare, has effect in five member countries of ESAPIRO (Ghana, Malawi, Sudan, Uganda and Zimbabwe); iii) The patents granted by the African Intellectual Property Organization in Yaounde have effect in 12 member countries of the Libreville Agreement (Benin, Cameroon, the Central African Republic, Chad, Congo, Ivory Coast, Gabon, Mauritania, Niger, Senegal, Togo and Burkina Faso (Upper Volta)).

[47] This principle is expressed in the various national laws which cover aspects such as the requirements of patentability, the obligations of the patentee, the term of the patent, the exclusion from patentability etc.

Given the principle of territoriality, if a patentee desired protection for his invention in several countries, he had to secure such protection in each country separately.[48] Consequently, foreigners experienced extreme difficulties in securing their rights. Two obvious impediments were the diversity of domestic laws and the considerable limitation on the patents of foreigners. It was apparent that the overall situation in respect to patent protection for foreigners was uncertain and inadequate and created cumbersome problems. Out of these problems emerged the need to protect the inventors' rights on an international level.[49]

The inadequacy of international protection for patents and for industrial property became particularly apparent in an International Exposition that took place in Vienna in 1873 and which amazed the world with all the latest inventions.[50] The inventors were reluctant to place their inventions in the exposition because of the lack of protection. As a result of the negative climate towards patent protection, the Congress for Patent Reform[51]

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[48] To mention just a few of these diversities, it was possible that a patent obtained by a patentee in his country for his invention might not be patentable in another country. His invention might not qualify for the novelty requirement set forth by the law of another country. Furthermore, the patentee had to apply for a patent to all the countries at exactly the same time in order to safeguard the novelty of his invention. Some countries would contend that publication in other countries constituted breach of their own novelty requirement. To these substantive obstacles, we could add administrative problems such as proper documentation and different times for payment of fees.

[49] Mention should be made here of the very first acts that emerged in the evolution of the international protection of industrial property. These were provisions based on the system of reciprocity and were incorporated in bipartite treaties between various countries. Up to 1883, there were signed sixty-nine bipartite treaties of commerce or of friendship, special declarations, agreements, or conventions. Yet only a tiny fraction of these acts provided provisions for the reciprocal protection of patents: The Customs Convention of 1876 between Austria-Hungary-Liechtenstein and the Treaty of Commerce of 1881 between Austria-Hungary-Germany. The rest of the treaties dealt with other rights of industrial property law such as trademarks and tradenames. See list of all 69 treaties in S. Ladas, Patents, Trademarks, and Related Rights - National and International Protection (Cambridge: Harvard University Press, 1975), Vol. 1 at pp. 43-45 (hereinafter Ladas)

[50] Id., at p. 59.

[51] Congress for Patent Reform, August 4 to 9, 1873.

was convened at Vienna "to bring about an international understanding upon patent protection"[52] in order to accomplish uniformity in the area of patent law.

Following the Vienna Congress for Patent Reform, the International Congress on Industrial Property met at Paris in 1878 and created a permanent International Commission to convoke "an official international conference with the task of determining the basis of a uniform legislation."[53]

Accordingly, the "Projet d'une Union Internationale pour la protection de la Propriété Industrielle"[54] was drafted and circulated to other states inviting them to an official conference. This Conference took place in 1880 in Paris and analyzed the draft with the aim of promulgating "provisions suitable for incorporation in an international convention."[55]

Thus, the focus has shifted from "uniform legislation" to "provisions suitable... in an international convention" within the context of a Union which would provide general rights and principles in order to secure the rights of industrial property on both national and international levels.

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[52] Resolution III (f). See Ladas, supra note 49 at p. 60.

[53] September 5-17, 1878. The Commission met on Sept. 18-19, 1878. Ten wealthy and powerful countries were officially represented. None of them was a developing country in relevant terms.

[54] Journal de Droit International Privé (1880), p. 678 cited in Ladas, supra note 49 at p. 63. The author of the draft was Jagerschmidt from the French Delegation.

[55] Conférence Internationale de Paris pour la Protection de la Propriété Industrielle, November 4 to 20, 1880. Twenty countries were represented. Seven were not as wealthy and powerful as the other thirteen.

1.2.2 The Principles of the Paris Convention

In 1883, in Paris, the International Conference approved and opened for signature the draft Convention, and thus the International Union for the Protection of Industrial Property was created.[56] Eleven countries were the original parties to the Paris Convention, namely: Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, El Salvador, Serbia, Spain and Switzerland.[57] With the Union, a permanent International System of Industrial Property was created. The Paris Convention "constitutes the most important general international instrument in the field of industrial property."[58]

The aim of the Paris Convention is to protect the Industrial Property rights: "the countries to which the present Convention applies constitute themselves into a Union for the protection of industrial property."[59]

Two fundamental principles define the scope and dimensions of the protection of industrial property provided by the Paris Union: A) The National Treatment Principle and B) The so-called "Unionist" Treatment Principle.

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[56] Paris Convention for the Protection of Industrial Property, 13 U.S.T. 1, 27-28, T.I.A.S. No. 4931, at pp. 27-28 (hereinafter Paris Convention). The Paris Convention was signed by Belgium, Brazil, France, Guatemala, Italy, the Netherlands, Portugal, Salvador, Serbia, Spain and Switzerland on March 20, 1883. It was ratified by the representatives of the 11 countries that signed the Convention on June 6, 1884 and came into effect on July 7, 1884.

[57] El Salvador denounced the Paris Convention and withdrew on December 26, 1885. Guatemala denounced the Paris Convention and withdrew on November 8, 1894. Brazil is the only original party developing country that remains member to the Paris Convention.

[58] Klaus Pfanner, Deputy Director General of WIPO, "The World Intellectual Property Organization" (1970), 10 I. I. C. at p. 10.

[59] Art. 1, para 2 of the Paris Convention.

A) According to the National Treatment principle,[60] nationals of each of the contracting countries enjoy in all other member countries of the Union the advantages that the laws of these countries grant to their respective nationals. Thus, the principle of National Treatment consists in "the application, without any discrimination, of the national law as applied to nationals of the country itself."[61]

By definition, this principle is opposed to the principle of reciprocity, since foreigners are assimilated to nationals and enjoy the same protection that is available for nationals. A country that imposes few restrictions, such as low taxes and fees, cannot claim analogous treatment in other countries. Similarly, a citizen of a country that does not recognize patent rights can be granted such rights in another country of the Union since no reciprocity is recognized in the Convention. Hence, the principle of National Treatment may lead to inequalities given the different circumstances that prevail in every country.[62] The obligation to grant National Treatment raises a problematic issue as far as developing countries are concerned because it "is not in harmony with the interests of developing countries."[63] In the past, this obligation may have been adequate to protect industrial property rights since it was applied to countries with basically similar economic structures. Today, the majority of member countries of the Paris Convention are developing countries which are basically poor and lag behind in technological and industrial development. As

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[60] Art. 2, para 1 of the Paris Convention.

[61] G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property (Geneva: BIRPI, 1967) at p. 129, (hereinafter Bodenhausen).

[62] See Ladas, supra note 49 referring to the concerns expressed by the United States.

[63] C. Vaitsos, "The Revision of the International Patent System: Legal Considerations for a Third World Position" (1976), 4 World Development 85 at p. 89., (hereinafter Vaitsos-Legal Considerations).

will be seen, practically all economically important patents issued by developing countries are owned by foreigners.[64]

The National Treatment principle means that foreigners are placed on an equal basis with nationals. The grant of equality, however, only makes sense when the parties involved are in a general way equal; when they are not, equality of treatment simply gives the stronger party unlimited freedom to utilize his power at the expense of the weaker party.

This principle tries to create a legal equality between member countries and especially between foreigners and nationals. The National Treatment principle, however, does not succeed in achieving this goal. When and if national patent laws become harmonized and if countries achieve a relatively equal economic development, then this principle will become more acceptable and efficient.

For this reason, developing countries are concerned about the unfavourable terms[65] and they are trying to revise the National Treatment Principle.

B) According to the "Unionist" Treatment principle of the Paris Convention, nationals of each of the contracting countries enjoy special rights and advantages that the Convention recognizes over and above the rights that are provided to nationals by the national law of each country.

Thus, the Paris Convention contains a number of common rules which apply to all members of the Union, "purporting to furnish an equitable solution of the problems

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[64] See infra text at p. 39.

[65] See Vaitsos - Legal Considerations, supra note 63 at p. 88.

arising from the diversities of legislation and the need for protection of vested rights of industrial property having a really international character."[66]

Among the provisions that establish common legislation to all members of the Union is the right of priority, which permits a patentee who has filed an application for a patent in one of the member countries to obtain recognition for his claim in the other countries, i.e., he has the right to file subsequent applications in other member countries.[67] The patentee enjoys a priority of twelve months to file subsequent applications in the other countries without the novelty of his invention being destroyed or invalidated in the meantime by publication or exploitation or other parties obtaining any rights before him.

Furthermore, a special advantage constitutes the independence of rights,[68] which declares that a patent applied for a particular invention in any of the member countries of the Union shall be independent of all other patents obtained for the same invention in other countries of the Union. Thus, pursuant to this provision, revocation or nullity or duration of one patent does not affect another patent in another country of the Union, for the same invention.

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[66] See Ladas, supra note 49 at p. 271.

[67] Art. 4 of the Paris Convention. It was created out of the problems posed by the principle of territoriality. In the past (before the PC), the patentee was faced with serious problems, such as the burden of simultaneously applying for a patent in all countries in order to obtain patent protection, a fact that was extremely difficult and expensive, if not impossible. Moreover, another party might have applied for a patent in another country ahead of the patentee and thus might steal his right. Further problems derived from the novelty requirements of some countries which required a universal absolute novelty, and prior publication in another country would destroy the newness of an invention and therefore deprive the patentee from acquiring a patent for his invention. It was these problems that the right of priority sought to solve.

[68] Art. 4bis of the Paris Convention. It was introduced at the Revision in Burssels in 1900.

Other important rights and advantages that constitute common legislation are the abolition of forfeiture for importation of patented articles,[69] the right of the patentee of a process patent to import[70] and the restrictions and limitations on the obligation to work and compulsory licences and revocation of patents which are discussed in the fourth chapter.[71]

Notwithstanding the existence of the "Unionist" Treatment principle with all its constituent common rules, member countries of the Union are free to establish their own laws and regulations taking into consideration their national interests and needs.[72] Consequently, among the areas that are left free for each member country to legislate are the criteria for patentability, the choice of a first-to-file or first-to-invent system, the choice of an examination or registration system, the duration of the patent grant, the choice to grant patents for products or processes and the choice of which fields would be covered by patents.[73]

1.2.3 The Administration of the Paris Convention - WIPO

The Paris Convention provided for periodical conferences of revision with the aim of introducing amendments to improve its system. Such conferences of revision were held in Rome in 1886, in Madrid in 1890-1891, in Brussels in 1897 and 1900, and in

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[69] Art. 5(A)(1) of the Paris Convention to be discussed later.

[70] Art. 5 quater of the Paris Convention.

[71] Arts. 5(A)(2) and 5(A)(3). In addition to all these fundamental rights and advantages, other rights constituting common legislation and accorded by the Paris Convention are: The right of the patentee to be named in the patent even in these countries where this is not required (Art. 4ter) and the right to a period of grace for the payment of fees for the maintenance of patent rights (Art. 5bis).

[72] See Bodenhausen, supra note 61 at p. 15.

[73] See infra text at p. 79 et seq.

Washington in 1911; after World War I, conferences of revision were held in The Hague in 1925, in London in 1934, in Lisbon in 1958 and in Stockholm in 1967.[74]

Despite the various periodic revisions that took place, the Paris Convention forms a juristic union. The successive Acts of the Convention do not constitute independent treaties but constitute rather varied texts of one and the same organized Union as a consequence of which a state enters or leaves the Union as a whole. For example, a member state cannot denounce the Stockholm text and declare that it remains bound by the Lisbon or London text. Similarly, a state can accede to the Union only to the last revised text and not to an earlier text. Thus, for example, a state that joins the Union can only accede to the Stockholm text, whereas a member of the Union which has already acceded to the Hague or London text can only accede to the Stockholm text and not to the Lisbon text.[75]

Because of these periodic revisions of the Paris Convention member countries may not necessarily be bound by the same text but rather by different texts. Thus, when a new country accedes to the Stockholm Act, it is necessarily bound to all other member states which have acceded to earlier acts of the Convention by the text of the Convention

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[74] The Paris Convention for the Protection of Industrial Property of 20 March 1883, revised at Brussels on 14 December, 1900, at Washington on 2 June 1911, at The Hague on 6 November 1925, at London on 2 June 1934, at Lisbon on 31 October 1958, and at Stockholm on 14 July 1967. See Paris Convention, supra note 56.

[75] Id., Art. 23(a): "After the entry into force of this Act in its entirety, a country may not accede to earlier Acts of this Convention." New countries can accede to the Union by notifying a declaration of accession to the Director General of the International Bureau. The accession produces its effects three months after the Director General's notification to the members of the Union of such accession unless a subsequent date is indicated in the instrument of accession. See Articles 21, 22, 23 of the Stockholm text.

applicable to them and it is not only bound to those that have acceded to the Stockholm Act.[76]

For example, between a new country A which has acceded to the Stockholm text and a member country B which has acceded to the Lisbon text, the Lisbon text is applied. Furthermore, between a member country C which has acceded to the London text and the administrative provisions of the Stockholm text, and country D, which has acceded to the Stockholm Act after having acceded to the Lisbon Act on question of substance, the applicable text is the London text.[77]

A state which accedes to the union automatically accepts all rights and obligations of the Union.[78] Any possibility of making reservations with regard to any of the clauses is excluded.[79]

The Paris Convention has not only formed a traditional treaty which establishes rights and obligations for its parties, but a juristic union with separate organs to carry out

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[76] The relations between countries are governed by Art. 27 of the Paris Convention; see also Bodenhausen, supra note 61 at p. 212.

[77] Art. 27(2) and (3). This is the case between Canada and the USA.

[78] Art. 22 of the Paris Convention.

[79] There are two exceptions: Art. 20 (1)(b) and Art. 28 (2): A member state has the right to exclude the application of Articles 1 to 12 or 13 to 17 and any state member to the Paris Convention or not acceding to the Stockholm Act may declare that it does not agree to be bound by the jurisdiction clause of Art. 28(1), which regulates the settlement of disputes between member states.

its objectives. Thus, the Union has established the Assembly[80], the Executive Committee,[81] the International Bureau[82] and the Conferences of Revision.[83]

The International Bureau is entrusted with the administrative tasks of the Paris Convention.[84] After the Stockholm revision of the Convention, the International Bureau was placed under the auspices of the World Intellectual Property Organization (WIPO).[85] The International Bureau acts as a secretariat of WIPO and of the various other organs of the Paris Convention. Thus the Director General of WIPO is also the Chief Executive of the Paris Convention.[86]

WIPO's task is "to promote the protection of intellectual Property throughout the world."[87] WIPO accomplishes its task by the following means: It concludes new

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[80] Art. 13, established after the Stockholm Revision.

[81] Art. 14, established after the Stockholm Revision.

[82] Art. 15, reorganized at the Stockholm Revision.

[83] Art. 18(2), reorganized at the Stockholm Revision.

[84] The International Bureau was set up in 1884. In 1893 it was united with the International Bureau of the Berne Convention for the Protection of Literary and Artistic Works (1886) and formed the United International Bureaus for the Protection of Intellectual Property (BIRPI: Bureaux Internationaux Réunis pour la protection de la Propriété Intellectuelle). In 1960 its headquarters were transferred from Berne to Geneva. In the Stockholm revision of the Paris Convention (1967), BIRPI underwent a comprehensive administrative reform, achieved with the Convention establishing the World Intellectual Property Organization (WIPO), which was signed at Stockholm on July 14, 1967. Finally, on December 17, 1974, WIPO, the continuation of BIRPI, became the 14th specialized agency of the UN. See Ladas, supra note 49 at p. 145 and Bodenhausen, supra note 61 at pp. 175-178.

[85] Convention Establishing the World Intellectual Property Organization 21 U.S.T. 1749, T.I.A.S. No 6932, 828 U.N.T.S. 3.

[86] Art. 15(1)(c) of the Paris Convention.

[87] Preamble of the WIPO Convention adopted at Stockholm on July 14, 1967.

international treaties and agreements,[88] such as the Patent Cooperation Treaty (PCT),[89] administers various systems of international classification,[90] and makes efforts towards the harmonization of patent documentation and procedural steps among the member states.[91]

Furthermore, WIPO makes significant efforts towards a substantive revision of the Paris Convention in order to introduce new provisions and to change certain existing provisions to meet better the needs of developing countries.[92] With regard to developing countries, the attention of WIPO has been focused on providing legal-technical assistance in the Industrial Property field in order to aid the developing countries in their development process. For this particular task, WIPO has created a Permanent Program for Development Co-operation Related to Industrial Property.[93] The task of this program of WIPO is to assist the developing countries in the following areas: training specialists, conducting workshops and seminars on the law of industrial property, creating or improving domestic legislation and governmental institutions in the field of industrial property, stimulating inventive activity, conducting studies on the acquisition, on improved terms, of foreign

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[88] Among the recent treaties and agreements are: The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977) and the Geneva Treaty on the International Recording of Scientific Discoveries (1978).

[89] Patent Cooperation Treaty, 28 U.S.T. 7645, T.I.A.S. No. 8733, (1970) 9 Int'l Legal Materials 978. The PCT was signed on June 19, 1970 at the Washington Diplomatic Conference and remained open for signature until December 1970 when thirty-five states became signatories. The treaty entered into force on January 24, 1978. Canada acceded in 1989. The purpose of the PCT is to simplify the filing of patent applications by centralizing the filing procedure and standardizing the applications. Mention should be made of Art. 51 of the PCT which provides for the establishment of a Committee for Technical Assistance to developing countries.

[90] E.g., The International Patent Classification consisting of 51,000 divisions.

[91] E.g., The International Patent Documentation Centre (INPADOC) in Vienna, established in 1972 which contains the most significant bibliographic data on patents throughout the world.

[92] See infra text at p. 157 and note 468.

[93] WIPO Doc. PC/IP/X/9. Tenth session, (April 8-11, 1986).

patented technology and finally exploiting technological information contained in patent documents.[94]

1.3 Concluding Remarks

In conclusion, the Paris Convention imposes the obligation on its members to grant National Treatment to nationals of other member countries and requires that this National Treatment conforms with the common rules determined by the Unionist treatment and at the same time leaves certain areas to the legislative discretion of its members.

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[94] WIPO Doc. AB/XV/2. Fifteen series of meetings, Sept. 24-28, 1984; See also WIPO Doc. AB/XV/3, July 30, 1984; WIPO Doc. PC/IP/IX/3, July 31, 1984; WIPO Doc. PC/IP/IX/3, July 31, 1984. Numerous cases of assistance such as assistance in the control of technology licensing agreements and drafting of patent laws, workshops and seminars are organized by WIPO such as the 1972 Draft Patent Licence Convention, the Workshop on Industrial Property Licences and Technology Transfer Arrangements held in Manila on Nov. 1983, the Seminar on Patent Licensing in Industry held in Jakarta on May 1984, the Seminar on Patents in ASEAN Countries held in Kuala Lumpur on Sept. 1983, etc. Furthermore, in 1974, the Permanent Committee of WIPO decided to revise the BIRPI Model law for Developing Countries on Inventions and in 1978 New Model law was created in order to accommodate the needs of developing countries since the 1965 model law was found inadequate to protect their interests. The New Model law for Developing Countries on Inventions and Know-How was drafted in order to assist developing countries in the process of drafting legislation in the field of industrial property. Furthermore, WIPO provides assistance to states to draft their national patent laws or improve it as, for example, the assistance given to the African Intellectual Property Organization (OAPI) to revise the Libreville Agreement Relating to the Creation of an African and Malagasy Industrial Property Office (Sept. 13, 1962).

CHAPTER II

THE ROLE OF THE INTERNATIONAL PATENT SYSTEM IN THE TRANSFER OF TECHNOLOGY TO DEVELOPING COUNTRIES

Developing countries need technology in order to advance their development and industrialization. Among the different institutions that govern the flow of technology is the international patent system. This chapter discusses the role of the international patent system in developing countries. It focuses on the role of the patent system in developing countries, rather than in developed countries where different considerations may apply, as will be seen later. Therefore, in order to assess the role of the patent grant we will compare the benefits and costs that a developing country may have in granting patents, in order to evaluate them and see if the benefits outweigh the costs or if the international patent system works against the interest of the developing countries. Then, we will examine under what conditions the international patent system may be of help to the industrialization of developing countries.

2.1 The Traditional Role of Patents

Traditionally four theories have been used to justify the grant of patents: The natural law theory, the reward theory, the disclosure theory and the incentive to invent theory. The first section discusses these theories in order to set the background and then considers the question whether the same set of theories can apply to countries of fundamentally different infrastructure.

2.1.1 The Natural Law Theory was derived from the natural law philosophy of the late 18th to early 19th century in Europe and especially from the ideas of the French revolution of 1789. This theory alleged that by natural law a man had a preexisting property right on his own ideas and any unauthorized appropriation was to be regarded as "theft". This theory went through many debates, was strongly criticized and finally abandoned.[95]

2.1.2 The Reward to the Inventor Theory considers that there exists an obligation to society to reward the inventors for the services they provide. The reward should be proportional to the inventor's efforts and the social usefulness of his services. The fairest method to provide a "just reward" is by granting an exclusive temporary monopoly.

The problem that arises with the reward theory is the absence of a proportional correlation between the reward and the services. Grounds for criticism may be the argument that inventions which represent a major advance in knowledge and which are of special usefulness to the public and which require time and expense and a considerable effort receive the same reward as inventions that are not so difficult and complicated to make and which have a rather limited field of application and usefulness.[96]

This theory has been severely attacked on the grounds that it does not have the strength that it had in the past to provide a justified reason for the patent grant. Today the inventor is not the sole researcher who works on his own with limited means. He is

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[95] See Penrose, supra note 18 at p. 23. The main criticisms were: 1) One idea can derive from many different minds and thus it is not correct to maintain that it is the property only of one mind. 2) One idea is based on previous ideas and thus an inventor in order to claim a right to his own idea he must first relinquish all ideas on which his own idea is based. 3) Once an idea has been communicated to others then the inventor shares it with them and can not claim exclusive rights on it. 4) If property in ideas was based on a natural law how could it be justified to limit it to 14 or 20 years and not to recognize it for ever? For a further analysis see: Penrose pp. 21-26. Due to the many discrepancies this theory has been abandoned. Contra see G. Folk Patents and Industrial Progress (New York, 1942).

[96] See Anderfelt, supra note 19 at p. 44.

usually an employee and part of a research team. Often it is his employer who exploits the invention and reaps the benefits and not the inventor himself.[97]

However, while the corporation instead of the inventor, may provide the research funds and benefit from the invention, it should be realized that there exist considerable risk of failure and considerable expenses so that at least some reward should be made available for patents. Therefore, since society should recognize and reward success, the reward theory constitutes a sound argument in justification for the patent grant.[98]

2.1.3 The Incentive to Disclosure of Secrets Theory [99] assumes that a patent is the best method to induce an inventor to disclose his invention.

The patent is justified on the rationale that instead of inventions being kept secret and essentially being lost after the death of the inventor, society would benefit if the inventor disclosed his invention and in return received an exclusive monopoly.

The arguments that have been advanced for the defence of this theory focus on the point that the invention will be disclosed at the time of the patent grant and thus, on the one hand, will not be kept secret and lost and, on the other hand, that the information will be made known at the time of the grant. Furthermore, the publication related to the patent would benefit scientists and induce them to work on related areas. After the expiration of the patent, society would further benefit as the invention would be free to be exploited.

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[97] Id., at pp. 30-34; see also Penrose, supra note 18 at p. 30.

[98] For a further analysis of this theory see Machlup, supra note 25 at pp. 23 and 29-31.

[99] Machlup uses the term "Exchange-for-secrets" theory, supra note 18 at p. 32 and Anderfelt prefers the term "utility of disclosure to society" theory, supra note 19 at p. 36.

This theory has been criticized on many points. First, the inventor will only disclose his invention and reveal his secrets when he fears that it is impossible to keep it secret or when others may arrive at the same conclusions.[100] Furthermore, it is impossible to determine to what extent disclosure really prevents ideas being lost or kept secret.[101]

Another important point that has been made to attack this theory is that inventors avoid completely disclosing their secret and thus they obtain a patent after a partial disclosure. With incomplete disclosure the purpose of granting a patent is circumvented because the missing information is very essential and crucial for scientists to learn and effectively apply the invention. Thus patents without the know-how are of little value.[102]

Furthermore, a point can be made about the exchange of the patent for information that society would get anyway without trading monopoly privileges since, given the present conditions of industrial development, it is questionable whether products can be processed in secrecy for an extended period of time.[103]

Finally, it is an inherent assumption in this theory that after the patent expires the invention becomes free for any interested party to exploit. Given though the present conditions of industrial production and the continuous progress on research and development, especially in the pharmaceutical industry, it is uncertain that an invention continues to hold the same value after 15 or 20 years.

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[100] See Anderfelt, supra note 19 at p. 36.

[101] See Penrose, supra 18 at p. 34.

[102] Ibid.

[103] Arnold Plant, "The Economic Theory Concerning Patents for Inventions" (1934), 1 Economica 30 at p. 44.

2.1.4 Finally, the Incentive to Inventive Activity Theory justifies the patent grant on the grounds that there must exist a special incentive to lure the inventor to become dedicated in an inventive activity. The best method to do that is by granting the inventor an exclusive monopoly.

In the past, when the inventor was usually an individual, no doubt this theory would have served well and played a major role as a good incentive for the inventor. Given, however, the contemporary reality of the individual being part of a research team and usually not working independently but as an employee, the value of this argument seems questionable and doubtful.[104] Moreover it is difficult to measure to what extent patents provide an inducement to inventive activity. The possibility that patents play a role as an inducement to such activity cannot be denied. However, other financial incentives and subsidies provided by government may be of a greater impact than the patent grant.[105]

Notwithstanding the criticism, these theories may constitute sound justification for the granting of patents within the context of a developed country. As Machlup stated

> "If one does not know whether a system "as a whole" (in contrast to certain features of it) is good or bad, the safest "policy conclusions" is to "muddle through" - either with it, if one has long lived with it, or without it, of one has lived without it. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system, for a long time, it would be irresponsible, on the basis of our present knowledge to recommend abolishing it. This last statement refers to a country such as the United States of America -not to a small country and not a predominantly non-industrial country where a different weight of argument might well suggest another conclusion".[106]

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[104] See Anderfelt, supra note 19 at p. 37.

[105] Id., at p. 41. See also Machlup, supra note 25 at p. 35.

[106] Machlup, supra note 25 at p. 80.

2.2 The Traditional Theories about Patents Within the Context of Developing Countries

The issue that arises at this point is whether the same theories can equally apply to countries with a fundamentally different set of circumstances, needs and interests, i.e., the developing countries.

As a framework of reference we should mention the reality of existing conditions in patent matters in developing countries. It has been estimated that the developing countries grant 6% of the world total of patent grants.[107] Of this share no more than 1% is held by nationals of developing countries within their country.[108] Most patents in developing countries are owned by foreigners; the United Nations classical study of the issue reports 80 to 85% or 5/6 of patents in developing countries are owned by foreigners mainly MNCs[109] and only 1/6 of patents are owned by nationals of these countries within their own country[110] whereas 2/3 of 1% are owned by nationals abroad.[111]

Furthermore, the majority of these foreign-owned patents are rarely used in production in these countries. Ninety-five per cent of the patents held by foreigners are never used locally but are rather used as a means to secure the monopoly position of the

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[107] The Role of the Patent System in the Transfer of Technology to Developing Countries UN Doc. TD/B/AC.11/19/Rev.1 (1975) para 257 at p. 37, (hereinafter The Role of the Patent System).

[108] Id., para 263 at p. 38.

[109] Id., para 286 at p. 42.

[110] Id., para 263 at p. 38.

[111] Id., para. 266 at p. 38.

patentee by securing the importation of the patented invention.[112] Consequently the patentee secures his export market and enjoys control on the market. In other words the patentee has the monopoly on imports and thus uses his patent as an exclusive import permit.

Vaitsos, in this respect, reports that in Colombia from a total of 3,513 product or process patents (2,534 of them referred to the pharmaceutical industry) only 10 were actually worked in Colombia in 1970.[113] Furthermore he reports that in Peru out of 4,872 patents issued from 1960 to 1970 only 54 were worked in the country, i.e., "only about 1.1 per cent of the total".[114] These findings made Vaitsos conclude that patents in developing countries are mostly foreign owned and are mostly totally unused.[115]

This overwhelming majority of foreign owned patents has led to the often stated characterization of developing countries as being "in the periphery of the patent system."[116]

Furthermore, this 1% share of patents held by nationals of developing countries is of questionable quality and importance. A study conducted in Latin America by J.Katz revealed that only a tiny fraction of local inventions (6% to 8%) was considered to have significance and "technological importance".[117] This portion does not contain any

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[112] C. Vaitsos, "Patents Revisited: Their Function in Developing Countries" in C. Cooper (ed.), Science, Technology and Development p. 73 at p. 74. Originally published in Special issue on Science and Technology in Development, (1972), 9:2 Journal of Development Studies. (hereinafter C. Vaitsos-Patents Revisited.)

[113] Id., at p. 81.

[114] Id., at p. 75.

[115] Id., at p. 77.

[116] This expression is used within UNCTAD and by various scholars such as C. Vaitsos.

[117] Jorge Katz, Patents, the Paris Convention and Less-developed Countries, Discussion Paper No 190 (Yale University:Economic Growth Centre, 1973), at p. 44, (hereinafter Katz).

pharmaceutical invention whatsoever but rather consists of minor uneconomic and unimportant inventions. The results of his study made Katz conclude that "the local inventors are very poorly integrated into the expanding system and only play a very marginal role in the advancement of domestic technology"[118].

Given this context one cannot accept that developing countries grant patents based on the same considerations that developed countries may justify their grant.

Thus, considering first the reward theory it is not possible to sustain that developing countries provide protection to the foreign inventions with the purpose to reward their inventors, who have in any way already received their reward in their country.

Furthermore, given the developing countries' infrastructure with regard to the above mentioned share of patents granted and owned by nationals of these countries and by foreigners and given the level of industrial development, one cannot consider that patents give an incentive to inventive activity in developing countries.

As has been stated above 84% of the total number of patents are owned by foreigners for reasons associated with the securing of their position in the market, i.e., protection of their import market in developing countries, and only 1/6 of patents or 1% of the world total is owned by nationals of developing countries.[119] Thus, the argument that patents act as an incentive to domestic inventive activity seems to carry little weight within the context of a developing country and it cannot be used to justify the patent grant in these countries. This argument cannot justify the maintenance of the patent system in developing countries where the majority of patents are foreign-owned and only a slight fraction of patents are owned by nationals of these countries.

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[118] Id., at p. 47.

[119] The Role of the Patent System, supra note 107 at p. 36.

Finally, the disclosure of secrets theory does not carry much weight in the developing countries' context either. Developing countries are characterized by a technological gap that separates them from the developed world. When a country grants a patent, disclosure of invention has already taken place. Thus at the time when a developing country uses a new product or process, this particular product or process has already been disclosed and known on the International Community for a considerable amount of time. Hence it does not seem logical nor in the developing countries' interests to grant a patent on the basis of encouraging the disclosure of patents, since a developing country can legally obtain the same information from other sources such as the official Gazettes published by various Patents Offices and need not grant a patent just for the purpose of repeating such disclosure.[120]

Thus, the patent grant in developing countries cannot be justified on the basis of the four traditional theories since their assigned role is not fulfilled in the context of developing countries.

Consequently the logical question that follows is on what grounds developing countries support the patent system and provide for patent grants. Therefore, in order to take into account the infrastructure that exists in developing countries, their interests and the technological changes that have occurred, two interrelated arguments may be advanced to justify the patent institution in these countries: the foreign investment and the flow of technology arguments. In other words the patent grant may be justified on the grounds that patents may facilitate the flow of technology with the exclusive right they provide to the patentee which acts as an inducement for investment. However we will see under

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[120] See Katz, supra note 117 at p. 17.

what conditions this is likely to happen since patents may equally hinder such flow of technology.

2.3 The Impact of the International Patent System on Developing Countries

Within the context of this infrastructure that exists in developing countries, we will examine the impact that the international patent system and specifically the granting of patents to foreigners has for developing countries, especially on their industrialization development process.

Many arguments have been advanced with regard to the role that patents play in the context of developing countries. As we shall see, on the one hand, the proponents of the international patent system assert that patents facilitate the flow of technology to developing countries and promote foreign investment. On the other hand, the opponents of the international patent system assert that patents hinder the flow of technology as well as restrict local technological advance through patent imitation.

To assess the impact of the patent institution and the two divergent positions a cost-benefit examination is required.[121] In other words we will examine the possible benefits and costs that might be incurred when the patent is not used in production in the country that granted it but instead is used as a means to secure imports. Then we will examine the effects in the case when a patent is worked locally and attempt to evaluate them.

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[121] S. Lall, "The Patent System and the Transfer of Technology to Less-Developed Countries" (1976), 10 J. World Trade L. 1 at p.10. (hereinafter Lall (1976)); in evaluating the costs and benefits in order to find out if patents help or hinder the transfer of foreign technology and foreign investment, we should mention that in any case we should neither overestimate nor underestimate the role of patents. See also Martine Hiance and Yves Plasseraud, Brevets et Sous-Développement. La Protection des Inventions dans le Tiers-Monde (Paris: Librairies Techniques, 1972) passim.

