

## **INTERNATIONAL COMPULSORY LICENSING: THE RATIONALES AND THE REALITY [n.1]**

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### I. INTRODUCTION

The purpose of this paper is to analyze the involuntary contract known as a compulsory license. To this end it will first define prevalent compulsory licensing provisions, as well as the situations of their use. Second, differences in the perception of intellectual property protection by developing and developed nations will be examined. Third, arguments relating to compulsory licensing will be evaluated. Fourth, proposed compulsory licensing provisions that take into account the needs of all nations will be set forth. And fifth, this note will discuss why the General Agreement on Tariffs and Trade is the appropriate forum for an agreement aimed at raising the minimal level of intellectual property protection, the relevant provisions of the Trade Related Aspects of Intellectual Property draft agreement, and suggestions for additions to this draft.

### II. COMPULSORY LICENSING

"A compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state." [n.3] A survey of international intellectual property law reveals that the three most prevalent compulsory licensing provisions are applicable where a dependent patent is being blocked, where a patent is not being worked, or where an invention relates to food or medicine. [n.4] Additionally, compulsory licensing may be implemented as a remedy in antitrust or misuse situations, where the invention is important to national defense or where the entity acquiring the compulsory license is the sovereign.

#### A. The Dependent Patent

A dependent patent cannot be worked without infringing an earlier issued patent. This may result in a situation where it is not possible to exploit the later issuing patent due to the inability of the two patent holders to come to a licensing agreement. [n.5] The ramifications of this depend upon whether the improvement invention protected by the dependent patent is of greater or lesser value than the invention protected by the original

patent. This 'holdup' problem may be significant in the case where the original patent contributes very little value as compared to the improvement. [n.6] Additionally, the refusal to license may be detrimental to society as it prevents the introduction of the improvement until the original patent has expired, and/or delays the introduction due to time spent in litigation; leading to higher consumer cost. "[The] inability to work a dependent patent is [also] seen, in some countries, as being contrary to the public interest in having the unencumbered working of all patented inventions." [n.7] To remedy this, many States have adopted compulsory licensing provisions. [n.8] An example of such a law is Article 36 of the Swiss Patent Law, which provides:

If a patented invention cannot be used without violating the prior patent, the owner of the more recent patent shall have the right to the grant of a license to the extent required for such use of his invention, provided that that invention serves a purpose entirely different from that of the prior patent, or that it involves a considerable technical advance. Where both inventions serve the same economic purpose, the registered owner of the prior patent may grant the license on the condition that the owner of the junior patent in turn grants him a license or the use of his invention. In case of dispute, the judge shall decide on the grant of the licenses, their extent and duration and on the compensation to be paid. [n.9]

Through implementation of a statute of this nature, a State creates a more favorable environment for post "pioneer invention" development and improvement, thereby providing an incentive for the furtherance of technical and economic development.

However, partially due to safeguards implemented by various countries, this type of compulsory license is rarely granted. [n.10] The reason for this is of a practical nature: prior to application for a compulsory license, an improvement invention must be created, a patent application granted, the improvement patent applicant may have had to survive a lengthy opposition proceeding, and an attempt at voluntary negotiations must have been made. These steps discourage compulsory license applications owing to the time and money involved. It seems where the improvement is an important technological advance, a cross license would best meet the economic interests of both parties.

## B. Non-Use

Every nation has a strong interest in promoting the working of patents, as this assures the populace is supplied with new and better goods. [n.11] Additionally, many nations regard a patent grant as a contract between a state and an individual, where the patentee is given the right to prevent others from using the invention under the implied condition that the patent holder will exploit the invention in the State, thereby benefiting the community. Under this view, the patent holder who fails to put his invention into practice within the State has breached his implied condition and may therefore have his patent grant reduced or revoked. [n.12] Non-use provisions are thus implemented with the goal of promoting local working of patented inventions and to prevent the patentee from denying the public access to novel and needed subject matter, where to withhold such subject matter is unreasonable or contrary to the public interest. [n.13] These provisions

appear in the patent laws in two forms, compulsory working and compulsory licensing. 'Compulsory working' means a patent must be commercially worked within the country granting the patent, or the patent will be revoked. 'Compulsory licensing' refers to a non-voluntary licensing arrangement between private entities and arranged by the government. Generally the patent is only revoked when, for some reason, compulsory licensing fails.

The right of countries to impose compulsory licensing provisions of this nature is recognized by Article 5 of the Paris Convention, which states:

1. Member states may legislate measures providing for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example for failure to work.

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 three years from the date of application for the patent, or four 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 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. [n.14]

The majority of the countries set forth in Appendix A, provide for the compulsory licensing of patents in non-use situations. Common circumstances where this provision may be applied are when the patent owner fails to work his patent within the requisite time after patent issuance/patent application and also refuses to license the patent to another on reasonable terms, when the patent owner fails to meet the demand for the product, and when the patent is being used to block the use of another patent. [n.15]

### C. Provisions Relating to National Sovereignty

Miscellaneous provisions pertaining to compulsory licensing are most commonly used by the sovereign as a means to correct anticompetitive practices, for reasons of national defense, to promote the public interest or public health, and in cases of emergency. The laws of Chile and the Republic of Korea provide examples of this type of provision. In Chile a compulsory license may be granted when the patent holder has committed a monopoly abuse according to the Resolution Committee established under Decree-Law no. 211 of 1973. [n.16] In the Republic of Korea a nonexclusive compulsory license may be required if the working of the patented invention is necessary in the public interest. [n.17]

### D. Food & Medicine

Many reasons are offered as to why countries may have a legitimate interest in maintaining and fostering their own domestic, science based pharmaceutical industry. [n.18] First, a science-based pharmaceutical industry may aid in the employment of the country's chemists, physiologists, toxicologists, pharmacologists, pharmacists, doctors and the like; thus diminishing the likelihood that they will leave the country due to a lack of employment opportunities. Second, a domestic pharmaceutical industry could be a significant contributor to the national economy. Third, a home-based industry might be in a better position to produce medication compatible with the average local income, because the cost of labor would be commensurate with the average income. Fourth, due to the astronomical cost of developing a new medicine, (estimated at over \$231,000,000 U.S. and 12 years per each new drug introduced to market) [n.19] a small country that is not a base for a multinational corporation is not in a position to develop new medications. Fifth, maintaining a domestic industry in the area of medication production is important for reasons of national defense.

Compulsory licensing in the case of food [n.20] and medications is the least prevalent of the provisions under consideration. Of the countries listed in Appendix A, approximately 20 percent have implemented a provision of this nature. Of these, compensation for the license varies tremendously, from those countries which base the value on what would have been agreed upon by a willing licensee and a willing licensor to those assessing only a token value, where the foremost interest in setting royalty is providing the drug to the populace at the lowest possible price.

