

**TRADE-RELATED AGENDA,
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WORKING PAPERS

5

**INTELLECTUAL PROPERTY RIGHTS
AND THE USE OF
COMPULSORY LICENSES:
OPTIONS FOR
DEVELOPING COUNTRIES**

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SOUTH CENTRE

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THE SOUTH CENTRE

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LIST OF ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
API	Applications Programming Interface
ERDA	Federal Non-Nuclear Energy Research and Development Act
HIV	Human Immune Deficiency Virus
ITP	Independent Television Publications Limited
NAFTA	North American Free Trade Agreement
R & D	Research and Development
RTE	Radio Telefis Eireann
UPOV	International Convention for the Protection of New Varieties of Plants
USCA	United States Clean Air Act
USTR	United States Trade Representative

Organizations

FTC	Federal Trade Commission
WTO	World Trade Organization

PREFACE

The South Centre, with funding support from UNDP TCDC Unit, has established a pilot project to monitor and analyse the work of WTO from the perspective of developing countries. Recognizing the limited human and financial resources available to the project, it focuses on selected issues in the WTO identified by a number of developing countries as deserving priority attention. It is hoped that the project will lead to more systematic and longer term activities by the South Centre on WTO issues.

An important objective of the project is to respond, to the extent possible within the limited resources, to the needs of developing country negotiators in the WTO for concise and timely analytical inputs on selected key issues under negotiation in that organization. The publication of analytical *cum* policy papers under the T.R.A.D.E. working paper series is an attempt to achieve this objective. These working papers will comprise brief analyses of chosen topics from the perspective of developing countries rather than exhaustive treatises on each and every aspect of the issue.

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South Centre, October 1999

I. INTRODUCTION

Intellectual property law has undergone more changes in the last ten years than in the rest of this century. These changes, prompted by the adoption of the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1994, have led to an expansion of intellectual property rights into new fields and to a significant strengthening of the title-holder's legal position.¹

The extension of intellectual property rights, especially in the patent field, and the enhanced powers conferred on title-holders, have raised concerns in developing countries about the extent to which the essentially commercial interests protected by intellectual property rights may be given primacy over other of society's interests, such as those relating to public health and consumer protection.

While developing countries have been obliged to adopt massive changes in their intellectual property systems, little consideration has been given to the imbalances that the adoption of higher standards of protection -- essentially modeled on those in force in developed countries -- may create in those countries. For instance, little attention has been paid to the fact that the strengthening of intellectual property rights has taken place in the developed countries in the context of legal systems with a solid tradition in the area of competition law and consumer protection. In contrast, in most developing countries mechanisms aiming at controlling restrictive business practices or the misuse of intellectual property rights are weak or non-existent. Similarly, developing countries are generally unprepared or unable to neutralize the impact that price increases resulting from the establishment or reinforcement of intellectual property rights may have on access to protected products, particularly by the low income population.

In this context, the possible use of compulsory licenses as one of the tools to mitigate the impact of exclusive rights is receiving growing attention. In particular, the dramatic situation reported in some countries where costly drugs are not affordable for a great part of the population,² and the opposition by the US government to compulsory licenses,³ has revived the debate about the use of such licenses to attain public interest objectives.

In view of the forthcoming review of the implementation of the TRIPs Agreement, and of a possible revision of its provisions in future WTO negotiations, it seems important that information is available to developing countries on the ways in which compulsory

¹ See, *The TRIPs Agreement: A Guide for the South. The Uruguay Round Agreement on Trade-Related Intellectual Property Rights*, South Centre, November 1997, Geneva, Switzerland.

² A provision relating to the US foreign-aid bill has blocked assistance to South Africa due to the clauses in South African legislation which provide for parallel importation and compulsory licenses of medicines. It is estimated that around 3.2 million South Africans are HIV positive and AIDS drugs are sold at prices which are unaffordable for most of the population (see <http://www.cptech.org>).

³ The United States, for instance, signed bilateral agreements with Sri Lanka and Albania which limit the grounds for granting compulsory licenses. A large number of developing countries has been listed by the US Trade Representative (USTR) in 1999 as possible targets for retaliation due to, among other reasons, the provisions on compulsory licenses in their national laws or draft laws (see USTR Press Release, April 30, 1999).

licenses have been provided for and used in developed and developing countries. Such information, as presented below, indicates the importance of retaining, and possibly expanding, the flexibility to design a compulsory licensing system that fits national needs and objectives.

The purpose of this paper is to provide concrete examples on how compulsory licenses have been provided for in national laws and, in particular, to illustrate the grounds and conditions on which such licenses have been granted in specific instances. The emphasis of the paper is not on the general principles relevant to the matter, but on the ways in which compulsory licenses have been actually provided for or used in order to satisfy diverse public interests. Many of the decisions pertaining to the granting of compulsory licenses in the developed countries may be useful in indicating the options available to developing countries wishing to have adequate legislation at the national level on this matter.⁴ The decisions referred to also make it clear that compulsory licensing is firmly rooted in the legal systems of developed countries, including those that seem to oppose that concept in international fora.

Though the application of compulsory licensing in a number of different areas of intellectual property is addressed, this paper focuses mainly on its application in the field of patents. The paper first gives a brief background history of compulsory licensing, including the origin and diffusion of the concept in different areas of intellectual property rights. This is followed by an analysis of the concept of compulsory licenses and of its regulation under the TRIPs Agreement. Based on comparative law and jurisprudence,⁵ the grounds for granting compulsory licenses are then reviewed, including examples of decisions taken in particular cases. Finally, the paper discusses available evidence on the extent to which the compulsory licensing system has been effective in achieving its intended aims in different countries.

⁴ For a more detailed analysis on the scope for implementing compulsory licensing at the national level, see Correa and Yusuf, 1998, and Correa 1999, forthcoming.

⁵ There is no intention, however, to cover national laws exhaustively. Only illustrative provisions are mentioned.

II. ORIGINS AND DIFFUSION OF THE CONCEPT OF COMPULSORY LICENCES

A “compulsory license”⁶ is an authorization given by a national authority to a person, without or against the consent of the title-holder, for the exploitation of a subject matter protected by a patent or other intellectual property rights. In some cases, particularly in the area of copyright and neighbouring rights, “statutory licenses” are established. These are licenses *ex lege* that may be enjoyed by anyone without being specifically authorized, generally against the payment of compensation to the title-holder.

II.1 Compulsory licenses for patents

The birth of the concept of compulsory licenses is linked to the obligation, introduced by the UK Statute of Monopolies in 1623 and recognized in many national patent laws during the XIX century, to work locally⁷ a patented invention. Some laws, such as the French law, imposed the forfeiture of a patent in the case of non-working. The granting of compulsory licenses appeared as a means to mitigate that drastic measure of direct forfeiture. A system of compulsory licenses was adopted in the UK under the Patent Act of 1883 for cases in which the patent was not being worked in the UK, the reasonable requirements of the public were not satisfied, or any person was prevented from working or using an invention (section 22). This provision had a great influence on patent laws subsequently adopted in UK and in other countries, as well as in the development of the International Convention for the Protection of Industrial Property (Paris Convention).