2.3.1 Benefits and Costs of Non-Use of Patents

At the outset we should mention that the issue of the impact of the international patent system on developing countries arises when the patented invention is desirable to be produced in the country, as part of the country's development plan and such production is considered preferable to imports. Thus, it is either produced or not as a deliberate choice of the patentee who prefers instead to import, although, it could have been profitably produced in the country to the developing country's advantage. The issue does not arise when the developing country prefers to import and when the patented invention is not of economic and significant value to be worked.[122]

The first alleged benefit that is set forth in favour of the patent system refers to the inducement it provides to inventive activity. The argument runs that the patent system improves the rate of invention since a foreign firm has an additional incentive to invent. This incentive derives from the possibility of getting extended protection in its foreign markets. Thus, Kunz-Hallstein ascertains that patents promote innovation and favourably promote technological progress.[123] Similarly Mangalo considers the patent system as important for innovation.[124]

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[122] Penrose, supra note 18, ch.V.

[123] Kunz-Hallstein, "The Revision of the International System of Patent Protection in the Interest of Developing Countries" (1979), 10:6 I. I. C. 649 at p. 664. (hereinafter Kunz-Hallstein (1979)).

[124] N. Mangalo, "Patent Protection and Technology Transfer in the North-South Conflict" (1978), 9:2 I. I. C. 100 at p. 106 (hereinafter Mangalo).

However, within the specific context of developing countries, as Penrose states, this argument "can be dismissed as unimportant"[125] since developing countries do not have the infrastructure and after all the foreign patentee is not motivated to innovate by the patent in the developing country. This role is played by the patent in the developed country. Most patented innovations are designed for consumers' needs in developed countries and therefore the innovation would not be affected if developing countries did not issue patents.

Professor Firestone in his survey conducted in a number of companies in Canada reveals that a large part of R&D would continue to take place even in the absence of a patent system.[126]

Hence, the inducement to foreign innovating activity argument is considered of minor practical impact. With particular reference to the pharmaceutical sector of developing countries it may be stated that this incentive "must be even less significant as an incentive to solve technological problems of more limited application".[127]

Furthermore, a benefit that is attributed to the granting of patents to foreigners is a creation of a favourable climate for attracting foreign investments.[128] This argument maintains that the existence of a patent system in a developing country attracts possible prospective investors to invest in the country considerable capital and even if the patented

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[125] E. Penrose, supra note 18 at p. 113.

[126] O.J. Firestone, Economic Implications of Patents (Ottawa: University of Ottawa Press, 1971), at p.169, (hereinafter Firestone).

[127] See Anderfelt, supra note 19 at p. 130.

[128] See The Role of the Patent System, supra note 107 at pp. 56-57, para 363; see also Peter O'Brien, "Developing Countries and the Patent System: An Economic Appraisal" (1974), 2:9, World Development 27 at p. 33 (hereinafter Peter O'Brien).

invention is not being worked in the country[129] the fact of the grant of patents may encourage foreign investment. In other words, it is argued the patent system attracts capital and foreign businessmen to invest thus contributes towards the flow of foreign technology into the country.[130]

Developing countries need investments in order to improve their infrastructure. A good means to induce investors to invest is to provide incentives that will attract investors and influence their investment decisions. The patent grant with the exclusive rights that allow the patentee to build a monopoly and shield his product from other competitors, provides these incentives.

However, this incentive to invest argument is very difficult to evaluate. Penrose has compiled an interesting list of divergent assertions about whether a patent is an incentive to invest for businessmen. It is clearly shown there that there can not be a correct answer but it is purely a matter of opinion since "it is impossible to test adequately"[131] or as Anderfelt put it "it cannot be either proved or disproved factually".[132]

However, there exists evidence that patents may not necessarily have such a strong impact on the investment decision. A study conducted by Vaitsos concludes that "patents are rarely a significant factor in promoting foreign investments. In most cases, patents guarantee secure export markets for the patent holders and consequently are a major

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[129] Ibid., Peter O'Brien; see also Mangalo, supra note 124 at p. 109.

[130] H. Stumpf, "Interests and Conflicts in Technology Transfer - The Role of Patents" (1978), 9:4 I. I. C. 309 at p. 311.

[131] E. Penrose "International Patenting and the Less-Developed Countries" (1973), 83 Econ J. 768 at p.775. (hereinafter Penrose (1973)); see also Penrose, supra note 18 at p. 35 and 39.

[132] Anderfelt, supra note 19 at p. 190.

obstacle in the conditions that stimulate foreign investment".[133] Professor Vernon in his study concluded that patent protection is rarely a determining factor in the ultimate decision whether to invest.[134] Similarly, Bang reported that patent considerations had not been a significant factor in deciding whether or not to participate in Joint Ventures with foreigners.[135]

An interesting study was conducted in Turkey within the specific context of the pharmaceutical industry. Kirim found that the amount of foreign capital investment even without patent protection in the pharmaceutical industry, rose substantially.[136] Interestingly, foreign investment in the pharmaceutical industry has been the highest among all other industries where patent protection was available."[137]

Hence, it is seen that patents may not be a strong decisive factor in a business firm debating whether to invest or not. Investment is a part of an overall strategic policy of market defence in order to exclude competitors and protect against adverse foreign patents.

Patents may play a role since the monopoly that they confer attracts investors, a point which may be of psychological value for the foreign investor. Patents are significant at least in inducing foreign firms to sell the required unpatented know-

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[133] Vaitsos - Patents Revisited, supra, note 112 at p. 80.

[134] R. Vernon, The International Patent System and Foreign Policy, Study of the Subcommittee on Patents, Trademarks and copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No 5 (Washington: Government Printing Office, 1957) at p. 17.

[135] R. B. Bangs, "Use of Industrial Property in Foreign Countries: A Further Report" (1970), 13:4 IDEA at p. 557.

[136] A. Kirim, "Reconsidering Patents and Economic Development: A Case of the Turkish Pharmaceutical Industry" (1985), 13:2 World Development 219 at p. 224. See also Firestone, supra note 126 at p. 171.

[137] Id., Kirim., at p. 225 and Table 6.

how.[138] Furthermore, it is argued that the patent system, even if a patented invention is not used in the country, benefits the country since the patent conveys very important information which is contained in the patent document and is made available to the public with the disclosure of the patent. However, given the reality of the conditions that prevail in the patent system, information can be obtained cheaply through other sources, for example, in other countries where the invention has already been patented and published.[139] It should be mentioned within this context that usually the patent disclosure does not contain the necessary know-how and without it the patent is not quite as valuable.

A benefit that accrues to the country even when the patent is not used locally, are the fees that the patentee must pay in order to get his patent (the so-called basic fees) and, in some countries, the fees that he must pay in order to maintain his patent (the so-called annual fees). However, although fees could benefit developing countries, this does not always happen because of the low level of basic fees ranging from $2 in Venezuela, $8 in Spain and $165 in the USA.[140] As far as the annual fees are concerned, these range from $254 in Italy to $1404 in West Germany.[141] The fact that some countries do not even charge annual fees is quite inexplicable since they could use them as a policy of economic development.

We turn now to the costs associated with the case when a patent is not being worked in the country. As stated above, the majority of patents in developing countries are rarely used in production. This might be understandable; a MNC cannot establish a

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[138] Penrose (1973), supra note 131 at p. 775.

[139] Katz, supra note 117 at p. 16.

[140] The Role of the Patent System, supra note 107 at p. 59, para 384.

[141] Id., at para 386.

branch in every single developing country that has granted a patent. However, one may ask, why apply, then, for patent protection?

The main motives for a company acquiring in patents abroad are to secure an export market and create a legal basis for licensing rights and to protect itself from adverse foreign patents by excluding competitors, thus trying to maintain a monopoly position. In this regard, Penrose reports that many foreign companies "take out patents in countries where the inventions could be advantageously worked and deliberately suppress them in order to protect their own position, thus retarding the national industry of the country which granted the patents."[142] Thus, patents are used to secure imports and are not used for production in developing countries. In this way, they prevent the import of cheaper drugs from non-patented sources, and they prevent local firms from producing the patented product or using the process.

In other words, generally the patentee applies for a patent in a developing country and, all conditions being satisfied, the country grants him a patent for his invention which has been produced and patented in another country. Then, the patentee does not use it for production in the country, but instead uses it either to import the product into the country from another country, or to prevent others from producing or importing it. In both cases, the country has a lot to lose.

The patentee, since he has the patent, has a monopoly over the product and thus he can import it and charge whatever price he wishes. The price is high since there exist no other competitors and, if the patentee does not import, nobody else can either without his licence. This reality made Vaitsos conclude that patents are "in most cases nothing

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[142] Penrose (1973), supra note 131 at p. 776; see also Vaitsos - Patents Revisited, supra note 112 at p. 81.

more than import permits"[143], and he stated that "patents are a means for limiting or restricting the flow of technology from the industrialized to developing countries.[144]

The high prices and the monopoly on imports result in an adverse balance of payments in developing countries. Furthermore, the country cannot shop around to find alternative cheaper sources, but instead is dependent on the patentee. When he does not even import the product, the country has an additional cost since it is prevented from even having the product available in its market.

In the case when the patent is not used and the product is imported, then besides the high prices another considerable cost emerges which is the outflow of currency abroad. Furthermore, the failure to use the natural resources of the developing country, including the local human resources, add to the whole burden of costs. Such failure to use local resources contributes to limitation of the learning-by-doing benefit and the hindrance of the possibility of starting a local industry.[145]

Thus, within this context, technology cannot be transferred and advantageously developed in the developing country since patents are not worked but instead are used to import the product.

For these reasons the Andean Pact countries have eliminated the exclusive right of importation from among the rights conferred by a patent to the patentee.[146] However

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[143] Vaitsos-Patents Revisited, supra note 112 at p. 82; see also Katz, supra note 117 at p. 67.

[144] Vaitsos-Patents Revisited, supra note 112, at p. 83; see also Pedro Roffe, "Abuses of Patent Monopoly: A Legal Appraisal" (1974), 2:9 World Development 15.

[145] The Role of the Patent System, supra note 107 at p. 57; para 367.

[146] Decision No 85 of the Commission of the Cartagena Agreement, 13 sess., 27 May - 5 June 1974, Regulations for the Application of Rules Concerning Industrial Property, Art. 28.

these countries are not members to the Paris Convention and thus they are free to legislate without repercussions of violating their International obligation.

The Paris Convention has formally established and legalized this monopoly for the patentee with the overall protection of Art. 5(A)(1) and Art. 5 quater where it stipulates that importation "shall not entail forfeiture of the patent".[147] Consequently, a developing country cannot revoke or threaten to revoke the patent that is used as an import permit and hence the patentee is free to continue to import with all the aforementioned adverse effects that this situation creates.

Because of this burden, it is in the developing countries' interest to have this provision eliminated from the Paris Convention. As a matter of fact, this is one of the "points of revision" that developing countries have identified that should be re-examined.[148]

Thus, it is seen that the evaluation of costs and benefits in the case of non-use of patents entails substantial costs to developing countries and questionable benefits.

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[147] Art. 5A (1) of the Paris Convention.

[148] See infra note 463.

2.3.2 Benefits and Costs in the Case of Use of the Patent

We will now turn to the examination of costs and benefits in the case where the patented invention is used in production in the developing country.

The discussion on the benefits of the fees, the alleged incentive to innovation and a creation of a favourable climate to invest, mentioned under the section of the benefits derived in the case of non-use of a patent, apply equally when the patent is used locally in production.

In addition to these benefits, it is considered that many benefits accrue to the country which granted the patent. Thus, foreign capital flows into the country and fosters the economy. Jobs are created for the nationals, and hence employment rates increase and consequently the standard of living improves. Furthermore, the country gains in knowledge and technical skills, and labour skills are developed. Moreover, by working the patent in the country, the product is locally manufactured. Therefore, since it is not necessary to import the product, foreign exchange is saved and the balance of payments improves. In addition, the country gains from the tax revenue that it imposes on the foreign established plants. Finally, in some countries, the possibility exists that a portion of the local manufactured products be exported and an additional foreign exchange revenue be gained. All these benefits foster the economy, improve the standard of living, and assist the industrialization and developmental process of a country.

However, it should be noted that these benefits may be credited to patents only if patents were a decisive factor in the decision to start production in the country.

Otherwise, they remain benefits that do not derive from the international patent system, but rather from the foreign investment policy and industrialization process.[149]

Despite the above benefits, it is argued that many costs may derive from the operation of the patent system. We will now examine these costs in order to determine whether the costs outweigh the above benefits and burden the developing country or whether the reverse is happening.

The granting of a patent to the foreign patentee creates, as known, a monopoly to sell, produce, use and import the invention. This monopolistic condition results in all costs associated with any monopoly, such as high prices, restrictive output, and high royalties.[150] Since the patentee has the monopoly over the product, he can charge a higher price than he could if other competitors were in the market. Thus, the developing country is given a burden to pay the patentee's prices and at the same time it cannot shop around to find cheaper sources of supply, but rather is dependent on the patentee for its drug needs. Thus, the country has exchange costs which have a reverse effect on its balance of payments and its terms of trade.

Moreover, in addition to the standard monopoly costs, another cost that may be attributed to the patent system is the transfer of pricing.[151] Vaitsos reports many such instances in Latin America with regard to the pharmaceutical industry. However, this cost cannot be exclusively attributed to patents. It should be mentioned, however, that this does not exclude the possibility that in some instances this cost may depend on patents.

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[149] Lall (1976), supra note 121 at pp. 9-10.

[150] Penrose, supra note 18 at p. 101.

[151] See infra text at p. 63.

Another cost that may derive from patents are restrictive clauses in the licensing agreements. Patents are very often the basis to conclude a licensing contract with a variety of restrictive clauses, mainly export restrictions and various "tie-in" clauses. Territorial restrictions on exports can take the form of a total ban on exports, when the patentee, ie. the licensor, prohibits the production of the patented invention for the purpose of exporting it. They may lead to market sharing divisions and can take the form of a partial ban, where the patentee bans exports to certain countries or allows exports only to certain designated countries. These territorial restrictions, referring to the territory which is affected by the patent law, may not be objectionable but restrictions on exports may be against the competition law.[152]

In "tie-in" clauses the licensor dictates the channels of supply of the raw or the intermediate products used in the manufacture of the end product. This practice results in the so-called "transfer pricing" which, as will be seen, is very common in the pharmaceutical industry. According to the tie-in clause, the licencee is forced to pay higher prices since he is not free to shop around for the best available alternative price in the global market for a product that also meets the standard requirements of quality and safety. Consequently, the licencee is obliged to follow the terms imposed by the licensor and pay the price that the latter determines. These "tie-in" clauses are not justifiable and should only be accepted under conditions such as guarantee for the quality and safety of the products used. Similar "tie-in" restrictions may be placed on the size of production output or on sales.

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[152] In practice, the territorial restrictions may be limited due to the so-called theory of "exhaustion of patent right". This theory refers to the situation where the first sale under a full licence of a patented article exhausts the patent monopoly with the result that the product is free to be resold in any part of the country and outside, despite the licence provisions. This theory applies within the EEC by virtue of Articles 34 and 36 of the Treaty of Rome and if applied at the International level - International Exhaustion of patent right - it would undoubtedly help trade considerably.

Moreover, patents may create cartels, patent-pools or cross licence arrangements with a multitude of various restrictions that the licensor (ie., the patentee) may impose on the licencee, thus abusing his dominant position in the market. Cross licences or patent pools arise when participants of an industry arrange to share their patents mutually. These practices may be permitted under limited circumstances such as small specific fields or dependent patents and when the public is served by the technical benefits. When these kinds of arrangements are complemented by other restrictive arrangements such as quantity restrictions, price fixing, market division and general territorial restrictions, a case is made that calls for competition law application to counteract them.

Furthermore, package licences and grant-back provisions are common to patent licensing arrangements. In package licences, the licencee is bound to obtain a group of patent licences that he originally did not want in order to acquire the one that he intended to get. Package licences may be regarded as Restrictive Business Practices and require the appropriate measures to counteract them when the licensor compels the licencee to accept this group of patents, exploiting the dominant position that he has obtained from his possession of many patents. Grant-back restrictions refer to the limitations imposed by the licensor in regard to the improvements that the licencee may make. The reasoning for such provisions is based on the patentee's concern that by issuing a licence he might in the future confront a potential competitor if the licencee improves the patent thus placing him in a second place. Thus, the licensor imposes a "grant-back" restriction requiring that he will be granted the right to all potential future improvements.

Other types of restrictions may refer to clauses such as not contesting the validity of the patent, and to the employees that will staff the branch and the management. Finally, an additional common practice in patent licences is the payment of royalties for

the use of the patented invention that extends beyond the life span of the patent. This obliges the licencee to pay royalties beyond the patent term.

These restrictive clauses can have costly effects on the developing countries, if incorporated in the patent licensing agreements. However, not all these practices constitute ipso jure unlawful business practices that are objectionable and thus susceptible to countermeasures. Under particular circumstances, it may be deemed that a case is made for counteraction. Therefore, generally domestic patent laws contain provisions that deal with specific restrictive clauses that are deemed abuses of the patent right.[153] They are considered objectionable and unacceptable in licence agreements and may be countered by the issuance of compulsory licences and revocation, in order to put constraints on the rights conferred by the patent monopoly and prevent these abuses. With such provisions, the patent law seeks to ensure that foreign patentees work their patents in the country and do not misuse or abuse their legal monopoly. Hence, they do not hinder the progress of the industry, or do not intend to curtail the import of products equivalent to the patented one, but produced in other countries by other manufacturers.

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[153] Countries have tried to regulate Restrictive Business Practices (RBPs) by using various mechanisms such as patent law provisions, anti-trust laws (called also competition law), and special laws on transfer of technology and registration of agreements at both national and regional levels. Patent laws were not originally designed to prevent RBPs, and their restraint on trade, thus it is essential to provide for a specific system that directly counteracts their harmful effects. Thus, Antitrust or Competition laws are directly used to regulate RBPs and may be applicable to patents that create restriction. Some countries incorporate in their anti-trust law or competition law specific reference concerning the patent right. Examples of such countries are: Belgium, Canada, France, W. Germany and U.S.A. Other countries do not contain specific provisions alluding to patents (e.g. Spain). Theoretically, however, it is possible that their competition law may be applied to patents that impose restrictions which restrain competition. These laws are relatively new, and are seldom applied to cases involving restrictions that result from the use of patent rights. In Europe, in few cases, the various national competition law provisions have been applied to the restrictions contained in patents and licensing agreements. In recent years, W. Germany has begun to apply its competition law to patent licenses. On the other hand, U.S.A. by means of its anti-trust law has created a considerable case load with regard to its application to restrictions created by patents. Canada, Combines Investigation Act R.S.C. 1970, c. C-23, s.29 as am. Competition Act, S.C. 1986, c.1, ss. 29 and 51(5); USA, Clayton Act, 15 U.S.C.S. secs. 12-27 (1985), 35 Stat. 730 (1914), as am.; Robinson-Patman Act, 15 U.S.C.S. secs. 13-13b, 21a (1982), 49 Stat. 1526 (1936), as am.; Sherman Act, 15 U.S.C.S. secs. 1-7 (1985), 26 Stat. 209 (1980), as am.

However, we should emphasize that patents are not responsible for the existence of restrictive business practices, but they facilitate the unlawful operation of such practices which are common in patent licensing agreements. From this point of view, they are mentioned in this paper, as they may have an impact on the working of patents in developing countries. Further analysis is beyond the scope of this thesis.

Hence, working of the patent under licence with restrictions attached, does not seem the best solution for a developing country. The reason is that these restrictive clauses may have harmful effects and result in a substantial burden of costs such as overpricing of products, import substitutions, and adverse balance of payments. Thus, these costs would outweigh by far the benefits of working the patent and consequently would perpetuate the dependency of developing countries on developed countries, creating the so-called phenomenon of economic colonialism or neocolonialism.

The main logic that patents are usually issued to foreign patentees is the assumption that the costs that may derive from their existence would be outweighed or balanced by the benefits that nationals would have abroad from equivalent patent protection through the National Treatment Principle of the Paris Convention. However, this does not apply to developing countries because they do not grant many patents to their nationals, nor do their nationals apply for foreign patents. Thus, for the time being, developing countries have little to gain from this setting of mutual interests. If nationals of developing countries acquire patents at a faster rate and especially if nationals buy increasing numbers of patents in other countries then this present situation will change and developing countries would have a lot to gain since then there would exist a setting of mutual interests and the National Treatment Principle would work to their benefit. For the

developed countries, this balance may be different in the future since the exporting companies expect to gain from patent protection abroad. The majority of developing countries, however, do not hold patents abroad; they expect only the acquisition of foreign technology and foreign investment and not the granting of equivalent patent protection abroad.

2.3.3 Concluding Remarks

In conclusion, it may be said that both arguments in favour or against the patent system have their merits and demerits and it is a matter of opinion whether one position is right or wrong. In my opinion, when patents are not used in the country for production, it is difficult to speak of a transfer of technology. As was seen the costs are substantial and outweigh the benefits. The patented invention is not worked locally but rather is used to secure imports. Consequently, patents will not help industrialize the country and will prevent the import of cheaper products and restrict the flow of technology. Thus, if patents remain unexploited the country will "gain little or nothing, or may even lose."[154] Furthermore, a country with a limited local industry and export trade would not realize substantial benefits from granting patents to foreigners for inventions patented and worked abroad, since it does not expect to gain equivalent patent protection abroad but only to shield itself from foreign retaliatory actions.

When patents are used in production, although it is not the rule as we saw, a case can be made that they facilitate the flow of technology. However, this can only be feasible if restrictive clauses do not restrict the freedom of the licencee, if the royalties

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[154] See Penrose (1973), supra note 131 at p. 704.

are not excessively high and if product prices are not excessively high in which case the burden on the balance of payments might reverse the balance.

Notwithstanding these conditions that may render possible the transfer of technology to developing countries, the fact of the matter is that even if patents are used locally and they may make possible the flow of investment, they may prevent the import of cheaper products and the establishment of a local industry. It should be realized, however, that foreign technology is in private hands and not in the government's hands. Consequently, developing countries, in deciding about the patent system, should take into consideration that MNCs seek to operate where the conditions are most favourable, ie., within a familiar environment that offers incentives. Certainly, these incentives may not necessarily be exclusively the patent system but may be other fiscal guarantees and subsidies. Yet the MNCs should accept reduced patent privileges, both as recognition of grants received and as encouragement for social and economic progress.[155] Such reduced patent privilege may be the exclusion or limitation of pharmaceuticals from the patent system for overriding reasons of public health. We will deal with these issues in the next chapter.

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[155] S. Ladas, "Industrial Property as a Factor in Technical Development and Economic Progress" (1973), 10:3 Ind. Prop. 81 at p. 83; see also K. Lachman, "The Role of Industrial Property in the Dissemination of Technical Information in the World Context" (1965), 9 IDEA, 180 at p. 183.

CHAPTER III

CATEGORIES OF PATENTS RELEVANT TO THE PHARMACEUTICAL INDUSTRY AND THEIR ROLE IN DEVELOPING COUNTRIES

This chapter deals with the categories of patents relevant to pharmaceuticals and their role in developing countries. First, an overview of the main features of the pharmaceutical industry is necessary in order to highlight the major constraints that influence the developing countries' process of obtaining essential drugs at reasonable prices and hinder the growth of a national pharmaceutical industry.

Pharmaceuticals may be granted different kinds of patent protection which create different results. This chapter discusses the kinds of patent rights that are available for pharmaceuticals and their impact on developing countries. It deals with the limitation of patentability for pharmaceuticals as well as the exclusion of pharmaceuticals from patent protection and attempts to discuss which form of patent fits better within the infrastructure of developing countries taking into consideration their national interests within the interdependent world.

3.1 The Structure of the Pharmaceutical Industry

3.1.1 Geographical and Structural Concentration

The pharmaceutical industry consists of a small number of large multinational corporations (hereinafter MNCs) and a large number of small national firms. Thus, world

production of drugs is highly concentrated both in geographical and structural terms.[156]

In structural terms the 50-60 largest international corporations manufacture nearly two thirds of total pharmaceutical sales.[157] For example, in the case of bulk chemicals, of the 650 different types manufactured in the U.S.A., 500 were produced from a single domestic source.[158] In the case of different therapeutic groups, in 1975 three firms controlled 60% of a particular submarket and five firms controlled more than 75% of another submarket.[159] In developing countries, four companies manufactured 67% of the antibiotics, three other companies controlled all the oral hypoglycaemic market, two companies manufactured over 60% of oral diuretics.[160] The examples are numerous.[161] In geographical terms, world production of drugs is heavily concentrated in Western developed countries, mainly in the USA, West Germany, Switzerland, Great Britain, France and

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[156] The power of the pharmaceutical industry as a whole is not enjoyed by only a select few enterprises, but it is shared by many firms. Unlike other high technology industries, the pharmaceutical industry is very heterogeneous. It develops a wide variety of products which form economically distinct submarkets. In comparison to the industry as a whole, the power at the submarket level is highly concentrated. At the various submarkets, pharmaceutical products which have different medical properties and different purposes are manufactured such as analgesics, antibiotics, diuretics, etc. See, W. Duncan Reekie, The Economics of the Pharmaceutical Industry (London: The MacMillan Press, 1975), at p. 21, (hereinafter Reekie).

[157] The Pharmaceutical Industry: An Industry Like No Other, (Paris: O.E.C.D., 1975) Table 11. In 1978 the 25 largest international pharmaceutical corporations manufactured 44% of total pharmaceuticals.

[158] Transnational Corporations and the Pharmaceutical Industry, UN Commission on Transnational Corporations, UN Doc. ST/CTC/9 (1979), at p. 3, (hereinafter CTC Doc. 1979).

[159] Id. at p. 12.

[160] CTC Doc. 1979, supra note 158 at pp. 125-126, Table 14.

[161] See The Report of the Commission of Inquiry on the Pharmaceutical Industry, H. C. Eastman, (Ottawa, 1985), at p. 245 and 246, Table 5.14, (hereinafter The Eastman Report).

Japan, where 80% of drugs are produced.[162]

One hundred firms from developed market economy countries that invest in developing countries control 70 to 90% of sales in those countries. For example, in Argentina, MNCs controlled 70% of the drug market and in Colombia 90% of the market in the 1970s.[163] Only 11 percent of drugs are produced in developing countries where 3/4 of the world population lives.[164] This 11% of production is mainly confined to very few developing countries but even there is dominated by MNCs through FDI, Joint Ventures and licences. These few countries have established production capabilities for the manufacture of intermediates, for the production of bulk drugs from intermediates and for the development of research activities.[165] The majority of developing countries, however, rely either on imports, have no pharmaceutical industry whatsoever, or their pharmaceutical industry is limited to packaging and formulation in finished form of imported drugs.[166] This dependency involves the so-called policy of transfer-pricing.

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[162] See Technology Policies and Planning for the Pharmaceutical Sector in Developing Countries, UN. Doc. TD/B/C.6/56. (1980) at p. 20 (hereinafter Technology Planning); see also Guidelines on Technology Issues in the Pharmaceutical Sector in the Developing Countries, UN.Doc. UNCTAD/TT/49 (1983) at p.9, (hereinafter Guidelines on the Pharmaceutical Sector); see also The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects, UN Doc. UNIDO ID/204 (1978) at p. 4.

[163] See Daniel Chudnovsky, "The Challenge by Domestic Enterprises to the Transnational Corporation's Domination: A Case Study of the Argentine Pharmaceutical Industry" (1979), 7:1 World Development 45 at p. 47, (hereinafter Chudnovsky).

[164] See Global Study of the Pharmaceutical Industry, First Consultation Meeting on the Pharmaceutical Industry, Lisbon, Portugal, UN Doc. UNIDO ID/WG 331/6 (1980) where it is stated that 11% of drugs are produced in developing countries, 70% in developed countries and 19% in centrally planned economy countries.

[165] Mainly Mexico, India, Egypt, Brazil and Argentina.

[166] See Appropriate Industrial Technology for Drugs and Pharmaceuticals UN Doc. UNIDO ID/232/10 (1980).

3.1.2 Transfer Pricing

International price differences in the intermediate products among companies of the same MNC are known as Transfer Prices and the technique as International Transfer Pricing.[167] The elements that constitute Transfer Pricing are price differentials which occur on intermediate products[168] between affiliated companies of the same MNC located in different countries.

Transfer Pricing involves an underpricing or overpricing process.[169] Exports to an affiliated company are underpriced and the additional funds are transferred from the seller to the buyer within the same MNC. Imports from an affiliated company are overpriced and the additional untaxed profits are transferred from the buyer to the seller. The objective of this mechanism is to control a MNC's global tax burden by transferring funds out of a country without paying taxes on them.[170] Hence, the transnational parent company uses the classic rule of business "buy low - sell high", when dealing with its

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[167] The classic case of overpricing came to light in the early 1970s in Great Britain with the UK Monopolies Commission Report and involved Hoffman-La-Roche, a MNC in Switzerland and its subsidiary in Great Britain. See The Monopolies Commission Report on the Supply of Chlordiazepoxide and Diazepam, presented to the UK Parliament on the 11th April, 1973, (hereinafter The Monopolies Commission Report).

[168] In contrast to "price differences in the intermediate products" are the "price differences in a finished product" which appear between different buyers, different countries and different brand names and generics of equivalent products. The examples are innumerable and prices may range "up to over 1000 percent higher than others"; see e.g. Sanjaya Lall, "The International Pharmaceutical Industry and Less-Developed Countries, With Special Reference to India" (1974), 36 Oxf. Bulletin of Econ. and Stat. 143 at p. 152, (hereinafter Lall (1974)); See also the Eastman Report, supra note 161 at p. 324 and 325, Tables A7.1, A7.2 on International Price Comparisons.

[169] Sanjaya Lall, "Transfer Pricing and Developing Countries: Some Problems of Investigation" (1979), 7:1 World Development pp. 59-71, (hereinafter (Lall (1979)).

[170] Transnational Corporations in the Pharmaceutical Industry of Developing Countries, UN Doc. ST/CTC/49 (1981), at p. 16, (hereinafter CTC Doc. 1981).

foreign subsidiary, especially in the less developed countries, "thus minimizing the host country's income and raising local drug prices to the consumers."[171]

Examples of price differences in drug intermediates are numerous. In Colombia, in 1974, Vaitsos found that Diazepam was imported at a price that was 6,400% more than the lowest price available elsewhere.[172] In Mexico, Gereffi found that the rate of overpricing is more than 1000% in several cases, reaching a high of 5,650%... [thus] large amounts of taxable income were lost to Mexico.[173]

Some factors that induce MNCs to indulge in Transfer Pricing are exchange controls, profit ceilings, unstable currencies, political instability, higher tax rates than in tax havens, and nationalization trends.

3.1.3 Product Competition

Pharmaceutical firms compete with each other by way of product innovation and through product differentiation, the situation where a firm develops drugs which are similar, but not identical to those of other firms.[174] These alternative drugs are different enough

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[171] See Gereffi, supra note 9 at p. 99.

[172] Id., at p. 196.

[173] Id., at p. 147; see also pp. 145 and 148, Table 5.2; see generally Pradham, supra note 13 at p. 127; Anil Agarwal, Drugs and the Third World (London: Earthsquan, 1978) at p. 41, (hereinafter Agarwal); Lall (1975), supra note 9 at pp. 29-30, see also S. Lall, "Transfer Pricing by Multinational Manufacturing Firms" (1973), 35 Oxf. Bulletin of Econ. and Stat. 173. (hereinafter (Lall (1973)).

[174] The difference can be found in the drug's molecular structure, its dosage form, or its therapeutic characteristics. See Reekie, supra note 156 at p. 58.

to get a patent and be marketed under a different brand name.[175] Thus, product competition is closely related to the patent system because it occurs in therapeutic submarkets of the industry which develop patent-protected products. The patent confers the necessary protection against imitation. This leads pharmaceutical firms to compete through innovation. Thus, they set their prices at very high levels and enjoy a safe and considerable share of the market.

The research involved in the process of product differentiation is a very important and necessary element of product competition. It is an inherent part of the industry, and a very costly, risky, lengthy and complex process.[176] The research expenditures of the industry have, however, been criticized. Lall has argued that R&D is misallocated as it is primarily directed at product differentiation.[177] At any rate, research is very concentrated among large pharmaceutical companies[178] which spend 10 to 15% of their turnover in this area.[179] Interestingly, less than 5 percent of R&D goes to research for tropical diseases, (malaria, filariasis, dysentery). Only 2 to 3% of the world's R&D

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[175] It is estimated that more than 40% of the trademarks in the world are associated with pharmaceuticals. See Guidelines on the Pharmaceutical Sector, supra note 162 at p. 8. Argentina is one of the leaders in pharmaceutical brand name and trademark proliferation in the whole world. For 3,000 drugs there exist 17,000 trademarks. See Chudnovsky, Supra., note 163 at p. 49.

[176] E.Jucker, Patents and Pharmaceuticals (Basle: Buchdruckerei Gasser und Cie AG, 1980), at p. 43, (hereinafter Jucker); see also S. Pradhan, supra note 13 at p. 52; see also David Tucker, The World Health Market. The Future of the Pharmaceutical Industry (Euromonitor, 1984) at p. 61.

[177] See Lall (1975), supra note 9.

[178] USA, W. Germany, Switzerland, Japan, France, and the United Kingdom share 95% of the global pharmaceutical R&D. See Guidelines on the Pharmaceutical Sector, supra note 162 at p. 52.

[179] See Agarwall, supra note 173 at p. 14, figure 5; see also The Monopolies Commission Report, supra note 167 at p. 44, where it is reported that 7-12% of the annual turnover of large pharmaceutical companies is spent in research.

in any industry occurs in developing countries. In the pharmaceutical industry, the developing countries' participation in R&D is almost nil.[180]

3.1.4 Promotional Competition

In addition to product differentiation and product competition, another activity that is very intense in the industry is promotional competition. Promotional competition refers to the promotion oriented towards medical personnel regarding scientific information on new products.[181] The pharmaceutical industry spends a vast amount of money on promoting its products since this type of competition strengthens its monopoly position.[182] In 1961, the Kefauver Committee revealed that 25% of total profits are spent on advertisement and only 6% are spent on R&D.[183]

Promotional competition seeks to gain and increase a strong demand for a product by creating preference among medical personnel regarding specific brand names.