#### E. U.S. Provisions

In general the U.S. position on compulsory licensing is that "compulsory licenses for the benefit of private competitors are not favored by the tradition of America statute law, except as sanctions for actual violation of the antitrust laws." [n.21] In addition to the antitrust use of compulsory licensing, certain statutory provisions automatically license the government to use inventions in industries such as defense and aerospace. [n.22] Moreover, 28 U.S.C. Section 1498(a), permits the U.S. Government and its contractors to use any U.S. patent. [n.23] The patentee's sole option is to bring suit for this 'unlicensed use' with the only potential remedy being just compensation as required under the Fifth Amendment. [n.24] Finally, compulsory licensing has occasionally been implemented in the U.S. through judicial action motivated by a concern for the public welfare. An example of such a case is *Milwaukee v. Activated Sludge*, [n.25] where the patent holder of an invention pertaining to sewage treatment was denied injunctive relief as the injunction would block the continued use of the sewage treatment plant and thereby endanger the health of the citizens. In effect, a de facto compulsory license was granted as the patent holder was merely awarded damages for the infringing use.

### III. COMMON PERCEPTIONS OF INTELLECTUAL PROPERTY PROTECTION

## A. Developing Nations

The implementation of a system to protect intellectual property is a costly enterprise. The most obvious expense is administrative: that is, training and managing the patent system bureaucracy. [n.26] As over 80 percent of all patents granted in less-developed countries belong to citizens from developed countries, [n.27] "it is hardly surprising that Third World countries see little advantage in developing an elaborate and costly administrative mechanism to enforce the protection of intellectual property of foreign transnational companies." [n.28] In addition, this may in part explain the general perception of developing nations that protection of intellectual property only serves to assist the developed nations in maintaining their economic power and international control. A commonly expressed opinion of developing nations is that their economic advancement is a goal, which if achieved, benefits all nations. Since knowledge is the common heritage of mankind, and since this knowledge would contribute to their economic development, some submit that the intellectual property of all nations should be provided to them at little or no cost. [n.29]

There are additional economic reasons for the hesitancy of many developing nations to implement strong protection of intellectual property. In order to advance, the developing nation needs maximum access to the intellectual property of developed nations. So long as their intellectual property laws, and the enforcement thereof, are weak, the piracy [n.30] of intellectual property pays off handsomely. "Through piracy, developing countries can procure needed goods and services at little cost, while industries that specialize in producing counterfeit goods employ thousands of workers. When compared to these tangible gains, the threat that investment from Western countries might be withdrawn is secondary to immediate development needs." [n.31]

Due to these differing needs, the developing and the developed nations have vastly differing viewpoints concerning compulsory licensing. The developing nations fear multinational companies will exploit the local consumers by charging high prices for goods made in foreign countries, resulting in a populace that comes to depend upon goods for which there is no local production. This argument seems to have particular legitimacy where the product is essential to the well being of the populace. For these reasons, developing nations are generally strong advocates of maintaining a system which allows compulsory licensing, thereby limiting the scope of protection and rights available to foreign companies and individuals.

## B. Developed Nations

The principal goals of a patent system are to encourage invention, promote manufacture, foster investment in research and development, and urge the disclosure of inventions. To this end, the patentee is granted a limited exclusive right to use the invention. "Absent sufficient protection, creators can no longer recover the cost of their investment in research and development, resulting in lower production, fewer trading opportunities and

higher costs to the consumer." [n.32] Therefore the public view of many developed nations is that any diminution of the patent grant would make inventive research less attractive as well as deter entrepreneurial investment.

A patent at best is a precarious and highly speculative kind of property, hence any new business undertaking based on a new invention is a risky proposition. Anything that will interfere with the exclusive right of the owner of the patent to work it, will certainly discourage investment in this type of enterprise because of the consequent reduction in the possibility of commercial success. [n.33]

A system of compulsory licensing could only have the effect of making investment in patented inventions less secure and less attractive. "Rather than engage in expensive research, companies would be inclined to sit back and let others do the scientific exploration, and then apply for a license as of right if a worthwhile invention was developed." [n.34] Compulsory licensing is therefore viewed as having no place in U.S. patent law. [n.35] In addition, those nations which implement provisions of this nature have been strongly criticized by the U.S. government as well as by foreign multinational firms on the grounds that while they reap the benefits, they do not contribute their fair share to research and development costs.

Many believe the social benefits created through a patent system outweigh any perceived losses such a system may impose on a developing nation, and indeed, a strong patent system is the key to industrialization and self reliance. In support of this view it is contended a patent system facilitates technology transfer and investment between developed and developing nations. This point was asserted in a recent submission from the Patent and Trademark Institute of Canada to the Canadian Government:

Prospective vendors or licensors of technology tend to be willing to transfer the technology to a recipient only in circumstances in which the legal, economic, political and social environment is conducive to adequate continuing protection for the transferor and a fair reliable return to the transferor for the technology transferred ... The intellectual property law environment ... also tends to be very important because transferors of technology generally are uncomfortable relying for their legal protection only on the contractual obligation assumed by the recipient of the technology. They usually like to have the security of enforceable patent, design, copyright and trademark protection where applicable in the country in which the recipient is located ... This back-up security--the possibility of a patent infringement lawsuit should the rest of the agreement fall apart--tends as a practical matter to be of value only in those countries in which patent rights are enforceable at the instance of a foreign patentee against domestic defendants. So, the intellectual property regime, and especially the patent law regime in countries seeking to import technology, can be a very important factor in the determination whether a given technology owner is willing or unwilling to transfer the technology to a recipient in the country in question. [n.36]

This is illustrated by a study conducted by Edwin Mansfield of the University of Pennsylvania. [n.37] In an attempt to determine the perceived importance of intellectual property rights on the nature and amount of technology transferred to a county by way of direct foreign investment, Mansfield requested information from 100 major U.S. firms as

to the importance of intellectual property rights in their determination of whether to make direct foreign investments of various kinds. He found some industries regard intellectual property protection as more important than others, with the food and transportation equipment industries being the lowest and chemistry, (including pharmaceuticals) being the highest. Mansfield also noted a very high correlation between an industry's ranking in this study and its ranking in previous studies, [n.38] with the general case being more research-and- development intensive industries seeming to place a higher priority on intellectual property rights. The proportion of firms which considered intellectual property rights important in their determination as to whether to make a particular type of foreign investment were as follows:

Type of Investment	Percentage
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Sales and Distribution Outlets	20%
Rudimentary Production and Assembly Facilities	32%
Facilities to Manufacture Components	48%
Facilities to Manufacture Complete Products	59%
Research and Development	80%

Therefore, as investments in facilities for research and development and the manufacture of components or complete products are likely to raise a country's technological level to a greater extent than investments in sales and distribution outlets or in rudimentary production and assembly facilities, and as these are the types of investment decisions where intellectual property rights play an increasingly important role, the implementation of these rights would seem to attract external investment of this nature to the benefit of the developing nation. [n.39] Thus, intellectual property should be regarded as a development tool: it raises a country's technology base by drawing local and international funds, by supporting local research efforts, and by encouraging the introduction of growth producing new technology into the economy. [n.40]

Technological change is understood to be an engine of economic development. Economic growth, which means output growing faster than population, requires increases in productivity. Increases in productivity require technological innovation so that a country can produce more output of products as well as to develop new products that enhance the quality of life or enable society to produce yet more goods and services. [n.41]

Intellectual property is thus an important part of a nation's infrastructure. [n.42]