The negotiation of the Paris Convention reflected the conflicting views that the issue of local working and compulsory licenses generated at the end of the century. The Conference of 1883, that adopted the said Convention, accepted the “working obligation”, despite opposition from the United States and other countries. After a turbulent process of negotiation, the Conference held at the Hague in 1925 adopted compulsory licensing as the main means to ensure the exploitation of a patent. The forfeiture of the patent would only apply where a compulsory license proved to be ineffective as a means of addressing the non-working of a patent (article 5A), that is, forfeiture became a subsidiary measure only applicable if a compulsory license had failed to remedy non-exploitation.

The Paris Convention, which applies to patents on inventions, utility models, industrial designs, trademarks and trade-names, recognizes the right of member countries to establish compulsory licenses but with certain limitations under the Convention:

1. Member states may (but are not obliged to) provide for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example for failure to work.

⁶ Often called also “non-voluntary license”. The TRIPs Agreement refers to it as “Other use without the authorization of the right holder” (Article 31).

⁷ “Local working” means the industrial use of the invention in the country of registration of the patent.

2. Forfeiture of the patent will not be provided for except where the grant of compulsory licenses is not sufficient to prevent abuses. Forfeiture or revocation of a patent will not be instituted before the expiration of three years from the grant of the first compulsory license.
3. A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of four years from the date of application for the patent, 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/her inaction by "legitimate reasons".⁸
4. A compulsory license 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.⁹

The provision of compulsory licenses became a typical feature in patent laws worldwide. At the beginning of the 1990s around one hundred countries recognized such licenses. The process of diffusion of compulsory licenses in national laws took place in parallel to the broadening of the grounds under which such licenses may be granted. If, as mentioned, they were originally related to the lack of working, they were gradually extended to other situations, such as public interest, government use and anti-competitive behaviour. Moreover, in some countries (such as the United Kingdom and Canada), compulsory licenses were specifically provided for certain products, such as food, medicines and surgical or curative devices.¹⁰

II.2 Statutory licenses for copyrights

Further, the concept of compulsory licenses extended from the field of patent to another area of intellectual property rights, namely copyright. In this latter area, "statutory licenses" are often established to permit third parties to use a copyrighted work in exchange for a fee, which is fixed either in the legislation itself or by a public or private agency authorized to fix, collect and distribute license fees. The exclusive rights are replaced in these cases (such as photocopying, lending of books, recording of phonograms or videograms) by a "remuneration right", due to the fact that the author cannot individually assert his/her rights "since it is not possible to monitor mass use, even by collecting societies which operate with lump sum rates." (Beier, 1999, p. 257.)

The Berne Convention provides for statutory compulsory licensing under certain circumstances. This is the case of performers' rights regarding the transmission of their works via radio, telephone or other equivalent apparatus. Under Article 80 of the Berne Convention performers do not have an exclusive right to forbid these forms of exploitation but they are entitled to equitable compensation for such uses. A similar right

⁸ The determination of what constitutes "legitimate reasons" is to be made by the competent national authority.

⁹ This means that the non-exclusive licensee can not transfer his/her license to a third party, who would need to seek authorization from the competent authority for such transfer.

¹⁰ See, for instance, the UK Patents Act of 1949.

is granted to the phonogram producer for the broadcast of his/her records by radio, cinema, television and in public premises (Article 73). In addition, in accordance with article 13 of the Convention, member countries may impose reservations on the exclusive right granted to the author of a musical work or to the author of the words which go with such musical work, where the latter has already been authorized so that third parties can produce those works. However, such reservations can only apply in the countries where the member country has legislation covering it, and must also not be prejudicial to the rights of the author to obtain compensation.

At the national level, an example of statutory licenses is provided by licenses for the recording of musical works in the United States. The US Copyright Act includes statutory provisions for compulsory licensing on non-dramatic musical compositions for reproduction in phonorecords (i.e. records, tapes and compact discs) under certain circumstances. The compulsory license applies only after the copyright owner has granted the first license for distribution of phonorecords containing his/her musical composition. Once such authorized distribution has been made, any other person may obtain a compulsory license to make and distribute phonorecords of the work, if the primary purpose of such distribution to the public is for private use. This gives the songwriter the right to choose the first recording artist to record the song, but precludes him/her from barring other singers from recording the song, as long as they pay the prescribed royalty (Scott, 1988, pp. 319-325).

In the United Kingdom a statutory license was introduced in 1995 when the copyright term of protection was extended from fifty years to seventy years after the author's death. Statutory licenses apply, in certain circumstances, for works for which protection had already expired but which was revived by virtue of a later law (Latham, 1996, p. 25).¹¹

II.3 Compulsory licenses in other areas

Design protection law has also been influenced by compulsory licenses. A very clear example is the introduction of "licenses of right" into the UK Copyright, Patent and Design Act 1988 for registered designs in certain circumstances, and for all unregistered designs. Licenses of right can be obtained during the last five years of the design right term; therefore, the design right owner has an exclusive claim to the design only for five years after his/her initial exploitation of the protected design (MacQueen, 1995, p. 80). Several licenses have been granted under the provisions of the UK law (Barron, 1999).

The European Commission proposed that the Directive on design rights should include compulsory licenses so as to permit the use of a design for the repair of a product, provided that the public is informed as to the origin of the product and the holder of the design was informed about the intended use and offered a fair and reasonable remuneration (Latham, 1996, p. 26). This proposal has followed the prevailing view on the need to exempt spare parts from the scope of design rights, as stated in *British Leyland v. Armstrong* (1986). The UK House of Lords in this case held that the owner

¹¹ In the USA, the House of Representatives voted in April 1999 a bill (HR 1554) to extend for five years the compulsory license for satellite carriers to retransmit superstations and distant signals and to reduce fees payable by subscribers. Thus, broadcasts would be made widely available to satellite television viewers.

of copyrights on parts for a motor vehicle could not enforce such copyright against manufacturers of spare parts “as this would in practice prevent the owner of a car from being able to exercise his right to repair if such spare parts were not freely available from competing sources” (Field, 1993/1994, p. 47).¹²

Compulsory licenses have also been granted, in exceptional cases, in relation to trademarks. In the United States, the Federal Trade Commission (FTC) proposed, in the case *FTC v. Cereal Companies*, the creation of five completely new companies and required the major existing firms (Kellogg, General Mills and General Food) to license their trademarks. In *FTC v. Borden Company*, the FTC found market dominance in the lemon juice market and the judge decided to compulsorily license the “Realemon” trademark (Goldstein, 1977, p. 124).

Finally, in some cases know-how and other information have been subject to a compulsory license in association with or independently of the compulsory licensing of patents. For instance, on 6 July 1994, the US Federal Trade Commission (FTC) required Dow Chemical to license to a potential entrant intangible dicyclomine assets, including “all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master File, and all information relating to the United States Food and Drug Administration Approvals” that are not part of the acquired company’s physical facilities or other tangible assets. Moreover, during a transition period, while the new entrant sought Food and Drug Administration (FDA) approvals of its own, the FTC required Dow to manufacture and deliver dicyclomine tablets and capsules to the new entrant at a price that did not exceed 48 per cent of the average wholesale price of the acquired company’s dicyclomine tablets as of 2 July 1993.