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[180] See Guidelines on the Pharmaceutical Sector, supra note 162 at p. 9; see also L. Sarrett, "The United States Pharmaceutical Industry", in Pharmaceuticals for Developing Countries, Institute of Medicine, Conference Proceedings, (Washington, D.C.: National Academy of Sciences, 1979) at p. 130. A great imbalance also exists in types of drug consumption between developing and developed countries. In 1980 developing countries consumed 13.8% of world drug products whereas developed countries consumed 86.2%; the per capita drug consumption in developing countries is $3-13 per year whereas in developed countries it is $36-50. See CTC DOC. 1981, supra note 170 at pp. 2-3.

[181] Promotion takes the form of printed or sampled advertisements, direct mail to prescribing medical personnel, medical journals, visits by medical representatives to practitioners and educational conferences.

[182] See L. G. Schifrin, "The Ethical Drug Industry: The Case for Compulsory Patent Licensing" (1967), 12 Antitrust Bulletin 717 at p. 900: Expenditures for advertising and promotion account for roughly 25% of the sales dollar and one third of total cost of production of large firms. The advertising element alone is approximately twice that of R&D for the typical large firm. (hereinafter Schifrin); see also Pradhan, supra note 13 at p. 144, Table 7.1.

[183] Report of the Committee on the Judiciary, United States Senate, Subcommittee on Antitrust and Monopoly, 87th Congress 1st sess., Report No. 448, Part IV Advertising and Promotion of Drugs (Washington: Government Printing Office, 1961) at p. 156. (hereinafter The Kefauver Report).

The standard original drug maintains a very strong market share if the doctor continues to prescribe by the original brand name, even though the patent has expired or the drug is produced by a licencee. Thus, through the promotional activities of a firm, the firm even after its patent has expired, continues to profit from this monopolistic situation that has been created.

Many economists have criticized the promotional activities of the industry on the basis that they are excessive, create a powerful monopoly and are a means employed by the industry to avoid price competition.[184] Others regard the promotion techniques as necessary method that provides information to doctors.[185] There is no doubt that promotion conveys information. The quality of the promotion techniques, however, especially in developing countries, is highly questionable. Instances of questionable tactics have occurred and have been seriously criticized on the grounds of the double standards policy of the industry.[186] Various discrepancies have been reported such as variations in product information in different countries, substandard product information, exaggerated claims about drugs, misleading claims of before and after therapy, a "tendency to keep negative information to a minimum",[187] abuse of marketing methods that leads to "excessive and

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[184] See Reekie, supra note 156, at pp. 71-75; see also S. Lall in Pharmaceuticals and Health Policy (Editors R. Blum, A. Herhheimer, C. Stenzl, J. Woodcock, 1981) at p. 196 (hereinafter R. Blum ed.).

[185] See David Schwartzman, Innovation in the Pharmaceutical Industry (Baltimore: John Hopkins University Press, 1976), at p. 188 and p. 341 (hereinafter Schwartzman).

[186] See Dianna Melrose, Bitter Pills, Medicines and the Third World Poor (London: OXFAM, 1982) at pp. 73-75 (hereinafter Bitter Pills). Melrose refers to the case of the drug Orabolin, where doctors in Great Britain warned that Orabolin "is not recommended for children "and may cause tumours of the liver". In Bangladesh, doctors were advised that "it is especially meant for young children and infants" and "is free from harmful effects on liver", e.g. pp. 103-104 and pp. 99-116. See also Mike Muller, The Health of Nations, A North-South Investigation (London: Faber and Faber, 1982), at p.30 where he refers to a similar incident involving the drug chloramphenicol.

[187] See Bitter Pills, supra note 186 at pp. 75.

irrational prescribing"[188] and to the creation of inappropriate needs and finally even withholding possible side effects information.[189]

While developed countries have instituted laws to check on the safety of drugs, to regulate prices, to control the promotion and advertising standards and especially to disclose side effects, most developing countries have laws which are less strict or have no adequate laws whatsoever and they face considerable political and economic problems initiating such reforms.[190]

3.1.5 Price Competition and the Industry

Price competition does not occur in the pharmaceutical industry due to three reasons.[191]

First, the nature of the products of the industry is of such a vital importance to life that the whole structure of demand operates under different rules. Demand is

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[188] Id., at p. 64.

[189] See Milton Silverman, Philip Lee, Mia Lydecker, Prescriptions for Death. The Drugging of the Third World (Berkeley: University of California Press, 1982) at p. 112; see also M. Silverman, M. Lydecker, "The Promotion of Prescription Drugs and Other Puzzles" in R. Blum. ed., supra note 184, at p.78; see also Seneka Bibile, Pharmaceutical Policies in Sri Lanka, UN Doc., TD/B/C.6/21 (1977), (hereinafter Pharmaceutical Policies); see also David McKie "Drug Dumping in the Third World", (1986) Int'l Perspectives, 17 at p. 18.

[190] See Bitter Pills, supra note 186 at p. 65; see also I.F.P.M.A. Voluntary Code of Marketing practices (1982) and W.H.O. Code on Essential Drugs. Many developing countries have initiated joint strategies within the framework of regional co-operation such as Regional Cooperative Production and Technology Centres (COPPTECs) in countries of the CEAO (West African Economic Community), in countries of SPEC (South Pacific Common Market for Economic Co-operation), in the five ASEAN countries (Indonesia, Malaysia, Philippines, Singapore and Thailand), in the Commonwealth Regional countries for the East Central and Southern Africa region, in the CARICOM (Central American Common Market and Caribbean Market) etc.

[191] See CTC Doc. 1981, supra note 170 at p. 15. Price competition may exist in a few situations such as generic drugs, drugs whose patents have expired and multiple source drugs which have been licensed.

particularly inelastic in contrast to other industries where prices are set by the demand which, in turn, is affected by changes in price. In the pharmaceutical industry, demand is unresponsive to changes in price because drugs are a substantial necessity to life; sometimes they mean the difference between life and death. Their sensitive nature causes their consumption to be qualified by disease patterns and not by price. Any person in need of a drug will try to buy the necessary prescribed drug without considering the possibility of there being lower priced alternatives. The drug buyer rarely takes the time to examine what competition exists as he normally would when purchasing other goods.[192]

Second, the inelastic demand for drugs is influenced by the medical profession.[193] It is not the individual patient who makes the choice, but the doctor who prescribes the drug and who does not pay for it. This is necessary and has been created for the safety of the consumers given the potentially harmful nature of the products, but in the process of prescribing drugs the doctor's selection is not necessarily determined by financial considerations. Hence, the choice is made by the prescribing physicians who base their choice on the medical properties and qualities of the drug and less on the prices, and thus may prescribe a drug that they are accustomed to. The doctors are obviously less price-sensitive than the person who eventually pays for the drug.[194]

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[192] See Reekie, supra note 156 at p. 36.

[193] See H. Steele, "Monopoly and Price Competition in the Ethical Drug Market" (1952), 5 J. L. Econ. 131 at p. 146.

[194] In the words of Senator Estes Kefauver: "he who orders does not pay; he who pays does not order". Many physicians are unaware of drug prices since their principal sources of drug information, such as "The Physician's Desk Reference", does not include data on prices. Estes Kefauver, In a Few Hands. Monopoly Power in America (New York: Pantheon Books, 1965).

The third reason for which price competition does not occur in the pharmaceutical industry is the patents and the way they operate. We will discuss this matter in the following section.

3.2 Patents in the Pharmaceutical Industry

Patents[195] constitute a very significant component of the pharmaceutical industry and they form a crucial determinant of this industry's profitability.[196] The majority of the pharmaceutical industry's products are protected by patents and are sold only by one firm or a few firms.[197] Patents are used as a barrier to entry. This portion of the industry's products are the most profitable.

A patent confers the right to the inventor to produce, sell, import and use his invention for a number of years and to exclude unauthorized parties from such acts. The right conferred by the patent is absolute, exclusive and limited in time. It is absolute because it confers the total power of exploitation and transfer of this power. It is exclusive because it does not allow another party to use, sell, import or produce the patented invention without the permission of the patentee. Finally, it is limited in time because it is granted for a specified period of time. Thus, we could define the concept of a patent as the absolute and exclusive right granted to the patentee, i.e., the inventor, for

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[195] The word patent derives from the Latin "literae patentes" and means letters open to public scrutiny, i.e., open letters written on a sheet of paper with the seal of the sovereign at the bottom.

[196] See CTC Doc. 1981, supra note 170 at p. 46.

[197] These patent drugs are known as ethical or prescription drugs and because they are often sold by only one firm, they are called one-source drugs. Drugs which are not protected by patents are called proprietary or generic drugs. Those which are protected by patents and which have been licensed to a wide number of licensees and hence produced by many suppliers are known as multiple-source drugs.

a limited period of time to sell, produce, import and use his invention. In other words, the patent confers a limited monopoly over sale, use, manufacture, and importation of the patented invention.[198]

The importance of patents to the pharmaceutical industry is substantial, given the specific structure of the industry and the nature of its products.[199] Pharmaceuticals can be very easily imitated. Scientists with appropriate skills and education can analyze the chemical structure of the drug and then proceed to duplicate it without difficulty, a situation that does not occur with the same degree of convenience in other industries (e.g., aircrafts, computers). After discovering a drug, a company seeks to protect it with a patent. Patents provide the necessary protection against imitation and shield the firm from the competition of other firms for the given period stated by law.[200]

Patents create that shield from competition because they confer a monopoly over the manufacturing, the sale and the importation of the drug in the face of potential competitors. Once the patent expires, a number of small firms, they so-called generic firms, are attracted to produce the so-called "generic drugs" of the same chemical composition but at a much lower price than the patented drug. While the drugs are protected by the patents, the firm profits from a temporary monopoly over the products so it sets its prices freely on whatever it seems the market can bear.

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[198] See The Role of the Patent System, supra note 107 para. 6 at p. 11. Patent is a legally enforceable right granted by virtue of law to a person to exclude, for a limited time, others from certain acts in relation to a described new invention; the privilege is granted by a government authority as a matter of right to the person who is entitled to apply for it and who fulfils the prescribed conditions.

[199] The top 50 transnational pharmaceutical companies are extremely active in this sector, See CTC Doc. 1979, supra note 158, Table 17.

[200] See, The Role of the Patent System, supra note 107, at p. 53, para. 351. The term of a patent grant varies from 1 to 20 years in various countries. See also Table 54.

Thus, the way patents operate, i.e., creating a temporary monopoly over drugs, in conjunction with the nature of the products and their inelastic demand and the role of physicians prescribing drugs and making the choices, result in curtailing the normal price competition which would otherwise occur.[201]

Even drugs on which patents have expired do not always enhance competition, contrary to what one would expect. Usually by the time a given product is no longer protected by a patent, it can be produced by several firms. As a result, competition would cause prices to fall. Even after the expiration of a patent, however, a doctor prefers to prescribe a familiar drug.

Hence, trade names may take the place of patents and perpetuate their role as an impediment to price competition, i.e., trade marks, combined with patents or without, create monopoly and prevent price competition.

The strong barriers to the entry of new firms in the market (created by the aforementioned product differentiation, the high promotional expenditures, the high concentration in production and research and in particular by the way patents operate creating monopolistic conditions) as an immediate consequence raise profit margins and prices to above average levels.[202] The pharmaceutical industry has a tremendous profitability rate. It is considered one of the most profitable industries. The industry "has

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[201] A possible source of price competition may be brand substitution of generic drugs where possible. This practice is followed in certain developed countries such as the United Kingdom, Canada and Sweden. A pharmacist may, within the parameters of the law, substitute prescriptions with a lower priced generic drug. Thus, price competition may come alive. See Schwartzman , supra note 185 at p. 272.

[202] See CTC Doc. 1981, supra note 170 at p. 46-47.

since the mid-fifties consistently recorded profits substantially higher than the average for all industries in both the US and the UK."[203]

Every industry which involves a high rate of risk requires substantial profits in order to attract investors. Although the pharmaceutical industry is very capital and research intensive, its profit margins and high prices are beyond all reasonable levels and "derive mainly from a monopolistic situation which seems to be very secure."[204] Thus, the aforementioned features of this industry make it susceptible to monopolistic power, high prices and lucrative profits to the detriment of the consumer and the economic health of the country.

3.3 Pharmaceutical Sector and Developing Countries

Developing countries are concerned with the constraints that affect the supply and the demand of pharmaceutical products and processes, that limit access to much needed drugs, that raise the cost of imported drugs, and that limit the possibilities of establishing a national pharmaceutical industry.

Their concerns were considered at the Conferences of non-aligned countries at Colombo in 1976 and Havana in 1979. As it will be seen in the following paragraph, among other things, these conferences called for the need to re-examine the existing patent system within the scope of the special needs of developing countries.

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[203] See Lall (1974), supra note 168 at p. 155. For example, the pharmaceutical industry had a return of 20.3% as compared to 13% for all manufacturing in 1960 in the United States. In the United Kingdom in 1970, 110 firms showed a return of 26% as compared to 12.6% for all manufacturing; see also the Monopolies Commission Report, supra note 167 at para 218: Profits made by Roche products were "quite unjustified" and "manifestly too high"; see generally Schwartzman, supra note 185 at p. 161.

[204] See Lall (1974), supra note 168 at p. 156.

At the Colombo Conference[205] resolution 25 was passed on co-operation among developing countries in the area of patents. Resolution 25, after considering the proposals made in Georgetown, Guyana by a group of experts on pharmaceuticals, approved certain recommendations. These suggested new pharmaceutical policies in developing countries. Specifically related to our topic, these recommendations advised the developing countries to consider at the national level, in the context of the revision of the Industrial Property system, the exclusion of pharmaceutical products from patentability or, alternatively, the curtailment of the duration of patents for pharmaceuticals.

Three years later, the Sixth Conference of non-aligned states took place in Havana, Cuba.[206] The Havana Conference considered a report entitled "Pharmaceuticals in the Developing World: Policies on Drugs, Trade and Production", which was prepared jointly by various UN agencies. The Conference adopted resolution 8, accepting the 27 recommendations of the report. Among the recommendations, mention should be made here of both the possibility of exclusion of pharmaceutical products and processes from patent protection, and of shortening the duration of patents. This recommendation was along the lines of the Colombo Conference recommendation, but encouraged the developing countries not only to exclude pharmaceutical products[207] from patent protection but process patents as well.

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[205] Resolution No. 25 on Co-operation among Developing Countries in the Production, Procurement and Distribution of Pharmaceuticals, adopted by the Fifth Conference of Heads of State or Governments of non-aligned countries, Colombo, Sri Lanka, 1976. Reprinted in UN Doc. UNCTAD/TT/49 (1981) supra, note 162 at Annex I.

[206] Resolution No. 8 on Economic Co-operation among Developing Countries in the Field of Pharmaceuticals, adopted by the Sixth Conference of Heads of State or Governments of non-aligned countries, Havana, Cuba, 1979. Reprinted in UN Doc. UNCTAD/TT/49, (1981) supra note 162 at Annex VI.

[207] See Infra, text at p. 79 et seq.

Following these two conferences, the major components of a pharmaceutical policy have been identified in various reports prepared by the United Nations and other related bodies. Thus, the Guidelines on technology issues in the pharmaceutical sector identified certain elements that form such a pharmaceutical policy.[208] Among the most important recommendations was the one relating to the re-examination of the Industrial Property System. Furthermore, the guidelines identified the following elements: selection of essential drugs; regulation of drug promotion; use of generic names; centralized drug procurement of generics through methods such as international tendering and competitive bidding; choice of the cheapest supplier subject to quality assurance, drug control and safety regulation; and regulations on pharmaceutical prices. In addition to this policy, the guidelines recommended a technological plan in order to start up a national pharmaceutical industry and reduce dependency on imports. Such a plan starts with packaging and formulation, continues with production in stages of pharmaceuticals and ultimately undertakes R&D.[209]

Furthermore, the Workshop on Trade and Technology Policies [210] in the pharmaceutical sector has recommended certain policies that are relevant to the pharmaceutical industry in developing countries: the health policy, the policy on trade (levies, customs duties), the policy on imports, a financial policy and the policy on credits

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[208] See Guidelines on the Pharmaceutical Sector, supra note 162. These guidelines were prepared by the UNCTAD secretariat in co-operation with many consultants. For a list of the consultants, see p. 2 of the Guidelines.

[209] Id., at p. 11, chapter III.

[210] This workshop was organized by UNCTAD in co-operation with ARCT (African Regional Centre for Technology) in Abidjan, Ivory Coast, on October 12-23, 1981.

and exchange rates, the policy on education, R&D, the policy on transfer of technology and Foreign Direct Investment, and the policy on Industrial Property.[211]

Thus, for example, a Foreign Direct Investment policy is necessary since most of the transfer takes place within the framework of a MNC and its subsidiaries which are wholly or partially owned.[212] Foreign investment policy could encompass various elements such as requirements of equity participation, for example, specific requirements of national capital participation, and prohibitions imposed on MNCs, for example, foreign firms could be prohibited from producing cough syrups and vitamins in developing countries and concentrate instead on priority essential drugs which are needed to fight local tropical diseases such as malaria and dysentery.

Moreover, a transfer of technology policy is necessary since very few countries are capable of developing pharmaceutical products for their drug needs and most developing countries are totally dependent on MNCs. Developing countries need a policy which regulates and controls the transfer of technology and takes into account their needs and circumstances. In addition to this policy, since most transfer of technology takes place via licence agreements, a restrictive business policy is needed to regulate restrictive clauses in licensing agreements by imposing a framework which is necessary in order to supervise and control the agreements and screen all restrictive clauses that impede the transfer and the development of the national pharmaceutical industry. As a matter of fact, some countries have re-examined their policies and have taken action towards these goals. Hence, special laws on Transfer of Technology and Registration of Agreements have

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[211] See Report and Recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector, UN Doc. UNCTAD/TT/48, (1981) at p. 11, (hereinafter Report and Recommendations).

[212] See Technology Planning, supra, note 162 at p. 16, para 53.

emerged in some developing countries with the purpose of counteracting the harmful effects of restrictive clauses in the agreements.[213] For example, Mexico,[214] Brazil,[215] and Argentina[216] have established rules on the regulation of transfer of technology. Similarly, Decision 24 of 1970 of the Andean Group of countries[217] requires that all contracts on the transfer of technology of patents must be examined and stipulates that the law shall not authorize the inclusion in the contracts of patents of certain restrictive clauses.[218]

Hence, these special laws on Registration of Agreements which contain restricting clauses are used by the Ministry or various national agencies and institutes to examine these agreements.[219] These bodies strike out restrictive clauses that are prohibited by national law and then register them, giving them freedom to operate.

All these special laws that have emerged on transfer of technology and registration of agreements are remarkable attempts to counteract restrictive clauses and

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[213] See Restructuring the Legal Environment: International Transfer of Technology. Common Approaches to Laws and Regulations on the Transfer and Acquisition of Technology, UN Doc. TD/B/C.6/91 (1982), (hereinafter Laws and Regulations).

[214] Mexican Law on the Control and Registration of the Transfer of Technology and the Use and Exploitation of Patents and Trademarks, effective February 11, 1982.

[215] Brazilian Code of Industrial Property Law No. 5772 of December 21, 1971, effective December 31, 1971; Normative Act No. 76, effective October 1, 1985.

[216] Argentinean Law on Transfer of Technology No. 22, 426, of April 1, 1981 and Decree No. 580 (Regulations Under Law No. 22, 426).

[217] The Andean Group of countries comprises Bolivia, Columbia, Ecuador, Peru and Venezuela.

[218] Decision No. 24 of the Commission of the Cartagena Agreement, December 31, 1970, as amended by Decision 109, November 30, 1976. See text at (1977), 16 Int'l Legal Materials 138; see also Compilation of Legal Material Dealing with Transfer and Development of Technology, UN Doc. TD/B/C.6/81 (August 4, 1982) at p. 227 (hereinafter Compilation); see also Policies Relating to Technology of the Countries of the Andean Group: Their Foundations, UN Doc. TD/107 (1971).

[219] E.g. The National Institute of Industrial Property (INPI) in Brazil and the Ministry of Patrimony and Industrial Development in Mexico.

control the transfer of technology. Because of their relatively recent origin, however, it is too soon to measure their effectiveness.

In any case, it would be advisable for all developing countries to re-examine all laws and policies that pertain to their pharmaceutical industry. Although, as has been mentioned above, this paper focuses on the industrial property element of the overall policy, and in particular on some aspects of the patent law, it should be mentioned that the above policies are interrelated; a combination of all these policies is, in fact, necessary in order to achieve rapid development in the pharmaceutical sector, to ensure supply of essential drugs at reasonable prices and to build up a strong national industry. In this way, dependence on supplies from MNCs is reduced and industrialization in developing countries is boosted.

3.4 The Exclusion or Limitation of Pharmaceuticals from the Patent System and their Role in Developing Countries

3.4.1 Patentability

A substantial element of every patent law is the patentability, i.e., the requirements that an invention must meet in order to be granted a patent. Although patent laws in many countries have a plethora of provisions that differ, the existence of a set of conditions for patentability is a common feature of every national patent law.

Thus, the typical patent requirements of an invention to be granted a patent are: 1) Novelty, i.e., the invention must not be included "in the state of the art"[220]; 2) Industrial applicability, i.e., the invention can "be made or used in any kind of industry"[221]; 3) Inventive step[222] or the analogous "inventive activity" of the French law or the "inventive height" of the Greek and German law or the equivalent "non-obviousness" of the American law[223], i.e., the invention must have an "essential difference as compared with the known art."[224] Furthermore, the Model law on Patents for inventions for the

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[220] Strasbourg Convention on Unification of Certain Points of Substantive Law on Patents (1963), Art. 4 signed on November 27, 1963, Council of Europe, European Treaty Series, no. 47. (hereinafter Strasburg Convention).

[221] Id., Art. 3.

[222] There exist subtle differences in the notions used by various national patent laws. See Ladas at p. 296. See also European Patent Convention (EPC), Art. 56.

[223] Section 103, Title 35 U.S.C. 1952.

[224] Nordic Patent of 1966. See also Strasbourg Convention, supra note 220. Art. 1: "Patents shall be granted for inventions which are susceptible of industrial application which are new and which involve an inventive step." Also the EPC Art. 52(1) recognizes the same requirements.

Developing Countries recognizes that "any invention which is new, results from inventive activity and is capable of industrial application is patentable."[225]

Although an invention can meet all the above requirements of patentability, it may not be patentable under the patent law in a given country. The reasons for this are that some inventions are not patentable for overriding reasons of public interest, such as inventions relating to national defence, atomic and nuclear energy, agriculture and public health.[226] The INPADOC database has recognized 19 technological fields, including pharmaceutical products and pharmaceutical processes for which patent protection is not available in certain countries.[227]

Based on the content of the pharmaceutical invention a distinction can be made among different kinds of patents for pharmaceuticals: 1) Product patents; 2) Process patents; and 3) Product by Process patents.

3.4.2 Product Patents

Product patent protection is the kind of patent that confers protection on a new compound, substance or end product.[228]

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[225] Model Law on Patents for Inventions for the Developing Countries, Art. 3. (Geneva: BIRPI Doc. 801(E), 1965).

[226] See S. C. Oppenheim "The Public Interest in Legal Protection of Industrial and Intellectual Property" (1950), 32:12 J. Pat. Off. Soc. 904; See also M. Fishbein, "Are Patents on Medicinal Discoveries and on Foods in the Public Interest?" (1937), 19:12 J. Pat. Off. Soc. 891.

[227] Exclusions from Patent Production, see WIPO Doc. HL/CE/IV/INF/I (November 2-6, 1987) at p. 6, para 8.

[228] The form in which the product is used or sold are not important. In the description of the patent, the potential patentee need only provide one way of producing the pharmaceutical and only one industrial application of the product. To be patentable a product must satisfy all needed requirements, i.e., it must be new, useful and must have an industrial application.

The product patent is a strong form of protection and provides the patentee with a wide spectrum of rights in the areas of production, use, sale and importation of the product.

The essence of this kind of patent is that it confers a complete monopoly over the pharmaceutical: the patentee has the exclusive right of use, manufacture, sale and importation of the drug.

The direct consequence of the product patent is that, as a result of the protection conferred by the patent, the patentee has a legal claim against any third party that uses, produces or sells his products. This applies even if the third party does so "bona fide" or even if he produces it by a different or better method. Hence the patentee is the only person entitled to the use of his right with the exception of an assignee or licencee.

3.4.2.1 Product Patents and Developing Countries

This form of patent taken within the context of a developing country creates the following repercussions:

The majority of developing countries have no production capabilities for pharmaceuticals and consequently imports constitute the only channel to acquire the necessary drugs. These countries are almost or totally dependent on imports for their pharmaceutical needs.

As was previously mentioned, the patent protection on products confers to the patentee, among other rights the right to import and exclude others from doing so. Since the patentee is the only eligible person who has the exclusive right to manufacture, sell and import the pharmaceutical, then, as a result, the developing country cannot and will

not be allowed to import the pharmaceutical from other sources. It will be obliged to rely exclusively on the patentee who will have the exclusive distributorship of the pharmaceutical in the country and who would enjoy an air-tight monopoly having excluded any other competitor.

Thus, when developing countries issue a patent, they provide the patentee with the exclusive right to import into their country the product in question and hence they deprive themselves of existing alternative international sources which accommodate more competitive prices. However, when they do not allow product protection they are in a better position since they are able to widen the selection of sources for drug supplies and hence lower the prices of drugs.

Some developing countries have reached a certain degree of development in relevant terms with regard to their pharmaceutical industry, such as formulation of dosage forms from imported raw materials and envisage the production of pharmaceuticals as a channel to industrialization.

When these countries provide for a product patent they consequently give the patentee the exclusive right to import unless they stay outside the Paris Convention, as for example, India. Thus, they have limited sources to procure the raw materials needed in order to manufacture the drug.

When they do not provide for a product patent the local firms are in a better position, as the synthesis of raw materials is more economical through the alternative ways of importation, since they can import the raw materials from a source of their choice. In this manner, they are not subject to terms of the profit motivated patentee and his licencees which impose onerous restrictive terms.

Furthermore, since the patentee is the only one who has the right to produce, these developing countries that have built up a certain infrastructure and have established a pharmaceutical industry, even if only in the first stages, would be deprived of manufacturing the pharmaceutical. Consequently, this would deter them from developing further a local industry. Even in the case when the patentee grants licences and permits others to produce, he could impose such onerous and restrictive conditions that the picture does not change.

For these reasons, this kind of patent does not seem appropriate for developing countries, which strive to import good quality but cheaper drugs and develop a local pharmaceutical industry. This is the reason why many developing countries today do not provide for product patents in their patent law.[229]

Product patents are mainly granted in those developed countries that are the primary producers of pharmaceuticals and which want to safeguard their interests and secure their monopoly in the market. Thus, for example, West Germany, Switzerland, the USA, France and Japan grant patents for pharmaceutical products. These are the countries that are the main producers of pharmaceuticals.[230]

However, it should be highlighted at this point that these countries instituted such provisions only very recently, i.e., during the last two decades, when they had already reached a considerable stage of development. Before they did not grant product patents

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[229] Many developing countries do not grant patents for pharmaceutical products: Bolivia, Brazil, Colombia, India, Mexico, Egypt, Peru, Chad, Thailand, Turkey, Venezuela, Zimbabwe etc. See Anne-Marie Greene, Patents Throughout the World, 2nd ed. (New York: Clark Boardman, 1984), (hereinafter Anne-Marie Greene).

[230] Furthermore, the Netherlands, the Nordic countries and Ireland grant also patents for pharmaceutical products.

for drugs, but only process patents. For example, Germany introduced patents for products in 1968, Switzerland in 1978, Japan in 1976.[231]

At this point it is interesting to note that Canada provided only for process patents and excluded product protection from the patent law. With the recent amendments, however, Canada no longer provides only for process patents but for product ones as well.[232]

Italy, in particular, did not provide for either kind of patents and excluded pharmaceuticals altogether from the patent law. However, in 1978, the Supreme Court of Italy held that the exclusion of drugs from the patent law was unconstitutional, and thus since then Italy grants product patents for pharmaceuticals.[233]

Although some developed market economy countries do not grant product patents for pharmaceuticals,[234] generally it can be stated that in developed countries there is a trend towards complete protection.

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[231] W. Germany introduced patents for pharmaceutical products in 1968, Japan in 1976, Italy in 1978, France in 1960, England in 1949, Switzerland in 1978, the Nordic countries in 1968 and Canada in 1987.

[232] See infra at p. 139.

[233] In 1978 the Corte Constitutionale of Italy held that Decree 1127 of 1939 was unconstitutional. See Samperi, "Patentability of Pharmaceutical Products in Italy - Background and Recent Developments" (1979), 18 Ind. Prop. 128.

[234] E.g. Austria, New Zealand, Spain, Greece, Portugal, do not grant patents for pharmaceutical products.

3.4.3 Process Patents

Process patent is the kind of patent that confers protection on a new method of manufacturing a product. A process may be a "technical solution consisting of a series of steps, and the result of a process may be a product."[235]

The justification for the existence of process patents stems from the desirability to encourage the inventor to develop better and more efficient methods to produce drugs. Thus, if the public is to receive the benefit of new pharmaceutical products at a reasonable price and in amounts sufficient to meet the demand, this "could only be accomplished by [limiting] the inventor to his process so that others will be encouraged to invent a new and improved process which will make the product cheaper and available in greater quantities."[236]

What is protected by this kind of patent is the method to produce the product and not the product itself, i.e., the protection does not extend to the product itself. The direct consequence of the process patent is that the product is free to be produced by other processes or imported by other competitors.

The process patent is a weaker type of protection from the point of view of the pharmaceutical industry, since it only provides the patentee with the right to prevent the use of the patented method that produces a drug. For this reason, this kind of patent protection is not very popular in the industry which prefers, instead, the stronger product protection.

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[235] Extension of Patent Protection of a Process to the Products Obtained by that Process, see WIPO Doc. HL/CE/II/5 (1986) at p. 3, (hereinafter WIPO Doc. 1986).

[236] See The Kefauver Report, supra note 183 at p. 106.

Under the process patent protection, the inventor has a legal claim only against the producer of the drug and his method and not against the persons that sell the pharmaceutical. The producer uses and exploits the process protected by a patent. Consequently, the patentee can ask for the prohibition of the production of the drug and sue the producer. In contrast, the persons that market the pharmaceutical sell it free from any right whatsoever and consequently the patentee cannot ask for the confiscation or destruction of the already produced drugs and he cannot sue them.

3.4.3.1 (b) Process Patents and Developing Countries

If we apply this kind of patent protection within the context of developing countries, then different considerations appear than those under the product patent. Process patents fit better within the infrastructure of a developing country since under this type of protection, only the use of the method to produce the product is shielded from the competition and not the product itself.

Consequently, developing countries are allowed to import the pharmaceutical and have the freedom to produce it without infringing the patentee's patent and his rights.

Thus, in the absence of the restrictions imposed by the patentee, the developing country can shop around and find alternative sources of supply and better prices, as the patentee does not have a legal claim against the persons that sell the pharmaceutical but only against the producer of the drug and his methods. The patentee cannot prohibit the production of the drug by other methods or the importation of the product.

Process patent protection is generally provided in those developed countries that are not economically as strong as the producers of pharmaceuticals, but are rather dominated by multinational pharmaceutical firms.[237]

Furthermore, in addition to developed countries, many developing countries such as Venezuela, Colombia, Argentina, Egypt and India, do not allow patents for pharmaceutical products but grant only process patents.[238] In particular, Colombia provides such patents under the condition that the invention is exploited in Colombia.[239]

In contrast to developed countries, developing countries seem to be in favour of patent protection only for process. For example, in 1970, Argentina, in American Cyanamid v. Unifa upheld the constitutional validity of the exclusion of pharmaceutical products from patentability.[240] This remarkably opposite trend appears to reflect the existent economical and technological differences that prevail in the two groups of countries. Some countries even exclude both pharmaceutical products and processes from patent protection.[241] It is important, within this context, to repeat that when the developed countries provided for the product protection they had already achieved significant progress in their pharmaceutical industry. Thus, for example, Great Britain until 1949 did not grant

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[237] E.g. Spain, Greece, Portugal, Austria and New Zealand.

[238] Only process patents are granted in the Andean countries (i.e. Bolivia, Columbia, Peru, Ecuador and Venezuela, pursuant to Decision 85 of the Cartagena Agreement Art. 5(1)), Lebanon, Libya, Pakistan, Syria, Tynsia, China, Morocco, Chad, Zambia, Thailand, Iraq, Cuba, Egypt and Peru.

[239] Art. 538 of the Colombian Commercial Code of 1972. See also Cavalier Abogados, "Patentability of Pharmaceutical Inventions in Colombia" (1972), Pat. Trademark Rev. at pp. 414-418.

[240] American Cyanamid v. Unifa (1971), 2:3 I. I. C. 219.

[241] E.g. Brazil eliminated process patents in 1969. Furthermore, Australia, Mexico, Colombia, Turkey, Zambia, Malawi, Zimbabwe excluded both products and processes from the patent law.

patents for pharmaceutical products and similarly, France introduced product patents for drugs in 1960.[242]

The apparent present trend in developing countries to exclude product protection has not been enthusiastically greeted by the pharmaceutical industry, especially the MNCs. The strong form of patent protection is of an extreme importance for the interests of the industry. The industry's interests do not coincide with the interests of developing countries which favour opposite schemes, more adequate to their special needs, circumstances and interests.