Many developing nations believe their needs are adequately provided for through the practice of "free riding" or "pirating" others' accomplishments. As the skills acquired in copying are generally not useful in the transition to innovation, a policy of this nature condemns the nation to perpetual catch-up. This becomes particularly true as technology becomes more complex and advances at ever increasing speed. Also, when technology is acquired through piracy the nation will generally be unable to access valuable know-how and trade secrets related to the technology. They will thus be unable to use this technology to its full potential. [n.43] Additionally, a nation which allows piracy to take place is engaging in an unfair trade practice, for the pirated good competes with the original in all world markets. The effect of this practice being twofold: first, inventors will have less incentive to patent their innovation and second, it will be increasingly difficult for industries to recover their innovation costs. [n.44]

It is argued that free riding is particularly legitimate in the area of pharmaceuticals, as the population of the developing nation may procure a drug similar to the patented article at a greatly reduced price. However, an analysis of the realities in the area of pharmaceuticals shows that for the following reasons this is not so. First, it generally seems products produced through imitation are sold at high prices, even though they have accrued no innovation costs. Thus, the "high social rate of return is sacrificed in favor of a high private rate of return for a few." [n.45] Second, of the drugs included in the current Essential Drugs List published by the World Health Organization, over 90 percent are not protected by United States patents. [n.46] Third, many pharmaceutical firms provide essential drugs on noncommercial terms and provide assistance to developing countries in appropriate distribution, quality control and administrative techniques. [n.47] Fourth, patented pharmaceutical products must compete with other products of the same chemical or therapeutic class. [n.48] Fifth, and most importantly, many developing nations have implemented price regulation schemes. In these situations "intellectual property protection poses no threat of noncompetitive pricing [as the] government ha[s] taken the risky step of overriding the market with price regulation." [n.49] It therefore seems compulsory licensing is neither an efficient nor necessary cost controlling measure.

A final argument put forth in support of strong intellectual property protection concerns the welfare and safety of the consumers. First, the well being of these consumers may be threatened by infringing products of substandard quality. [n.50] A prime example of this danger is inferior quality pharmaceutical products. These products may be of varying strengths and may contain dangerous impurities, and yet may be sold as if they were the patented article. Second, there are many diseases unique to the developing world. [n.51] Strong intellectual property rights provide the incentive to invest the required resources needed to investigate these diseases and their potential treatments. [n.52]

#### IV. AN ANALYSIS OF ARGUMENTS



Arguments relating to compulsory licensing which have been set forth in Sections II and III of this paper break down into the following:

1. Whether the economic growth of a nation is best fostered with an infrastructure of strong patent rights or by allowing a nation to develop their technological skills through copying.
2. Whether compulsory licensing is an effective means of cost/quantity control.
3. Whether the possibility of compulsory licensing in the dependent patent scenario would speed up technical progress.
4. Whether compulsory licensing is warranted when deemed necessary by a government to maintain essential supplies and services.

Each will be addressed in turn.

#### A. Economic Growth

As mentioned in Section III.B. of this paper, innovation is necessary for a nation's economic growth. It is therefore important to scrutinize the relationship of intellectual property protection to innovation. Should it be shown that strong intellectual property rights are an important prerequisite to innovation it follows that they are an important prerequisite to economic growth. However, while much has been said on the relationship between intellectual property protection and economic growth, very little is backed with tangible findings. An excellent beginning is the work being done by Robert Sherwood [n.53] and Edwin Mansfield [n.54] among others. [n.55] Substantive works of this nature cut through the rhetoric presenting a factually based analysis. The findings of the aforementioned individuals support the conclusion that a strong patent system is necessary for investment and innovation. Compulsory licensing would only serve to weaken granted rights, thus diminishing foreign investment and local innovation and thereby decreasing opportunities for economic growth.

#### B. Cost/Quantity Control

In many nations, price and quantity of goods is regulated through the invisible hand of the market. In certain circumstances, these market economies may implement government action to correct perceived inequities. One such situation is that of antitrust violations. In this case the nation is justified in crafting a remedy that will best correct the anticompetitive practice.

A second situation is where the government deems a certain class of products should be available to the populace at a reduced price. This most generally occurs with pharmaceuticals and may be implemented through price control boards or compulsory licensing. An example of a price control board is the Patented Medicine Prices Review Board (PMPRB) that exists in Canada. The Canadian Parliament has given initial approval to Bill C-91, [n.56] which upon passage would confer even greater powers upon the PMPRB, including the powers to order price rollbacks and reimbursement of excess

revenues from patented pharmaceuticals. As implementation of compulsory licensing provisions are more likely to insure profits to generic companies, rather than lower prices to the public, the preferred governmental method of price control is the price control board.

A third situation occurs when an able patentee refuses to provide a country's populace with access to patented inventions in the public interest. If the patentee has had adequate time to enter the market and has no legitimate reason to justify the inaction, a compulsory license may be the most equitable solution. It seems the patentee will not suffer economic harm, as due to the compulsory license, the patentee will acquire royalties from a market that he or she had no plans of entering.

In general, two definitions have been set forth as to what constitutes working of a patent. Some countries recognize importation of the patented product as working; others use compulsory licensing to force local working of the patent. This second definition appears to have its roots in the past practice of import substitution, whereby a nation would attempt to alter the percentage of local currency that was leaving the country to buy imported goods. Import substitution has no place in today's global market. In light of the realities of economies of scale and the international nature of the market, resources will be best allocated if importation is deemed working. To require local working is wasteful and will result in a higher price to the nation's populace.

### C. Dependent Patent

It is interesting that compulsory licenses rarely issue to insure the working of a dependent invention. As stated, this could be for a variety of reasons. First, the possibility of a compulsory license may serve as an incentive for licensing. Second, where the improvement is an important technological advance, the parties may recognize it is in their economic interest to cross-license. Third, the time and monetary costs of acquiring a compulsory license may be prohibitive. However, even though the causes remain unclear, a provision of this nature may indeed serve to foster technical progress and should not be overlooked.

### D. Essential Supplies and Services

Inherent in the idea of a sovereign nation is the right of the nation's government to govern within its national boundaries without external interference. Compulsory licensing must thus be an allowable option to governments facing situations of extreme urgency, whether the urgency be related to defense, economics or health. Should a compulsory license be implemented in such a situation, equity demands the patent holder be given a fair royalty.

## V. HARMONIZATION PROPOSAL

In order to be viable, any harmonization proposal must take into account the differing needs of the least developed or dependent nations, [n.57] as compared to those generalized needs of advanced developing, [n.58] newly industrialized, [n.59] and developed nations. [n.60] In light of considerations of this nature, the following 'model laws' are submitted as a proposed harmonization of patent laws relating to compulsory licensing. The author believes implementation of these provisions would be economically beneficial to all but the least developed nations.

#### A. Dependent Patent

A basic goal of patent law is to encourage inventive rivalry and thereby generate rapid technical progress. History has shown that where the development of a technology is controlled by a small number of companies, technical advance moves slowly. [n.61] Examples of this include the Edison lamp patent, [n.62] the Selden auto patent, [n.63] and the Wright brothers patent. [n.64] It is thus suggested that a compulsory licensing provision relating to dependent patents should read as follows:

[Five] years from grant or 6 years from application of the earlier patent, whichever is later, if the dependent invention is an important technological advance, and if the owner of the earlier patent refuses to license on reasonable terms, a nonexclusive compulsory license will be granted to the extent necessary to exploit the dependent invention. Patentee will receive adequate compensation in an amount fixed by either the parties or the Court. The senior patentee may then obtain a cross license, with royalty again fixed on reasonable terms fixed either by the parties or by the Court.