In another case (*FTC v. Xerox Corporation*), a Consent Decree was issued in the United States according to which the patent and know-how barriers to competition developed by Xerox were eliminated by requiring Xerox to license some of its patents free of royalty, and the rest at low royalties, and to offer all of its office copier know-how royalty-free to US patent licensees. The Silicon Graphics case (1995) involved a compulsory license of technical information, including software applications programming interface (API) information, as part of a settlement of FTC concerns regarding the anti-competitive impact of the acquisition of software companies Alias and Wavefront.

¹² The Court of Appeal of Turin (18 January 1993) decided that registered design protection of car body-panels has to be denied because of its anti-competitive effects. The arguments relied upon were the following:

- The creative efforts of car designers are entirely rewarded with the grant of an exclusive right on the whole body design;
- Additional protection of body-panels through an independent right aims only at doubling exclusive rights, without additional justification as to further creative effort;
- Through design protection of spare parts, car producers manage to extend their market power to a derivative market and to restrict or avoid competition in this market; thus design protection of body-panels has to be denied (Latham and Geissmar, 1995, p. 10).

III. LIMITATIONS TO EXCLUSIVE RIGHTS GRANTED UNDER PATENTS

Inherent to patent rights is the granting of exclusive rights to the patent holder. These give him/her the power to prevent third parties from using, producing or commercializing the protected invention. It is this *ius prohibendi* which provides the basis for the patent holder to obtain a monopolistic rent while the patent is in force.

III.1 Exceptions to exclusive rights and compulsory licenses

Patent rights, however, are not absolute. National laws have traditionally identified certain situations in which patents are not to be granted. Many countries, for instance, excluded pharmaceutical products from patentability,¹³ a practice that is bound to change with the entry into force of the TRIPs Agreement. Though the TRIPs Agreement has limited the freedom of states to define non-patentable items, WTO Members can exclude from patentability plants and animals, therapeutical, surgical and diagnostic methods, as well as inventions which are contrary to morality or *ordre public*.

A typical feature in most patent laws has also been to provide for exceptions to exclusive rights, by specifying categories of acts relating to the patented invention that third parties are allowed to undertake without the authorization of the patent holder. Such acts generally include, for instance, the use of the invention for private purposes, for teaching and for scientific research. In many countries experimentation for commercial purposes is also allowed. In the case of pharmaceutical patents, some countries specifically permit the initiation of procedures for the registration of a medicine by a third party before the expiry date of the respective patents, so as to speed up the commercialization of a generic product after that date.¹⁴

The exceptions to exclusive rights operate automatically, that is, there is no need to request authorization from the patent holder or from a court or other authority to use the invention in the form provided for under the exception. In addition, any third party can benefit from an exception at any time during the lifetime of a patent, and the use is not subject to any compensation.

Compulsory licenses also limit the exercise of the patent rights, but they do not work in the same way as exceptions. A compulsory license allows the use of an invention but only by the person that has been so permitted by an authority (court or administration) after determination that certain requirements established by the law are met.

¹³ At the beginning of the Uruguay Round in 1986, around 50 countries did not recognize product patents for pharmaceuticals.

¹⁴ This exception is usually known as "early working" or the "Bolar exception". It was first introduced by US law in 1984. See Correa, 1999 (forthcoming).

Both the request for a compulsory license and its use may be subject to time restrictions, and to the payment of compensation to the patent holder as well.

While the circumstances that may justify an exception are rather limited,¹⁵ compulsory licenses may be granted on a great variety of grounds, subject to certain conditions and requirements. These latter include conditions relating to the applicant of a compulsory license and to the modalities of its use. Thus, compulsory licenses are generally non-exclusive¹⁶ and subject to the granting of compensation for the patent owner.

III.2 Compulsory licenses under the TRIPs Agreement

WTO Member countries may provide for different forms of compulsory licenses in respect of patents which are explicitly authorized by the TRIPs Agreement (article 31 "Other use without the authorization of the right holder"). The TRIPs Agreement specifically refers to various grounds for the granting of compulsory licenses in that field:

- Emergency and extreme urgency;
- Anti-competitive practices;
- Public non-commercial use;
- Dependent patents.

The TRIPs Agreement does not limit the Members' right, however, to establish compulsory licenses on grounds other than those explicitly mentioned therein, for instance, in order to protect the environment (as recommended by the "Agenda 21"), or for reasons of "public interest" (as provided for by the German patent law).

While Article 31 of the TRIPs Agreement does not restrict the grounds for granting compulsory licenses, it contains a detailed set of conditions therefor, including the need to grant them on a case-by-case-basis, the requirement (in some cases) of a prior request to the patent holder on reasonable commercial terms, the non-exclusive character of the licenses, the stipulation of compensation based on the economic value of the license, and conditions for termination of the authorization. Article 31.g, in particular, imposes a serious burden on the compulsory licensing system, as it opens up the possibility that a compulsory license be terminated as soon as the circumstances which led to its granting have ceased to exist. If literally applied, this condition would discourage applications for compulsory licenses, since the licensee may be exposed to the revocation of his/her right at any time. Moreover, the more efficient he/she is under the license, the greater the chance of sooner losing the right to use the invention.¹⁷

The only case in which the Agreement does restrict the freedom to determine the grounds for compulsory licenses relates to "semi-conductor technology", which can only be

¹⁵ See article 30 of the TRIPs Agreement.

¹⁶ "Non-exclusive" means that compulsory licenses may be granted to several third parties, none of which will enjoy an exclusive right to use the invention. Developing countries sought unsuccessfully during the early 1980s to be allowed the granting of exclusive compulsory licenses, in the framework of an uncompleted revision of the Paris Convention.

¹⁷ See Correa and Yusuf, 1998, pp. 208-216.

subject to compulsory licenses for public non-commercial use and to remedy anti-competitive practices.

It should be noted that in some cases, for instance, emergency and public non-commercial use, there is no need to previously request a voluntary license, as required by Article 31.b of the Agreement. Moreover, in the case of public non-commercial use the patent holder may be informed after the use of the invention has taken place, as soon as it is reasonably practicable (Article 31.b). The licenses to remedy anti-competitive practices are subject to special treatment with regard to the remuneration to be paid to the patent-holder. Article 31.k may be interpreted by national authorities as allowing for a reduced remuneration or even for a "royalty-free" license.¹⁸

The TRIPs Agreement does not prevent the granting of compulsory licenses in cases of lack of or insufficient working. However, Article 27.1 of the Agreement stipulates that "patent rights shall be enjoyable without discrimination ... whether the products are imported or locally produced". The interpretation of this clause is debatable. Though Article 27.1 has been understood as prohibiting national laws from imposing an obligation to execute locally a patented invention, this interpretation is not unanimous.¹⁹ The Preamble of the Agreement, as well as Articles 7 and 8, make it clear that one of the objectives of the Agreement is to promote technology transfer, which may be ensured in some circumstances by means of compulsory licenses on grounds of non-working. Article 5(A)2 of the Paris Convention, as amended in Stockholm in 1967, may be construed as requiring industrial working of the patent in the country, as interpreted by Bodenhausen, former Director of the Bureau for the International Protection of Industrial Property.²⁰ The interpretation of this article is likely to be finally settled in accordance with WTO procedures if a dispute thereon arises between WTO Members.