However, notwithstanding the above considerations on the impact of product patents and process patents on developing countries, not all developing countries have excluded product patents from their patent laws; some developing countries provide for product patents.[243] Their decision to provide product patents may appear beyond any logical justification since it contradicts developmental aspirations and interests. The reasons, however, may be based either on ignorance of the technicalities of the law, pressures from industry and fears of retaliatory economic sanctions or, most probably, the desire to attract investors in the country.

However, as was seen before, this is not an absolute consideration since there exist other incentives to attract investors. For example, Brazil's experience clearly shows that investments could flow to the country even in the absence of a product patent.[244] The

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[242] See supra p. 83.

[243] E.g. Tanzania, Zaire and Sudan.

[244] In Brazil between 1971-1979, foreign investment rose from $ 11.4 million to $ 646.45 million. See Examination of the Economic, Commercial and Developmental Aspects of Industrial Property in the Transfer of Technology to Developing Countries. Review of Recent Trends in Patents in Developing Countries, UN Doc. TD/B/C.6/AC.5/3 (1981) para. 108.

absence of product patents is not necessarily a discouraging factor in the decision of investors to invest.

3.4.3 Product-by-Process Patents

Related to process patent protection, another kind of patent protection which exists in some countries is "the product-by-process protection."[245] This type of patent protects the process and the product that is produced by this particular process. What is protected under this patent is not only the process but also the product which is produced directly by this particular process.[246] Countries such as Austria, France, Germany, Japan, the Netherlands, Switzerland, Sweden, the United Kingdom and the Community Patent Convention (CPC) and the European Patent Convention (EPC) provide for product-by-process protection, i.e., protection of the product obtained by the patented process.[247]

The product by process provision is not provided in many patent laws and the Paris Convention leaves the freedom to member countries to decide on the issue.

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[245] See WIPO Doc. (1986), supra note 235 at p. 4.

[246] Ibid.

[247] This product-by-process protection usually involves a reverse burden of proof. The patentee would be in a difficult position if he was obligated to find evidence that third parties used his method for producing a product.For this particular reason, the legislator provides for the reverse burden of proof. Accordingly, when a patent relates to a process for obtaining a new product, the same product, when produced by any other party, is deemed to have been obtained by the patented process, unless that other party, can prove the contrary. In other words, any new product of the same chemical constitution and composition is deemed to have been produced from the process protected by the patent. Consequently, when the product is the same, the plaintiff (the patentee) is relieved from proving the use of the patented process by the defendant; instead the defendant must prove that the product was obtained by a process other than the patented process and consequently, not by the patented process. In other words, third parties are obligated to prove that their product has been produced by a different process than the patentee's one. Countries such as Austria, Germany, Japan, the Netherlands, Switzerland, the United Kingdom and also the Community Patent Convention provide for a reverse burden of proof provision, whereas France, the European Patent Convention, Brazil, Australia, Spain and Sweden do not provide for such provision.

However, the Paris Convention contains a provision, Article 5 quater, which obliges those countries that have adopted such provision (extension of patent protection of a process to the product obtained by that particular process) to "recognize the effects of the extension of patent protection of a process with respect to imported products in the same way as with respect to products manufactured in the country."[248] In other words, "all rights granted by national law on the basis of the process patent, to products manufactured according to the patented process in the country itself, must also apply in the case of importation of such products if they are manufactured according to the said process in another country, even if that process is not patented in the said other country."[249]

Thus it can clearly be seen that this kind of patent protection for pharmaceuticals is not in developing countries' interests mainly because of the consequences that it creates with regard to the application of Article 5 quater of the Paris Convention.

3.4.4 Concluding Remarks

Given the aforementioned role, effects and implications derived from the product patent protection and the process patent protection, it is understandable why the majority of developing countries prefer to allow only protection for processes and do not provide for product protection. Developing countries perceive protection for processes as more appropriate to their circumstances which are not the same as those which prevail in developed countries. What is appropriate for developed countries is not necessarily appropriate for developing countries where completely different circumstances exist.

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[248] See WIPO Doc. 1986, supra note 235 at p. 5.

[249] See Bodenhausen, supra note 61 at p. 85.

Developing countries could follow the practice of excluding pharmaceutical products from patent protection while allowing for pharmaceutical processes. As has been seen in the first chapter, the Paris Convention leaves member countries free to legislate in certain areas. The choice to grant or exclude patents for products or processes for certain sectors is one of these areas that member countries are free to legislate. However, developing countries should also consider the possibility of foreign investors being driven away by this approach.

CHAPTER IV

COMPULSORY WORKING OF PATENTS AND THE SANCTIONS IN THE CASE OF NON-WORKING

Compulsory working is an important obligation imposed on the patentee, since only when an invention is being worked, as was seen, may benefits flow into the country and under these circumstances may technology be transferred. Otherwise, it is of no use to the developing country and, worse, it may be detrimental since it would be used as a means to secure an import network by impeding others from importing. Therefore, the working of a patent is a very significant provision for a developing country, otherwise the patent becomes meaningless and gradually detrimental to the country.

This chapter discusses the working of the patent and the sanctions against non-working and demonstrates the importance that these provisions have in developing countries. It discusses the evolution of these institutions within the Paris Convention, in order to provide the background of Article 5A and highlight the strong opposition towards these provisions, expressed by many countries during the revision conferences as well as the strong support of various countries in favour of these provisions, beliefs that today pertain equally to developing and developed countries. The issues that concern developing countries are the same as those which concerned, in the past, countries that today are considered developed. This chapter also analyses the question of interpretation and problems that arise with the compulsory licence and revocation provisions as are embodied in Article 5A of the Paris Convention and examines the national interpretation and measures that have been taken with Article 5A. The purpose is to evaluate these

provisions and decide whether these provisions can adequately protect the public interest in developing countries or whether there are constraints that limit their effectiveness and the freedom of developing countries to legislate.

4.1 Compulsory Working

The primary purpose of the patent grant is to encourage industrial exploitation of the invention and foster technological development. In order to achieve this purpose, most countries in exchange for the patent grant require patentees to work the patented invention within the country. The obligation to work is the most important obligation imposed on the patentee by the majority of countries in order to safeguard the assigned purpose of the patent grant and prevent non-use or insufficient use of patents. With this device, the patentee is bound to work his invention, i.e., he either has to produce, use, sell or licence others to produce or use his patented invention.

The Canadian Patent Act, for example, specifies that patents are granted "to secure that new inventions shall so far as possible be worked on a commercial scale in Canada without undue delay."[250] Similarly, Colombia provides for "the permanent and steady use of the patented methods or the manufacture of the product covered by the patent for the purpose of supplying the market with the final result in reasonable conditions of quantity, quality and price, whenever such acts would take place in Colombia."[251] And

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[250] s.67(3) of the Canadian Patent Act 1970, R.S.C. 1985, c.P-4; see also F. Neumayer, Compulsory Licensing of Patents Under Some Non-American Systems, Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No. 19 (Washington: Government Printing Office, 1959) at p. 15 where he states that Canada emphasized "distinctly and unmistakably the working of inventions", (hereinafter Neumayer)

[251] Art. 558(2) of the Colombian Commercial Code of 1972.

in Brazil the patent law provides for patent grants if such grants contribute to permanent industrial development.[252] The obligation to exploit the patented invention has always been considered important and was contained in the early patent laws of many countries.[253] These countries considered working as an element of the industrialization process of their country.[254] That stage of development of these countries is comparable to the contemporary developing countries' stage of development and their concerns about industrialization.

As it has been stated before, the majority of patents in developing countries are foreign-owned and most are never used in production in these countries, but are rather kept in order to protect imports in developing countries.[255] Hence, compulsory working is a provision of primary importance to developed countries and in particular to developing countries because only the working of the invention in the country can bring about the benefits that justify the existence of the patent system in these countries. These benefits are mainly the transfer of patented technology and its industrial application and local exploitation of the invention. These are only feasible when the patented invention is exploited in the country and does not remain unexploited.[256]

The task of analyzing and defining the concept of working is left with each country. The Paris Convention does not provide any interpretation of what constitutes

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[252] Art. 39(a) of the Brazilian Code of Industrial Property Law No. 5752 of 1971.

[253] Compulsory working was part of the Venetian patent of 1474, the French Patent law of 1844, the first Patent law of Germany of 1877, the Belgian law of 1954, the Canadian Patent Act of 1869 (s.28) and the Argentinean Law of 1864.

[254] See Penrose, supra note 18 at p. 137.

[255] See supra, pp. 39-40.

[256] E.g. E. Jiménes Batalla, "A Glance at the Law and Practice in the Matter of Working of Patents in all Iberoamerican Countries", (Part I) (1974), 56:11 J. Pat. Off. Soc. 746, Part II (1974), 56:12 J. Pat. Off. Soc. 805.

"working".[257] Hence, each country gives its own interpretation to what it considers as the most appropriate and important policy to follow. The majority of countries require actual local use of the patented invention.[258] These countries interpret "working" to encompass the element of actual manufacture of the product or actual application of the process and the element of undertaking these activities within the territory of the country that issued the patent.

Thus, for example, Decision 85 of the Andean Group defines working as "the permanent and regular use of the patented process or the manufacture of the product covered by the patent, in order to put the end result on the market under reasonable marketing conditions, provided that such acts have occurred on the territory of the member country which granted the patent."[259] Furthermore, "working the invention must be done in a reasonable and adequate way so as to satisfy the demand of the product in the country and make the product available at a reasonable price."[260] The production, in other words, must be undertaken "to an adequate extent and supply on reasonable terms the patented article."[261]

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[257] At the Rome conference a proposal was tabled pursuant to which each country on its own may determine the concept of working the patent. With the influence of France, the essence of this proposal was adopted at the Madrid revision conference.

[258] Very few countries in the world do not require working: Chile, Panama, El Salvador, Ghana, Kenya, Uganda, Tanzania and USA. These countries perceive working of the patent to be very onerous on the patentee and thus do not require him to exploit his patented invention. USA, however, from 1832 to 1870 limited the issuance of patents to aliens on the condition that they would work the invention in the country.

[259] Art. 31 of Decision No 85 of the Commission of the Cartagena Agreement: Regulations for the Application of Rules Concerning Industrial Property, see Compilation, supra note 218.

[260] s.67(2)(c) of the Canadian Patent Act, R.S.C. 1985, c.P-4.

[261] s.70(11) of the Indian Patents Act of. 1970; Similarly Art. 43 of the Mexican Law on Inventions and Trademarks of 1976 as am. in 1982 states that "exploitation shall be the permanent use of the patented process or the manufacture of the product covered by the patent, in quantities that amount to effective industrial exploitation and on satisfactory conditions as to quality and price."

The product must "satisfy the needs of the national economy" except if the patentee is a national of a country with which there exists a reciprocity agreement.[262] In cases where the demand is not being satisfied and prices are too high, the working requirement is not being met. Thus, the patentee is obliged to supply the market with products "in reasonable condition of a good quality, quantity and price.[263]

All countries that provide for actual working of the patented invention in their patent law specify the term within which the working must start[264] and require that working must not be interrupted for a specified term.[265]

Importation and sale of the invention is not considered to be included within the concept of compulsory working.[266] Hence, it does not qualify as exploitation of the invention when working "on a commercial scale is being prevented or hindered by the

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[262] Some countries have lessened the strength of compulsory working obligation with regard to certain other countries on a reciprocal basis. Thus, the nationals of these countries are relieved from the obligation to work the invention in those countries with which there exists an agreement. Such agreements exist in Germany, Switzerland, USA and Greece. Similarly, Costa Rica has a reciprocity agreement with all central American countries, and Honduras and Libya allow for reciprocity with all countries. See Ladas, supra note 49 at p. 425.

[263] Art. 558(2), of the Colombian Commercial Code of 1972. Similarly, the African Union requires working to be pursued "by an effective and serious establishment, on a scale which is adequate and reasonable in the circumstances."

[264] For example, Honduras, Nicaragua and Guatemala require 1 year, Peru, Venezuela, Argentina and Mexico require 2 years, France, Sweden, Norway, Austria, Denmark, Italy, Japan, Switzerland, Brazil require 3 years and the Dominican Republic requires 5 years. See J. W. Baxter, World Patent Law and Practice (London: Sweet and Maxwell, 1973) at p. 147, (hereinafter Baxter)

[265] For example, Greece, Belgium, Bolivia, Brazil and Columbia provide 1 year, Argentina, Egypt, Venezuela 2 years, and a 3 year term is provided in the African Union, Dominican Republic, Portugal and France.

[266] In early patent laws importation instead of working was also deemed not to constitute working and was prohibited. The provided sanction for it was revocation of the patent. Such provision was contained in the aforementioned French law of 1844. Today with the influence of Art. 5A of the Paris Union the sanction against importation is not revocation any more but compulsory licence.

importation from abroad of the patented article.[267] The Patent Act of India, for example, does not qualify as working when the working of the patented article "on a commercial scale is being prevented or hindered by the importation from abroad of the patented product."[268]

Although the majority of countries require actual working of the patented invention, some countries are satisfied with the so-called nominal working which only involves advertising in local, official or trade journals to sell the product or to grant a licence.[269]

If the patentee does not work his invention he is deemed to be abusing his right, unless he can provide "legitimate excuses". Thus the patentee is relieved of the obligation to work if he can come forth with a "legitimate excuse" as the Paris Convention states in Art. 5[270] or with a "satisfactory reason" as the equivalent provision of the Canadian Patent Act stipulates.[271] Each country determines what amounts to "legitimate excuses". In the patent law of a number of countries such legitimate excuses are deemed to exist in cases of local economic or technical events that hinder local exploitation. The Brazilian Code

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[267] Sec. 67(2)(b) of the Canadian Patent Act, R.S.C. 1985, c. P-4. Similar provisions exist in Mexico and Greece.

[268] s.90 of the Indian Patents Act of 1970. Few countries including, Cuba, Nicaragua and Venezuela, perceive importation as working and value it just as if exploitation occurred within the country.

[269] Nominal working satisfies the law in Argentina, Bolivia, Ireland, Nicaragua and Turkey.

[270] Art. 5A(4) of the Paris Convention.

[271] Art. 67(2)(a) of the Canadian Patent Act, R.S.C.1985, c.P-4. See also Harold G. Fox, Canadian Laws and Practice Relating to Letters Patent for Inventions (Toronto: University of Toronto Press, 1969) at pp. 545-546 where it is stated that each individual case should be judged on its own, considering its unique situation and the nature of the particular patent. (hereinafter Fox)

on Industrial Property and the Argentine Patent Law only admit "force majeure" as legitimate excuses.[272]

When "legitimate excuses" do not seem to exist and the patentee does not properly work his invention, the purpose of the patent grant is not met and then the patentee is considered in most countries to be abusing the patent in disregarding of the public interest. Thus, abuse of the patent monopoly occurs "when the social objectives which it is supposed to serve are not promoted but rather jeopardized by the way it is used."[273]

There exist different criteria that determine the cases of abuse in different countries. Non-working or insufficient working of the patent is clearly one of the cases that the majority of countries consider as abuses of the patent grant.

A typical provision which refers to cases where the exclusionary interest conferred by the patent "shall be deemed to have been abused" is s.67(2) of the Canadian Patent Act. The Canadian Patent Act recognizes 6 cases where abuse of the patent monopoly has occurred:[274] 1) where there is failure to work the patented invention and no satisfactory reason can be given for such non-working,[275] 2) where working is prevented or hindered by importation of the patented article to the detriment of domestic manufacturers,[276] 3) when the demand for the patented product is not being satisfied to an

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[272] Argentina and Venezuela consider as legitimate excuses only the existence of a "forfeiture case or force majeure". See also Art. 23 of the Brazilian Code of Industrial Property Law, No. 5752 of 1971.

[273] See Machlup, supra note 25 at p. 10.

[274] The Canadian cases of abuse are similar to the British Patents Act of 1949.

[275] s.67(2)(a) of the Canadian Patent Act, R.S.C. 1985, c.P-4.

[276] Ibid., s.67(b).

adequate extent and on reasonable terms,[277] 4) when the already existing trade or industry or the establishment of new trade or industry in Canada is prejudiced and a licence is being refused,[278] 5) when a patent is used with restrictive tying arrangements in licences,[279] and 6) when a patent for a process is being used to prejudice the production or use of materials used in that process.[280]

Similar provisions exist in other countries,[281] an example is the Patents Act of India which provides analogous cases where the patent right is considered to have been abused."[282]

The Paris Convention does not enumerate cases of abuse of the patent right, however, it gives failure to work as an example of such abuse.[283] It should be mentioned at this point that the words "for example, failure to work" were incorporated in the text of Art. 5 of the Paris Convention on the initiative of the Canadian delegation so as to clarify that failure to work constitutes an abuse of the patent right.[284]

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[277] Ibid., s.67(c).

[278] Ibid., s.67(d).

[279] Ibid., s.67(e).

[280] Ibid., s.67(f) For a good analysis on the Canadian cases of abuse see Fox, supra note 271 at pp. 541-557.

[281] E.g., s.37(2)(a)-(e) of the British Patents Act of 1949 (12, 13 and 14 Geo.61.1.87) as am. s.48 (2)(a)-(e) of the British Patents Act of 1977, c.37.

[282] s.90(a) of the Indian Patents Act of 1970.

[283] Art. 5A(2) of the Paris Convention.

[284] Actes de la Conférence de la Hague (1926) at p. 519.

4.2 The Sanctions for not Working the Patent: Compulsory Licence and Revocation

The patent right can only be justified if the patentee works his patented invention. When the patentee does not conform with the law and abuses his right, he harms the economy and consequently the society. Developing countries, in particular, lose the benefits from the operation of the patent system, i.e., the transfer of the patented technology and the related know-how.

Thus, when the patent remains unexploited, there "is potentially always a burden to local economy,"[285] therefore effective sanctions are called for which are simply remedies to limit such costs. The sanctions that most countries impose in the case of abuse of the patent and in particular for non-working the patented invention are compulsory licence and/or revocation of the patent.[286]

Compulsory licence is a sanction ordered with the purpose to authorize acts which would not otherwise be permitted by the patentee, upon the payment of a reasonable royalty, "set on general principles in the commercial field."[287] The compulsory licence may

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[285] See Anderfelt, supra note 19 at p. 147.

[286] This compulsory licence is ordered in the case of failure to work or insufficient working. Some countries have instituted two other kinds of compulsory licences: 1) Compulsory licence for dependent patents which is ordered when a patented invention cannot be used on its own but must be used in conjunction with an earlier, patented invention that belongs to another patentee. See, for example, U.K. s.37(a)(b), Switzerland s.20, the Netherlands s.34. The oldest example of this licence is the 1769 patent in Great Britain of James Watt's steam engine. 2) Compulsory licence in antitrust cases. An example of this kind of compulsory licence is in the USA where compulsory licence is not included as a direct provision in any American patent law or antitrust law, but has been developed as a judicial doctrine since the Harford Empire case in 1945 when it was held that the comptroller may have the jurisdiction to impose compulsory licences upon the payment of a reasonable royalty. Such a compulsory licence is imposed when it is deemed appropriate "to achieve the antitrust objective of restoring the balance of competition" of the Sherman Act. After this landmark case compulsory licences have been imposed as sanctions along with the payment of royalties in cases where an antitrust violation has been established.

[287] See Fox, supra note 271 at p. 559.

be defined as the licence granted by a competent authority without the consent of the patentee to any applicant who can successfully establish a case of abuse of the patent by the patentee.[288]

The Paris Convention gives the right to member countries "to take legislative measures... to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[289]

Thus, when the patented invention is not being worked, or the working "does not meet on reasonable terms the demand of the product"[290] or the working "is being prevented or hindered by importation,"[291] or the patentee refuses to grant licences on reasonable terms and as a result "the establishment or development of industrial or commercial activities is unfairly and substantially prejudiced"[292], then a compulsory licence may be applied.

The application for a compulsory licence, however, may not be made before the lapse of three years from the date of the grant of the patent or four years from the date of filing the patented application.[293]

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[288] See: Ladas, supra note 49 at p. 427; See also Gordon Johnson et al v. Callwood (1960), 20 Fox Pat. C. 94 at p. 99 and The Role of the Patent System, supra note 107 at p. 10, para 83.

[289] Art. 5A(2) of the Paris Convention.

[290] Art. 44(1)(ii) Agreement Relating to the Creation of an African Intellectual Property Organization (the Libreville Agreement of 1982) constituting a revision of the Agreement Relating to the creation of an African and Malagasy office of Industrial Property (Libreville Agreement of 1963). The African Union provides for a supranational patent covering all 12 member countries.

[291] Art. 44(1)(iii) of the Libreville Agreement.

[292] Art. 44(1)(iv) of the Libreville Agreement; See also s.37(2) of the British Patent Act and s.67(1) of the Canadian Patent Act. A similar provision is contained in Art. 16(1) of the Greek Law on Unfair Competition and Innovation No. 1023 of 1980.

[293] Art. 5A(4) of the Paris Convention.

Hence the patentee is given an exclusive period for the use of his patent. Within this period he has the opportunity to appeal any imposition of compulsory licences. After the expiration of this period, however, a compulsory licence is imposed "on the ground of failure to work or insufficient working."[294]

In countries whose law is based on common law the competent authority to impose a compulsory licence and to determine the appropriate royalty is the Commissioner of Patents.[295] For example, in Canada, the Commissioner imposes compulsory licence and sets the royalties.

In countries that follow the civil law system, the authority is the court that has jurisdiction on the matter and which orders the issuance of the licence and determines the royalty that must be paid. For example, in France the Tribunal Civil de Première instance of the domicile of the patentee or the Tribunal Civil de la Seine[296] has competence to decide on the issue of the compulsory licence.

The compulsory licence is a non-exclusive licence, i.e., many compulsory licences can be imposed. It is also non-transferable, i.e., the licencee cannot sublicence or assign it to a third party. The non-exclusivity and non-transferability of the licence has been established on an international level at the revision conference in the Hague.[297]

The second legislative measure available in case of abuse of the patent right is revocation of the patent. Revocation is a measure terminating the patent when valid

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[294] Ibid.

[295] The Commissioner of Patents is a quasi-judicial authority responsible for the administration and enforcement of the Patent Act. In Canada, the Commissioner is part of the Department of Consumer and Corporate Affairs. Section 87(1) of the Canadian Patent Act entitles him to order a compulsory licence and fix a royalty.

[296] In the case of a foreign patentee that has established his business in that country.

[297] Art. 5A(4) of the Hague text of the Paris Convention.

grounds exist, i.e., non-working of the patented invention. It is the first sanction that has been established in the case of non-working the patent.[298] Revocation, however, as will be seen, has been supplemented and gradually replaced by the compulsory licensing provisions. This was due to the influence of the revision conferences of the Paris Convention.[299]

Compulsory licence and revocation are necessary elements of the patent law since they constitute a legal remedy intending to maintain competition against the patentee's monopoly. This remedy provides for an optimal exploitation of the patent right. The object of both sanctions is to avoid the patent being used to the detriment of the local industry or trade. It is to assure that production of the patented invention will be carried out on a commercial scale. Thus, the state safeguards its power on the monopoly that it has conferred on the patentee, by limiting his right.

However, when only compulsory licence is provided and revocation is not contained in the law as a supplementary measure to compulsory licence, then the country does not properly safeguard its power since the patentee will not be threatened by losing his patent because revocation after all acts as a threat to induce the patentee to work his patent.

In conclusion, compulsory licence and revocation are the only methods by which the legislator can safeguard the two conflicting interests - those of the patentee and those of society, and at the same time ensure optimal exploitation of the patent. When the

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[298] Revocation was deemed the appropriate measure to take in order to ensure that foreigners would explore their patent and manufacture the patented invention within the country so that the economy would benefit. See for example the old French Patent law of July 5, 1844, Art. 32.

[299] See infra, text at p. 104 et seq.

monopoly given to the patentee acts as an impediment to the technical progress, it is waived by ordering the granting of compulsory licence and by revoking the patent. It is only in this respect that a country and, in particular, a developing country, may benefit from the patent system. Thus the compulsory working provision and the sanctions to ensure it are the most crucial provisions of the patent law for the developing countries. Therefore, the analysis of their evolution within the framework of the Paris Convention is essential in order to examine how we got here and where we go from here.

4.3 Compulsory Working and Licensing: Their Evolution Within the Framework of the Paris Convention and their Impact on Developing Countries

4.3.1 History of Text of Art. 5.

The obligation to work and the sanctions in the case of non-working, i.e., compulsory licensing and revocation had, in the words of Prof. Penrose, a "turbulent history because they touch directly on the conflict between the interest of the national economy as a whole and the interest of the individual patentee in obtaining the maximum return from his patent."[300]

Belgium started the first attack in the first revision conference of the Paris Union in Brussels[301] in 1900, when it introduced a proposal for abolition of revocation in the case of non-working. This proposal was rejected because the majority of delegates

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[300] See Penrose, supra note 18 at p. 80.

[301] For the revisisons of the Paris Convention see supra, note 74. For the Brussels text of the Paris Convention, see Appendix A.

believed that the abolition of the compulsory working provision would harm their national interests of their countries since foreign patentees instead of working would have been importing the patented article.[302] Developing countries today are encountering the same problems that developed countries previously encountered.

In the next revision Conference in Washington[303], in 1911, the United States joined Germany in her efforts to abolish compulsory working but they were met with strong opposition by the British, who in 1907 had introduced compulsory working provisions in their Patent Act, and by the French, Dutch and the Spanish. The French based their opposition on the fact that the working obligation had its rationale in the "economic necessity, that of feeding the national industry of each country with the discoveries and inventions"[304] there patented.

In Washington, however, the first erosion of the sanction of revocation took place. A proposal[305] was incorporated in the text pursuant to which revocation would be allowed but with the restriction that the patent "may not be forfeited for non-working in one of the countries of the Union until after a period of 3 years from the date of filing the application in that country, and only in case the patentee cannot justify his inaction."[306]

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[302] See Penrose, supra note 18 at p. 80.

[303] For the Washington text of the Paris Convention, see Appendix A.

[304] Actes de la Conférence de Washington (1911), at p. 282.

[305] This proposal is the 1900 Brussels proposal that was incorporated in the Washington text in 1911.

[306] Art. 5(2) of the Washington text of the Paris Convention.

It was decided that each country was free to choose the concept of justification of inaction and to determine the acts that constituted it.[307]

In the next revision conference in The Hague[308], in 1925, the Bureau took into consideration the wishes expressed by IAPIP and ICC[309] and suggested the elimination of compulsory working provisions and again proposed to replace them by compulsory licensing. This suggestion was, however, opposed by many countries, mainly Japan, Spain, Poland and Yugoslavia. Spain, opposing the abolition of compulsory working and revocation, stated that the abolition of these provisions may be favourable to the large countries since they can secure their export markets, however "such a measure would prejudice the interests of less industrialized countries by transforming the patent monopoly into a trading monopoly inimical to the development of local industry."[310]

Furthermore, Polish delegates held that in Poland "industry is far from being as developed as that of the great western powers [thus, this situation] does not permit them to agree to the suppression of the obligation to export. Poland has the duty of protecting its national production and of assuring the development of its industry. She cannot therefore consent to that which would stifle her industry by the importation of merchandise produced under the protection of patents.[311]

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[307] "Justify his inaction" meaning failure to work (exploit, use) the patented invention. See Actes de la Conférence de Washington at p. 282.

[308] For The Hague text of the Paris Convention, see Appendix A.

[309] International Association for the Protection of Industrial Property and International Chamber of Commerce.

[310] Actes de la Conférence de la Hague (1924), at p. 432.

[311] Id., at pp. 431-432.

Due to the strong opposition the Bureau's proposal to abolish compulsory working and to replace it by compulsory licensing was not accepted. To compromise and satisfy all the interests involved a text was then introduced by Great Britain and the United States and was adopted by The Hague Revision Conference of the Paris Convention:

> "Nevertheless, each contracting country shall have the right to take the necessary measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work."[312]
>
> "These measures shall not provide for forfeiture of the patent unless the grant of compulsory licences is insufficient to prevent such abuses."[313]
>
> "In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant or if the patentee proves the existence of legitimate excuses."[314]

As can be seen, a significant addition was introduced in this text; revocation of the patent was maintained but it was to be used only when compulsory licence "is insufficient to prevent such abuses."[315] With this addition, a great deal of controversy arose. We will examine the problem of interpretation in the next section.

It is interesting to note the changes made in the Hague Conference with respect to Art. 5: Sanctions against non-working would be prohibited before the lapse of 3 years from the "date of grant" (Hague text), rather than from the "date of filing" (Washington

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[312] Art. 5(2) of the Hague text of the Paris Convention.

[313] Ibid., Art. 5(3).

[314] Ibid., Art. 5(4).

[315] Supra, note 313.

text), and if the patentee provides "legitimate excuses" (Hague text) rather than "if he justifies his inaction" (Washington text).

In the following revision conference, in London,[316] revocation was again tried as the Bureau made an unsuccessful effort to abolish it.[317] Revocation was maintained with an additional restriction: that it would be implemented after 2 years from the issuance of the first compulsory licence.[318] With this addition, the controversy that arose in The Hague was solved and it was clear that the primary sanction was the compulsory licence and not revocation which could be imposed only after 2 years from the grant of the compulsory licence.

The Bureau again tried to eliminate the sanction of revocation in Lisbon.[319] Once more several countries opposed the Bureau's efforts, mainly Yugoslavia, Austria, Italy, Spain, Mexico, Iraq and Brazil. The grounds were that compulsory licences especially for small countries, were insufficient in view of the scarcity of local entrepreneurs to work the patented invention. They opposed the proposal for the abolition of revocation because such a measure would risk delaying the working of patents in small countries and it would hold back the advancement of the country.[320]

A remarkable change took place in Lisbon: "a patent cannot be revoked unless the grant of a compulsory licence is insufficient" (Hague text), was changed to "would not

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[316] Actes de la Conférence de Londres (1934). For the London text of the Paris Convention, see Appendix A.

[317] Id., at p. 262. Abolition of the sanction of revocation was not accepted because many countries wanted to prevent abuses detrimental to their local industries.

[318] Art. 5A(4) of the London text of the Paris Convention.

[319] Actes de la Conférence de Lisbonne (1963). For the Lisbon text of the Paris Convention, see Appendix A.

[320] Id., at p. 412. These concerns were expressed by the delegate from Austria.

have been sufficient" (Lisbon text).[321] Another important change took place in Lisbon. Pursuant to this addition no compulsory licence could be issued before the lapse of three years from the date of the grant of the patent (already in the London text) or four years from the filing of the patent application (added in the Lisbon text).[322]

Thus, in summary in the Lisbon text, the status of the sanctions in the case of non-working the invention became more apparent. Revocation does not constitute a primary sanction any more as it used to do but it becomes a supplementary sanction to the compulsory licence. Revocation has been curtailed in cases where a compulsory licence would not have been sufficient to prevent non-working and it may be granted after 2 years from the grant of the compulsory licence. Moreover compulsory licence in the case of non-working cannot be granted before 3 years from the date of grant or 4 years from the date of filing the patent application. Hence a patent cannot be revoked unless the compulsory licence has not sufficed to prevent non-working.

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[321] Art. 5(1) of the Lisbon text of the Paris Convention.

[322] Ibid., Art 5A(4). For a good discussion on the Lisbon Conference see supra note 319.

4.3.2 Question of Interpretation of Article 5A(3)

Divergent opinions have been expressed concerning the issue of interpretation of Art. 5A(3) of The Hague and Lisbon texts. The problem of interpretation that arose was whether a patent could be revoked before or after a compulsory licence had been issued in cases where the latter was considered insufficient. In other words, the test of insufficiency had to be an actual one, done after a compulsory licence had been granted, or alternatively it had to be a schematic one, done before a compulsory licence had been issued, based on the consideration that it would have been insufficient to prevent non-working. An example given in the conference was that there could be a scarcity of local entrepreneurs in some small countries.

Ladas interpreted this paragraph of Art. 5 as meaning that a compulsory licence had to be issued before it could be proven to be sufficient and only then could revocation be applied. According to him "the meaning is that it is not possible to determine that a compulsory licence is insufficient to prevent abuse of the monopoly right unless it has been tried out."[323] Casalonga agreed with Ladas when he stated that a compulsory licence would have to be found to be insufficient before revocation was allowed.[324] Casalogna was of the opinion that revocation should be imposed after a compulsory licence was shown to be insufficient. Ackerman[325] believed that each country is free to decide

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[323] See Ladas, supra note 49 at p. 530.

[324] See A. Casalonga, "Forfeiture of Patents for Non-Working", (1951), 33 J. of the Pat. Off. Soc. 714 at p.720.

[325] See G. Ackerman, L'Obligation d'Exploiter et la License Obligatoire en Matière de Bevet d'Invention, (Paris: Sirey, 1936) at. p. 141, cited by Anderfelt, supra note 19 at p. 72.

about the compulsory licence if it is going to be insufficient and if only revocation will effectively sanction the abuses.

In order to give the correct interpretation of an ambiguous international text, the Vienna Convention on the Law of Treaties stipulates that where text is ambiguous, as it is here, the "Travaux Preparatoires" aid in interpreting a Convention.[326] According to the drafting subcommittee of Art. 5, the meaning is that revocation is possible in case a compulsory licence is shown insufficient "in fact." This "in fact" implies that an actual test of insufficiency is necessary before the sanction of revocation can be applied.

This interpretation leads to a problematic issue: if a compulsory licence is "in fact" needed to have already been granted and proven insufficient before revocation could be applied, what would happen to the Paris Convention member countries that do not provide for a compulsory licence in their national patent law? (For the non-member countries of the Paris Convention, the problem does not arise since they are free to implement a policy of their choice without repercussions.) Would that mean that these member countries, because they lack the sanction of compulsory licence as an immediate consequence, they also lose the recourse to revocation? Then, that leaves them deprived of any sanctions whatsoever, a situation that is outside the spirit of the patent law. And if these countries provide for revocation and do not provide for compulsory licence, does that mean they violate their international obligation?