##### i. Analysis of Proposed Provision

The time period which must expire prior to an application for a compulsory license of this nature has been extended in the proposed provision. This is to compensate for the longer commercialization lead times existing in most every industry. [n.65]

This provision is geared towards those circumstances where the original patent contributes very little value as compared to the improvement. Thus, in order to be eligible for a compulsory license under the proposed provision, the dependent invention must be an important technological advance. Under the patent law of the United States, valuation of the worth of an inventor's contribution is left to the public and is not to be considered in the determination of patentability. Thus, an "important technological advance" would be an invention that in addition to meeting standards of patentability, also is deemed of particular importance to the public by the licensing boards. [n.66]

A compulsory license of this nature will probably rarely issue for the reasons listed in Section IIA. However, the possibility of the dependent patent holder attaining such a license provides an incentive for the successful resolution of voluntary negotiations

between the dependent patent holder and the senior patentee. In consideration of judicial economy an application for a compulsory license of this nature will only be considered after the breakdown of negotiations.

Should a license issue, it will be nonexclusive, with its scope confirmed to the extent necessary to practice the improvement invention. The senior patentee may obtain a cross license. These terms are in accordance with the purpose of this provision; that is, to encourage inventive rivalry and thereby generate rapid technical progress.

Finally, a reasonable royalty is to be set either by the parties or by the court with the value based on what would have been agreed upon by a willing licensee and a willing licensor.

## B. Non-Use

In order to prevent the patentee from denying public access to novel and needed subject matter, where to withhold such subject matter is unreasonable or contrary to the public interest, the following compulsory licensing provision relating to non use is proposed:

An individual may apply for a nonexclusive, nontransferrable compulsory license for the use of an invention in the public interest, on the ground of failure to work or insufficient working. Said application may be made after the expiration of 5 years from the date of patent grant or if the invention is inadequately worked for any 2 year period after this date. The application shall be refused if the patentee justifies his inaction by legitimate reasons. Working shall include importation of the patented product.

### i. Analysis of Proposed Provision

The purpose of this provision is to ensure that the populace of a country has access to inventions in the public interest. The time period within which the patent holder must begin working the invention has been expanded from that set forth in the Paris Convention in acknowledgement of the actual time involved to bring an invention all the way to market such as establishing production, implementing quality control, determining marketing channels, effecting the transportation of goods, and the like. [n.67] In this provision, working includes the importation of the patented product. This recognizes the economic realities of present day manufacturing technologies and the free movement of products throughout the global market. Thus, while companies would be able to produce their products in the most cost effective manner, this provision ensures that the patentee may not deny public access to the product.

## C. Provisions Relating to National Sovereignty

Under the fundamental principle of sovereignty, [n.68] a Nation must have the right to regulate conduct within its borders. Thus, where a judicial or administrative process has

deemed a practice to be anticompetitive, it is the prerogative of the Nation to determine an appropriate remedy. Should the Nation correct the anticompetitive practice through compulsory licensing it should be entitled to consider the nature of the abuse when establishing the appropriate remuneration given to the patent holder in exchange for use of his patent. A Government is also entitled to use an invention, or authorize a third party to use an invention, where such use is essential to national defense, national economy or public health. In these situations the patent holder is entitled to adequate remuneration.

#### D. Food & Medicine

The compulsory licensing of inventions relating to food and medicine is an issue of strong emotional content. Research in the area of pharmaceuticals is so expensive that any country attempting to take a free ride on such research through the use of compulsory licensing is certain to be a target of severe international criticism. While developing countries have a justifiably strong interest in insuring that foods and medicines are available to their citizens at a reasonable price, they also have a strong interest in providing the incentive to research those diseases particular to the developing nations. Pharmaceuticals are therefore too important not to protect. [n.69] Accordingly:

Inventions relating to food and medicines are to be accorded no special status. A compulsory license shall be granted in the case of an invention pertaining to food or medicine only if the applicant qualifies for such a license through a differing compulsory licensing provision.

##### i. Analysis of Proposed Provision

Thus, inventions relating to food or medicine will be treated in a similar manner to any other invention; that is, compulsory licensing would be available for food or medicine only where the invention meets the terms of either a dependent patent provision, a non-use provision, or a provision relating to national sovereignty. Pricing of these products may be determined by the market or through the government's implementation of a price regulation scheme. [n.70]

## VI. URUGUAY ROUND

We are now in an information age where global competition is the norm. Intellectual property has become a key production factor comparable to other factors such as labor, raw materials and capital. [n.71] Under the theory of comparative advantage, a nation competes by taking advantage of those production factors which they possess in abundance; [n.72] thus non- protection of intellectual property distorts trade, for it provides the pirate with an artificial competitive advantage. International treaties have provided a limited resolution to this problem. However, as these treaties do not have effective dispute settlement provisions, [n.73] these rights must be protected through

another forum. The Uruguay Round of the general Agreement on Tariffs and Trade, (GATT) has been proposed as the vehicle by which this problem may be resolved. [n.74] "The GATT provides an existing foundation for consultation and dispute mechanisms, as well as enforcement procedures," [n.75] and provides an additional advantage in that its "broader negotiating framework enhances the chances of reaching compromises in the form of package deals." [n.76]

The GATT is an international agreement with 92 countries as contracting parties participating in multilateral trade negotiations. [n.77] It is aimed at expanding international trade and thereby raising world welfare, by reducing the uncertainty associated with commercial transactions across national borders. [n.78] The primary principle underlying the GATT is the most favored nation clause, with the purpose of this clause being to prevent economic discrimination between nations. [n.79]

In furtherance of this purpose, the Trade Related Aspects of Intellectual Property Agreement, (TRIPS) has been included in the Uruguay round of the GATT under the mandate "to reduce the distortions and impediments to international trade, taking into consideration the need to promote effective and adequate protection for intellectual property rights." [n.80] Articles 30 and 31 of the Dunkel text of the draft agreement on TRIPS are set forth in Appendix B. [n.81] These articles set forth a minimum standard of guidelines to be followed by a State, where the law of the State provides for use of the subject matter of a patent without the authorization of the patent holder; that is, where the laws of the State provide for compulsory licensing.

The provisions set forth in the Dunkel text of a draft agreement on TRIPS, seem justified based on the considerations presented in this paper. However, it does not seem to go far enough. The following principal revisions should be made:

1. The time period that must expire prior to application for compulsory license in either the non-working or dependent patent situation should be lengthened.
2. Working should expressly include importation of the patented product.
3. It should be expressly stated that food and medicine are to be accorded no special status.

A proposed draft agreement incorporating these and additional minor revisions is presented in Appendix C.

Whether or not a final agreement on the Uruguay Round of GATT is reached, due to the numerous meetings, negotiations and agreements that have taken place throughout the Uruguay Round, the final draft version of the Trade Related Aspects of Intellectual Property Agreement will have acquired more than a modicum of legitimacy as accepted customary practice. It is thus imperative for all nations take an active role in molding drafts presented and procedural outcomes.