A possible option is to provide -- in line with Article 8.1 of the TRIPs Agreement -- for the granting of compulsory licenses in qualified cases of lack of working, for instance, when such a lack affects the commercial or industrial development in the country of sectors of vital interest.

¹⁸ As mentioned elsewhere, in the United States many compulsory licenses have been granted in order to remedy anti-competitive practices. In some cases, these licenses have been granted "royalty free".

¹⁹ Thus, the Brazilian patent law (1996) has included an obligation to exploit locally the patented inventions.

²⁰ The opinion of Bodenhausen is quoted by Halewood, who also considers that compulsory licenses for industrial non-working can be deemed as permitted under article 30 (relating to exceptions) of the TRIPs Agreement (Halewood, 1997, p. 253 and 271).

IV. GROUNDS FOR GRANTING COMPULSORY LICENSES

As mentioned above, compulsory licenses may be granted on diverse grounds, to be determined by national laws. The different modalities of compulsory licenses are briefly reviewed in this section. The use of such licenses in other fields of intellectual property fields are also mentioned in order to illustrate the broad use of this mechanism.

IV. 1 Refusal to deal

In principle, the right of the patent owner to give or not give a license to a third party is recognized. In some jurisdictions this is considered an essential element of intellectual property rights, as stated in *Berkey Photo Inc. vs. Eastman Kodak Co.* (1979) in the United States,²¹ and in the case of *Volvo AB v. Erik Veng (UK) Ltd.* (1989) in Europe (Breier, 1999, p. 274).

The UK law authorizes the granting of compulsory licenses when, by reason of the conditions imposed by the patentee on the grant of a license, a market for the export of any patented product made in the United Kingdom is not being supplied, the working or efficient working of any other patented invention which makes a substantial contribution to the art is prevented, or the establishment or development of commercial or industrial activities is unfairly prejudiced (article 48(3)(d)).

Questions have also been raised recently in the United States regarding whether "the refusal to deal" (that is, the refusal to grant a license on reasonable terms) may be anti-competitive when this allows a patentee to block follow-on research, particularly if the initial patent is overly broad (McFetridge, 1998, p. 91).

An example of how a compulsory license can be based on "refusal to deal" is provided by a decision of the European Court of Justice of 6 April 1995 in the *Magill* case. In its judgement, the Court confirmed that *Radio Telefis Eireann (RTE)* and *Independent Television Publications Limited (ITP)*, who were the only sources of basic information on programme scheduling, which is indispensable raw material for compiling a weekly television guide, could not rely on national copyright provisions to refuse to provide that information to third parties. Such a refusal, the Court held, in this case constituted the exercise of an intellectual property right beyond its specific subject matter and, thus, an abuse of a dominant position under Article 86 of the Treaty of Rome.

The court argued that *RTE* and *ITP* held a dominant position, because they were the only source in Ireland of the basic information necessary to produce weekly television programming guides and were thus in a position to reserve for themselves the secondary market for weekly television guides by excluding all competition from that market. The Court considered that, whilst refusal to grant a license in exercising an intellectual property

²¹ The failure to work or refusal to license cannot be sanctioned by the granting of a compulsory license in US antitrust law (Beier, 1999, p. 265).

right is not of itself an abuse of a dominant position, it may be an abuse where special circumstances exist. Such circumstances included the lack of an actual or potential substitute for a weekly television guide, the existence of a specific, constant and regular demand for such a guide, and the fact that the refusal to grant a license to Magill to produce such a guide prevented the appearance of a new product on the market which RTE and ITP did not offer (Latham and Geissmar, 1995, p. 9).

A decision by the Belgium courts in 1995 also imposed a compulsory license on two copyright collecting societies in favor of two cable distributors who had been refused the right to transmit by cable in Belgium programmes from the German Cable SATI. Refusing the authorization for a reasonable remuneration was deemed to be abusive (Latham, 1996, p. 25). In Australia, a compulsory license for “refusal to deal” may be granted unless the patentee can prove that it would equally refuse to license in a competitive situation (O'Bryan, 1992, p. 10).

The “refusal to deal” as a ground for granting a compulsory license has been provided in many national laws, such as the patent laws of China, Argentina and Israel.²²

In the United Kingdom and in other countries that have followed the model of UK legislation, “refusal to deal” may lead to a compulsory license when an export market is not being supplied, the working of any other patented invention which makes a substantial contribution is prevented or hindered, or the establishment or development of commercial or industrial activities in the country is unfairly prejudiced (Section 48.3.d of the UK Patent Act, as revised in 1977). Similarly, in South Africa, a license can be granted in the case of the refusal to grant a license on reasonable terms, where trade or industry or agriculture or the establishment of a new trade or industry in the country is prejudiced, and it is in the public interest that a license be granted (section 56(2)(d), Patents Act No. 57 of 1978).

The hypothesis of “refusal to deal” has also been provided for in the area of breeders' rights. For instance, the law of Poland on plant varieties protection (1987) stipulates that a compulsory license may be granted when the title-holder does not offer a license allowing third parties to meet unsatisfied needs of the national economy, or makes the grant of a voluntary license subject to unfair conditions (Article 29).

IV.2 Non-working and inadequate supply

As mentioned, the origin of compulsory licenses is linked to the obligation to work a patent. Following the Paris Convention, a large number of developed²³ and developing countries established compulsory licenses for lack of or insufficient working. In the laws of Austria, France and Japan (Fauver, 1988, p. 672), this obligation was generally understood as the *industrial* use of the invention. But in many developed countries this concept was gradually replaced by the *commercial* use of the invention. In other words, the

²² See Cohn, 1997, p. 27.

²³ A noticeable exception is the United States, where it has been held (such as in *Hartford-Empire Co. vs. United States*, 324 US 570, 1945) that a patent owner has no obligation to use the patent or to grant its use to others (Fauver, 1988, p. 672).

obligation to work a patent could be satisfied by means of the mere importation of the protected product.

For instance, the introduction into, or the sale in the territory of, Italy of items manufactured in foreign countries was not considered by Italian law to constitute working of the invention. However, in 1992 the European Court of Justice condemned Italy and established that the working requirement was satisfied on the domestic market by imports of products manufactured in another EC member state. The Court held that if, after 3 years from the date of grant of a patent, or 4 years from the filing date of the application, the proprietor of a patent or his successor in title has not worked the patented invention, directly or through one or more licensees, by way of production in the territory of the state, or by way of importation from one of the member states of the European Community, or has worked it to an extent seriously disproportionate with the needs of the country, a compulsory license for the non-exclusive use of the invention may be granted to any person applying for it (Grippiotti, 1994, p. 40).

A similar development took place in Spain, which has changed its law to address the compulsory licensing provisions of the TRIPs Agreement. The Spanish patent law now provides that:

“the exploitation of the patented invention by means of imports coming from the practising of the invention in a member state of the World Trade Organization shall have the same effect as the practising of the invention in the national territory”.

In some countries (for example, the United Kingdom), the granting of a compulsory license has been linked to the insufficiency of supply on reasonable terms, including the supply of export markets.

Compulsory licenses for inadequacy of supply have been provided for in some laws relating to the protection of design laws such as in the United Kingdom and Ireland (Beier, 1999, p. 267), despite the fact that the Paris Convention established that they shall not be subject "to any forfeiture, either by reason of failure to work or by reason of the importation of articles corresponding to those which are protected" (article 5B).