The remarkable change that took place in Lisbon opened the way to a completely different set of interpretation, than those given in The Hague (Lisbon). Whereas the former wording (Hague text) gives the interpretation that an actual test of

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[326] Art. 32(a) of the Vienna Convention of the Law of Treaties.

insufficiency is needed, i.e., that a compulsory licence is, in fact, necessary to be granted and prove itself insufficient, the latter wording (Lisbon text) implies a schematic test of insufficiency, i.e. that it is permitted to only consider the effects of the compulsory licence. It is not necessary to actually grant a compulsory licence and prove its insufficiency. It is derived from the letter of the law, and it is within the spirit of the law to only consider that the licence "would have been sufficient"[327] in the case that it would have been tried even though this has not actually occurred.

The sentence that follows, however, "no.. revocation may be instituted before the expiration of 2 years from the grant of the first compulsory licence"[328] seems to negate this approach. If we join the two phrases then the interpretation would seem to be one that we accepted within the framework of the Hague text. The sentence quoted above seems to imply that a compulsory licence should first be tried in fact, in spite of the expression "would have been insufficient" that seems to contradict this. It is apparent that the wording of the Lisbon text is not clear at all and has led to interpretations with quite different consequences as will be seen in the next section.

4.3.3. National Measures and Interpretation of Convention

The Paris Convention while providing that each member country shall have the freedom to take legislative measures to prevent abuses, nevertheless, restricts this freedom by imposing two mandatory requirements on the order in which these measures may be

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[327] Art. 5A(3) of the Lisbon text of the Paris Convention.

[328] Ibid.,

applied. Thus, revocation may be ordered only if the compulsory licence is not sufficient to prevent the abuses. Moreover, revocation cannot be ordered before the expiration of two years from the grant of the first compulsory licence.[329]

These mandatory restrictions on the order in which revocation may be applied and conditioned upon the compulsory licence has influenced the patent legislation of many countries.[330] Today, the majority of countries provide for compulsory licences, either as the only sanction or as the primary sanction in the case of non-working the patented invention.

Many countries provide for both measures, i.e., compulsory licence and revocation as a supplementary measure to compulsory licence.[331] There are, however, some countries that provide only for compulsory licence and do not provide for revocation of the patent.[332] Since the Paris Convention sets out that each country shall have the right to take the necessary legislative measures to prevent abuses and only restricts the time and the order in which revocation may be applied, it follows that a country has the right not to provide for revocation and only provide for a compulsory licence without being at variance with the international convention. Thus, this situation does not create any problem as far as international obligations are concerned. Whether this is the appropriate policy to follow

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[329] Art. 5A(3) of the Paris Convention.

[330] Several countries enacted a compulsory licensing provision: Austria (1928), Spain (1929), Switzerland (1928).

[331] For example, both sanctions are provided for in Australia, Austria, Canada, Germany, Greece, Italy, Switzerland, United Kingdom, Brazil, Egypt, India, Israel, Peru, Pakistan, Zambia. Very few countries do not provide for any sanction: Chile, Ghana, Kenya, Salvador, Tanzania, Uganda, USA and Vietnam. See Anne-Marie Greene, supra note 229; see also Baxter, supra note 264 at pp. 148-149.

[332] For example, compulsory licence is the only measure provided for in France (after 1958), Japan, The Netherlands, Nordic countries, Zambia, Niger, Philippines, Sudan, African Union, Portugal, Spain.

in order for a country to protect its national interests is a separate issue which is dealt with in the next section.

There are, however, some countries that do not contain any compulsory licences provision in their national patent law and provide for revocation as soon as the exclusivity period given to the patentee for the exclusive use of his patent expires and the patent remains unused.[333] It is with these countries that the problem of interpretation of the Convention arises.

Given that revocation "shall not be provided for except in cases where the grant of compulsory licence would not have been sufficient"[334] and given that revocation of a patent may not be ordered "before the expiration of two years from the grant of the first compulsory licence",[335] does it follow that in countries whose national patent law provides for revocation and does not provide for compulsory licence[336] and who are parties to the Paris Convention[337] revocation of the patent will not be possible? Consequently, if they provide for revocation, do these countries violate their international obligation?[338]

Thus, a great deal of controversy was created in many countries as a result of paragraph 3 of Art. 5 and many have regulated the issue in different ways. The revision

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[333] For example, revocation is the only measure provided for in Argentina, Venezuela, Tunisia, Lebanon, Morocco, Turkey, Bolivia and Peru.

[334] Art. 5A(3) of the Lisbon text of the Paris Convention.

[335] Ibid.

[336] See supra note 333.

[337] For the non-members of the Union, the problem does not arise since they are free to legislate without any international restriction (e.g. Venezuela).

[338] See infra p. 117.

that took place in The Hague resulted in controversy since many countries had not enacted any provision for compulsory licence, and only provided for revocation of the patent.

This controversy however arises only in those countries that recognize self-executing provisions of a treaty. As will be seen, it does not apply to those countries that do not recognize such provisions. Hence, the first issue in order to solve the problem of interpretation was whether this paragraph was self-executing and then directly effective as law, or was not self-executing and then not effective as law. If it was the latter a compulsory licence provision would first have to be inserted into the national laws.

Thus, the issue that must be addressed here in the context of these provisions is whether they have the force of law and can be immediately applicable in a country after ratification or accession, or whether a separate further legislative enactment is necessary in order to implement them in the national legal order of a country. In other words, the question is whether the common legislation which is established by Art. 5(3) constitutes what in international law is known as "self-executing provisions" or "self sufficient application legal rules."

The answer to this issue depends on the general principles affecting the relationship between international and national law and/or the Constitution that prevails in a particular country, whether it provides for self-executing provisions directly applicable to private parties or whether further legislation is necessary to render those provisions applicable.

Although every country follows its own particular practice, in most countries which follow the common law system[339] provisions of an international convention cannot directly affect private rights of nationals and consequently the Paris Convention's

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[339] Such as Canada, Great Britain, Australia, New Zealand, India.

provisions, which apply common legislation, cannot be self-executing. These provisions are indirectly applicable to private parties by virtue of further parliamentary approval, i.e. through an act of Parliament.

Hence, in common law countries, the question of interpretation by the courts does not arise since these countries do not recognize the possibility of self-executing treaties in their national legal system. For example, Canada does not recognize self-execution of treaties. Implementation, through national legislation, is always required if the treaty intends to change domestic law.*

A practice fundamentally different from the above exists in countries that follow the civil law system.[340] In these countries the Constitution grants the right to the judicial and administrative bodies to apply provisions that are of a self-executing nature to private parties, without any further legislative steps being taken or notwithstanding any contrary national legislation.

Thus, in countries that follow the civil law system, a controversy regarding the interpretation of Article 5A arose. To recall, the problem was whether in these countries a patent cannot be revoked because compulsory licence was not provided. As will be seen the question has been answered both negatively and affirmatively. According to Bodenhausen, in countries which do not provide for compulsory licences in their patent laws, revocation of a patent on the basis of an abuse situation will not be possible.[341] Thus in The Netherlands it was held that revocation was not possible except upon proof

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* A. Gotlieb, Canadian Treaty-Making (Toronto: Butterworths, 1968); A. Gotlieb "Canadian Treaty-Making, Informal Agreements and Interdepartmental Agreements" in R. MacDonald et al., Canadian Perspectives on International Law and Organization (1974), p. 229; R MacDonald, "International Law and the Domestic Law of Canada" (1975), 2 Dal. Law. J. p. 307.

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[340] Such as Sweden, France, W. Germany, The Netherlands, Greece, Italy, Latin America countries and French-speaking African countries.

[341] See Bodenhausen, supra note 61 at p. 72.

that the compulsory licence had been insufficient.[342] Similarly in Belgium the Council of State held that revocation could not be invoked notwithstanding the fact that since there did not exist a compulsory licence provision recourse to the sanction of revocation would be lost.[343]

In France, where a compulsory licence provision was not provided until 1953, after the amendments in The Hague and London, a critical problem arose because France contravened the international obligations that were set forth at these two conventions. The issue that arose was which law prevailed: the text of the Paris Convention providing for a system of compulsory licence or the national French law providing only for revocation. Most French courts resolved the conflicting issue by giving preference to the Paris Convention. Their decision was justified by the fact that the French Constitution, based on the civil law principles, regarded international treaties and agreements as superseding national law without calling for legislative action.[344] The French Cour de Cassation held the opposite view and gave preference to the national law thus it held that revocation was still the only valid sanction in France. The Cour de Cassation interpreted the Paris Convention as providing only a guideline to national legislators. If France did not take positive action to implement a law on compulsory licence then compulsory licence would not exist.[345]

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[342] Ladas, supra note 49 at p. 530.

[343] Decision of May 8, 1958.

[344] Art. 26 of the French Constitution (October 27, 1946): "Diplomatic treaties, duly ratified and published, shall be regarded as acts of Parliament, even in the case where they are in contradiction with internal French acts, without necessitating the application thereof legal dispositions other than those required by the ratification thereof."

[345] Mantelet v. Simon, Cour de Cassation, March 26, 1946, et Cour de Cassation, June 26, 1957. Sirey 46.1.125, Gazette du Palais 46.1.218 For a list of cases adjudicated in France see André Armenaug, "Lapse of Patents for Non-Working in France" (1949), 31:7 J. Pat. Off. Soc. 544.

In order to resolve this dispute, France, under pressure from the international community because it was not complying with her obligations set up a committee to examine the relation between the two conflicting provisions. This committee, after analyzing the matter, recommended the enactment of a decree to regulate the issue. Thus decree 53-970[346] was set forth that created a system of compulsory licence which was drafted in conformity with the Paris Convention in order to "enable France to observe its international obligation." Under this system of non-exclusive compulsory licence, non-working of the patent was a ground for issuing the compulsory licence.[347]

However, Italy did not follow the interpretation given by France, Belgium and the Netherlands, but as will be seen, it was decided that since Italy had no compulsory licence provision in the patent law, revocation was possible.

Italy distinguishes between two kinds of provisions contained in a treaty: complete and incomplete provisions. Complete provisions render a provision immediately enforceable without need of implementing legislation[348] and contain elements that render them self-executing and as thus they are "diretto, automatico, permanente, continuo e completo."[349] Incomplete provisions do not contain the above elements and their

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[346] Decree 53-970, September 30, 1953 Journal Officiel, 1 Octobre 1953 and (1949), 31:7 J. Pat. Off. Soc. 544.

[347] Decree 53-970 has been repealed by Patent law 68-1 (Law to Promote Inventive Activity and Revise the Patent System, No. 68-1 of January 2, 1968) pursuant to which a compulsory licence may be issued if the patentee has not begun exploiting the patented invention in France or made "effective preparations" to do so, or if working has been abandoned for more than three years without providing "acceptable excuse". Furthermore a licence is ordered by the Minister of Industrial Property if the working does not satisfy the needs of national economy.

[348] Art. 10 of the Italian Constitution.

[349] A. Sereni, Diritto Internazionale, I, 226, Milano 1956.

applicability is subject to the issuance of an act which ratifies them and transfers them into the national legal order (the so-called ordine di esecuzione).[350]

Thus it was decided that Art. 5(3) of the Paris Convention constitutes an incomplete self-executing provision[351] and therefore was not to be applied in Italy as law until a system of compulsory licence was instituted.[352]

Argentina has taken a stand similar to Italy's position and held that revocation was the primary sanction against non-working of the patent. The Supreme Court of Argentina, in 1972, in Franco Duranti v. Supramar established that according to Art. 47 of the Argentinean Patent law, revocation was possible if the patent had not been worked in the country after 2 years from the grant of the patent.[353] The interpretation given by Argentina to Art. 5A(3) of the Convention was that "the Convention authorizes the countries of the Union to prevent abuses, and adds that forfeiture can only be provided for after two years have elapsed from the grant of the first compulsory licence. That is, the existence of compulsory licensing is assumed so that where the state does not establish and legislate for compulsory licensing, the revocation provided by the law prevails."[354]

It is interesting that in the United States, which is a common law country, practice is conditioned by the Constitution, which stipulates that Treaties are "the Supreme

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[350] Art. 87 of the Italian Constitution.

[351] Court of Appeals of Milan, Decision of November 7, 1938.

[352] Italy allowed for a compulsory licence in 1968 with Presidential Decree No. 849 of February 26, 1968.

[353] Franco Duranti v. Supramar S.A., (November 15, 1972) Fallos. T. 284, p. 197.

[354] See Pascual di Gugliemo, "La Invencion Patentable, Commetario de la Ley 111 y el Subdesarollo Industrial de la Republica". (Victor P. De Zavalia, Buenos Aires, 1968) p. 122, cited in English in The International Patent System: The Revision of the Paris Convention for the Protection of Industrial Property, UN. Doc. TD/B/C.6/AC.3/2 (1977) at p. 13.

law of the land"[355] and by the distinction between self-executing and non self-executing provisions. This distinction was first drawn in Foster v. Neilson by Mr. Chief Justice Marshall, in 1829, who defined the self-executing treaty "whenever it operates in itself without the aid of any legislative provision."[356] With regard to the provisions of the Paris Convention, Attorney General Miller in 1889 was of the opinion that the Patent Convention was not self-executing but "required legislation to render it effective for the modification of existing laws." However, in 1909, Judge Archibald had a different opinion and in Hennebigue Co v. Meyers he held that the provisions of the Paris Convention were self-executing.[357] Similarly Mr. Chief Justice Hughes in Bacardi Corp. v. Domenech in 1940 confirmed the fact that the Paris Convention contains self-executing provisions.[358] Hence, in the United States the practice in respect to the issue under consideration resembles the one prevailing in civil law countries and not the one prevailing in all other common law countries.

In summary, a controversy was created because of Article 5A of the Paris Convention, because many countries did not provide for compulsory licences in their national patent laws, and only provided for revocation of the patent. Article 5A of the Paris Convention provided that revocation of the patent could be addressed if the

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[355] Art. VI, sec. 2 of the United States Constitution of 1789.

[356] Foster v. Neilson (U.S. 1829), 2 Peters 253, at p.314.

[357] Hennebigue Co. v. Geyers (1909), 172 F. 869. Judge Archibald held that "A treaty is a law of the land, as an act of Congress is" and "nothing further, by our laws was necessary to put them into operation".

[358] Bacardi Corp. v. Domenech (1940), 311 US 150. For a detailed discussion see Ladas, supra note 49 at p. 224, see also S. Ladas "The Self-Executing Character of International Conventions on Industrial Property and their Effects on Substantive Rights" (1941), 36 Trademark Bulletin 5.

compulsory licence had been insufficient and after the lapse of two years from the date of grant of the first compulsory licence. Thus, the problem was whether these countries, because they lacked the sanction of compulsory licence, would also lose the sanction of revocation. Before answering this problem, the issue was whether or not such a provision was self-executing. In common law countries, with the above exception of the USA, the question of interpretation of Art. 5A(3) does not arise since these countries do not recognize self-executing provisions of treaties but rather require an Act of Parliament in order to transfer them into their national legal order. In civil law countries however where the Conventional law applies, i.e. the International rules of treaties constitute the supreme law of the country and have precedence over national law, the question of interpretation of Art. 5(3) arises and as a matter of fact it created a substantial judicial dispute which, as has been seen, has been answered in different ways by the various countries. Thus, other countries abolished revocation because they did not provide for a compulsory licence and lost recourse to this sanction and other countries retain revocation but in this way they violated their international obligation.

4.4 Concluding Remarks

It can be concluded that due to the strong influence exerted in the revision conferences of the Paris Convention by certain countries, the obligation to work the patented invention and the sanctions in the case of non-working it, i.e. compulsory licence and revocation, were not completely eliminated from the text of the convention but were maintained. However, the amendments to these provisions resulted in strengthening the

position of the patentee while not adequately safeguarding the public interest of member countries of the Union that grant patents to the patentees.

Thus, as far as the sanction of compulsory licence for non-working the patent and other abuses is concerned, its use is subject to conditions and delays which render its effectiveness doubtful. Compulsory licence will not be granted if the patentee justifies his inaction by legitimate reasons and in any case can not be granted before the expiration of 3 years from the date of grant or 4 years from filing the application for a patent.

Another factor that renders the impact of such sanction even more doubtful is the provision that refers to the non-exclusive nature of the compulsory licence. Consequently, the patentee will be able either to grant other licences and/or continue to import thus securing for himself an import market for a long-period of time. Therefore, the local licencee will be in competition with the foreign patentee who, being able to continue to import, may even prohibit the licencee from exporting to countries where the patentee has secured patents.

As far as revocation of a patent is concerned it has been complemented and gradually curtailed by the compulsory licence provision. Revocation, which could have been the optimum sanction, became a supplementary sanction conditional upon the issuance of compulsory licence only to be addressed if the compulsory licence were insufficient and in any case after 2 years from the grant of the first licence. Consequently, given that a compulsory licence may not be applied for until 3 years from the date of grant or 4 years from the date of filing the patent application, a patent cannot be revoked before the lapse of 5(i.e., 3+2) or 6(i.e., 4+2) years from the date of grant or filing of the patent. Therefore, developing countries lose the benefit that they could have obtained from this sanction, since its power has diminished and does not represent any real threat to the

patentee nor any inducement to work his patent and benefit the country as it does not apply any pressure on him. As a result the patentee may enjoy an import monopoly for a long time since "importation shall not entail forfeiture of the patent."

In addition, the unclear wording of the text of the Paris Convention had, as was seen above, led to controversial interpretations and led other countries even to abolish revocation where a compulsory licence was not provided, and thus lost recourse to this important remedy, or to confirm revocation as the primary sanction for non-working with the repercussion to violate their international obligations. If this is the case, then the solution to this problem would be for these countries to conform with the Paris Convention and adopt their national laws following the example of France, i.e., enact a compulsory licence provision, or to try to modify the relevant provision within the general framework of the revision process that the Convention currently undergoes.

Therefore it is seen that compulsory licence and revocation, as they stand today within the text of the Paris Convention, are inadequate and ineffective in protecting interests of developing countries which grant patents to foreigners, not because these sanctions are not good but because the legislation that supports them is ineffective. In the light of these conditions, limitations and delays, the value of these provisions of the Paris Convention is substantially reduced to a point where developing countries seriously question whether the Convention and in particular the provisions of Art. 5A really promote their interests and needs.

CHAPTER V

COMPULSORY LICENCES FOR PHARMACEUTICALS

At this point a key question arises whether compulsory licensing which is limited to abuse situations as it now stands in the Paris Convention is an effective protection of the public interest. Could a developing country impose compulsory licences in the areas of national economic development and public health under different rules? Could a developing country impose compulsory licences at any time after the patent grant, even where there is no abuse with regard to a specific area of products in the public interest, in order to facilitate the flow of technology in this sector and consequently its economic development? What would be the impact of such licences? Would they be more effective than the licences ordered in the case of abuse? What is the existing practice today? Would such provisions on compulsory licences be in accordance with the Paris Convention or would they be a violation of the International Convention? Finally, what steps have developing countries been taking with the Paris Convention? The next chapter deals with these questions and attempts to draw some conclusions.

5.1 Compulsory Licences for Pharmaceuticals: International Developments

Public interest is an element inherent in patent law since it is alleged that a patent is granted not only to the inventor's benefit but to society's as well. For this reason the law imposes certain limitations on the patentee, such as the exclusion or limitation of pharmaceuticals from the patent system, the obligation to work the patented

invention so as to benefit society, and imposes sanctions in the case when the patentee does not conform with the requirements of the law, such as the compulsory licence in the case of abuse of the right conferred by the patent, discussed above.

In particular areas, however, such as public health, national economy and national defence, these limitations are not deemed to be enough to safeguard the public interest. In these sectors many countries provide for a special compulsory licence, justifying it by the fact that the public interest takes precedence over private interests and calls for additional safeguards.

Thus, some countries provide for compulsory licences "in the public interest" without mentioning a specific sector,[359] whereas other countries specify in their patent law the national defence[360] or the national economy[361] and the public health aspect[362] of the public interest. The determining factor in these special compulsory licences is the impact that the invention would have on the national economy, defence, or public health of the country.

Accordingly, the new patent legislation of the Andean States provides for a compulsory licence of patents which are of particular interest to national development.[363] Similarly the Colombian law provides for a special system of compulsory licences when

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[359] E.g. Switzerland (s. 38, Patent Act 1954), The Netherlands (s. 32, Patent Act 1910-1963), Austria (s. 9, Patent Act 1950), France (Art. 37, Patent Law 1968), Nordic countries (Arts. 47, 75, New Scandinavian Law, 1967), BIRPI Model Law on Inventions for Developing Countries (s. 36). See Anne-Marie Greene, supra note 229; see also Neumayer, supra note 250.

[360] E.g. USA, France, Austria, Egypt, Mexico, Israel, Kuwait, Nigeria, Sudan and Tunisia.

[361] E.g. France, Colombia, Nigeria, Sudan, Peru and Costa Rica.

[362] E.g. France, Greece, Ireland, Brazil, Colombia, Mexico, Egypt and Nigeria.

[363] Art. 39, Resolution of the Commission of the Cartagena Agreement. See Compilation, supra note 218.

the Minister of Public Health establishes that the patent is of a particular interest to public health, to the economic development of a country or when the patented drug is priced excessively.[364]

A similar provision exists in Brazil[365] and in Egypt where patents concerning health are declared of national interest and are subject to exclusive exploitation by an agency in which the national administration participates.[366]

The area of public health is an indisputable area of public interest because it is in the public interest that good quality and safe pharmaceuticals are available to the public at the lowest possible price.[367] Therefore many countries provide for such compulsory licences either in the form of a provision for a compulsory licence in the public health or in the form of a specific reference to pharmaceuticals so as "to ensure the public with a reasonable quality of medical supplies.[368]

In any case, the primary justification for such compulsory licences is based on the objective to minimize drug prices. Thus, the consideration involved is that drugs are of vital interest to the country and for this reason their production should be immune from monopoly constraints by making them available at reasonable prices.[369] The means to achieve this goal is through a compulsory licence for pharmaceuticals.

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[364] Art. 565 of the Colombian Commercial Code of 1971.

[365] Art. 39(b) of the Brazilian, Code of Industrial Property Law. No. 5772 of 1971.

[366] Art. 33 of the Egyptian Patents and Design Law No. 132 of 1949 as am. in 1955.

[367] Art. 16(b) of the Greek Law on Unfair Competition and Innovation No. 1023 of 1980.

[368] Art. 120 of the Israeli Patents Law No. 5727 of 1967.

[369] See Schifrin, supra note 182 at p. 912; see also, Hoffman-La-Roche v. Bell Craig Pharmaceuticals (1970) 61 C.P.R. 243 where it was held that the public interest is more important than the patentee's interest; see also Parke Davis v. Fine Chemicals (1959) 30 C.P.R. 65.

Thus a consideration of public health confers the right to any interested person to apply for a compulsory licence if the patent is a substance capable of being used as medicine or a process of producing such a substance.

A remarkable cornerstone in the evolution of patents relating to pharmaceuticals was set with Decree 971 in France in 1953.[370] This law provided that any person could apply for a compulsory licence for pharmaceuticals when the prescribed reasons existed.[371] The grounds for this special case of compulsory licence were: when the drug was not available in the market in "sufficient quantities" or when it was available but at too high prices, or when the quality was not satisfactory. When any one of these grounds was established by the Ministry of Industrial Property, any person could be granted a compulsory licence for drugs.

This remarkable law set the foundation of compulsory licences for pharmaceuticals in France. This law has been repealed by the new patent law of 1968[372] which provides that the Minister of Health may order a compulsory licence in respect of a pharmaceutical or a "licence of right" when the public health requires it. Such grounds exist when the patented drug is not sufficiently available on the market or it is available at very high prices.

Compulsory licences for pharmaceuticals open the way to competitors to produce the drug. Hence, generic firms, the licencees, enter the market and compete for similar

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[370] Decree 53-971, September 30, 1953. Journal Officiel, 1 Octobre 1953. The Brevet de Medicaments Specials (BSM) created a special and separate licensing system relating to patents covering process apparatus and means for obtaining pharmaceutical products.

[371] Ibid., Art. 37.

[372] See supra, note 347.

products at lower prices, thus impede the monopolization of high prices and lucrative profits by the patent-holder firms. As a result the price of the drug falls substantially. It is for this reason that this provision is unpopular with the pharmaceutical industry, which tries through a powerful lobbying to safeguard its interests.

The patent-holding firms object to the compulsory licence system because it runs counter to their interest as it undermines their competitive advantage and destroys their monopolistic pricing practices. On the other hand the generic manufacturers, the licencees, support the compulsory licence system because it is the ticket to their entry into the market of new drugs, which incidentally results in price decreases.

It is clear that the answer to the issue on the merits of the compulsory licence system is based on one's interests, one's perception of interests and on one's political philosophy. Politicians have to make choices, within the parameters of economic reality. Accordingly the law of each country seeks to create a happy medium in order to satisfy the conflicting interests involved.

Thus, in many countries a compromise solution is sought to accommodate the public interest and not to disregard private interests which in any case are, and should be, respected in market economy political systems. Accordingly, the compromise is realized by providing for royalties to be paid to the patentee as a percentage of the sales in exchange for a compulsory licence for drugs to the licencee in order to permit him to enter the market. India, for example, which is not a party to the Paris Convention, provides that patents that refer to the production of pharmaceuticals are endorsed "licences of right" so that any person may obtain a compulsory licence if he provides the patentee with a royalty

of 4% of all sales during the first 3 years after the grant of the patent.[373] In Greece, the court in settling the terms of the compulsory licence for pharmaceuticals must endeavour to ensure that drugs are available to the public at the lowest possible price.[374]

In other countries and other patent Acts, however, the line is drawn in a different way. Thus, for example, the special compulsory licensing system for drugs does not exist in the United States[375] and in the United Kingdom. However, in the past, in Great Britain a special system of compulsory licences for pharmaceuticals was introduced in the Patents and Designs Act of 1919. This was at a time when it was feared that the pharmaceutical industry would fall into foreign control unless some precautions were taken.[376] The British compulsory licence system for drugs of section 41 was maintained in the Patents Act for 58 years.[377] Section 41 was eliminated from the Patents Act of 1977, after much lobbying by various strong industrial groups of the pharmaceutical industry who did not enjoy losing their monopoly on the production and prices of drugs.

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[373] s.87 of the Indian Patents Act of 1970, see also S. Vedaraman, "Patent law in India as a means towards accelerating industrial development," in WIPO Colombo Symposium, supra note 4.

[374] See supra, note 367 Art. 16(e).

[375] In the USA, not even a general compulsory licence exists. See supra note 331; see also G. Frost, "The Case Against Drug Patent Compulsory Licensing" (1965), Pat. Trademark Copyright J. Research Education, pp. 84-101.

[376] The British Patents Act of 1919 was very innovative for its time. A special compulsory licence for drugs was introduced and patents for pharmaceutical products were excluded and only patents for pharmaceutical processes were allowed. It is believed that the fear from the uprising German pharmaceutical industry played a role in introducing these provisions.

[377] The 1919 compulsory licence provision was incorporated into section 41 of the 1949 Patents Act on recommendation of the Swan Committee Report of 1947 (Departmental Committee on the Patents and Designs Act, chairman Sir K. Swan), but was eliminated from the 1977 Act on the recommendation of the Banks Committee Report (Report of the Committee to Examine the Patent System and Patent Law, London, 1970 at p. 118.)

As is seen, many developed and many more developing countries provide for a separate type of compulsory licence in respect to pharmaceuticals when "overriding grounds of public interest" require it.

This special type of compulsory licence for drugs and the compulsory licence, discussed in the fourth chapter, issued in the case when the patentee does not exploit his patented invention, differ in the purposes that they seek to accomplish.

On one hand, the compulsory licence for drugs seeks to minimize the price of the patented invention (the drug) taking into consideration a reasonable reward for the patentee in order not to defeat the goal of the Patent System.

On the other hand, the compulsory licence in the case of abuse seeks to maximize the output of the patented invention, taking into consideration a reasonable monopoly profit. To order a compulsory licence of this latter type, a case of abuse of the monopoly right must be established.

The compulsory licence for a drug, however, does not require such a case to be established. The mere fact that the patent is for a pharmaceutical automatically makes the patent eligible for a licence.

5.2 The System of Compulsory Licences for Pharmaceuticals in Canada

5.2.1 Before the New Regime

Since 1923 Canada provided for compulsory licences to manufacture pharmaceuticals.[378] The legislative intent of the relevant section[379] was in essence to lower drug prices by providing for compulsory licences to produce drugs in Canada, thus enhancing competition between the patentee and the applicant of the licence.[380]

This objective is well illustrated in Hoffman-La-Roche v. Bell Craig[381] where it was stated that "in the public interest, there should be competition in the production and marketing [of food and medicine] in order that they may be available to the public at the lowest possible price."[382]

Accordingly, the Commissioner, unless he could see "good reason to the contrary"[383] had "no alternative but to grant the licence."[384] Most of the time the

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[378] Patent Act, S.C. 1923, c.23, s. 17(2).

[379] This section was taken from the British Patents Act of 1907 amended in 1919. Section 17 of the Patent Act of 1923 changed to s. 40 with the 1935 revision of the Canadian Patent Act and was further renumbered to s. 41(3) with the 1952 revision of the patent Act.

[380] See Fox supra note 271 at p. 304; also see I. Goldsmith. "Drugs in Canadian Patent Law" (1967), 13:2 McGill L. J. 232 at p. 239.

[381] Hoffman-La-Roche v. Bell Craig Pharmaceutical (1967) 48 C.P.R. 137

[382] Id., at p. 144. See also Parke Davis and Co. v. Fine Chemicals of Canada (1959) 30 C.P.R. 59 per Rand J., who stated "new medicines prepared from patented processes are in the public interest to be free from legalized monopoly."

[383] s.41(3) Canadian Patent Act, R.S.C. 1985, c. P-4, s. 39(1).

[384] Frank W. Horner Ltd v. Sharp and Dohme (Can) Ltd. (1952) 15 C.P.R. 68 at p. 70; see also Martland J. in Hoffman La Roche v. Delmar Chemicals Ltd (1967) 51 C.P.R. 11 at p. 13.

Commissioner,[385] notwithstanding the patentee's allegations to the contrary, has been convinced that the applicant was qualified professionally[386] and could manufacture the product in commercial quantities[387] and that the market was not saturated by the products.[388] Hence the Commissioner awarded compulsory licences giving to the inventor due reward for the research leading to the invention.[389]

In the 1960s when almost everything was being questioned s. 41 did not escape investigation. It became the subject of scrutiny by many parliamentary committees and royal commissions. Thus ir 1960, the Ilsely Commission issued a Report on Patents stating that compulsory licences on pharmaceuticals should be retained.[390] In 1963, the Restrictive Trade Practices Commission in its report concerning the manufacture and sale of drugs proposed that patents with respect to pharmaceuticals be abolished.[391]

In 1965, the Hall Commission recommended in its Report on Health Services, that patents on pharmaceuticals should be retained. It proposed, however, that a further

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[385] Exception to this is Gilbert Surgical Supply Co. Ltd v. Parke, Davis and Co. (1958) 30 C.P.R. 21 at p. 23, where the Commissioner saw a good reason to the contrary and refused the compulsory licence.

[386] Frank W. Horner Ltd. v. Sharp and Dohme (Can) Ltd. (1952) 15 C.P.R. 68; see also Micro Chemicals Ltd. v. Société des Usines Chimiques Rhone-Poulenac (1962) 37 C.P.R. 93.

[387] Delmar Chemicals Ltd v. American Cyanamid Co., (1960) 32 C.P.R. 40.

[388] Parke Davis and Co. v. Fine Chemicals of Canada Ltd. (1959) 30 C.P.R. 59 at pp. 65-67.

[389] See Frank W. Horner v. Hoffman-La-Rcche (1970) 61 C.P.R. 234 at p. 262 where the Commissioner fixed the royalty at 4% of the net selling price of the drug and thus a rule of thumb was established.

[390] Canada, Royal Commission on Patents, Copyright and Industrial Design, Report on Patents of Invention (Ottawa: Queen's Printer, 1960), at pp. 92-97.

[391] Canada, Department of Justice, Restrictive Trade Practices Commission, Report Concerning the Manufacture, Distribution and Sale of Drugs (Ottawa: Queen's Printer, 1963), at pp. 516-524.

safeguard for the public interest be created by a provision for an efficient compulsory licence system to manufacture and import pharmaceuticals.[392]

In 1966, the Harley Committee in its Report on Drug Costs and Prices proposed amendments to the Patent Act in order to provide for "compulsory licences to import pharmaceuticals in all forms.[393]

A common concern and denominator of all these Canadian studies was that the pharmaceutical industry in Canada profited from a remarkable market power which expressed itself by high prices in relation to the production costs and in comparison with other developed countries' prices. Furthermore there were common concerns over the ways to decrease high drug prices.

As a result of these studies, in 1969, following the recommendations made by the Hall Report and the Harley Committee, the Patent Act was amended to permit compulsory licences to import pharmaceuticals.[394]

Hence, with the new amended s. 41(4), the Commissioner was empowered not only to issue a compulsory licence to manufacture a drug (which existed since 1923) but also to import pharmaceuticals into Canada. In Frank Horner v. Hoffman -La-Roche Ltd. it was held that: "the basic change to s. 41 was to enable the Commissioner of patents to issue compulsory licences for the importation of medicines produced by patented processes used in the preparation of production of medicines whereas prior to the new

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[392] Canada, Royal Commission on Health Services, Report of the Royal Commission on Health Services (Ottawa: Queen's Printer, 1964), at pp. 701-709.

[393] Canada, House of Commons, Special Committee on Drug Costs and Prices, Report of the Standing Committee on Drug Costs and Prices (Ottawa: Queen's Printer, 1966).