## VII. SUMMARY

In order to be accepted, adhered to and viable, any agreement to raise the minimum level of intellectual property protection must take into consideration the needs of all nations. This report has discussed several of the more common usages of compulsory licensing and the rationalizations behind these usages. In addition, it has attempted to objectively analyze the needs of various nations. In light of these considerations a proposed draft agreement concerning compulsory licensing has been set forth. It is this author's belief, that acceptance of this draft would deliver mutual gain to the developed and developing nations, promoting effective and adequate protection of intellectual property rights while protecting the legitimate concerns of nations.

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[n.2] M.I.P. (1993), J.D. (1992), Franklin Pierce Law Center.

[n.3] P. Gorecki, *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes*, (Economic Council of Canada, 1981).

[n.4] See Appendix A for a summary of compulsory licensing provisions in various countries.

[n.5] The situations of non-use and dependent patents may be intertwined; an example being blocking patents, where due to an entities' acquisition of large patent holdings in a particular field, the inventor's sole option is to sell their dependent innovation to this large entity. The large entity may acquire these innovations with the sole purpose of protecting their position and without any intention to further develop the technology or to exploit the acquired patent. Kaysen & Turner, *Antitrust Policy*, 165-166, (1959).

[n.6] Merges, *On The Complex Economics of Patent Scope*, 90 *Colum.L.Rev.* 839, 861-867 (1990).

[n.7] International Bureau of WIPO, *Compulsory or Non-voluntary Licenses in Respect of Patents for Invention, from Meeting Of Experts On The Acquisition By Developing Countries of Environmental Relevant Technology Protected By Intellectual Property*, U.N.Doc. WIPO/UNCED/CE/6 (1991).

[n.8] One commentator has suggested that incentive for improvement inventions should be maintained in the United States by the claim scope accorded when analyzing infringement under the doctrine of equivalents and reverse doctrine of equivalents. He has proposed that in determining the appropriate claim scope a court should consider the importance of the advance represented by the improvement, tailoring the scope of protection such that an incentive for improvement remains. See Merges, *supra* note 6.

[n.9] *Systematische Sammlung des Bundesrechts (SR)* (catalogue of Swiss Law), 232.14, reprinted in Walter, *Compulsory Licenses and Dependent Patents*, 21 IIC 532 (1990).

[n.10] The last grant of a dependent compulsory license in Japan was over 20 years ago, Wegner, *Patent Harmonization*, C554 Ali- Aba 171 (1990); "In Switzerland the Federal Court has never had to deal with a case of this kind since the current law came into force on 1 January 1956." Walter, *supra* note 9 at 536.

[n.11] Bhatnager, *GATT IPP Proposals in Context with Developing Countries and the Paris Convention*, 40 *Patent World* 33 (1992).

[n.12] A. Mian, *Compulsory Licensing--Copyright and Patents*, as presented at the Regional Forum on the Judiciary and the Intellectual Property System, Islamabad, Pakistan (1986).

[n.13] 1 S.P. Ladas, *Patents, Trademarks and Related Rights: National and International Protection* § § 245-249, at 423-436 (1975). The reason for non-use may be of a political nature; see generally, Cohn, *Compulsory licensing in Israel under pharmaceutical patents--a political issue?* 27 *Patent World* 22 (1990).

[n.14] *International Convention for the Protection of Industrial Property*, Mar. 20, 1883, 25 Stat. 1372, T.S. No. 379; as revised: at Brussels on Dec. 14, 1900, 32 Stat. 1936, T.S. No. 411; at Washington on June 2, 1911, 38 Stat. 1645, T.S. No. 579; at the Hague on Nov. 6, 1925, 47 Stat. 1789, T.S. No. 834, 74 L.N.T.S. 289; at London on June 2, 1934, 53 Stat. 1748, T.S. No. 941, 192 L.N.T.S. 17; at Lisbon on Oct. 31, 1958, 13 U.S.T. 1, T.I.A.S. No. 4931; at Stockholm on July 14, 1967, 21 U.S.T. 1583 and 24 U.S.T. 2140, T.I.A.S. Nos. 6923 and 7727. The United States is a party to the convention.

[n.15] Scott, *Compulsory Licensing of Intellectual Property in International Transactions*, 11 *EIPR* 319, (1988); also see Murphy, *The Process Patents Amendments Act of 1988* 9



J.L. & Com. 267 (1989); blocking patents have tremendous social costs in that they block entry of new competitors into the market, hinder the ability of existing competitors to compete, inhibit inventive activity in that field by reducing opportunities for non-infringing solutions and eliminate research and manufacture of infringing yet unexploited solutions.

[n.16] Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights, (Ley Num. 19.039 Establece normas aplicables a los privilegios industriales y proteccion de los derechos de propiedad industrial) Diario Oficial de la Republica de Chile, No. 33.877 of January 25, 1991, pp. 1 et seq, as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 2.

[n.17] Laws and Enforcement Decrees of Industrial Property, The Office of Patents Administration The Republic of Korea, translated by the Office of Patents Administration, Articles 51, 59 and 60, 1988 edition; The Korean Industrial Property Laws, Korean Invention and Patent Association, Translated by Korean Industrial Property Office, Sections 107 and 138 1991 ed.; Hee Lee, Non-Working Under Korean Patent Act, 14 Pat. World 24 (1989); Seung-ho, Compulsory Licensing Procedures, 21 IP ASIA 28 (1991).

[n.18] Cohn, *supra* note 13.

[n.19] Developing a New Drug Costs \$231 Million, Tufts Center Study Finds, Pharmaceutical Manufacturers Association Newsletter 32 (23 April, 1990): 4-5.

[n.20] While most compulsory licensing applications of this nature concern a medication, *Cangene Corp. v GD Searle & Co of Canada Ltd*, (Commissioner of Patents) 28 CPR (3d) 230, (1990), concerned a recent application for the compulsory licensing of aspartame. The Commissioner held that while aspartame is not a food, it is used in the production of food, and he could therefore see no reason to refuse the granting of a license.

[n.21] Frost, Legal Incidents of Non-Use of Patented Inventions Reconsidered, 14 Geo.Wash.L.R., 273, 435 (1945).

[n.22] Under 35 USC § 181 a patent containing subject matter that may pose a threat to the national security will be made available to defense agencies for inspection. If they deem the granting of the patent would be detrimental to the national security, the

Commissioner of Patents and Trademarks will issue a secrecy order. Requests for compensation must be made to the defense agency which will make the determination under the provisions of 35 USC § 183. Additional provisions relating to the Department of Energy and the National Aeronautics and Space Administration are set forth in Title 42 of the USC § § 2182 and 2457.

[n.23] 28 U.S.C. § 1498(a); See McGrath, *The Unauthorized Use of Patents by the U.S. Government or its Contractors*, 18 A.I.P.L.A. 349, 1991.

[n.24] *Leesona Corp. v. United States*, 599 F.2d 958, 964 (Ct.Cl.1979); U.S. CONST. amend. V.

[n.25] *City of Milwaukee v. Activated Sludge*, 69 F.2d 577, 593 (7th Cir.), cert. denied, 293 U.S. 576, 55 S.Ct. 87, 79 L.Ed. 673 (1934).