Such licenses are also found in many national laws on breeders' rights. For instance, the laws of Argentina (1973), New Zealand (1987, as amended in 1994) and Poland (1987) provided for such licenses when the supply of the cultivar is not adequate in terms of quantity, quality and/or price. Similarly, in the United States a variety may be declared of "open use" when the owner is unwilling or unable to supply the public needs for the variety at a fair price.

Finally, in the area of copyright, under the Berne Convention a compulsory non-exclusive and non-transferable license is available in developing countries to publish in printed form certain works if, after three years following the publication of a work, a translation of that work has not been published in a language in general use in the developing country, or if the relevant translations are out of print. The period of three years can be reduced by agreement, but not to less than one year. Furthermore, such

reduction of time is not permissible where the relevant language is English, French or Spanish.

Furthermore, no license obtainable under the provisions referred to can be granted before a period of six months after the three years has elapsed so as to give the author the opportunity to publish a translation in the appropriate language. The license is also limited so as to apply only for the purposes of teaching, scholarship or research. The license can be terminated if the owner of the right produces a translation at a reasonable price subsequent to the license being granted. In recognition of authors' moral rights, no license can be granted if the author has himself/herself withdrawn from circulation all copies of the work.

Likewise, developing countries can grant non-exclusive non-transferable licenses to publish works where copies of an edition have not been distributed in the country to the general public by the owner of the right at a price reasonably related to that normally charged in the country for comparable works. This right is subject to similar limitations as those referred to in the preceding paragraphs.

IV.3 Public interest

The "public interest" is established in many laws as a ground for compulsory licenses. The concept of what constitutes the "public interest" varies amongst countries and over time. It will be the task of the courts or administrative authorities to judge when the public interest is to be ensured or protected via the granting of a compulsory license. Thus, in certain jurisdictions such as the United States, it has been argued that insufficient working, the dependency of patents, or the interest of consumers in obtaining a protected product at the lowest possible price, do not constitute a sufficient basis for the granting of compulsory licenses on grounds of public interest (Beier, 1999, p. 265). However, in countries with limited industrial development, "public interest" may be deemed to include the opportunity to develop national industry (Fauver, 1988, p. 671).

However, the US government has created compulsory licenses when it felt that the country's public interest was at stake. Such is the case of the Atomic Energy Act (42 U.S.C.A. Sec. 2183) and of the Clean Air Act (1970) which sets forth particular situations where a private party could demand a license from a US patent owner.²⁴ The "energy crisis" of 1973 also provides a good example. As part of the government's policy to overcome national dependency on one source of energy and the inflationary effect of the increases in oil prices, the Federal Non-Nuclear Energy Research and Development Act (ERDA) was passed in 1974 (42 U.S.C.A. Sec. 5908 (n)), under which the Administration of ERDA was mandated to make recommendations on compulsory licensing (Finnegan, 1977, p. 147).

The German patent law authorizes compulsory licenses to be granted when "it is indispensable for the public interest". A compulsory license has been granted in only one instance by the German Federal Patent Court, on June 7, 1991. The applicant (Bioferon) manufactured a pharmaceutical product (polyferon) for the treatment of chronic

²⁴ See also the US Federal Non-Nuclear Energy Research and Development Act (ERDA), mentioned below.

polyarthritis and obtained approval, under the pharmaceuticals law, for application of the product. The applicant also held dependent patents in respect of specified uses of human immune interferon. The Federal Patents Court found that there was a public interest in the medical use of polyferon which was dependent upon the dominant substance patent on human immune interferon.

The Federal Supreme Court disagreed with the Federal Patent Court and in December 1995 it decided that "a compulsory license cannot be granted for a pharmaceutical if the public interest can be satisfied with other, more or less equivalent, alternative preparations".

The Supreme Court based its decision on the fact that the substantially improved therapeutic properties of the license's applicant (Bioferon) as compared to conventional medications had not been established. However, according to two commentators,

"The fact that the Federal Supreme Court -- in contrast to the Federal Patent Court -- refused the grant of a compulsory license in the present case cannot be understood as an entire rejection of the instrument of the compulsory license. It should be emphasized that, in the opinion of the Federal Supreme Court, the petitioner was not successful in proving from a medical viewpoint that, instead of an advantageous use of "polyferon", no other similarly effective preparation for the treatment of rheumatoid arthritis is available" (von Meibom and Pitz, p. 33).

The granting of compulsory licenses on grounds of public interest have been provided for in the patent laws of some developing countries, such as Argentina and the Andean Group (Decision 344). They have also been established in breeders' rights legislation, including in the most recent laws on the matter. The granting of compulsory licenses is recognized in the UPOV Convention, as revised in 1991, only for reasons of "public interest" (Article 17) and against an "equitable remuneration".

IV. 4 Anti-competitive practices

Although in the United States the patent law does not provide for compulsory licenses, this is probably the country with the richest experience in the granting of compulsory licenses to remedy anti-competitive practices. More than one hundred such licenses have been granted (Scherer, 1999). Compulsory licenses have been granted in the United States in relation to present and future patents. Generally such licenses have been granted against a reasonable royalty, generally determined on the basis of the "willing-buyer, willing-seller" formulation (Finnegan, 1977, p. 140). However, in some cases, the compulsory licenses were conferred royalty free.²⁵ In some cases, moreover, the patentee was required to make the results of its research readily available to other industry members,²⁶ or to transfer the know-how actually used in production.²⁷ Box 1 contains a

²⁵ For instance, in *FTC v. Xerox Corporation* (Goldstein, 1077, p. 124).

²⁶ *Hartford-Empire case* (Finnegan, 1977, p. 139).

²⁷ For instance, in *FTC v. Xerox Corporation* (Goldstein, 1077, p. 124). See also Correa and Bergel, 1996.

summary of some compulsory licenses granted by courts in the United States under the antitrust legislation upon request of the Department of Justice.

Box 1

Earlier examples of compulsory licenses granted by courts in the United States under the antitrust legislation

1. *Hartford-Empire Company v. U.S.*, 65 *United States Patent Quarterly (USPQ)* 1 (1945).

The Supreme Court held that the defendants violated the antitrust law (Sherman Act and Clayton Act), and it required them to grant licenses under their glassmaking machinery patents at “uniform reasonable royalties.” The court stated that it had no authority to order dedication of the patents which would be equivalent to royalty-free compulsory licensing.

2. *U.S. v. National Lead Company*, 73 *United States Patent Quarterly (USPQ)* 498 (1947).

The Supreme Court used compulsory licensing with royalty payments to promote competition where the defendants conspired or combined to restrain trade in titanium products. The court stated that royalty-free compulsory licensing was an open matter to be decided in a future case. The decision did provide for the licensing of technology at a reasonable charge and limited to a three year period.

3. *U.S. v. General Electric Company*, 99 *United States Patent Quarterly (USPQ)* 76 (1953).

The District Court ordered the granting of licenses at reasonable royalties under patents acquired within five years of the decree.

5. *U.S. v. Glaxo Group Limited*, 176 *United States Patent Quarterly (USPQ)* 289.