[394] In 1968, Bill C-102 set forth an amendment to s.41(3) of the 1953 Patent Act. This Bill was passed on March 26, 1969. Act to Amend the Patent Act, the Trade Marks Act and the Food and Drugs Act, R.S.C. 1985, c. P-4 s.1.

enactment the Commissioner had authority only to issue to applicants compulsory licences to manufacture under the patent.[395]

With respect to the principles that would apply to compulsory licences to import drugs, it was held that the principles which had been established by the Courts in regard to the interpretation of s.41(3) "still remain applicable" to the interpretation of s.41(4).[396]

Different views have been expressed concerning the impact of compulsory licences for pharmaceuticals. As is mentioned above the concern over the high prices of pharmaceuticals led to the enactment of the compulsory licence system to import drugs. There have been studies that concluded that the objective of the licence system has been met, whereas other studies do not seem to attribute the same results to the system.[397]

It is worth mentioning at this point the two characteristically opposing associations of pharmaceutical firms in Canada: The Pharmaceutical Manufacturers'

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[395] Frank W. Horner Ltd. v. Hoffman-La-Roche Ltd., (1970) 61 C.P.R. 243 at pp. 248-249; In Smith, Kline and French s. 41(4) was unseccesfully challenged on grounds that it was ultra vires the Parliament and null and void as contrary to the Canadian Charter of Rights and Freedoms. Smith, Kline and French Laboratories Limited et al. v. Attorney General of Canada, F.C.T.D. Strayer J.; 18 November, 1985.

[396] Frank Horner v. Hoffman-La-Roche is the first case concerned with the amended section; see also Novopharm Ltd. v. Pfizer and Co. Inc. (1970), 62 C.P.R. 92; Jules R. Gilbert Ltd v. Société des Usines Chimiques Rhone Poulenac and Sandoz Patents Ltd (1971), 64 C.P.R. 158.

[397] See T. K. Fulda and P. F. Dickens. "Controlling the Cost of Drugs: The Canadian Experience" (1979), Health Care Financing Rev. 59 at p. 63. This study found that on the period of 1970 to 1974 decreases of 10.4 per cent occurred on the price of drugs that were included in generic competition (i.e. with compulsory licences). See also Compulsory Licensing of Pharmaceuticals. A Review of s. 41 of the Patent Act, (Ottawa: Minister of Consumer and Corporate Affairs, 1983) at p. 41. This review, made by the Government of Canada on the impact of the 1969 amendments to the pharmaceutical industry concluded that "generic competition puts downward pressure on drug prices or reduces rates of return to patentees" (hereinafter Minister's Review). See also P. K. Gorecki, H. Henderson," Compulsory Patent Licensing of Drugs in Canada: A Comment on the Debate" (1981), 8 Canadian Public Policy 559 at p. 562.

Association of Canada (PMAC)[398] and the Canadian Drug Manufacturers' Association (CDMA).[399]

The CDMA, through Frank Horner, one of its 4 most important members, alleged that savings due to compulsory licences were in the range of 124 million dollars for one drug (diazepan). For obvious reasons the PMAC held a different view and tried to understate the effects of compulsory licences. PMAC held that over the same period (i.e. from 1970 to 1982) there were savings in the range of 35 million for all drugs.[400] Even though these figures do not coincide, PMAC does not deny that there has been a greater amount of competition and a lowering of prices, though it tries to minimize the effect.

In 1985, the Royal Commission of Inquiry on the Pharmaceutical Industry, headed by Professor Eastman, an expert in the field, reported that in 1983 for 42 compulsorily licenced drugs, the sale prices of generic drugs were 51 per cent lower than the sale prices of the patent-holding firms of these 42 drugs; the Eastman Commission reported that in 1983, 211 million dollars worth of savings were realized due to the

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[398] The P.M.A.C. represents the innovating firms, the patentees, usually the Multinational Corporations (MNCs).

[399] The C.D.M.A. represents the generic firms, the licensees. Membership to CDMA is restricted to companies 51 per cent Canadian owned.

[400] See G. A. Seaby. "Drug Licensing: Should s. 41(4) be retained?" (1984), 1 Pat. and Trademark Inst. Can. Rev. 37 at p. 44. (hereinafter Seaby).

compulsory licence for pharmaceuticals.[401]

The Eastman report stated that the Canadian experience "indicates that generic drugs can be and are sold for prices that in the majority of cases are substantially below 50 per cent of the patent holder's price."[402] The Eastman Commission reported that "the whole of the pharmaceutical industry including patent holding and generic firms has been doing well since that time [1969] in terms of growth and profits compared to the rest of Canadian industry. On the whole compulsory licensing has caused no decline in the economic health of the patent-holding firms."[403] The Eastman report concluded that "compulsory licence has not had a discernible negative impact on the profitability and rate of growth of the pharmaceutical industry in Canada as a whole"[404] and recommended that compulsory licensing to import and to manufacture should be retained, "together with

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[401] See The Eastman Report, supra note 161 at p. 318; see also the study by Gorecki who evaluated the price effects of compulsory licences on drugs and comparing many data concluded that "prices have declined in Canada for compulsorily licensed drugs where the licensee has marketed a competitive product to a much greater extent than licensed drugs for which a competitive product is not sold. In other words for those compulsorily licensed drugs which are worked the object of s.41(4) has been achieved: prices have fallen in some instances dramatically." P. K. Gorecki Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection and Government Reimbursement Programs, Technical Report No. 8, Economic Council of Canada, Ottawa (1981) at p. 126.

[402] See Id., The Eastman Report at p. 319. The CDMA investigated the differences between prices of generic drugs and brand name drugs and presented a brief to the Eastman Commission which reported that "of the 62 price comparisons, 14 or some 22.6% had the generic price in the range of 50 to 74.9% of the patentee's price. Twenty seven observations or approximately 43.6% indicated the generic price was in the range of 25 to 49.9% of the patentee's price. The remaining 21 observations, or approximately 33.9% of the total, describe the generic price as in the range of zero to 24.9% of the patentee's price. In no case was the generic price equivalent to 75% or more of the patentee's price." Id., at p. 318.

[403] Id.,at p. 349. The report stated that there were no "adverse effects from the introduction of compulsory licensing to import in 1969. Compulsory licensing has had no visible effect on the profitability of the pharmaceutical industry in Canada. It has adversely affected the profits of particular firms, but this effect has been compensated by the high profits of others. Neither does the growth of the industry reflect adverse effect from compulsory licensing.

[404] Id., at p. XIX.

appropriate royalty rates and a short period of exclusivity should be given to patentees following the issuance of their Notice of Compliance."[405]

Notwithstanding the above evidence that compulsory licence contributes to the decrease of prices, the patent-holding companies disapproved the compulsory licence provision because it undermines their competitive advantage and is against their interest.[406]

5.2.2 The New Canadian Regime

All the patent-holding companies' reaction and also pressure from US and European Governments cumulated to exert pressure on the government of Canada and, the time being fruitful, succeeded in contributing towards the creation of a brand-new system affecting pharmaceutical patents and licences for drugs in Canada.

In June 27, 1986 the Minister of Consumer and Corporate Affairs of Canada announced major changes in the Canadian Patent Act with the objective of transforming Canada's pharmaceutical sector into a world-class, innovative industry while ensuring that Canadian consumers will enjoy fair priced drugs.[407] "The new policy," the Minister said, "will bring an unprecedented private sector investment in Research and Development in

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[405] Id., at p. 352.

[406] The patent-holding companies intensified the debate with arguments about the reduction of employment through the relocation of specific companies. According to the Minister's Review, however, employment increased by 6% during 1960 to 1981. Furthermore the Eastman Commission reported that employment grew from 74% to 91% from 1967 to 1982. Moreover they made allegations on the generic's quality standards used in the production of drugs. In this respect the Minister's review is relative where it is stated that "the safety of generic drugs has not been successfully challenged despite extensive testing by both patent-holding companies and competing, generic firms. See the Minister's Review, supra, note 397 at p. 30. For an analysis on the arguments set forth by the patent holding firms and their refutation see Seaby, supra note 400.

[407] See Notes for Remarks by the Hon. M. Côté, Minister of Consumer and Corporate Affairs, Canada, June 27, 1986, Doc. S-86-38.

Canada."[408] The unprecedented aspect of this Bill,[409] however, is in the long time and rigorous scrutiny that it has undergone.

The legislative process of Bill C-22 has been turbulent since diametrically opposed economic interests and different political beliefs have been involved and opinions have been divided on the issue. Bill C-22 was stalled in the Senate for a considerable amount of time. It took more than a year and three Committees to thoroughly scrutinize it. Numerous witnesses appeared before these committees and provided their opinions.[410] The Bill went back and forth to the House of Commons and the Senate several times[411] as

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[408] Patent Act Amendments to Result in Unprecedented Pharmaceutical Industry Investment and Research, News Release, Consumer and Corporate Affairs, Canada, Doc. NR-86-12.

[409] Bill C-22, An Act to Amend the Patent Act and to Provide for Certain Matters in Relation Thereto, (2nd sess., 33rd Parliament), (House of Commons, May 5, 1987).

[410] A large number of organizations and individuals appeared before the Committee such as the Canadian Drug Manufacturers'Association (CDMA), the Pharmaceutical Manufacturers' Association of Canada (PMAC), the Patent and Trademark Institute of Canada, the Canadian Labour Congress, the Canadian Chamber of Commerce, the Canadian Health Coalition, the Canadian Economic Council, the federal government of Canada, provincial governments, expert professors and lawyers, labour unions and concerned consumers.

[411] Bill C-22 was announced initially on June 26, 1986. After some modifications it was introduced in the House of Commons on November 7, 1986. In Canada, in order for a Bill to be passed and become law it has to be read three times in the elected House of Commons and then three times in the appointed Senate. Bill C-22 received its first reading on November 7, 1986. It was read a second time on December 8, 1986 when it was referred to a Legislative Committee headed by S.A. Malone. Bill C-22 was reported with amendments to the House of Commons on March 16, 1987. It received a third reading on May 5 and 6 when it was passed by the House of Commons. Bill C-22 was then sent to the Senate where it was read for the first time on May 7, 1987. On April 2, 1987 a special committee of the Senate had been appointed in order to examine the Bill and report to the Senate before the second reading. This Senate Committee headed by Senator M. Lorne Bonnell on June 23 issued its third report after it had heard evidence by a wide variety of more than 200 witnesses. Bill C-22 received a second reading on June 25, 1987. The Senate Committee proposed various amendments to Bill C-22 taking into account recommendations of the Eastman Commission of 1985. (See 6th, 7th Report of the Special Committee of the Senate, Issue No. 24, August 10-12, 1987). Bill C-22 was then returned to the House of Commons on August 13, 1987 for consideration on the proposed amendments. It was debated from August 21 to August 28. On August 31 Bill C-22 returned to the Senate for approval. The Senate referred Bill C-22 to the Standing Committee on Banking, Trade and Commerce on September 3, 1987. On October 21 the Committee presented its report to the Senate. Bill C-22 was then sent to the House of Commons for further consideration on October 29. On November 3 and 4 it was debated in relation to the Senate amendments. On November 5 it was passed. Bill C-22 was then returned to the Senate on November 17 and finally on November 19, 1987 received the Royal Assent and came partly in force on December 7, 1987.

opposing views were too strong to accommodate any one policy. Finally, after 15 months, on November 19, 1987 Bill C-22 received the Royal Assent and thus it came partly in force on December 7, 1987.[412]

5.2.2.1 The Amendments

The fundamental modifications to the Patent Act that were introduced with Bill C-22 can be categorized in general amendments"[413] to the Patent Act and in specialized amendments related to the pharmaceutical industry.

The specialized set of amendments is directed to the pharmaceutical industry and relates to patents for pharmaceuticals. Major changes have been introduced:

A. Product patent protection is established; thus a stronger form of patent protection is created. Product patents for pharmaceuticals can now be granted and not only process patents for pharmaceuticals as previously existed."[414]

B. A new compulsory licence system is created. Compulsory licences are retained but in modified form:

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[412] Certain sections were to come into force on a day to be fixed by proclamation.

[413] The general amendments comprise fundamental changes such as the introduction of the first--to-file system instead of the first-to-invent system, opening the possibility of Canadian ratification of the Patent Cooperation Treaty, the term of the patent of 20 years instead of 17 years, the dating of patents from the date of filing instead of from the date of the grant, the recording of licences, the imposing of renewal fees on patents on a periodical basis, the absolute novelty requirement instead of relative novelty with 1 year period of grace instead of two and the deferred examination system instead of the simple examination system. It should be mentioned that the Senate had not opposed the general amendments. See General Amendments to the Patent Act, Consumer and Corporate Affairs, Canada, Doc. NR-86-21; Notes for Remarks by the Hon. Harvie André, Minister of Consumer and Corporate Affairs for a Press Statement on the Amendments to the Patent Act, Ottawa, November 6, 1986, Doc. S-86-52.

[414] Patent Act, R.S.C. 1985, c. P-4, s. 39(1) as am. R.S.C. 1985, c. 33, (3rd supp.), s. 14.

B(1). New Scheme : New Pharmaceuticals

(a) A compulsory licence to manufacture a new pharmaceutical will be granted to an applicant after 7 years from the introduction of the drug in the market by the patentee, if the applicant manufactures the fine chemicals in Canada.[415]

(b) A compulsory licence to import a new pharmaceutical (i.e. a drug not yet marketed) will be granted to an applicant after 10 years from the date the drug receives its first Notice of Compliance.[416]

B(2). Transitory Scheme : Existing Pharmaceuticals

In respect to existing pharmaceuticals, transitory provisions have been created; for these existing drugs that have been granted a compulsory licence but have not received a NOC to market in Canada and for those existing drugs that have neither been granted nor receive a compulsory licence or a NOC, periods of exclusivity of 7 and 8 years respectively have been implemented. (Those drugs that have been granted both a compulsory licence and a NOC have remained untouched by the new provisions.)

Thus, a compulsory licence to import a pharmaceutical currently on the market will be granted to an applicant after 7 years from the date the drug receives its first Notice of Compliance, where a s.41 compulsory licence has been granted in respect of the pharmaceutical to a generic company but no NOC has been issued to the licencee to market in Canada, or where a NOC in respect of the pharmaceutical has been issued to a person other than the patentee (the generic company), but no s.41 compulsory licence has

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[415] Ibid., sec. 39.14(1)(b).

[416] Ibid., sec 39.11(2)(c). The applicant of a compulsory licence must obtain a Notice of Compliance from the federal authorities before marketing the pharmaceutical. Food and Drug Regulations C.08.004 Can. Cons. Regs. ch. 870 (1978).

been granted to the person as of June 27, 1986. In other words, a compulsory licence to import will be granted after 7 years from the first NOC when a person other than the patentee has either a compulsory licence or a NOC but not both until June 27, 1986.[417] However, a compulsory licence to import an existing pharmaceutical will be granted to an applicant after 8 years from the date the drug receives its first NOC where neither a NOC nor a s.41 compulsory licence had been granted to a person other than the patentee on or before June 27, 1986.[418]

C. Furthermore the new compulsory licence system provides for a longer period of protection for pharmaceuticals invented and developed in Canada.[419] These may be entitled to the benefit of preferential treatment of sec. 39.16 pursuant to which they may be shielded from compulsory licence to import and manufacture the drug. These pharmaceuticals will receive full patent protection and would thus be exempted from compulsory licences to import. They will also be exempted from compulsory licences to manufacture provided they are manufactured in Canada within the 7 years of manufacturing exclusivity.[420]

D. The Patented Medicine Prices Review Board (PMPRB) has been created which will monitor prices for all drugs in order to examine whether the prices for a drug are excessive or not.[421] To meet its commitment the Board will take into account: the prices

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[417] Ibid., sec. 39.11(2)(a).

[418] Ibid., sec. 39.11(2)(b).

[419] Ibid., sec. 39.16.

[420] This full patent protection may however be forfeited and compulsory licences may be granted when the patentee is not making the drug in Canada after 7 years or when he fails to satisfy the Commission with documentation and information concerning the activity of making the drug, sec. 39.16(4) and sec. 39.16(10).

[421] Ibid., sec. 39.18(1) and sec. 39.15(2)(b); See also Doc. S-86-52, supra note 6 at p. 4.

for identical products in other countries, the prices of other comparable drugs in Canada, the Canadian Price Index, and the production and promotion cost of the drugs.[422] Using these criteria the Board is entitled to determine whether prices are excessive, in which case it has the power to direct the company to lower the price to a level that is not considered excessive in the opinion of the Board, thus setting a ceiling price.[423] If the company does not abide by the ruling, the Board is empowered to remove patent exclusivity for the excessively priced drug and for one other drug for which the company has a patent.[424]

E. Finally, the new Patent Act provides for a parliamentary review after 9 years and possible revocation by Order in Council of compulsory licensing provisions after 4 years.[425]

5.2.2.2 Concerns About the New Regime

The new legislation has been attacked on a number of grounds. Many concerns have been expressed during the process of the Bill becoming law. The Board has been scrutinized on many fronts. It has been challenged on the constitutional basis by Professor Magnet,[426] on the lack of clear and precise guidelines of what constitutes

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[422] Ibid., sec. 39.15(5)(a) to (d) and sec. 41.15 (6)(a) and sec. 41.15 (6)(b).

[423] Ibid., sec. 39.15(2)(e); See also Notes for Opening Remarks to Legislative Committee on Bill C-22 by the Hon. Harvie André, Minister of Consumer and Corporate Affaires, Canada, House of Commons, December 16, 1986, Doc. 5-86-59 at p. 9.

[424] Ibid., sec. 39.15(2)(d)(1) and sec. 39.15(2)(d)(ii). See also Milan Chromecek, "The Amended Canadian Patent Act: General Amendments and Pharmaceutical Patents. Compulsory Licensing Provisions" (1988), 11 Fordham Int'l L.J. pp. 504-548.

[425] Ibid., sec. 39.26(3) and 39.26(1)

[426] See Proceedings of the Special Committee of the Senate on the Subject Matter of Bill C-22, Chairman: The Hon. Senator M. Lorne Bonnell, (hereinafter Senate Committee), Issue No. 23 (June 29, 1987), at p. 10

"excessive prices", on the cost involved and on the waste of time tied with the possible litigation suits that might arise among the conflicting parties.[427]

Moreover, another attack was directed to the powers of the Board and its effectiveness. The degree of the impact and effectiveness of the Board has been seriously questioned since most fine chemicals are produced outside Canada. They are imported to Canada within the framework of the well established and commonly accepted practice of transfer pricing, resulting in high prices when drugs are marketed in Canada. The effectiveness of the Board has been seriously put in question on the grounds that the Board has limited power to subpoena information and conduct investigations outside Canada. As a matter of fact the Board has no statutory power to collect any information outside Canada; thus its effectiveness and its role are seriously undermined.[428] In addition to that its power to remove patent exclusivity has been limited to one drug plus another drug; the original version of the Bill applied this power to all drugs. It empowered the Board to remove patent exclusivity from all drugs marketed by the company that was guilty of excessive prices and this was supported by Professor Eastman. However, this power was unfortunately limited in the new draft.[429]

Moreover Bill C-22 has been scrutinized and questioned not only on the grounds of the Board's effectiveness in gathering information and its impact in reducing prices, but also on the exclusivity periods that would have to elapse in order to introduce a generic

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[427] See Minutes of Proceedings and Evidence of the Legislative Committee on the Subject Matter of Bill C-22, Chairman: Arnold Malone M.C., (hereinafter Legislative Committee), Issue No. 3 (January 20, 1981), at p. 15.

[428] See Senate Committee, supra note 426 Issue No. 2 (May 5, 1987) at p. 33; see also Id., Legislative Committee, Issue No. 1 (December 11-16, 1986) at p. 38.

[429] See Senate Committee, supra note 426 Issue No. 4 at p. 14; see also Legislative Committee, supra note 427, Issue 5 (January 22, 1987) at p. 13.

equivalent product. Serious concerns were expressed regarding the new law's ability to actually reduce drug prices. The proponents asserted that prices would fall. The opponents stated that the Bill would not achieve many of the objectives and alleged that prices not only would not be reduced but would be increased since there would be no competition for lengthy periods of time.

As we saw above, compulsory licences are not abolished but their granting is substantially delayed in order to provide the patentee with a period of exclusivity to market his product and strengthen his position in the market. Hence the patentee recoups his expenses and increases his profits. These new exclusivity periods are created with the objective of delaying the commencement of manufacture and importation of pharmaceuticals in the market in order to immunize the patentee for a period of 7 and 10 years respectively. Thus the reduction of prices is postponed. Furthermore, the delays may result in the obsolescence of the product since over that length of time a new product may have emerged and may have replaced it.[430]

The exclusivity period that is created with the new Canadian compulsory licence system is based along the lines of the Eastman Commission's Recommendations. The Eastman Commission had recommended however a 4 year period of exclusivity instead of 10.[431] Giving evidence before the Legislative Committee Professor Eastman, stated: "a period of exclusivity is a useful device, ... how long the periods ought to be is of course a matter of judgement",[432] since "going beyond 4 years would promote abuses and waste

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[430] See Legislative Committee, supra note 427, Issue No. 3 (January 20 1987) at pp. 5 and 7.

[431] See The Eastman Report, supra note 161 at p. 329.

[432] See Legislative Committee, supra note 427, Issue No. 5 (January 22,1987) at p. 12; See also Jeffrey Simpson, "The Price of Patents",Globe and Mail, November 18, 1986 at p. A6.

of resources and funds."[433] According to Professor Eastman "the effect of this change to legislation would then be to delay the introduction of generic products compared to what would happened under the present act, and that will then delay the erosion of the market position of the patentee, that erosion normally bringing a decline in prices from the introductory level and also eroding the market share of the patentee. So that will delay this process and hence the profitability of the patent-holding firms in Canada should be increased."[434] Thus "prices would not be reduced by competition for a longer period" but "would be higher than they would have been otherwise".[435]

The big pharmaceutical companies have promised to invest in Canada and conduct research and development.[436] Complaints however, have been expressed that there is no specific commitment written in the legislation on the part of the Industry that will carry out the announced research and development in Canada.[437] Furthermore it has been alleged that the enactment of this law is tied to the Free-Trade Agreement[438] between Canada and the United States. Although there may have been political connections there

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[433] See Legislative Committee, supra note 427, Issue No. 1 (December 11, 1986) at p. 19.

[434] See Legislative Committee, supra note 432.

[435] Id., at p. 17.

[436] Total committed announced investment: $770.5M. See Industry R&D Announcements, Consumer and Corporate Affairs, Canada, Information.

[437] See John Orr, "Drug Bill No Cure for Research Ailments", Globe and Mail, September 24, 1987 at p. A7; see also October 15 at p. A6 and October 10 at p. A5.

[438] Canada-United States Free-Trade Agreement, Jan. 2, 1988, reprinted in (1988) 27 Int'l Legal Materials 281, (hereinafter FTA).

is no reference whatsoever in the final text of the Free Trade Agreement to pharmaceutical and patent issues.[439]

In conclusion, I believe the concerns of those who argued against Bill C-22 are justified and their arguments sound. It may turn out that the previous compulsory licence system should not have been replaced by the new restricted compulsory licence system because the previous system was more efficient in reducing prices and boosting research. However, it is also felt that it is too early to pass judgement on the law.[440]

It is well known that the pharmaceutical industry's lobby is one of the most powerful and influential. However it is the right and obligation of each country to decide what represents better its priorities and national interests.

It should be noted at this point that the new Canadian law on patents and licences for pharmaceuticals might work well for Canada but it is not be a model that would benefit developing countries if they blindly imitate it. Rather, developing countries could take the Canadian model and adapt it to their particular circumstances and needs. Consequently, the most advanced countries amoung the developing countries could accord preferential treatment to pharmaceuticals invented and developed within their country. Thus, they could provide for a longer period of protection for inventions that are carried out in their country.

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[439] See editorial in Globe and Mail, by J. Lewington and C. Waddell, "Ottawa Made Drug Bill Pledge in Trade Pact," October 9, 1987 at p. A1. See also October 10, 1987 p. A1 and A5 where an earlier version of the FTA was published which contained a statement saying "Canada has agreed to pass the pending amendments contained in Bill C-22 in respect of compulsory licensing of pharmaceuticals". However this was alleged to be a typographical error and was deleted from the final text.

[440] See editorial in The Financial Post by Gayle MacDonald, "Firms learn to live with new drug law", June 19, 1989, section 4 at p. 35.

5.3 Compulsory Licences for Pharmaceuticals and the Paris Convention

The question that arises at this point is whether the various national patent laws that provide for compulsory licences for pharmaceuticals at any time after the grant of the patent, even where there is no case of abuse, are in accordance with the Paris Convention. Article 5A of the Paris Convention stipulates that the application for a grant of a compulsory licence is not permitted before 3 years from the date of grant or 4 years from the date of filing of the patent application.[441]

A problematic issue emerged with regard to the relation of the compulsory licence for pharmaceuticals with Article 5A of the Paris Convention since it was not clear if the time limits applied to compulsory licences for pharmaceuticals as well.

In my opinion the correct interpretation of this issue was given in the landmark case of Parke Davis in Great Britain.[442] In 1953, an independent producer, British Drug House applied to the Comptroller General of Patents for a compulsory licence on three patents owned by Parke Davis and Corporation, a wholly owned subsidiary of the American giant firm. The patent for which a compulsory licence was applied involved production steps in the synthesis of the antibiotic chloremycetin.

The applicant for the compulsory licence, the British Drug House, relied on s.41 which provided for a compulsory licence if the substance was capable of being used as

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[441] Art. 5A(4) of the Paris Convention as revised in Lisbon.

[442] Parke Davis and Co. v. Comptroller General of Patents (1953), 70 R.P.C. 161.

medicine or in the production of medicine, without imposing a time limit for the patent application.[443]

Parke-Davis tried to obtain a court order against the issuance of a compulsory licence in order to prohibit the Comptroller General of Patents from imposing this compulsory licence. The argument that Parke Davis presented to establish its case was that the grant of such a compulsory licence would contravene the British Patents Act which reads "No order shall be made in pursuance of any application under sections 37 to 42 of this Act which would be in variance with any treaty, convention or arrangement or engagement applying it to the United Kingdom and any Convention country.[444]

Thus, Parke Davis cited in its defence Art. 5A of the Paris Convention which required a 3 year period to have elapsed before a compulsory licence could be issued. No such period had expired since Parke Davis was granted the three patents and hence the compulsory licence should not be given. Parke Davis concluded that if such a licence were granted it would violate s.45 of the Patents Act and Article 5A of the Paris Convention.

Thus the issue of the dispute was centred on the meaning of Art. 5A and the Court dealt with its interpretation. The Court of Appeal held that Art. 5A(2) and (3) of the Convention dealt with the case where a patentee abuses his patent monopoly. Art. 5A(4) stipulates that an application for a compulsory licence may be made after the expiration of 3 years from the date of the issue of the patent and is limited to the case of abuses. The Court interpreted the wording "in any case" of paragraph 4 with the meaning

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[443] Sec. 41(2) of the British Patents Act of 1949 (12, 13 and 14 Geo. 6, 1.87) as am. by the British Patents Act of 1977.

[444] Ibid., sec. 45(3).

"in any such case", i.e., the case of abuse, stated in paragraphs 2 and 3. Furthermore the Court held that s.41 of the British Patents Act gives the Comptroller General the right to impose a compulsory licence in order to make a drug available at the lowest price while reasonably compensating the patentee. It held that this section is different from s.37 which refers to non-working and other cases of abuse of the patent and provides for compulsory licence.

The Court held that patents relating to pharmaceuticals are eligible for a compulsory licence regardless of the manner in which the patent is exploited. The Court stated that s.41 "is not subject to the restriction of Art. 5A(4) of the Paris Convention but it creates a right to issue a compulsory licence solely on account of the character of the invention and therefore an application can be permitted at any time without the three year ban or waiting period as there is in s.37"[445] and the Court dismissed the action of Parke Davis.

The famous Parke-Davis case was referred to at the subsequent revision Conference in Lisbon, in 1958, where Article 5A was further elaborated. At this revision conference, the International Bureau interpreted Art. 5 as "not being an obstacle to the provision by member countries of other measures dealing with patents relating to health, military security or affecting national or international development planning.[446]

As a matter of fact a similar case[447] was decided in Canada where the Commissioner of Patents held that Art. 5A of the Paris Convention refers only to compulsory licences whenever there has been an abuse of the patent right, whereas

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[445] Parke Davis and Co. v. Comptroller General of Patents (1954), 71 R.P.C. 169.

[446] Actes de la Conférence de Lisbonne (1963) at p. 393.

[447] Frank W. Horner Ltd. v. Sharp and Dohme (Can) Ltd. (1952) 15 C.P.R. 68.

sec. 41(3) of the Canadian Patent Act refers only to compulsory licensing of patents relating to food and drugs.[448]

Furthermore, Professor Bodenhausen, a former Director General of the World Intellectual Property Organization, whose opinion can be regarded as authoritative, wrote in his standard work on the Paris Convention that member countries are "free to provide analogous or different measures, for example compulsory licences on conditions other than those indicated in paragraph (4) in other cases where the public interest is deemed to require such measures. This may be the case when patents concern vital interests of the country in the fields of military security or public health ... In such cases the rules of paragraphs (3) and (4) ... do not apply so that the member States have freedom to legislate."[449]

In conclusion, the landmark case of Parke-Davis better defined Article 5A of the Paris Convention and distinguished clearly the separate features of compulsory licences for pharmaceuticals.

The Paris Convention does not hinder member countries' legislating and providing for a compulsory licence for drugs on terms that they choose, without restrictions on the time when compulsory licence may commence and without a case of abuse needed to be established. Consequently in a compulsory licence for drugs there are no constraints with regard to the time that the application and the granting of the licence may be made. Therefore a compulsory licence for drugs can be granted at any time after a patent is

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[448] Sec. 41(3) Patent Act, R.S.C. 1985, c.P-4.

[449] See Bodenhausen, supra note 61 at p. 70.

granted in the interest of public health (even where there is no abuse) and this does not constitute a violation of the international convention.

This is a very crucial point that developing countries should be aware of and should not permit delaying in legislating. Not all problems of developing countries with regard to transfer of technology to the pharmaceutical industry will be solved since, as was seen, there still exist the restrictions for other compulsory licences, i.e., compulsory licences within the context of non-working the patent which have a direct effect on the developing industry and economy.[450] With compulsory licences for pharmaceuticals, however, developing countries are able to acquire the patented technology immediately without waiting three years.

At any rate, developing countries should undertake to create a provision for compulsory licences on pharmaceuticals and find ways to make it effective, since as is seen, there exists evidence that the system of compulsory licences does not work effectively. It is not a correct approach to abandon and abolish altogether the compulsory licence system because then developing countries would be left with no protection. The correct approach would be to find a way to improve the licensing system.

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[450] See supra, p. 122.

5.4 The Attempts of Developing Countries to Revise Compulsory Licence Provisions of the Paris Convention

The Paris Convention as it was seen, has been established with the primary objectives of providing rights for patentees and securing their rights by unifying domestic patent laws. The creation of the Paris Convention was a remarkable step for its time. The Paris Convention has been revised six times with the successful purpose of strengthening the patentee's position, as for example in Article 5A.

However, in the 106 years since the establishment of the Convention many fundamental changes have taken place. When the Convention was set up, in 1883, developing countries were colonies and did not have the independent status of sovereign countries. Thus, when the rules of the Convention were being established developing countries did not have any input in this process whatsoever. For reference, only three developing countries were original parties to the Convention and of them two renounced it, thus leaving only one developing country, Brazil, to be an original party of the Union.[451] The reality today is different: the majority of member countries to the Convention are developing countries which have not however actively participated in shaping its rules.

A primary concern of developing countries is the absence of any reference to the importance of the public health and in general public interest or any written commitment or declaration on the developmental objectives of their countries. Developing countries

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[451] See supra, note 57. Many developing countries have never become parties to the convention as for example India, China and most countries in Latin America.

believe that the Paris Convention is so structured that there is an imbalance between the public interest and the private interest of the patentee.[452]

Hence, developing countries having realized the limitations of the sanctions allowed by the Paris Convention and the costs that the patent system may impose on their economies have taken steps towards revising the Paris Convention and in particular Article 5A.

The first time that the developing countries' concerns were heard in the international community was in 1961 when Brazil brought a draft resolution before the General Assembly of the United Nations.[453] This resolution called for a recognition of the special interests of developing countries in economic development within the international patent system.

As a consequence of the Brazilian resolution, and after a strong opposition which resulted in many amendments on the original draft resolution, the General Assembly adopted resolution 1713(XVI).[454] Resolution 1713 requested that a report be prepared by the Secretary General on selected countries' patent laws and their effects, analyzing the possibility of a revision of the patent system. In the final paragraph, the resolution recommended particularly the "advisability of holding an International Conference in order to examine the problems regarding the granting, protection and use of patents taking into

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[452] The Role of the Patent System, supra note 107 at para. 237; See also The International Patent System as an Instrument of Policy for National Development, UN Doc. TD/B/C.6/AC.2/3 (1975) at p. 6; see also The International Patent System: The Revision of the Paris Convention for the Protection of Industrial Property, UN Doc. TD/B/C.6/AC.3/2 (1977), para. 11 and 15.

[453] The Role of Patents in the Transfer of Technology to Undeveloped Countries, UN Doc. A/C.2/L.565 (1961).

[454] The Role of Patents in the Transfer of Technology to Underdeveloped Countries. G.A. Res. 1713, 16 GAOR UN Doc. A/5056 (December 19, 1961).

consideration the provisions of existing international conventions and the special needs of the developing countries."[455]

In 1964, the Secretary General published an important report entitled "The Role of Patents in the Transfer of Technology to Developing Countries."[456] The report did not provide for the recommendation given by resolution 1713 on the advisability to call an International Conference. Instead, the report encouraged the developing countries to concentrate on legislative measures at the national level rather than calling an International Conference, thus shifting the focus from the international level to the national level.