[n.26] There are several steps which could be taken to reduce these administrative costs, a few examples include: recognition of foreign patents, the formation of regional patent offices and the use of world wide search facilities; see, Field, *Pharmaceuticals and Intellectual Property*, 31 IDEA 22, (1991). Also, once the system is established and start-up costs are paid, application costs could generate a net profit to the government, see Emmert, *Intellectual Property in the Uruguay Round--Negotiating Strategies of the Western Industrialized Countries*, 11 Mich.J.Intl.L. 1317 (1990).

[n.27] Murphy, *supra* note 15.

[n.28] Leaffer, *Protecting United States Intellectual Property Abroad: Toward a New Multilateralism*, 76 Iowa L.Rev. 273, 281 (1991). Also see Oddi, *The International Patent System and Third World Development: Reality or Myth?* 1987 Duke L.J. 831.

[n.29] Mansfield, *Unauthorized Use of Intellectual Property*, A paper presented at the Conference on Global Dimensions of Intellectual Property in Science and Technology, Washington D.C. Jan. 8-9 1991. Contra, "some countries have oil, some countries have gold and some countries have technology--and the countries that have oil and gold do not give them away for free either--and oil and gold merely lie in the ground waiting to be extracted;" a statement made by Mr. Naboth Mvere, the Controller of Patents, Trademarks and Industrial Designs, Ministry of Justice, Zimbabwe, while a student of Master of Intellectual Property at Franklin Pierce Law Center; *Germeshausen Newsletter*, Vol. 1, No. 1, Spring 1991.

[n.30] Piracy: the unauthorized and uncompensated reproduction or use of someone else's creative intellectual achievement. Reichman, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 *Vand.J.Trans.Law*, 747, 775 (1989).

[n.31] Leaffer, *supra* note 28.

[n.32] *Id.*, at 277.

[n.33] Duncan, *Non Food and Drug Compulsory Licensing in Canada*, *Pat. & Tdmk. Inst. of Can.* Sept. 10, 1986.

[n.34] *Id.*

[n.35] But see above footnotes 21-25 and accompanying text.

[n.36] Barrigar, *T.R.I.P.S. Negotiations Under the GATT Uruguay Round*, 7 *Pat. & Tdmk. Inst. of Can.* 8, 13 (1990).

[n.37] Mansfield, *supra* note 29. A random sample of 100 major U.S. firms in 6 industries was chosen. The industries represented included: chemical (including pharmaceuticals), transportation equipment, electrical equipment, machinery, food and metals. Ninety four percent of the firms contacted responded, with the respondents being a mixture of patent attorneys, specialists in the firms international operations, and top executives.

[n.38] Taylor & Silberston, *The Economic Impact of the Patent System*, (Cambridge University Press, 1973); Mansfield, Schwartz & Wagner, *Imitation Costs and Patents: An Empirical Study*, *Economic Journal*, December 1981; Mansfield, *Patents and Innovation: An Empirical Study*, *Management Science*, February 1986; and Levin, Klevorick, Nelson & Winter, *Appropriating the Returns From Industrial Research and Development*, *Brookings Papers on Economic Activity*, no. 3, 1987; as referred to in Mansfield, *supra* note 29.

[n.39] Additional variables which may be important in an investment evaluation include: (1) size and growth of the country's domestic market; (2) degree of stability of the macroeconomic environment; (3) per capita gross domestic product; (4) level of

corporate taxation; (5) ratio of exports to imports; (6) extent of urbanization; (7) percentage of gross domestic product attributable to wholesale and retail trade, transport, and communication; and (8) the frequency of change of the national executive. Mansfield, *supra*, note 29. In light of the inherent risks involved in investing in a developing nation, intellectual property rights may be accorded an even higher priority in an investment decision, Sherwood, *Intellectual Property and Economic Development*, 77 (1990).

[n.40] Also see R. Sherwood, *Why a Uniform Intellectual Property System Makes Sense for the World*, a paper presented at the conference on *Global Dimensions of Intellectual Property in Science and Technology*, Washington D.C., January 8-9, 1991; R. Rapp and R. Rozek, *How Property Protection Fuels Economies*, *Les Nouvelles* 156, Sept. 1992; and R. Levin, A. Klevorick, R. Nelson, & S. Winter, *Appropriating the Returns From Industrial R & D*, *Brookings Papers on Economic Activity* 3, 783-831 (1987).

[n.41] R. Rapp and Rozek, *supra* note 40.

[n.42] "Although largely invisible, an intellectual property system which protects innovation and creative expression may be viewed as a helpful precondition to creating and using new technology which boosts economic growth and aids development. From this point of view, the intellectual property protection system may be considered a valuable part of a country's infrastructure." Sherwood, *supra* note 39, at 6.

[n.43] "An example is the know how required to switch from the use of CFCs [...] as a refrigerant to other substances, which often have a lower molecular size. While the basic refrigeration cycle remains the same, devices, such as air conditioners, using the new refrigerants would have to be redesigned to, among other things, provide tighter fits between parts which come into contact with the refrigerant so as to prevent leaks. While the patent may fully describe the new substances useful as refrigerants, and the way in which they can be made, it need not disclose the know-how needed to make air conditioners which can operate using them." International Bureau of WIPO, *supra* note 7 at 6.

[n.44] Emmert, *supra* note 26; also see Barks, *Accessing and Licensing Federal Technology*, 15 *Licensing Law & Business Report* 73, 76 (1992), for each commercialized product, it has been estimated that for every \$1 spent on research, \$10 was spent on development and \$100 was spent on bringing the product to market. Additionally, "recent reports show estimated losses [due to piracy] of up to \$50 billion annually for U.S. industries alone;" Emmert, *supra* note 26 referring to *Foreign Protection of I.P. Rights and the Effects on the U.S. Industry and Trade*, U.S.I.T.C. Pub. 2065, Inv. No. 332-245 (Feb. 1988).

[n.45] Sherwood, supra note 39, at 7.

[n.46] R. Rapp and R. Rozek, supra note 40 at 164.

[n.47] R. Rapp and R. Rozek, supra note 40 at 164.

[n.48] "... intellectual property can promote competition. It can encourage firms to compete through the development of new technology and thereby can result in additional choices for consumers, new and better products and services and cheaper prices," Andewelt, *The Antitrust Divisions Perspective on Intellectual Property Protection and Licensing--The Past, The Present, and the Future*, remarks before the American Bar Association, Patent, Trademark & Copyright Section, London, England, July 1985, as cited in Sherwood supra note 39, at 53.

[n.49] R. Rapp and R. Rozek, supra note 40 at 167.

[n.50] The use of substandard counterfeit product may be hazardous to an entire industry; e.g., the loss of 15% of the Kenyan coffee crop due to the use of an ineffective fungicide imitation; National Security and International Affairs Division, General Accounting Office, *Strengthening World Wide Protection of Intellectual Property Rights*, (1987).

[n.51] Tropical diseases cause about one half of all the illness in the world; S. Okie, 500 Million Infected with Tropical Ills; Research Control Efforts Lagging, *Washington Post* (28 March 1990). A4.

[n.52] "Most developing nations in South America, Africa, parts of Asia, do not accept patents ... And there's very little being done on tropical disease because people know that if they develop a drug, the market will be immediately overtaken by other people." Furland, *Betting the Farm on Research*, *New York Times*, September 27, 1988; as cited in Mansfield, supra note 29.