The US Supreme Court held that the government may litigate the validity of a patent, despite the fact that the defendant did not rely on the patent as defense against antitrust claims, where patent licenses and pooling agreements are *per se* unreasonable restraints on trade, and where the government’s claims for further relief are substantial. The court stated that mandatory sales and reasonable royalty licensing are well established forms of relief when necessary to an effective remedy, particularly where patents have provided leverage for, or have contributed to, an antitrust violation.

6. *U.S. v Copper Development Association, Inc.*

The government charged 11 copper fabricating companies and their trade association with violating Section 1 of the Sherman Act by conspiring to unlawfully restrict rights granted under jointly-owned patents for a single stack plumbing system. The government proposed a Consent Decree wherein the defendants agreed to license their patents and furnish technical data upon request at royalties not to exceed three per cent of the net selling price of certain components of the system.

7. *U.S. Manufacturers Aircraft Association, Inc.*

The government charged the defendants with violating Section 1 of the Sherman Act by utilizing patent pooling and cross-licensing arrangements to eliminate competition in research and development of aircraft inventions. The consent decree dissolves the association, cancels the cross-licensing arrangement, and provides for compulsory licensing of about 1,500 US patents at reasonable royalties.

Source: Goldstein, 1977.

The US government has, through the Federal Trade Commission, also granted recently a number of compulsory licenses, thus indicating that in that country the system still is used as a means of ensuring competition, despite the opposition by the same government to provisions for compulsory licensing in several developing countries (see Box 2).

Box 2
Recent examples of compulsory licenses in the United States
under antitrust legislation

Ciba-Geigy and Sandoz merger

The US Federal Trade Commission (FTC) issued on 24 March 1997 a Decision and Order concerning the merger between Swiss companies Ciba-Geigy and Sandoz into Novartis. The combined entity would also control Chiron, a biotechnology company. The FTC concluded that the merger would violate US antitrust laws, because the merged companies are current or potential competitors for several products. The FTC required divestiture of several products, and ordered compulsory licenses of intellectual property rights for a number of other healthcare inventions. For example, Ciba-Geigy, Sandoz and Chiron were required to license a large portfolio of patents, data and know-how relating to HSV-tk products, hemophilia gene rights and other products to Rhone-Poulenc Rorer. The new merged entity and Chiron were also required to grant non-exclusive licenses to any interested party of patents and other rights relating to Cytokine products.

In the case of the non-exclusive Cytokine licenses (which involve gene therapy), and the Anderson gene therapy patent, the FTC specified that the royalties can be no greater than three per cent of the net sales price.

Gargoyles, Inc. and Pro-Tec, Inc. v. The United States

On 20 May 1997, a decision was given by the United States Court of Appeals for the Federal Circuit (96-5089-5094 ;113 F.3 d 1572). In this case the private plaintiff -- who owned a patent subject to compulsory licenses -- sought "lost profits" rather than a "reasonable royalty" as compensation. The royalty set by the Court of Federal Claims was 10 per cent. The government considered this excessive and sought a reduction. The dispute involved US patent 4,471,611 for protective eyewear, which had been used by American Optical to provide the US Army with several thousand pairs of ballistic/laser protective spectacles. The Appeals court upheld the lower court decision and argued that "because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained'."

Acquisition of shares of Rugby-Darby Group Companies by Dow Chemical Co.

The FTC required Dow to license to a potential entrant intangible dicyclomine assets, including "all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master File, all information relating to the United States Food and Drug Administration Approvals" that are not part of the acquired company's physical facilities or other tangible assets.

Upjohn and Pharmacia Aktiebolag merger

Upjohn was required to divest certain intellectual property (including patents), or the FTC would appoint a trustee to issue an exclusive United States license and a non-exclusive rest-of-the-world license for Pharmacia's research and development assets related to 9-AC. These requirements would protect consumers from reduced competition and higher prices for topoisomerase I inhibitors.

Source: Love, 1997 and 1999.

Scherer analysed the extent to which the granting of compulsory licenses affected R&D expenditures by firms and, particularly, whether such licenses diminished or destroyed the incentives to undertake R&D by patent holders. His statistical findings relating to 70 companies showed no negative effect on R&D in companies subject to compulsory licenses but, on the contrary, a significant rise in such companies' R&D relative to companies of comparable size not subject to such licenses (Scherer, 1998, pp. 107-108). According to Tandon, moreover,

"Firms spend large sums of money on efforts to "invent around" the patents of their competitors. Under generalized compulsory licensing, these expenditures would be unnecessary, which might increase the welfare benefits" (Tandon, 1982, p. 485).

In Canada, the Competition Act (section 32 of The Canadian Competition Act, RSC 1985, c C-34, as amended) gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licenses and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been used to injure trade or commerce unduly or to prevent or lessen competition unduly (Grover, 1992, p. 14).²⁸ The Australian Trade Practices Act has been invoked in cases of refusal to deal (O'Bryan, 1992, p.10).

The existence of anti-competitive practices is also considered a ground for the granting of compulsory licenses in the laws of Chile (1991), Argentina (1995) and the Andean Group countries (Decision 344, 1993), among other countries. In South Africa, a compulsory license can be granted if the demand for a protected product is being met by importation and the price charged by the patentee is "excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title" (section 56(2)(e)).

IV.5 Governmental use

Under the 1883 UK Patent Act, the Crown was entitled to use patented inventions without the assent or the compensation of the patentee, though it was practice to reward the patentee *ex gratia*. According to the 1977 Act, compulsory licenses (relating to granted patents or applications) for government use are available for the "Crown services", against a remuneration except when the invention has been recorded by, or tried by, or on behalf of a government department before the relevant priority date otherwise than in consequence of a communication made in confidence directly or indirectly from the patentee. The license may be used by any person so authorized by a government department. The Crown enjoys the qualified right to sell other than for purposes of foreign defense or for production or supply of specified drugs and medicines (Young et al, 1994, pp. 477).

The US government has also made extensive use of compulsory licenses for governmental use. The governmental use of a patent is regarded as based on "eminent domain". The government's powers may be delegated to a contractor, who would act on its

²⁸ No cases had been brought under this section at least until 1997 (McFetridge, 1998, p. 90).

behalf. The government cannot commit the tort of a patent infringement, but can only be held liable to pay reasonable compensation.

The extensive use of governmental licenses in the United States has raised complaints from the European Union. According to the EU,

"Under US law (28 US Code Section 1498) a patent owner may not enjoin or recover damages on the basis of his patent for infringements due to the manufacture or use of goods by or for the US Government Authorities. This practice is particularly frequent in the activities of the Department of Defense but is also extremely widespread in practically all government departments. For obvious reasons this practice is particularly detrimental for foreign right-holders because they will generally not be able to detect governmental use and are thus very likely to miss the opportunity to initiate an administrative claims process.

Article 31 of the TRIPs Agreement introduces a requirement to inform promptly a right holder about government use of his patent, but no action has been taken by the US so far to bring their legislation into conformity with this provision" (European Commission, 1997).

IV.6 Facilitate the use of dependent patents

The TRIPs Agreement, as well as numerous national laws, permits the granting of compulsory licenses when the use of an invention (a dependent invention) is not possible without infringing another (the principal invention). The Agreement sets out a number of conditions which have to be met if such licenses are to be granted. However, there is considerable scope for flexibility²⁹ in the interpretation of those provisions, in particular, with respect to evaluating the economic and technical importance of the dependent invention.