In 1965, resolution 2091(XX) on Transfer of Technology, which was introduced by Brazil in the General Assembly, was adopted.[457] Resolution 2091(XX) questioned the appropriateness of existing international agreements. It also requested the Secretary General to pursue his inquiry on the adequacy of existing national and international practices for the transfer of patented and unpatented technology to developing countries.[458]

The next landmark in the process of initiatives taken by developing countries for the revision of the international patent system was established with resolution 39(III) on Transfer of Technology which called for a report to update the 1964 report. It also requested the Secretary General "to devote special consideration to the role of International

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[455] Ibid., para. 1(d).

[456] The Role of Patents in the Transfer of Technology to Developing Countries, UN Doc. E/3861/Rev. 1 (March 1, 1964).

[457] Transfer of Technology, G.A. Res. 2091, 20 GAOR UN DOC. A/C.2/L.824 (December 20, 1961).

[458] See also International Development Strategy for the Second United Nations Development Decade, G.A. Res. 2626, 25 GAOR Supp.No 28 UN Doc. A/8124 and Add. 1 (October 24, 1970), para 64. This resolution called for International Convetions on patents; see also The Charter of Algiers, UN Doc. A/C.2/237 (1967) which demonstrates the growing concern of developing countries about the inadequacy of the International Patent System; See generally International Symposium on Industrial Development, Athens, December 1967 in UNIDO Doc. ID/11 (1969) para. 122.

Patent System in such transfer (the transfer of technology), with a view to providing a better understanding of this role in the context of a future revision of the system."[459] Following the resolution a study was undertaken jointly by WIPO, UNCTAD and the Department of Economic and Social Affairs and published in 1975 under the title "The role of the Patent System in the Transfer of Technology to Developing Countries."[460]

This study was the main point of reference of the discussion at the third session of UNCTAD's intergovernmental group on Transfer of Technology held in Geneva.[461] At this session the group, after circulating the 1975 study on the role of the patent system in the transfer of technology to developing countries and acquiring their written comments, requested the Secretary General to "convene a group of experts to study all relevant aspects of the international patent system which have a bearing on the development process of developing countries with a view to providing a better understanding of the role of that system in the context of a possible future revision of the system aimed at reflecting the special needs of developing countries."[462]

Accordingly, in February 1975 a group of 150 governmental experts on the role of the patent system in the transfer of technology was convened in Geneva in order to examine the main points for the revision of the International Patent System. The group of governmental experts prepared 14 questions and requested the Director General of WIPO

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[459] United Nations Conference on Trade and Development (UNCTAD), Santiago, Chile, Res. 39(III) of May 1972, para. 10.

[460] The Role of the Patent System, supra note 107.

[461] Report of the Intergovernmental Group on Transfer of Technology, 3rd sess., Geneva, July 15 to 26, 1974, UN Doc. TD/B/520.

[462] Ibid., para. 1.

to study them and prepare a memorandum with his comments.[463] Accordingly, in December 1975 a declaration was adopted by the WIPO Ad Hoc group of governmental experts on the revision of the Paris Convention, which constitutes a landmark in the evolution of the International Patent System and specifically in the relation of patents with the developing countries. The declaration considered that the revision of the system should fulfil certain objectives in order to contribute to the "establishment of a new economic order in the world in which social justice prevails and economic inequalities between countries are reduced."[464] The experts from developing countries considered that the revision of the International Patent System should be based on the following objective: In order to facilitate the transfer of technology the international standards must adapt to the conditions that exist in developing countries and must not impede countries from adapting their laws to their own interests.

Following this declaration the Assembly of the Paris Convention created a Preparatory Intergovernmental Committee on the Revision of the Paris Convention.[465] This Committee created four Working Groups to better deal with the issues.[466] The Working Group on Article 5A of the Paris Convention was entrusted with questions of special

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[463] Report of the Ad Hoc Group of Governmental Experts on the Revisions of the Paris Convention, WIPO Doc. PR/GE/1/10, February 21, 1975; see also The Report of the Director General WIPO Doc. PR/GE/11/2 (September 5, 1975).

[464] Declaration on the Objectives of the Revision of the Paris Convention adopted by the Group of Governmental Experts on the Revision of the Paris Convention, WIPO Doc. PR/GE/11/3 (December 15-22, 1975).

[465] Preparatory Intergovernmental Committee on the Revision of the Paris Convention for the Protection of Industrial Property, 2nd Sess., June 29 - July 8, 1977, WIPO Doc. AB/VII/11 and AB/VII/23; see also (1977), 16 Ind. Prop. 167.

[466] The Working Group on Article 5A of the Paris Convention, the Working Group on Inventor's Certificates, the Working Group on Questions of Special Interest to Developing Countries and the Working Group on Conflict Between an Appellation of Origin and a Trade mark.

interest to developing countries, prepared a draft text of Article 5A and submitted it to the Committee, which unanimously approved it and forwarded it to the Session of the Executive Committee of the Paris Union, where a decision was reached that the Diplomatic Conference would convene in 1980 in Geneva in order to consider it.[467]

Consequently, in 1980, in Geneva, the Diplomatic Conference was convened from February 4 to March 4 under the auspices of WIPO with the objective to introduce new provisions and to change certain existing provisions in order to meet better the needs of developing countries.[468] Hence, for the first time in the history of the revisions of the Paris Convention the developing countries' interests are being discussed and taken under serious consideration.

The Conference for the revision of the Paris Convention thus far has taken place over four sessions: The first session was held in Geneva in 1980,[469] the second session in

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[467] Diplomatic Conference on the Revision of the Paris Convention. Basic Proposals, WIPO Doc. PR/DC/3 (June 25, 1980); see text of draft Article 5A at pp. 38-62.

[468] Diplomatic Conference on the Revision of the Paris Convention, Geneva, February 4 to March 4, 1980, WIPO Doc. PR/DC/15 (March 1, 1980).

[469] The First session was devoted to debates on procedural rules regarding voting. See WIPO Doc. PR/DC/15 for adopted rules of procedure; see also WIPO Doc. PR/DC/INF/13; U. Wasserman, "WIPO: Diplomatic Patent Conference (1980), 14 J. World Trade L. 254; M., Kirk." Diplomatic Conference on revision of the Paris Convention: Substantive Discussions" (1980), 12 Intel. Prop. L. Rev. pp. 13-27; A. Diamond, "The Geneva Diplomatic Conference on the Revision of the Paris Convention" (1980), 12 Intel. Prop. L. Rev. pp. 3-11; R. Benson, "The Geneva Diplomatic Conference for the Revision of the Paris Convention: Remarks from the Private Sector" (1980), 12 Intel. Prop. L. Rev. pp. 29-35.

Nairobi in 1981,[470] the third session in Geneva in 1982[471] and the fourth in Geneva in 1984.[472]

In Nairobi the task was to develop a new text for Art. 5A. The issues under scrutiny referred in particuiar to whether concessions to developing countries would be applied only to developing countries or would apply universally to all countries. A text was finally drafted after much deliberation and long debate.[473]

Thus, the present draft of Article 5A as tentatively agreed in Nairobi specifically states the right of national law to require that an invention be worked in the country that granted the patent.[474] Furthermore it is specifically stated that importation of products does not qualify as working the patented invention.[475] Both these provisions appear for the first time in a draft text of :he Paris Convention. Until then, no respective specific mention was made.

The status of sanctions, i.e., compulsory licence and revocation, remains unchanged[476] as compared with the Stockholm text. However, important changes follow

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[470] Diplomatic Confenrence on the Revision of the Paris Convention, Nairobi, September 28 to October 24, 1981, see WIPO Documents PR/DC/21, PR/DC/24, PR/DC/25, PR/DC/26, PR/DC/27, PR/DC/28, PR/DC/29, PR/DC/30, PR/DC/31, PR/DC/32, PR/DC/33 and WIPO Doc. PR/SM/5 (1981); see also M. Kirk, "Second Session of the Diplomatic Conference to Revise the Paris Convention". (1982), 14 Intel. Prop. L. Rev. pp. 139-151;

[471] Diplomatic Conference on the Revision of the Paris Convention, Geneva, October 29, 1982, see WIPO Doc. PR/DC/INF/34 (1982).

[472] Diplomatic Conference on the Revision of the Paris Convention, Geneva, February 27 - March 24, 1984, WIPO Doc. PR/SM/12 (May 31, 1985). See also Conference Diplomatique de Revision de la Convention de Paris. Tableaux Synoptiques des Articles Premier, 5A et 5Quater de la Convention de Faris pour la Propriete Industrielle, WIPO Doc. PR/DC/INF/51 (Septembre 1984).

[473] See text of draft Article 5A, the Nairobi text, in Appendix B.

[474] Ibid., Art. 5A(1)(a) of draft Art. 5A of Nairobi text.

[475] Ibid., Art. 5A(1)(b).

[476] Ibid., Articles 5A(3), (4) and (6).

with respect to developing countries, which would be, according to the text tentatively agreed at Nairobi, given preferential treatment.

These changes were tentatively introduced with Art. 5A(8) of the Nairobi text and would give developing countries the right to grant compulsory licences [477] for failure to work within 30 months from the grant of the patent unless justifications for non-working are set forward.[478] Such compulsory licence would be exclusive for a term of 4 1/2 years subject to the condition that the patent may not be revoked for non-working for an additional 18 months after the expiration of the exclusive licence.[479] Moreover, revocation for failure to work could occur before the expiration of five years from the grant of the patent provided that there exists a system of compulsory licence in the country and "in the opinion of the national authorities competent for forfeiture or revocation" the grant of a compulsory licence "would not ensure sufficient working of the patented invention."[480]

Hence, developing countries, and only they, are allowed to revoke the patent when the invention is not being worked by the patentee or his representative. Such revocation is allowed before the compulsory licence and it is not conditional upon the compulsory licence's effectiveness. In other words if it is seen by the competent authority that a compulsory licence would not ensure sufficient working, then revocation can be ordered. Hence, an actual test is not required, only a schematic one.[481]

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[477] Compulsory licence of the present Act is renamed to "non-voluntary licence" in the Nairobi text; see Art. 5A(2)(a).

[478] Ibid., Art. 5A(8)(a).

[479] Ibid., Art. 5A(8)(a bis).

[480] Ibid., Art. 5A(8)(b).

[481] See supra, text at p. 110.

A very important provision that is contained in the draft text is para. 5, which gives the right to any country to provide in its domestic law for exploitation of the patented invention at any time by the government or by third persons authorized by it.[482] Such exploitation would be justified in the public interest and in particular specific mention is made on the national security, food, health and the development of other vital sectors of the national economy.

These are in general lines, the main changes contained in the Nairobi text that, if adopted, would dramatically change the substance of the Paris Convention.

5.5. Concluding Comments

As was seen compulsory licences for pharmaceuticals confer the right on any interested person to apply for a licence at any time after the patent has been granted without a case of abuse of the patent right needed to be established, i.e., even if the patentee does not abuse his patent right, the mere fact that the patent covers a pharmaceutical means that a compulsory licence can be granted. As the Parke Davis case indicated, these licences for pharmaceuticals do not violate the Paris Convention. Thus a country can provide for such licences without violating its international obligations. As far as the Paris Convention is concerned, at the end of the revision conference in Nairobi, a decision could not be reached and the Chairman presented a compromise proposal, the so-called "Jimenez Davila text";[483] however it was not accepted and thus the Nairobi text remains the latest tentatively agreed text. Further elaboration on the ongoing process on

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[482] Ibid., Art. 5A(5).

[483] See WIPO Doc. PR/DC/37 (October 23, 1981).

the revision of the Paris Convention is beyond the scope of this thesis, as a revision has not yet been agreed upon. However, it may be worth mentioning that at the fourth session of the Diplomatic Conference in Geneva a recommendation was adopted which mentioned arrangements for the revision of the Convention. The Assembly of the Convention decided that the method would consist of consultative meetings in order to prepare the next session of the Conference. So far, four consultative meetings have taken place at Geneva: The first took place on June 24-28, 1985[484] and the second on January 26-31 and February 3, 1987,[485] when the group of developing countries put forward 4 proposals, "ideas", for the consideration of developed countries. These "ideas" were favourably received by the group of developed countries which at the third consultative meeting[486] presented a series of 6 questions about these "ideas" in order to clarify them[487]. In any case, it should be pointed out that there are ongoing discussions and debates in Geneva where delegations from the 3 groups of countries (developed, developing and socialist countries) meet, mainly senior legal counsellors and experts, to discuss, analyze and decide the future of the Convention. Undoubtedly developing countries have made considerable progress since 1961 and they have succeeded in having their interests discussed in the revision conference.

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[484] First Consultative Meeting on the Revision of the Paris Convention, Geneva, June 24-28, 1985; see WIPO Doc. PR/CM/I/3 (June 28, 1985).

[485] Second Consultative Meeting on the Revision of the Paris Convention, Geneva, January 26-31 and February 3, 1987; see WIPO Doc. PR/CM/II/1 (February 5, 1987).

[486] Third Consultative Meeting on the Revision of the Paris Convention, Geneva, May 18-23 and 26, 1987; see WIPO Doc. PR/CM/III/1 (May 26, 1987).

[487] Fourth Consultative Meeting on the Revision of the Paris Convention, Geneva, September 14-19 and 22, 1987; see WIPO Doc. PR/CM/IV/2 (September 22, 1987).

CONCLUSIONS

The concept of a patent emerged a few centuries ago in the city state of Venice and from there spread to most European countries and, eventually, to their colonies. After going through upheavals that revealed different facets of its nature, i.e., the antipatent movement and the feasibility of industrialization without it, it culminated at an international level in the Paris Convention which is the most important multilateral agreement on patents. The Paris Convention, revised six times since 1883 and based on two fundamental principles, the National Treatment principle and the Unionist Treatment principle with article 5A as a focal point, has significant implications for developing countries.

Evaluation of the role of patents in developing countries shows that patents may and may not transfer technology depending on the circumstances of the transfer; they also create significant costs and doubtful benefits. A benefit that may be said to flow from the international patent system in the developing countries is the transfer of technology which takes place when patents are used in production in the country by the patentee or his licensee, provided however that no restrictions are attached to the licence and that royalties are not excessively high.

As already stated, however, when patents are not used for production in the country but instead the patentee chooses to import the product into the country and thus he uses them as an exclusive import permit and as a means to exclude other importers and/or prevent local production, then a case can be made that patents restrict the flow of technology and hinder the industrialization of the country.

In order to avoid the costs and realize the benefits and facilitate the acquisition of technology, a network of safeguards is absolutely necessary. These safeguards concern

the obligation imposed on the patentee to work the patent, the compulsory licence and revocation provisions, as well as the provisions related to the exclusion or limitation from patentability of certain sectors in the public interest.

Two kinds of compulsory licences should be distinguished: the compulsory licence in the case when an abuse has occurred, as for example non-working of the patented invention, and compulsory licences for reasons of public health, i.e., compulsory licences for pharmaceuticals. As far as compulsory licences and revocation for non-working are concerned, the effect and impact of these provisions is questionable due to the delays and limitations that the Paris Convention imposes. In addition to the problems that the non-exclusive nature of the compulsory licence creates, a compulsory licence is subject to delays that render its effectiveness doubtful. A compulsory licence will be granted after the expiration of 3 years from the date of the grant of the patent or 4 years from the date of the filing of the application for the patent. Revocation which, as has been seen, through the various revisions of the Paris Convention, become a supplementary sanction, conditional upon the compulsory licence, will be imposed after 2 years from the grant of the first licence. Consequently, a patent cannot be revoked before the lapse of 5 or 6 years thus, the patentee enjoys an import nonopoly for a longer time. As far as compulsory licences for reasons of public health are concerned, they can be given at any time after a patent is granted because this grant does not violate the Paris Convention even if no case of abuse is established.

Given this distinction between the two different kinds and given the analysis regarding the interpretation and interaction between national patent laws and the Paris Convention, developing countries should first take action at the national level and in

particular in those areas that, as has been pointed out, the Paris Convention permits member countries to legislate. Such areas refer to the compulsory licence for reasons of public health and to the exclusion or limitation of pharmaceuticals from the patent system.

Developing countries should first take full advantage of these manifold opportunities. It does not make sense to attempt to revise the Paris Convention without first trying to improve their domestic law, at least within the parameters set by the Convention. Of course this consideration does not apply to all developing countries, since many have already initiated action in this direction. Nonetheless these initiatives should serve as a guide for those countries that have not used all the possibilities allowed by the Convention.

Clearly, developing countries should enact a compulsory licence system for reasons of public health, i.e., for pharmaceuticals. This is an essential provision since, as has been examined, the limitations that apply to compulsory licences for non-working do not apply to compulsory licences in the public health, i.e., for pharmaceuticals. Hence these licences could be granted immediately after the patent grant without a delay of 3 or 4 years and without a case of abuse needed to be established.

The impact of these licences is that they open the way to free competition; also, generic firms can freely enter the market, produce similar products and then sell them at lower prices. Consequently, the drug prices fall substantially and the patentee can not monopolize high prices and profits. As a result the economic development of a country and its industrialization are substantially helped and fostered. These licences can be considered more effective than the licences that are granted in the case of abuse of the patent right, where as we saw limits and delays set by the Paris Convention impose constraints. Many developing and developed countries provide for compulsory licences for

pharmaceuticals because they consider it in their interest to have access to low-priced drugs and to help the development of their pharmaceutical industry.

Developing countries should also consider, however, the possibility of foreign investors being driven away by this approach. Therefore, they could consider the new Canadian law on compulsory licensing for pharmaceuticals. As already stated, however, the new Canadian law might work well for Canada but it is not a model that could benefit developing countries if they blindly imitate it. Rather developing countries would use it analogically and provide for a longer period of protection for pharmaceuticals that have been invented and developed in their countries. This preferential treatment would not violate the National Treatment principle of the Paris Convention because it is based on a geographical consideration and not on a factor of nationality. It does not discriminate between national and foreigners; both are treated equally and have the same rights and obligations. However it distinguishes between inventions that have been carried out in the country and inventions for which the research and development has been conducted elsewhere. The inventions that are carried out entirely in the country are given, as an incentive, the benefit of preferential treatment and are shielded from compulsory licences to import and manufacture. In this way, the rights of the patentee are taken into fair consideration and he is given due reward for his invention and an incentive to invest. At the same time developing countries benefit from the research and development and working of the patented invention that takes place in their countries.

However, given that the patentee may not disclose all the necessary know-how and that local entrepreneurs may not have the necessary capital and skills to pursue such projects, developing countries should consider, either as an alternative or even as an additional measure, limiting or excluding pharmaceuticals from the patent system. They

could reexamine their patent laws and legislate on the patentability of pharmaceuticals. I believe that it is in the best interest of developing countries to eliminate pharmaceutical products from the patent system, while allowing for pharmaceutical processes. No patent protection is appropriate for pharmaceutical products although, as previously analysed, a case can be made for granting patents to processes. In consequence there would be no monopolies which limit access to drugs and raise their prices. It should be remembered that developed countries also introduced such provisions only recently, when they had reached a certain stage of development. Before that they did not grant patents for pharmaceutical products.

Developing countries should also try to make the working provision stronger in order to be more effective. A means to achieve this is by eliminating the right to import from the rights accorded to the patentee. Thus, importation would entail revocation instead of "importation should not entail revocation". Consequently the patentee will have to produce in the country since he will not be allowed to import on an exclusive base. This however is not easy to change because it is not within these areas where the member countries have freedom to legislate. Therefore a revision of Article 5A(1) of the Convention is necessary. Thus, developing countries could follow the example set by the Andean Pact countries who, not being members of the Convention, are free to legislate. For members of the Convention however the way of achieving the same result would be by changing, i.e. revising, the rules of the Convention.

At the international level developing countries should continue their efforts towards revising the Paris Convention. As has been stated developing countries, aware of the restraints and costs that the international patent system imposes on them have taken

steps towards a revision of the Paris Convention. As we saw they have reached a compromise text, the Nairobi text, which however has yet to be adopted. The Nairobi text, even if not adopted as a whole, represents a step towards mutual understanding in the process of the long-overdue revision of the Paris Convention.

Speaking realistically, it is very unlikely that a revision will be concluded within the next three years; it may take more time. The reason for this gloomy prospect is that opposing interest groups are pulling very hard and the revision process goes from one round of discussions slowly to another. It should be stated that the Group B, the so-called group of developed countries, in the United Nations terminology, will not adopt provisions that do not safeguard its interests just for the sake of giving a better chance to developing countries. By the same token, the Group of 77, the so-called group of developing countries, will not remain apathetic, but they will, and should, continue their efforts in revising the Paris Convention with consideration paid to developed countries' interests since after all they own the technology. However, recognition of the public interest and a specific statement within the text of the Convention regarding the interests of developing countries is absolutely necessary. We live in an interdependent world. Developing countries' interests can no longer be neglected or denied. The world has dramatically changed since 1958 when the Paris Convention was revised in Lisbon and definitely since 1883 when the Convention was established. The Paris Convention must adapt to the changes and needs of industrialization and economic development of the developing countries. Legal instruments should always have the capacity to improve their system and reflect and adapt to the changing world and needs of the people. Change may not have any dramatic effect for the short run but in the long run it would benefit both opposing groups.

The Geneva negotiations are aimed at perfecting the provisions of the system taking into consideration the developing countries' interests. Change brings positive developments if exercised with caution and prudence. Through constructive discussions a mutual goal may be reached that would be beneficial to all divergent groups. We must remember the interdependent nature of our world demands a balanced solution to all upcoming problems. The Nairobi text is a step in the right direction. The process will continue and hopefully in the 1990's we will witness many changes in this area and the deadlocks that stall the revision of the convention will be removed.

BIBLIOGRAPHY

1. Books and Monographs

1. Agarwal, Anil, Drugs and the Third World (London: Earthsquan, 1978).

2. Anderfelt, Ulf, The International Patent Legislation and Developing Countries (The Hague: Martinus Nijhoff, 1971).

3. Baxter, J.W., World Patent Law and Practice (London: Sweet and Maxwell, 1973).

4. Bodenhausen, G.H.C., Guide to the Application of the Paris Convention for the Protection of Industrial Property (Geneva: BIRPI, 1967).

5. Boehm, Klaus, The British Patent System (London: Cambridge University Press, 1967).

6. Firestone, O.J., Economic Implications of Patents (Ottawa: University of Ottawa Press, 1971).

7. Folk, G., Patents and Industrial Progress (New York: Harpers, 1942).

8. Forman, Howard (ed.), The Law of Chemical, Metallurgical and Pharmaceutical Patents (New York: Central Book Company, 1967).

9. Fox, Harold G., Canadian Laws and Practice Relating to Letters Patent for Inventions (Toronto: University of Toronto Press, 1969).

10. Gereffi, Gary, The Pharmaceutical Industry and Dependence in the Third World (Princeton: Princeton University Press, 1983).

11. Gorecki, P.K., Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection and Governmental Reimbursement Programs, Technical Report No. 8, Economic Council of Canada (Ottawa: 1981).

12. Greene, Anne-Marie, Patents Throughout the World, 2nd ed. (New York: Clark Boardman, 1984).

13. Hamilton, Walton, Patents and Free Enterprise, Monograph No. 31 (Washington: T.N.E.C., 1941).

14. Hiance, Martine and Plasseraud, Yves, Brevets et Sous-Développement. La Protection des Inventions dans le Tiers-Monde (Paris: Librairies Techniques, 1972).

15. Jucker, E., Patents and Pharmaceuticals (Basle: Buchdruckerei Gasser und Cie AG, 1980).

16. Katz, Jorge, Patents, the Paris Convention and Less-Developed Countries, Discussion Paper No. 190 (Yale University: Economic Growth Centre, 1973).

17. Kefauver, Estes, In a Few Hands. Monopoly Power in America (New York: Pantheon Books, 1965).

18. Kurian, George, T., The Encyclopedia of the Third World, 3rd ed. (New York: Facts on File, 1987).

19. Ladas, Stephen P., Patents, Trademarks, and Related Rights - National and International Protection (Cambridge: Harvard University Press, 1975).

20. Lipscomb, B. Ernest, Lipscomb's Walker on Patents, 3rd ed. (Bancroft-Whitney, 1984).

21. Melrose, Diana, Bitter Pills, Medicines and the Third World Poor (London: OXFAM, 1982).

22. Muller, Mike, The Health of Nations. A North-South Investigation (London: Faber and Faber, 1982).

23. Penrose, Edith, The Economics of the International Patent System (Baltimore: The John Hopkins University, 1971).

24. Pradham, Juresh B., International Pharmaceutical Marketing (Westport Connecticut: Quorum Books, 1983).

25. Reekie, Duncan W., The Economics of the Pharmaceutical Industry (London: The MacMillan Press, 1975).

26. Rosenberg, Peter D., Patent Law Fundamentals 2nd ed. (New York: Clark Boardman, 1988).

27. Sherer, F.M., "The Economic Effects of Compulsory Patent Licensing (New York: New York University Press, 1971).

28. Schiff, E., Industrialization Without Patents (Princeton: Princeton University Press, 1971).

29. Schwartzman, David, Innovation in the Pharmaceutical Industry (Baltimore: John Hopkins University Press, 1976).

30. Silverman, Milton and Lee, Philip and Lydecker, Mia, Prescriptions for Death. The Drugging of the Third World (Berkeley: University of California Press, 1982).

31. Spencer, Reuben and Gevers, Jacques, International Patent Law and Practice (New York: New York Practising Law Institute, 1971).

32. Staniforth, Ricketson, The Law of Intellectual Property (London: Sweet and Maxwell, 1984).

33. Stiefel, Maurice and Gevers, Jacques, European Patent Law and Practice (New York: New York Practising Law Institute, 1971).

34. Tang, Chin-Shih, A Guide to Legal Citation and Sources of Citation Aid 2nd ed. (Toronto: Richard De Boo, 1988).

35. Taylor, C.T. and Silberston, Z.A., The Economic Impact of the Patent System: A Study of the British Experiment, Monograph 23 (London: Cambridge University Press, 1973).

36. Tucker, David, The World Health Market. The Future of the Pharmaceutical Industry (Euromonitor, 1984).

37. Terrel, T., Terrel on the Law of Patents 13th ed. (London: Sweet and Maxwell, 1982).

38. White, Blanco, A.T., Patents, Trademarks, Copyright and Industrial Designs 2nd ed. (London: Sweet and Maxwell, 1978).

39. Wilson, Andrew H., Background to Invention, Science Council of Canada (1970).

40. Wortzell, L.H., Technology Transfer in the Pharmaceutical Industry (New York: UNITAR Study No. 14, 1971).

2. Articles

41. Ballard, William R., "Patents, Progress and Prosperity" (1954), 36:2 J. Pat. Off. Soc. 93-121.

42. Bangs, R.B., "Use of Industrial Property in Foreign Countries: A Further Report" (1970), 13:4 IDEA 557.

43. Banner, Donald, "The Proposals for Revising the Paris Convention" (1979), 5:8 Pat. Trademark Inst. Can. Bull. 195-204.

44. Barrett, Patrick J., "The Role of Patents in the Sale of Technology in Mexico" (1974), 22 Am. J. Comp. L. 230-281.

45. Barton, John H., "Technology Transfer and LDC's: A Proposal for a Preferential Patent System" (1971), 6 Stanford J. Int'l Studies 27-50.

46. Batalla, Enrique J., "A Glance at the Law and Practice in the Matter of Working of Patents in All Iberoamerican Countries" (1974), 56:11 J. Pat. Off. Soc. 746-812.

47. Beier, Friedrich K., "Future Problems of Patent Law" (1972), 3:4 I. I. C. 423-448.

48. Beier, Friedrich K., "One Hundred Years of International Cooperation - The Role of the Paris Convention in the Past, Present and the Future" (1984), 15:1 I. I. C. 1-20.

49. Beier, Friedrich K., "The Significance of the Patent System for Technical, Economic and Social Progress" (1980), 11:5 I. I. C. 563-584.

50. Benson, Robert B., " The Geneva Diplomatic Conference for the Revision of the Paris Convention: Remarks from the Private Sector" (1980), 12 Intell. Prop. L. Rev. 29-35.

51. Bhatnagar, M.P., "The Role of Patents in R&D in India" (1985), 24:5 Ind. Prop. 167-173.

52. Blair, O. Homer, "Technology Transfer as an Issue in North/South Negotiations" (1981), 14 Vanderbilt J. Transnat'l L. 301-326.

53. Casalonga, Alain, "The Compulsory Licence System in France" (1954), 36:1 J. Pat. Off. Soc. 19-29.

54. Casalonga, Alain, "Forfeiture of Patents for Non-Working" (1951), 33 J. Pat. Off. Soc. 714-728.

55. Castel, J.G., "Recent Trends in Compulsory Licensing in Case of Non-Use of Patents: A Comparative Analysis" (1954), 36:5 J. Pat. Off. Soc. 330-340.

56. Chudnovsky, Daniel, "The Challenge by Domestic Enterprises to the Transnational Corporation's Domination: A Case Study of the Argentine Pharmaceutical Industry" (1979), 7:1 World Development 45-58.

57. Chudnovsky, Daniel, "Patents and Trademarks in Pharmaceuticals" (1979), 7 World Development.

58. Chromecek, Milan, "The Amended Canadian Patent Act. General Amendments and Pharmaceutical Patents. Compulsory Licensing Provisions" (1988), 11 Fordham Int'l L. J. 504-548.

59. Coaracy, Robeto G., "The Role of Patent Information in Relation to Transfer of Technology" (1982), 4:4 World Pat. Information 159-163.

60. Cohen, Shlomo, "Compulsory Licensing of Patents - The Paris Convention Model" (1979), 20 IDEA 153-189.

61. Correa, Carlos M., "Transfer of Technology in Latin America: A Decade of Control (1981), 15 J. World Trade L. 388-409.

62. Creel, Thomas, C. and Wintringham, Drew, M., "Patent Systems and their Role in the Technological Advance of Developing Nations" (1984), 10 Rutgers Computer Tech. L. J. 255-301.

63. Delgado, Jaime, "Patent Working Under Mexican Law" (1980), 78:11 Pat. Trademark Rev. 443-446.

64. Diamond, Sidney A., "The Geneva Diplomatic Conference on the Revision of the Paris Convention" (1980), 12 Intell. Prop. L. Rev. 3-11.

65. Fishbein, Morris, "Are Patents on Medicinal Discoveries and on Foods in the Public Interest?" (1937), 19:12 J. Pat. Off. Soc. 891-904.

66. Frost, George, "The Case Against Patent Compulsory Licensing" (1965), Pat. Trademark Copyright J. Res. Ed. 84-102.

67. Freedman, Irving, "Certain Aspects of the Non-Use of Patented Inventions" (1958), 2 Pat. Trademark Copyright J. Res. Ed. 158-167.

68. Fulda, T.K. and Dickens, P.F., "Controlling the Cost of Drugs: The Canadian Experience" (1979), Health Care Financing Rev. 59.

69. Gerster, Richard, "Switzerland and the Revision of the Paris Convention" (1981), 15 J. World Trade L. 111-123.

70. Gilfillan, S.C., "The Root of Patents, or Squaring Patents by their Roots" (1949) 31:8 J. Pat. Off. Soc. 611-623.

71. Goldsmith, I., "Drugs in Canadian Patent Law" (1967), 13 McGill L. J. 232.

72. Gorecki, Paul K. and Henderson, I., "Compulsory Patent Licensing of Drugs in Canada: A Comment on the Debate" (1981), 8:4 Can. Public Policy 559-568.

73. Greer, Douglas, "The Case Against Patent Systems in Less Developed Countries" (1973), 8 J. Int'l L. Econ. 223-258.

74. Grundman, Heldge E., "Patent Laws in New African States" (1968), 1:7 J. Pat. Off. Soc. 486-502.

75. Hansen, Barbara, "Economic Aspects of Technology Transfer to Developing Countries" (1980), 11:4 I. I. C. 429-440.

76. Harris, Bryan, "Technology Transfer and Industrial Property Protection: Problems Underlying Various European Patent and Other Conventions" (1977-8), 19 IDEA 215-228.

77. Jayasuriya, D.C., "Pharmaceuticals, Patents and the Third World (1988), 22 J. World Trade L. 117-121.

78. Kirim, A., "Reconsidering Patents and Economic Development: A Case of the Turkish Pharmaceutical Industry" (1985), 13:2 World Development 219-236.

79. Kirk, Michael K., "Diplomatic Conference on Revision of the Paris Convention: "Substantive" Discussions" (1980), 12 Intell. Prop. L. Rev. 13-27.

80. Kirk, Michael K., "Second Session of the Diplomatic Conference to Revise the Paris Convention" (1982), 14 Intell. Prop. L. Rev. 139-197.

81. Krieger, Albrecht, "Intellectual and Industrial Property Under the Aspect of International Developments (1973), 4:2 I. I. C. 155-167.

82. Krieger, Albrecht, "A New International Organization for Intellectual Property?" (1966), 5 Ind. Prop. 37-48.

83. Kronstein, Heirich and Till, Irene, "A Reevaluation of the International Patent Convention: (1947), 12 Legal Contemp. Problems 765-781.

84. Kunz-Hallstein, Hans-Peter, "Patent Protection, Transfer of Technology and Developing Countries - A Survey of the Present Situation" (1975), 6:4 I. I. C. 427-453.

85. Kunz-Hallstein, Hans-Peter, "The Revision of the International System of Patent Protection in the Interest of Developing Countries" (1979), 10:6 I. I. C. 649-670.

86. Lachman, K., "The Role of Industrial Property in the Dissemination of Technical Information in the World Context" (1965), 9 IDEA 180-188.

87. Ladas, Stephen, P., "The Fundamental Bases of the International Protection of Industrial Property" (1954), 70 Ind. Prop. 93-97.