[n.53] Sherwood, supra note 39; Sherwood, supra note 40.

[n.54] Mansfield, supra note 29.

[n.55] Also see Rapp & Rozek, *supra* note 40; Levin, Klevorick, Nelson, & Winter, *supra* note 40; and Frischtak, *Harmonization vs Differentiation in IPR Regimes*, a paper prepared for the Conference "The Global Dimensions of Intellectual Property Rights in Science and Technology," Washington, D.C., January 8-9, 1992.

[n.56] *World Intellectual Property Report*, Vol. 7, No. 3, March 1993 p 60 (BNA).

[n.57] The worlds poorest countries, these nations "are generally characterized by low per capita incomes, literacy levels, and medical standards, subsistence agriculture, and a lack of exploitable minerals and competitive industries." *Business America*, September 29, 1986, reprinted in R. Folsom, et al, *International Business Transactions* 10 (Doc.Sup.1991); "they are nations which have not successfully exploited their natural resources and have yet to successfully utilize their human resources," R. Folsom, et al, *International Business Transactions* 15 (1991).

[n.58] For example, India or China.

[n.59] "Relatively advanced developing countries whose industrial production and exports have grown rapidly in recent years. Examples include Brazil, Hong Kong, Korea, Mexico, Singapore and Taiwan." Folsom *supra* note 57 at 12.

[n.60] According to C. Frischtak of the World Bank, a move towards uniformity based solely upon the parameters existing in more advanced nations would probably not be Pareto Superior from a utilitarian perspective, and certainly would not be considered optimal from an egalitarian or Rawlsian perspective, Frischtak, *supra* note 55; also see, Rawls, *A Theory of Justice*, Harvard University Press, 1971.

[n.61] See *Merges*, *supra* note 6 at 884-893.

[n.62] "Thus the broad Edison patent slowed down progress in the incandescent lighting field." *Id.* at 887.

[n.63] "As to Ford, the Selden patent did not stop him, but it did slow him down." *Id.* at 890.

[n.64] "There is good reason to believe that the Wright patent significantly held back the pace of the aircraft development in the United States by absorbing the energies and diverting the efforts of people like Curtiss." *Id.* at 890, 891.

[n.65] COMMERCIALIZATION LEAD TIMES

Industry	Years
Consumer Products	2-5
Biomedical	5-10
Electronics	5-15
Aerospace	5-15
Machine Tools	10-20
Automotive	10-20
Energy	15-20

Ronald Barks, Accelerated Product Development with Licensed Federal Technology, presented at LES Eastern Regional Conference, Hilton Head, S.C., June 1992.

[n.66] Harmon, *Patents and the Federal Circuit*, second ed., 9, (1991 BNA).

[n.67] *Supra* note 63.

[n.68] J. Sweeney, C. Oliver & N. Leech, *The International Legal System*, 323 (1988).

[n.69] Field, *supra* note 26, at 7.

[n.70] As discussed in Section IV.B. of this paper.

[n.71] National Security and International Affairs Division, General Accounting Office, *supra*, note 50.

[n.72] Porter, *The Competitive Advantage of Nations*, 11 (1990).

[n.73] The dispute settlement mechanism for the Patent Law Treaty is set forth in Article 30 of the proposed draft Treaty Supplement to the Paris Convention for the Protection of Industrial Property As Far As Patents Are Concerned, World International Patent Organization, 1991.

[n.74] It should be noted that while the "international competence of GATT to deal with questions of intellectual property can [...] hardly be questioned," Joos & Moufang, Report on the Second Ringberg Symposium, printed in Beier & Schriker, *IIC Studies--Studies in Industrial Property and Copyright Law*, Volume 11, 77, (1989); the belief that GATT is the proper forum for intellectual property protection is not unanimous, "[t]he reasons underlying the GATT approach may cast new discredit on intellectual property, change the nature and understanding of intellectual property protection and result in the introduction of different compensatory actions at the national level in the countries sought to be 'domesticated' to GATT--standards of intellectual property protection," Ullrich, *GATT Approach, Fair Trade and Development*, printed in Beier, at 127, 130.

[n.75] Sadler, *Intellectual Property Protection Through International Trade*, 14 *Houston J.Intl.L.* 393, 423 (1992).

[n.76] Joos & Moufang, Report on the Second Ringberg--Symposium, as printed in Beier, *supra* note 74 at 25. An additional basis for the United States' desire to include intellectual property protection in GATT may be related to the experience of the U.S. delegates during the Paris Convention revision conference, and their subsequent belief that it would not be possible to raise the level of intellectual property protection in this forum, K. Hallstein, *The U.S. Proposal for a GATT--Agreement on Intellectual Property and the Paris Convention for the protection of Industrial Property*, as printed in Beier, *supra* note 74 at 25.

[n.77] Leaffer, *supra* note 28.

[n.78] Folsom, *supra* note 57 at 18.



[n.79] All other GATT principles can basically be derived from this clause, Kretschmer, *The Present Position of the U.S., Japanese, and European Industry*, as printed in Beier, *supra* note 74 at 93, 103. Additional fundamental principles of GATT, that can be said to be included within the most favored nation clause, are transparency, binding dispute resolution mechanism, and provisions for retaliation or countervailing measures, see Barrigar, *supra* note 36.

[n.80] Ministerial Declaration on the Uruguay Round of Multilateral Trade Negotiations-Statement by the Chairman, 25 I.L.M. 1623 (1986).

[n.81] A. Dunkel, *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Submitted by GATT Director General Arthur Dunkel*, 6 *World Int.Prop.Rep.* 42 (1992).

## APPENDIX A

### A SURVEY OF NON WORKING & COMPULSORY LICENSING PROVISIONS EXISTING IN VARIOUS COUNTRIES [n.82]

#### African Intellectual Property Organization:

Non Working Provision: 3 years after patent grant or after 3 years of non-working.

Dependent Patent: May be granted to the extent necessary to allow the later patentee to use his invention, (earlier patentee may cross license).

#### Albania:

Dependent Patent: The patentee is granted a patent of dependence and may only practice the invention with the consent of earlier patentee.

#### Algeria:

Non Working Provision: 3 years after grant or 4 years from application date if not adequately worked.

Dependent Patent: May be granted to the extent necessary to allow the later patentee to use his invention, (earlier patentee may cross license).

Antigua:

No Provisions

Argentina:

Dependent Patent: Resolved by grants of patents of addition.

Australia: [n.83]

Non Working Provision: 3 years after grant if inadequately worked. Importation of the patented products is considered working. Inadequately worked means that the reasonable requirements of the public with respect to the patented invention have not been satisfied; and the patentee has given no satisfactory reason for failing to exploit the patent. The reasonable requirements of the public with respect to the patented invention are taken not to have been satisfied if the nonworking of the patent unfairly prejudices existing trade or industry in Australia, the establishment of new trade or industry in Australia, or if public demand is not met.

Austria: [n.84]

Non Working Provision: 3 years after grant or 4 years after application if inadequately worked; unless it is shown that the invention could not reasonably have been worked.

Dependent Patent: A compulsory license may be granted to a patentee of an invention of considerable commercial or industrial significance which cannot be worked without the use of the invention patented earlier. A cross license may be granted.