In the case of these compulsory licenses, the owner of the principal patent can benefit not only from compensation paid for the use of his/her patent, but also from the right to use the dependent patent.³⁰

A recent example of a compulsory cross-licensing license is provided by the European Directive on Biotechnological Inventions, which allows a breeder to request a compulsory license when he/she cannot acquire or exploit a plant variety without infringing a prior patent (article 12. 1). This would apply, for instance, when a breeder wishes to use a commercially available variety for further breeding. Though he/she could do that under plant variety protection laws (protected by the "breeders' exemption"), the owner of a patent on certain genes expressed in the variety may claim infringement of his/her patent.

²⁹ Such flexibility has been limited in the NAFTA agreement, under which licenses based on patent dependency can only be granted when needed to remedy anti-competitive practices (article 1709(10)(1)).

³⁰ This situation gives rise to a reciprocal or "cross license".

The Directive referred to above also provides for compulsory licenses for the reverse situation, in which it is the patent holder who can not use a protected variety without infringing third parties' rights (article 12.2). This right may disadvantage plant breeders, since it may be sufficient for a company to insert a gene in an existing variety to claim the right to obtain a compulsory license (Ardley, 1998. p. 136). A number of conditions, however, set out in article 12.3 need to be complied with in order to obtain that license.

IV. 7 Compulsory licenses for medicines

In some countries, compulsory licenses have been provided for some specific products, such as pharmaceuticals and food. The TRIPS Agreement has, in principle, prohibited this type of license, as national laws can not discriminate in the exercise of patent rights on the basis of the field of technology (Article 27.1). However, such licenses have proven to be an important tool to promote competition and to lower prices of protected products, as indicated below.

In Canada, compulsory licensing in respect of medicines was first introduced in 1923. The Patent Act, SC 1923 c 23, allowed for compulsory licenses to be granted for the manufacture, use and sale of patented medicines.

In 1969, the Canadian Patent Act was amended. The grant of compulsory licences became admissible for importation (not only manufacturing) of a patented medicine (Gaikis, 1992, p. 19). After the 1969 revision, a large number of compulsory licenses were granted against a 4 per cent royalty on net sales prices,³¹ the royalty was divided by the number of patents at stake if the medicine was composed of different active ingredients. (Gendreau, 1997, pp. 2-3).

As a result of the compulsory licensing system, a significant reduction in prices for medicines was reported in Canada. In 1983 compulsory licensing reduced the cost to consumers of the drugs so licensed by US\$ 211 million, and the compulsory licensing system was found by the Commission of Inquiry on the Pharmaceutical Industry (also known as the "Eastman Commission") as an "effective component of an appropriate patent policy for the pharmaceutical industry" (p. xix). In 1991-1992 (just before the repeal of the system) compulsory licensed generics were priced at 55.6 per cent of the equivalent brand name product; in the first year of marketing the generics price was 70 per cent of the brand name price. The savings for the consumer in 1991-1992 were estimated at US\$ 171 million (Shondelmeyer, 1993, pp. 3-4).

As of 7 December 1987, amendments to the Patent Act were introduced that restricted the use of compulsory licenses for patented medicines. While compulsory licensing in respect of pharmaceuticals was retained, the Patent Act deferred the exercise of compulsory licenses with respect to the importation of a patented medicine for 10 years after the date of the first notice of compliance was published in respect of the patented medicine, while compulsory licenses for the manufacture of the product would only be

³¹ In the case of sales of medicines for export, the royalty applied generally was 15 per cent of the net selling price in bulk (Gaikis, 1992, p. 21).

available after seven years from that date.³² This restriction on the manufacture of medicine only related to sales for consumption in Canada. Consequently there was no deferral in respect of medicines manufactured in Canada for the export market.

In addition, where the medicine had been invented and developed in Canada,³³ section 39.16 of the Patent Act provided that a compulsory license was only available for the making and not the importation of the medicine; and the making of the medicine under such a license was deferred for at least seven years and could be deferred for the life of the patent unless the Commissioner of Patents found upon application that the patentee or a voluntary licensee was not making the medicine in Canada for the purposes of completely or substantially supplying the Canadian market for the medicine (Gaikis, 1992, p. 20). This regime was supplemented by a monitoring of the prices of new patented medicines by the "Patent Medicines Prices Review Board" .

Shortly after this amendment, Canada abrogated the compulsory license system in order to comply with the country's commitments under the TRIPs Agreement.³⁴ Bill C-91 was approved for that purpose in February 1993, but it applied retroactively as of 20 December 1991, the date on which the TRIPs Agreement was deemed to become known. The compulsory license system was replaced by the supervision and control of the prices of patented medicines. The powers of the Patent Medicines Prices Review Board were enlarged so as to cover the prices of both new and existing medicines. The Board, among other measures, can order the patent owner to reduce the price of its medicine (Gendreau, 1997).

Compulsory licenses specifically related to medicines have been provided in other countries as well. For instance, French law authorizes them when medicines are "only available to the public in insufficient quantity or quality or at abnormally high prices". In Israel, a license can be granted if it is necessary to assure the public of a reasonable quantity of a product capable of being used as a medicament, or to manufacture a medicament or a patented process for manufacturing the latter (section 120(a)(1) and (2)).

IV. 8 Licenses of right

A particular modality of compulsory licenses is the "license of right" provided in the UK and other countries.³⁵ In 1977, the UK Patents Act of 1949 was amended. One of the major revisions was to extend the patent term from 16 years to 20 years. During the last four years of a patent (which was less than 11 years old on 1 June, 1978), non-exclusive

³² A notice of compliance indicates that a medicine has met the required Health Canada standards for use in humans or animals and that the product is approved for sale in Canada.

³³ For the purposes of section 39.16 of the Patent Act, an invention that is a medicine was deemed to be invented and developed in Canada if the major part of the inventing and the major part of the developing of the medicine to a marketable state have been conducted in Canada, including the major part of the design and control of Phase III clinical trials and, where possible, the major part of the conduct of Phase III clinical trials (Section 5 Patented Medicines Regulations).

³⁴ The TRIPs Agreement requires that compulsory licenses be granted on a case-by-case-basis (Article 31.a), thus making inconsistent with its rules a system of "automatic" licensing, as applied until then in Canada.

³⁵ "Licenses of rights" are also available under UK and other national laws when a patentee voluntarily throws his/her invention open to anyone who asks for a license on terms to be agreed upon with him/her or, in the absence of agreement, on terms to be settled by the Patent Office. (See Young et al, 1994, p.326).

licenses of rights were made available. Under such licenses, importation by the licensee was allowed if the patentee imported a major portion of the product into the United Kingdom and just carried out a minor production step (such as forming a salt or ester) there. Further, the licensee could only import the unformulated form of the product where the patentee imported the product but formulated³⁶ it in the United Kingdom. Exports (of formulated or unformulated products) by the licensee were allowed to countries where no parallel patents existed. The royalties paid varied from about 23 per cent to 31 per cent, while most of the reported royalty rates were between 25 per cent and 28 per cent of the licensee's selling price (Cohen, 1990, p. 28).