88. Ladas, Stephen, P., "Industrial Property as a Factor in Technical Development and Economic Progress" (1973), 10:3 Ind. Prop. 81-85.

89. Ladas, Stephen, P., "The Self-Executing Character of International Conventions on Industrial Property and their Effects on Substantive Rights" (1941), 36 Trademark Bull. 5.

90. Ladas, Stephen, P., "Some Suggestions on the Future of Industrial Property" (1975), 4:34 I. I. C. 326-335.

91. Lall, Sanjaya, "The Patent System and the Transfer of Technology to Less-Developed Countries" (1976), 10 J. World Trade L. 1-16.

92. Lall, Sanjaya, "Price Competition and the International Pharmaceutical Industry" (1978), 40 Oxf. Bull. Econ. Stat. 9-19.

93. Lall, Sanjaya, "The Political Economy of Controlling Transnationals: The Pharmaceutical Industry in Sri Lanka" (1977), 5:8 World Development 677-697.

94. Lall, Sanjaya, "The International Pharmaceutical Industry and Less-Developed Countries with Special Reference to India" (1974), 36 Oxf. Bull. Econ. Stat. 143-172.

95. Lall, Sanjaya, "Transfer Pricing and Developing Countries: Some Problems of Investigation" (1979), 7:1 World Development 59.

96. Lall, Sanjaya, "Transfer Pricing of Multinational Manufacturing Firms" (1973), 35 Oxf. Bull. Econ. Stat. 173-195.

97. Lehman, Michael, "The Theory of Property Rights and the Protection of Intellectual and Industrial Property" (1985), 16:5 I. I. C. 525-540.

98. Maier, Harold, G., "International Patent Conventions and Access to Foreign Technology" (1969), 4 J. L. Econ. Dev. 207-230.

99. Mandich, G., "Venetian Patents from 1450 to 1550" (1948), 30 J. Pat. Off. Soc. 162-224.

100. Mangalo, N., "Patent Protection and Technology Transfer in the North-South Conflict" (1978), 9:2 I. I. C. 100-120.

101. Matsui, Skoji, "The Transfer of Technology to Developing Countries: Some Proposals to Solve Current Problems" (1977), 59:10 J. Pat. Off. Soc. 612-622.

102. Medcalf, E.L., "Revision of the Paris Convention" (1976), 42:7 Pat. Trademark Inst. Can. Bull. 792-801.

103. Nolan, Maureen, P. and Oppenheim, Charles and Withers, Anna, "Patenting, Profitability and Marketing Characteristics of the Pharmaceutical Industry" (1980), 2:4 World Pat. Information 169-176.

104. O'Brien, Peter, "Developing Countries and the Patent System: An Economic Appraisal" (1974), 2:9 World Development 27-36.

105. Oddi, Samuel, A., "The International Patent System and Third World Development: Reality or Myth?" [1987] Duke L. J. 831-878.

106. Oppenheim, Chesterfield, "The Public Interest in Legal Protection of Industrial and Intellectual Property" (1950), 32:12 J. Pat. Off. Soc. 903-935.

107. Orleans, G.P., "Note on the Economic Rational of Patents" (1976), 42:7 Pat. Trademark Inst. Can. Bull. 779-790.

108. Oshins, Robert L., Dolezil Vladimir, "The Role of Patents in the Industrialization of the Developing Countries" (1968), 12 IDEA 210-219.

109. Patel, Surendra, "The Patent System and the Third World" (1974), 2:9 World Development 3-14.

110. Pfanner, Klaus, "The World Intellectual Property Organization" (1970), 10 I. I. C. 1-19.

111. Plant, Arnold, "The Economic Theory Concerning Patents for Invention" (1934), 1 Economica 30.

112. Prager, F.D., "A History of Intellectual Property from 1545 to 1787" (1944), 26 J. Pat. Off. Sec. 711-760.

113. Pretnar, S., "La Protection Internationale de la Propriété Industrielle et les Differents Stades du Développement Économique des États" (1953), 69 Ind. Prop. 213-223.

114. Pretnar, S., "More on the Legal Protection of Industrial Property" (1955), 71 Ind. Prop. Annex.

115. Penrose, E., "International Patenting and Less-Developed Countries" (1973), 83 Econ. J. 768-786.

116. Reitz, N.E., "Compulsory Licensing in the Industrial and Commercial Arena: A Compromise" (1966), 54 Calif. L. Rev. 1364-1381.

117. Robbins, Leonard, J., "Pharmaceutical Patents in Foreign Countries" (1955), 37: 4 J. Pat. Off. Soc. 271-288.

118. Roffe, Pedro, "Abuses of Patent Monopoly: A Legal Appraisal" (1974), 2:9 World Development 15-26.

119. Schifrin, L.G., "The Ethical Drug Industry: The Case for Compulsory Patent Licensing" (1967), 12 Antitrust Bulletin 893-915.

120. Seaby, G.A., "Drug Licensing: Should sec. 41(4) Be Retained?" (1984), 1 Pat. Trademark Inst. Can. Rev. 37-53.

121. Steele, H., "Monopoly and Price Competition in the Ethical Drug Market" (1952), 5 J.L. Econ. 131-163.

122. Spencer, Richard, "France Decides to Grant Patents for Pharmaceutical Products" (1960), XLII:9 J. Pat. Off. Soc. 640-643.

123. Spevack, David A., "Patents for Pharmaceuticals: Spur or Handicap to the Ultimate Public Good?" (1966), XLVIII:10 J. Pat. Off. Soc. 616-632.

124. Stumpf, H., "Interests and Conflicts in Technology Transfer - The Role of Patents" (1978), 9:4 I. I. C. 309-319.

125. Turner, Donald, F., "The Patent System and Competitive Policy" (1969), 44 New York Univ. L. Rev. 450-476.

126. Vaitsos, C., "Patents Revisited: Their Function in Developing Countries" (1972), 9:2 J. Dev. Studies 71-97.

127. Vaitsos, C., "The Revision of the International Patent System: Legal Considerations for a Third World Position" (1976), 4 World Development 85-102.

128. Yamashita, Kiyoshi, "Some Aspects of Pharmaceutical Patents in Japan" (1962), XLIV:5 J. Pat. Off. Soc. 291-308.

129. Wasserman, Ursula, "WIPO Diplomatic Patent Conference" (1980), 14 J. World Trade L. 254-256.

130. Wasserman, Ursula, "WIPO Diplomatic Patent Conference" (1979), 13 J. World Trade L. 564-577.

131. Wasserman, Ursula, "WIPO Diplomatic Patent Conference" (1983), 17 J. World Trade L. 171-172.

132. Watson, David and French, D. and Kirby, P., "The Great Debate Revision of the Canadian Patent Act", (1981), 10:8 Pat. Trademark Inst. Can. Bull. 579-609.

133. Wilner, Gabriel, M., "The Transfer of Technology to Latin America" (1981), 14 Vanderbilt J. Transnational L. 269-294.

134. Zikonda, Anderson, R., "The Patent System and the Transfer of Technology to Developing Nations" (1981), 3:4 World Pat. Information 149-153.

3. Documents of the United Nations

135. Appropriate Industrial Technology for Drugs and Pharmaceuticals, UN Doc. UNIDO ID/232/10 (1980).

136. Case Studies in the Transfer of Technology: The Pharmaceutical Industry in India, UN Doc. TD/B/C.6/20 (October 11, 1977).

137. Case Studies in Transfer of Technology: Pharmaceutical Policies in Sri Lanka, UN Doc. TD/B/C.6/21 (June 27, 1977).

138. The Channels and Mechanisms for the Transfer of Technology from Developed to Developing Countries, UN Doc. TB/B/AC.11/5 (April 27, 1971).

139. Compilation of Legal Material Dealing with Transfer and Development of Technology, UN Doc. TD/B/C.6/81 (August 4, 1982).

140. Examination of the Economic, Commercial and Developmental Aspects of Industrial Property in the Transfer of Technology to Developing Countries. Review of Recent Trends in Patents in Developing Countries, UN Doc. TD/B/C.6/AC.5/3 (November 24, 1981).

141. Global Study of the Pharmaceutical Industry, First Consultation Meeting on the Pharmaceutical Industry, UN Doc. UNIDO ID/WG 331/6 (1980).

142. The Growth of the Pharmaceutical Industry in Developing Countries: Problems and Prospects, UN Doc. UNIDO ID/204 (1978).

143. Guidelines for the Study of the Transfer of Technology to Developing Countries, UN Doc. TD/B/AC.11/9 (1972).

144. Guidelines on Technology Issues in the Pharmaceutical Sector in the Developing Countries, UN Doc. UNCTAD/TT/49 (1983).

145. The International Patent System as an Instrument of Policy for National Development, UN Doc. TD/B/C.6/AC.2/3 (1975).

146. The International Patent System: The Revision of the Paris Convention for the Protection of Industrial Property, UN Doc. TD/B/C.6/AC/3/2 (1977).

147. Major Issues Arising from the Transfer of Technology. A Case Study of Sri Lanka, UN Doc. TD/B/C.6/6 (October 8, 1975).

148. Major Issues Arising from the Transfer of Technology to Developing Countries: A Case Study of the Pharmaceutical Industry, UN Doc. TD/B/C.6/4 (October 8, 1975).

149. Major Issues Arising from the Transfer of Technology to Developing Countries, UN Doc. TD/B/AC.11/10 (1973).

150. Policies Relating to Technology of the Countries of the Andean Group: Their Foundations, UN Doc. TD/107 (1971).

151. Promotion of National, Scientific and Technological Capabilities and Revisions of the Patent System, UN Doc. TD/B.6/AC.2/2 (July 29, 1975).

152. Promotion of Transfer of Technology by Small and Medium-Sized Enterprises to Developing Countries: Public Policy Implications and Applicable Instruments, UN Doc. TD/B/C.6/79 (1982).

153. Questionnaire on the Transfer of Technology, Including Know-How and Patents, UN Doc. TD/B/AC.11/4 (April 30, 1971).

154. Report and Recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector, UN Doc. UNCTAD/TT/48 (February 9, 1982).

155. Report and Recommendations of the Workshop on Trade and Technology Policies in the Pharmaceutical Sector in the Caribbean Region, UN Doc. UNCTAD/TT/41/Rev.1 (August 29, 1980).

156. Report of the Group of Governmental Experts on the Economic, Commercial and Developmental Aspects of Industrial Property in the Transfer of Technology to Developing Countries, UN Doc. TD/B/C.6/76 and TD/B/C.6/AC.5/6 (February 26, 1982).

157. Report of the Group of Governmental Experts on the Role of the Industrial Property System in the Transfer of Technology, UN Doc. TD/B/C.2/24 and TD/B/C.6/AC.3/4 (October 26, 1977).

158. Report of the Group of Governmental Experts on the Role of the Patent System in the Transfer of Technology, UN Doc. TD/B/C.6/8 (October 21, 1975).

159. Report of the Intergovernmental Group on Transfer of Technology, UN Doc. TD/B/520 (July 26, 1974).

160. Restructuring the Legal Environment: International Transfer of Technology. Common Approaches to Laws and Regulations on the Transfer and Acquisition of Technology, UN Doc. TD/B/C.6/91 (October 7, 1982).

161. The Role of Patents in the Transfer of Technology to Developing Countries, UN Doc. E/3861/Rev.1 (March 1, 1964).

162. The Role of Patents in the Transfer of Technology to Underdeveloped Countries, UN Doc. A/C.2/L.565 (1961).

163. The Role of the Patent System in the Transfer of Technology to Developing Countries, UN Doc. TD/B/AC.11/19/Rev.1 (1975).

164. The Role of the Patent System in the Transfer of Technology to Developing Countries, UN Doc. TD/B/C.6/16 (December 10, 1975).

165. The Role of the Patent System in the Transfer of Technology. Summary of Replies from Governments to the Note Verbale of the Secretary-General of UNCTAD, UN Doc. TD/B/C.6/AC.2/5 (July 28, 1975).

166. The Role of Small and Medium-Sized Enterprises in the International Transfer of Technology: Issues for Research, UN Doc. TD/B/C.6/64 (1980).

167. Selected Legislation, Policies and Practices on the Transfer of Technology, UN Doc. TD/B/C.6/48 (August 28, 1979).

168. Strengthening the Technological Capacity of the Developing Countries Including Accelerating their Technological Transformation: Issues in Individual Sectors and Other Areas of Critical Importance to Developing Countries, UN Doc. TD/B/C.6/56 (October 17, 1980).

169. Systems, Including Industrial Property Systems, for Improving the National Scientific and Technological Infrastructure of the Developing Countries, UN Doc. TD/B/C.6/AC.2/4 (1975).

170. Technology and Development. Perspectives of the Pharmaceutical Sector in Ethiopia, UN Doc. UNCTAD/TT/58 (1984).

171. Technology Policies and Planning for the Pharmaceutical Sector in Developing Countries, UN Doc. TD/B/C.6/56 (1980).

172. Technology Policies in the Pharmaceutical Sector in Costa Rica, UN Doc. UNCTAD/TT/37 (May 6, 1982).

173. Technology Policies in the Pharmaceutical Sector in the Philippines, UN Doc. UNCTAD/TT/36 (October 24, 1980).

174. Technology Policies in the Pharmaceutical Sector in the United Republic of Tanzania, UN Doc. UNCTAD/TT/35 (October 29, 1980).

175. Technology Policies in the Pharmaceutical Sector in Venezuela, UN Doc. UNCTAD/TT/25 (March 31, 1982).

176. Transnational Corporations and the Pharmaceutical Industry, UN Doc. ST/CTC/9 (1979).

177. Transnational Corporations and the Pharmaceutical Industry of Developing Countries, UN Doc. ST/CTC/49 (1981).

178. Transnational Corporations in World Development: Third Survey, UN Doc. ST/CTC/46 (1983).

179. Trends and Problems in World Trade and Development, UN Doc. UNCTAD/TT/28 Suppl. (1987).

4. Government Publications

(1). Canada

180. Compulsory Licensing of Pharmaceuticals. A Review of sec. 41 of the Patent Act (Ottawa: Minister of Consumer and Corporate Affairs, 1983).

181. General Amendments to the Patent Act (Ottawa: Consumer and Corporate Affairs, 1986) (Doc. NR-86-21).

182. Industry R & D Announcements (Ottawa: Consumer and Corporate Affairs, Information).

183. Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-22, House of Commons, 2e Sess., 33 Leg., 1986-87; Issue No. 1 (December 11 and 16, 1986); Issue No. 2 (December 18, 1986); Issue No. 3 (January 20, 1987); Issue No. 4 (January 21, 1987); Issue No. 5 (January 22, 1987); Issue No. 6 (January 27, 1987); Issue No. 7 (January 28, 1987); Issue No. 8 (January 29, 1987); Issue No. 9 (February 3, 1987); Issue No. 10 (February 4, 1987); Issue No. 11 (February 5, 1987); Issue No. 12 (February 10, 1987); Issue No. 13 (February 11, 1987); Issue No. 14 (February 12, 1987); Issue No. 15 (February 17, 1987); Issue No. 16 (February 18 and 19, 1987); Issue No. 17 (March 3, 1987) and Issue No. 18 (March 16, 1987).

184. Notes for Opening Remarks to Legislative Committee on Bill C-22 by the Hon. Harvie André, Minister of Consumer and Corporate Affairs, Canada, House of Commons (December 16, 1986) (Doc. 5-86-59).

185. Notes for Remarks by the Hon. M. Côté, Minister of Consumer and Corporate Affairs, Canada, House of Commons (June 27, 1986) (Doc. 5-86-38).

186. Notes for Remarks by the Hon. Harvie André, Minister of Consumer and Corporate Affairs for a Press Statement on the Amendments to the Patent Act, Ottawa (November 6, 1986) (Doc. 5-86-52).

187. Proceedings of the Special Committee of the Senate on the Subject Matter of Bill C-22, Senate of Canada, 2nd Sess., 33 Leg. 1986-87; Issue No. 1 (April 9 and 14, 1987); Issue No. 2 (May 5, 1987); Issue No. 3 (May 6, 1987); Issue No. 4 (May 12, 1987); Issue No. 5 (May 13, 1987); Issue No. 6 (May 26, 1987); Issue No. 7 (May 27, 1987); Issue No. 8 (May 28, 1987); Issue No. 9 (May 29, 1987); Issue No. 10 (June 2, 1987); Issue No. 11 (June 3, 1987); Issue No. 12 (June 4, 1987); Issue No. 13 (June 5, 1987); Issue No. 14 (June 9 and 10, 1987); Issue No. 15 (June 11, 1987); Issue No. 16 (June 12, 1987); Issue No. 17 (June 16 and 17 1987); Issue No. 18 (June 18, 1987); Issue No. 19 (July 7, 1987); Issue No. 20 (July 9, 1987); Issue No. 21 (July 14, 1987); Issue No. 22 (July 15, 1987); Issue No. 23 (July 16, 1987) and Issue No. 24 (August 10 and 12, 1987).

188. The Report of the Commission of Inquiry on the Pharmaceutical Industry, H.C. Eastman, Ottawa, 1985.

189. Report Concerning the Manufacture, Distribution and Sale of Drugs, Department of Justice, Restrictive Trade Practices Commission (Ottawa: Queen's Printer, 1963).

190. Report on Patents of Invention, Royal Commission on Patents, Copyright and Industrial Design (Ottawa: Queen's Printer, 1960).

191. Report of the Royal Commission on Health Services, Royal Commission on Health Services (Ottawa: Queen's Printer, 1964).

192. Report of the Standing Committee on Drug Costs and Prices, House of Commons, Special Committee on Drugs and Prices (Ottawa: Queen's Printer, 1966).

(2). United States

193. Kefauver, E., Advertising and Promotion of Drugs, Report of the Committee on the Judiciary, United States Senate, 87th Congress, 1st Sess., Report No. 448 (Washington: Government Printing Office, 1961).

194. Machlup, Fritz, An Economic Review of the Patent System, Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No. 15 (Washington: Government Printing Office, 1958).

195. Neumayer, F., Compulsory Licensing of Patents Under Some Non-American Systems, Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No. 19 (Washington: Government Printing Office, 1959).

196. Vernon, R., The International Patent System and Foreign Policy, Study of the Sub-Committee on Patents, Trademarks and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, 2nd Sess., Study No. 5 (Washington: Government Printing Office, 1957).

5. Documents of the Organization for Economic Co-operation and Development

197. Gaps in Technology: Pharmaceuticals (Paris: OECD, 1969).

198. The Pharmaceutical Industry: An Industry Like No Other (Paris: OECD, 1975).

199. Restrictive Business Practicess Relating to Patents and Licences: Report by the Committee of Experts on RBPs (Paris: OECD, 1972).

6. Documents of the World Intellectual Property Organization

200. First Consultative Meeting on the Revision of the Paris Convention, Geneva, June 24-28, 1985, WIPO Doc. PR/CM/I/3 (June 28, 1985).

201. Second Consultative Meeting on the Revision of the Paris Convention, Geneva, January 26-31 and February 3, 1987, WIPO Doc. PR/CM/II/1 (February 5, 1987).

202. Third Consultative Meeting on the Revision of the Paris Convention, Geneva, May 18-23, and 26, 1987, WIPO Doc. PR/CM/III/1 (May 26, 1987).

203. Fourth Consultative Meeting on the Revision of the Paris Convention, Geneva, September 14-19 and 22, 1987, WIPO Doc. PR/CM/IV/2 (September 22, 1987).

204. Declaration on the Objectives of the Revision of the Paris Convention, Basic Proposals, WIPO Doc. PR/GE/11/3 (December 15-22, 1975).

205. Diplomatic Conference on the Revision of the Paris Convention, Basic Proposals, WIPO Doc. PR/DC/3 (June 25, 1980).

206. Diplomatic Conference on the Revision of the Paris Convention, First Sess., Geneva, February 4 - March 4, 1980, WIPO Doc. PR/DC/15 March 1, 1980).

207. Diplomatic Conference on the Revision of the Paris Convention, Second Sess., Nairobi, September 28 - October 24, 1981, WIPO Docs. PR/DC/21, PR/DC/24, PR/DC/25, PR/DC/26, PR/DC/27, PR/DC/28, PR/DC/29, PR/DC/30, PR/DC/31, PR/DC/32, PR/DC/33, PR/SM/5, PR/DC/37 (October 23, 1981) and PR/DC/39 (October 24, 1981).

208. Diplomatic Conference on the Revision of the Paris Convention, Third Sess., Geneva, October 29, 1982, WIPO Doc. PR/DC/INF/34 (1982).

209. Diplomatic Conference on the Revision of the Paris Convention, Fourth Sess., Geneva, February 27 - March 24, 1984, WIPO Docs. PR/SM/12 (May 31, 1985); PR/DC/50 (February 29, 1984); PR/DC/52 (March 5, 1984).

210. Exclusions from Patent Protection, WIPO Doc. HL/CE/IV/INF/1 (November 2-6, 1986).

211. Extention of Patent Protection of a Process to the Products Obtained by that Process, WIPO Doc. HL/CE/II/5 (1986).

212. The importance of the Patent System to Developing Countries: Collection of Lectures Given at the World Symposium Organized by the WIPO at Colombo, Sri Lanka in February 1977 (Geneva: WIPO, 1977).

213. Licensing Guide for Developing Countries (Geneva: WIPO, 1977).

214. Model Law on Patents for Inventions for the Developing Countries (Geneva: BIRPI Doc. 801(E), 1965).

215. Model Law for Developing Countries on Inventions (Geneva: WIPO Doc. 840 (E), 1980).

216. Preparatory Intergovernmental Committee on the Revision of the Paris Convention for the Protection of Industrial Property, 2nd Sess., June 29 - July 8, 1977, WIPO Doc. AB/VII/11 and AB/VII/23.

217. Report of the Ad Hoc Group of Governmental Experts on the Revisions of the Paris Convention, WIPO Doc. PR/GE/1/10 (February 21, 1975).

218. Tableaux Synoptiques des Articles Premier, 5A et 5Quater de la Convention de Paris pour la Propriété Industrielle OMPI Doc. PR/DC/INF/51 (Septembre 1984).

7. Articles in Newspapers

219. Breckenridge, Joan, "Drug Bill Won't Lead to Research in Canada, Senate Report Says", Globe and Mail, October 10, 1987 at p. A5.

220. Cameron, Stevie, "Influential People Shape Future of Powerful Pharmacy Trade", Globe and Mail, November 27, 1986 at p. A2.

221. Eklove, Debra, "Drug Bill a Bitter Pill to Swallow", Globe and Mail, October 21, 1987 at p. A7.

222. Editorial, "Canada Pulled Pledge to Link Drug Bill to Trade Pact, Says Report", Ottawa Citizen, October 9, 1987.

223. Editorial, "A Respect for Patents", Globe and Mail, December 11, 1986, at p. A1.

224. Editorial, "Subordinate Senators", Globe and Mail, October 26, 1987, at p. A6.

225. Editorial, "Intellectual Property", Globe and Mail, November 18, 1986, at p. A6.

226. Editorial, "Reining in the Senate", Globe and Mail, August 28, 1987, at p. A6.

227. Fraser, Graham, "Drug - Patent Law Introduced After Filibuster", Globe and Mail, November 8, 1987 at p. A9; "Ottawa's Regulator Differs with Minister Over Drug Price Rises", Globe and Mail, November 20, 1986 at p. A5, "Patent Law Will Not Increase Drug Prices, André Contends" Globe and Mail, December 7, 1987 at p. A1.

228. Gyay, Ray, "Price Major Factor in Drug Law Debate", Star - Phoenix, January 12, 1987 at p. A5.

229. Hall, Sall, "Drug Bill is Beyond Repair, No Incentive to Research", Globe and Mail, November 26, 1986 at p. A7.

230. Howard, Ross, "Drug Firms' Workers March in Ottawa to Support Tory Bill", Globe and Mail, August 26, 1987 at p. A3; "MPs Charge Tories Made Concenssions to U.S. on Drug Bill", Globe and Mail, October 16, 1987 at p. A5; "Turner Endorses Action by Senate on Drug Bill", Globe and Mail, October 31, 1987 at p. A5; "André Warns Senators to Accept Drug Bill", Globe and Mail, November 3, 1987 at p. A2; "PCs Plan Firm Stand in Drug Bill Dispute", Globe and Mail, November 4, 1987 at p. A8.

231. Kerton, Robert, R., "Canada Should Resist Lobby, Enact Drug Law that Serves Us", Ottawa Citizen, January 29, 1987 at p. A9.

232. Lewington, Jennifer, "Drug Patent Bill not Enough to Satisfy U.S. on Free Trade", Globe and Mail, August 13, 1987 at p. 1.

233. Lewington, Jennifer and Waddell, Christopher, "Ottawa Made Drug Bill Pledge in Trade Pact", Globe and Mail, October 9, 1987 at p. A1.

234. MacDonald, Gayle, "Firms Learn to Live With New Drug Law - Debate Rages On Over Brand Names Vs Generic Drugs", Financial Post, June 19, 1989 at p. 35.

235. McQuaig, Linda, "Revelations May Harden Senate's Attitude", Globe and Mail, October 10, 1987 at p. A5.

236. Orr, John, "Drug Bill No Cure for Research Ailments", Globe and Mail, September 24, 1987 at p. A7.

237. Priegert, Portia, "Battle Over Drug Bill Shows No Signs of Abating", Star - Phoenix, November 27, 1986 at p. A12.

238. Sallot, Jeff and Waddell, Christopher, "Drug Research Crippled, PM Says" Globe and Mail, August 20, 1987 at p. A1.

239. Simpson, Jeffrey, "The Price of Patents", Globe and Mail, November 18, 1986 at p. A6; "Lying in Wait", Globe and Mail, November 27, 1986 at p. A6.

240. Seeman, Philip, "Patent Change is Right Pill for Canada", Globe and Mail, November 25, 1986 at p. A7.

241. Stewart-Patterson, David, "Senate Panel Rejects Key Parts of New Drug Bill", Globe and Mail, August 11, 1987; "Drug Bill Proposal Would Aid Research, Liberals Say", Globe and Mail, August 21, 1987. "Tories Push Drug Row Closer to Constitutional Crisis", Globe and Mail, August 22, 1987 at p. A8; "Opposition MPs Prolong Debate on Drug Patent Bill", Globe and Mail, August 25, 1987 at p. A8; "Don't Stop Drug Bill, Liberal Senator Urged", Globe and Mail, August 27, 1987 at p. 1; "Drug Bill Final Vote to be Held on Monday", Globe and Mail, August 29, 1987 at p. A7; "Showdown on Drug Bill is Delayed in Senate" Globe and Mail, September 3, 1987 at p. A3.

242. Waddell, Christopher, "Drug Bill Batted Back by Senate; Minister Charges Political Mischief", Globe and Mail, September 4, 1987 at p. A5; "Ministers Differ on Linking of Trade, Drugs", Globe and Mail, October 10, 1987 at pp. A1 and A5; "André Will Let Drug Bill Die Rather Than Change It", Globe and Mail, October 22, 1987 at p. A1.

243. Warren, John, "Opposition Prepares for Fierce Battle Over Drug Bill", Ottawa Citizen, November 24, 1986 at p. 10.

244. Westell, Dan, "Drug Firms Juggle Profits of Subsidiaries", Globe and Mail, August 21, 1987 at p. A5.

245. Winsor, Hugh, "Senate Surgery on New Drug Bill Heightens Embarrassment for PM", Globe and Mail, August 12, 1987 at p. A1; "Relaxed Perspective Would Help to Diminish Senate Crisis", Globe and Mail, September 21, 1987 at p. A2; "If Cabinet Serious About C-22, André Should Be Put On Leash", Globe and Mail, November 2, 1987, at p. A2; "Tax Reform, Trade Deal, Drug Bill Don't Add Up to Major Change", Globe and Mail, November 23, 1987 at p. A2.

APPENDIX A

THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY

Article 5, Paris 1883

(1) "The importation by the patentee into the country where the patent has been granted of articles manufactured in any of the States of the Union shall not entail forfeiture of the patent.

(2) "Nevertheless, the patentee shall remain under the obligation to exploit his patent in ac-cordance with the laws of the country into which he introduces the patented articles."

The Paris Convention, as Revised at Brussels in 1900

Article 5

(1) (identical previous text)
(2) (identical previous text)

Proposal
3bis

"The patentee in each country shall not forfeit his patent for non-working until after a minimum period of three years from the filing of the application in the country in question and in case he cannot justify his inaction."

The Paris Convention, as Revised at Washington in 1911

Article 5

(1) "The importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) "Nevertheless, the patentee shall remain under the obligation to exploit his patent in accordance with the laws of the country into which he introduces the patented articles, but with the restriction that the patent may not be forfeited for non-working in one of the countries of the Union until after a period of three years of the date of filing the application in that country and only in case the patentee cannot justify his inaction".

The Paris Convention, as Revised at The Hague in 1925

Article 5A

(1) (identical to previous text)

(2) "Nevertheless, each contracting country shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.

(3) "These measures shall not provide for forfeiture of the patent unless the grant of compulsory licenses is insufficient to prevent such abuses.

(4) "In any case, the patent may not be subjected to such measures before the expiration of at least three years from the date of grant, or if the patentee proves the existence of legitimate excuses".

The Paris Convention, as Revised at London in 1934

Article 5.

(1) "The Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries in the Union shall not entail forfeiture of the patent.

(2) "Nevertheless, each of the countries of the Union shall have the right to take the necessary legislative measures to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) "These measures will only provide for the revocation of the patent if the granting of compulsory licenses shall not suffice to prevent these abuses.

(4) "In any case an application for the grant of a compulsory license may not be granted before the expiration of three years from the date of the grant of the patent and this license may be granted only if the patentee fails to justify himself by legitimate reasons. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license."

The Paris Convention, as Revised at Lisbon in 1958

Article 5A

(1) (identical to previous text)

(2) "Each country of the Union shall have the right to take legislative measures providing for the grant of a compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by the patent, for example, failure to work.

(3) "Forfeiture of the patent shall not be prescribed except in cases where the grant of compulsory licenses would not have been sufficient to prevent such abuses. No proceeding for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) "An application for a compulsory license may not be made on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period last expires; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, evening the form of the grant of a sublicense, except with that part of the enterprise or goodwill using such a license."

The Paris Convention, as Revised at Stockholm in 1967

Article 5A

A(1) "Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent."

(2) "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

(3) "Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license."

(4) "A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."

APPENDIX B

"NAIROBI TEXT"

Draft Article 5A

1(a) "Any country of the Union has the right to require by its national law that the inventions for which that country has granted a patent, or in the case of countries providing for a deferred examination when a provisional protection has been granted, be worked in its territory by the owner of the patent or under his authorization.

(b) Importation of articles incorporating the patented invention or made by the patented process does not constitute working of the patented invention. However, any country of the Union has the right to regard the importation of articles incorporating the patented invention or made by the patented process as fulfilling the requirements of working the patented invention.

2(a) "For the purposes of this Article, "non-voluntary license" means a license to work a patented invention without the authorization of the owner of the patent; it also means a license to work a patented invention given by the owner of the patent where the national law obliges him to give such a license.

(b) Any country of the Union has the right to adopt legislative measures to prevent abuses resulting from the exercising of the right granted by the patent. However, importation into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not, in the absence of circumstances constituting abuse of the patent rights, entail forfeiture of the patent.

(3) "Forfeiture of the Union shall not be provided for except in cases where the grant of non-voluntary licences would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of the patent may be instituted before the expiration of two years from the grant of the first non-voluntary license.

(4) "A non-voluntary license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent,whichever period expires last; it shall be refused if the owner of the patent proves, to the satisfaction of the national authorities competent to grant non-voluntary licenses, that there are circumstances which justify the non-working or insufficient working of the patented invention.

(5) "Any country of the Union has the right to provide in its national law, where the exploitation of the patented invention is required by reason of

public interest, in particular national security, nutrition, health or the development of other vital sectors of the national economy, for the possibility of exploitation, at any time, of the patented invention by the government of that country or by third persons authorized by it.

(6) "Any non-voluntary license shall be non-exclusive and shall not be transferable, even in the form of a grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

(7) "Any decision relating to the grant of a non-voluntary license or to exploitation in the public interest, including the amount of the just payment to which the patentee is entitled, or any decision relating to the revocation or forfeiture of a patent shall be subject to review at a distinct higher level in accordance with the applicable national law.

(8) "Notwithstanding anything contained in paragraphs (3), (4), and (6), developing countries have the right to apply the following provisions:

(a) Any developing country has the right to grant non-voluntary licenses where the patented invention is not worked, or is not sufficiently worked, by the owner of the patent or under his authorization in the territory of that country within 30 months from the grant of the patent in that country, unless the owner of the patent proves circumstances which in the judgment of the national authorities competent to grant non-voluntary licenses justify the non-working or insufficient working of the patented invention. Where national law provides for deferred examination for patentability and the procedure for such examination has not been initiated within three years from the filing of the patent application, the time limit referred to in the preceding sentence shall be four years from the filing of the said application.

(a bis) However, a non-voluntary license may be exclusive for a period of up to four and a half years in the case where it is determined by the national authority competent to grant non-voluntary licenses that there are circumstances constituting abuse of the patent rights and that the non-working or insufficient working is one of the constituent elements of the abuse, subject to the condition that the patent may not be forfeited or revoked for non-working or insufficient working for a further period of eighteen months after the expiration of the exclusive license.

(b) Any developing country has the right to provide in its national law that the patent may be forfeited or may be revoked where the patented invention is not worked or is not sufficiently worked, in the country before the expiration of five years from the grant of the patent in that country, provided that the national law of the country provides for a system of non-voluntary licenses applicable to that patent and that, in the opinion of the national authorities competent

for forfeiture or revocation, the grant of a non-voluntary license would not ensure sufficient working of the patented invention, unless the owner of the patent proves circumstances which in the judgment of the national authorities competent for forfeiture or revocation justify the non-working or insufficient working of the patented invention."