Under the transitional provisions of the UK 1988 Act, copyright in original drawings for industrial designs was continued for 10 years from the date of commencement of the Act (from 1 August 1989 to 1 August 1999). During the second half of this period licences of rights were available. For products where the only intellectual property protection was copyright, this meant that, if a company wished to copy that product, it was able to obtain a licence of right. There is no restriction or qualification on who can apply (Bodley, 1995, p. 180).

³⁶ In the case of medicines, for instance, the "formulation" of a product means the industrial process whereby the required excipients are added to the active ingredients in order to permit the administration of the product to the patient.

V. ASSESSMENT OF THE EXTENT OF USE OF COMPULSORY LICENSES

It has been observed, especially by those critical of the compulsory licensing system, that the number of compulsory licenses granted has been low. In the view of some observers, this would indicate that the system is ineffective and of little value.

However, as mentioned earlier, a large number of compulsory licenses have been granted in Canada. Between 1935 and 1970, 53 applications were submitted in Canada under Section 65 of the Patent Act, which provided for licenses for inadequate or lack of working and refusal to deal. Between 1970 and 1989 there were 43 applications for compulsory licenses under the same Section, six of which resulted in licenses granted, six were refused, 25 were withdrawn or deemed abandoned, and six were pending. In the case of the 25 withdrawn or abandoned applications, the parties reached voluntary agreements in four cases (McFetridge, 1998 p.79).

Regarding compulsory licenses relating to medicines in Canada, 22 licenses were granted (49 were applied for, 23 withdrawn and 4 refused) between 1923 and 1969, probably due to the fact few firms were in a position to comply with the local manufacturing requirement imposed by the law. As mentioned before, the Canadian law was amended in 1969 and compulsory licenses for the importation of medicines were allowed. Between 1969 and 1992, 1,030 applications were submitted with a view to importing or manufacturing medicines, and licenses were granted in 613 cases (McFetridge, 1998, pp. 81-82).

In the United States under antitrust laws, from August 1941 to January 1959 there were 107 judgements (13 in litigated cases and 94 by consent) in which patent rights were restricted. The use of compulsory licenses continued after that date: "literally tens of thousands of patents" have been compulsorily licensed in the United States (Scherer, 1998, p. 106), in more than one hundred cases. In one single case (U.S Manufacturers Aircraft Association Inc.), about 1,500 patents were compulsorily licensed (Finnegan 1997, p. 139; Goldstein, 1977, p. 123).

Between 1950 and 1972, 76 compulsory licenses were applied for under Section 41 of the United Kingdom Patent law, 25 of which were granted (Goldstein, 1977, p. 125). Nine applications were filed in the period 1988-1990 (Love, 1999). Licenses of rights established by the UK Patent Act of 1977 were applied for in 77 cases for drugs between 1985 and 1989. Over 100 applications for such licenses were reported until they were abolished in 1988 (Cohen, 1990, p. 28).

In other countries, the number of compulsory licenses applied for or granted seems to be quite small. In Germany, since the establishment of the Federal Patent Court in 1961, 12 compulsory licenses proceedings were initiated (von Meibom and Pitz, 1997, p. 27). In Israel a compulsory license for the manufacture of hepatitis B vaccine under a Biogen patent was granted by the Registrar of Patents, Designs and Trademarks in 1995 and upheld by a District Court in 1997 (Cohn, 1997, p. 28). In Australia, in at least two cases, the Trade Practices Act of 1974 was applied in relation to refusals to deal (O'Bryan,

1992, p. 10), and two applications for compulsory licenses -- that eventually were rejected -- were reported in South Africa in 1993 (Sheppard, 1994, pp. 23-28).

Even though in these and other countries the number of compulsory licenses has been low, authors generally agree that the importance of the institution can not be measured on the basis of the number of licenses granted. Ladas (1975) noted that "The practical value of the existence of compulsory license provisions in the Patent Law is that the threat of it usually induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished." (p. 427).

More recently, Beier (1999) has presented a similar view in a comprehensive study on the matter. He argues that compulsory licenses "through their mere existence as well as through the apprehension of compulsory license proceedings are liable to increase the willingness of a patent owner to grant a voluntary license" (p. 260).

In the case of Canada, it was found that the existence of compulsory licenses (under Section 65 of the Patent Act) had strengthened "the hand of potential users in dealing with the patentee The threat of applying for a compulsory license may benefit many more domestic licensees as well as result in more extensive licensing." (McFetridge, p. 80.)

For the case of Israel it has been observed that "the importance of compulsory licenses from the point of view of the Israel pharmaceutical industry exceeds by far the results achieved in a restricted number of decided cases, important as they may have been. It is extremely difficult to arrive at the relevant facts, but nevertheless it will be safe to say that the very existence of compulsory license provisions on the book, and the demonstration by a relatively small number of decided cases that under the right circumstances these provisions are applied, induced foreign patent owners to find ways for granting licenses without the need for a compulsory license" (Cohn, 1990, p. 25).

VI. CONCLUSIONS

As the above analysis indicates, the compulsory licensing system has become a typical feature of patent laws; it has also been widely adopted in other areas of intellectual property rights. Developed countries have largely relied on such licenses in order to limit exclusive rights and prevent or remedy abusive practices in several areas. As the study reveals, there is a broad range of grounds under which compulsory licenses may be granted in both developed and developing countries.

The compulsory license system is not a vestige of the past, as proven by recent legislative changes in developed as well as developing countries. Recent case law has also invigorated the use of compulsory licenses in several areas of intellectual property.

Though the number of applications for compulsory licenses related to patents is relatively small -- with the noticeable exception of the United States -- this does not mean that the system does not influence patent owners' behaviour. The vitality of the system would seem to indicate that it is a tool that may be useful in a variety of circumstances in order to mitigate the restrictive effect of exclusive rights and strike a balance between the title-holders' interests and those of the public in the diffusion of knowledge and the access to, and affordability of the outcomes of, innovation and creativity.

The grounds and conditions on which compulsory licenses have been regulated and granted in developed countries, as reviewed above, illustrate the flexibility and potential of the compulsory licensing system to address a multiplicity of public interests and concerns. The evidence presented also indicates that arguments -- often voiced by the developed countries' business community and governments -- against compulsory licenses as a deviation from acceptable standards for intellectual property rights, are not reflected in the policies actually applied in such countries.

Three main conclusions particularly relevant for developing countries may be drawn from the previous analysis.

- First, compulsory licenses should be considered as an essential element in patent laws and other intellectual property regimes. Developing countries should disregard any attempts by developed countries to limit under bilateral or other agreements the scope of and grounds for compulsory licensing.
- Second, the grounds and conditions for compulsory licenses should be carefully determined by national laws. The extent to which such licenses would be available and effective depend on the provisions of national legislation and on its adequate administration by informed national authorities.
- Third, developing countries should preserve the maximum possible freedom under international rules to design their compulsory licensing systems, according to their own interests and needs, including in such areas as the protection of health and the environment, and the promotion of transfer of

technology and local industrialization. Should the issue of compulsory licenses be included in the agenda of possible future negotiations in WTO, developing countries should seek to clarify the scope for the granting of such licenses in certain cases (e.g. of non-exploitation), as well as to remove some of the restrictive conditions imposed by the said TRIPs Agreement, notably under Article 31. g.

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