Bahamas: [n.85]

No Provisions

Bahrain:

No Provisions

Bangladesh:

No Provisions

Barbados: [n.86]

Non Working Provision: If after 4 years from filing date, or 3 years after patent grant, the invention for which a patent has been issued is not used or is insufficiently used. Importation constitutes working.

Dependent Patent: If the invention is an important technological advance the Director of the Industrial Property Office may, if requested, grant a statutory license to prevent infringement of the earlier patent. A cross license may be granted.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Belgium: [n.87]

Non Working Provision: 3 years from grant or 4 years from application date if inadequately worked or if needed to work another patent.

Dependent Patent: Compulsory license will be granted to the extent necessary to exploit the patented invention, patentee will receive adequate compensation in an amount fixed by either the parties or the Court.

Belize:

No Provisions

Bermuda:

No Provisions

Bolivia: [n.88]

Non Working Provision: 3 years after grant or 4 years after application if inadequately worked, or if working interrupted for any 1 year period, unless force majeure can be shown.

Brazil:

Non Working Provision: 3 years after grant or if work interrupted for more than 1 year.

Note: Brazil has recently signed the Stockholm revision of the Paris Convention, thus prior to requesting cancellation of a patent due to non- working a third party must first request a compulsory license.

Brunei:

No Provisions

Bulgaria:

Non Working Provision: 3 years after grant or 4 years after application. Importation of the patented products is considered working.

Dependent Patent: The patentee is granted a patent of dependence and may only practice the invention with the consent of earlier patentee.

Burundi:

No Provisions

Canada: [n.89]

Non Working Provision: May be ordered by Commissioner 3 years after grant, and if licenses are insufficient, patent may be revoked.

Food & Medicine: Unless he sees good reason to the contrary the Commissioner shall grant a license in the case of any patent intended or capable of being used in the preparation or production of food or medicine. The royalty shall be set having regard to the desirability of making the food available to the public at the lowest price while giving to the inventor due reward for the research leading to the invention. In the case of a license for the import and subsequent sale of medicine the compulsory license granted thereon may not be exercised until: 1.7 years after the date of Notice of Compliance that is first issued in respect to the medicine, where as of June 27, 1986 the notice of compliance has been so issued and either a compulsory license or a Notice of Compliance has been obtained by an individual other than the Patentee; 2.8 years after the notice of compliance as set forth supra, where neither a compulsory license nor a Notice of

Compliance has been issued to someone other than the Patentee; 3.10 years after the date of the notice of compliance, where the notice is issued after June 27, 1986.

In all other cases, including the case where the drug is manufactured and sold in Canada, the licensee is prohibited from using the license until 7 years after the date of notice of compliance, where the notice of compliance that is first issued is issued after June 27, 1986.

Chile: [n.90]

Misc.: Non voluntary licenses may only be granted where the patent holder has committed a monopoly abuse according to the Resolution Committee established under Decree-Law no. 211 of 1973.

China: [n.91]

Non Working Provision: In the area of pharmaceuticals, the granting of a compulsory license when the U.S. patent holder does not manufacture the product in China is now prohibited due to a recent US/China agreement (March 17, 1992). May be granted on an earlier patent if it is blocking exploitation of a later patent.

Dependent Patent: Where the later patented invention is technically superior to an earlier patented invention, the junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Note: Documents must be given to the Patent Office showing that the entity requesting the compulsory license was unable to conclude a license contract with the patentee on reasonable terms.

Columbia: [n.92]

Non Working Provision: 3 years after grant or 4 years after filing, (whichever last expires) if patent not adequately worked, and if force majeure is not shown.

Dependent Patent: Owner may apply for a License of Authority.

Food & Medicine: Any interested party may apply to the Patent Office for a non-exclusive license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Costa Rica:

**Dependent Patent:** Both the junior and senior patentee may acquire a compulsory license if the licensee is required to work the patent industrially in Costa Rica.

**Food & Medicine:** Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

The article specifically mentions medicine and agricultural chemicals as enjoying a proven public interest.

Croatia: [n.93]

**Non Working Provision:** 3 years from grant or 4 years from filing date, if inadequately worked, if working is interrupted for any 3 year period, or if needed to work another patent. The request will be denied if there is a well- founded acceptable excuse for the non-working. Importation will most probably not be deemed sufficient working. The compulsory license will only be granted if petitioner proves that he has requested a license from a patentee who refused to grant said license, and he is capable of working the invention. The license granted will be non-exclusive. If the invention is not exploited 2 years after the grant of a compulsory license, the revocation of the patent may be requested.

**Dependent Patent:** An application for compulsory license may be submitted 4 years after the filing date or 3 years after the registration date, (whichever is later), and may be granted if it is shown that the patent cannot be used without the license, and the invention represents a significant technical progress of special importance to the economy. A cross license is available to the Senior Patentee.

**Food & Medicine:** An official license may be granted if the patented invention is of general social interest. When determining whether to grant an official compulsory license, (a compulsory license in the public interest) the patent office must obtain a prior written opinion from both the Chamber of Commerce and the Council of Industrial Property.

**Note:** Official compulsory licenses may also be granted on patented inventions that are used to achieve unreasonably high prices on the Croatian market; inventions in the field of national defense or to protect or improve the environment; or those inventions which are particularly important for certain branches of the economy. In determining reasonable royalty the Patent Office must obtain an opinion from the Council of Industrial Property Office.

Cuba:

Non Working Provision: 3 years after grant, extensions available. Importation of the patented products is considered working.

Dependent Patent: If related to a technologically important accomplishment an obligatory license may be granted.

Food & Medicine: Only form of protection is an inventor's certificate.

Czechoslovakia: [n.94]

Non Working Provision: Use of a patent in the public interest may be ordered 4 years after filing or 3 years after grant, (whichever is later).

Dependent Patent: The patentee is granted a patent of dependence and may only practice the invention with the consent of earlier patentee.

Denmark: [n.95]

Non Working Provision: 3 years after grant and 4 years from application filing date, if inadequately worked, unless non working was due to a legitimate reason.

Dependent Patent: Junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Misc.: When required by important public interests.

Dominican Republic:

No Provisions

Ecuador: [n.96]

Non Working Provision: 3 years after grant or 4 years after application if inadequately worked, or if working interrupted for any 1 year period, unless force majeure can be shown.

Egypt:

Non Working Provision: 3 years after grant if inadequately worked, if working interrupted for any 2 year period, or if needed to work another invention.

Dependent Patent: If working the invention is of great importance to the industry, and if the owner refuses to license on reasonable terms, a compulsory license may be granted. If the earlier patent is of greater importance, the earlier patentee may be granted a compulsory license.

El Salvador:

Non Working Provision: 3 years after grant or working interrupted for more than 3 years.

Fiji:

No Provisions

Finland: [n.97]

Non Working Provision: 3 years after grant and 4 years from application, if inadequately worked or if needed to work another patent.

Dependent Patent: 3 years from grant or 4 years from application of the earlier patent, the junior patentee may obtain a non-exclusive compulsory license to the extent necessary to practice his invention, provided he can show the invention represents an important technological advance. The senior patentee may then obtain a cross license.

France: [n.98]

Non Working Provision: 3 years after grant or 4 years after filing, if inadequately worked, or if working discontinued for any 3 year period.

Dependent Patent: Junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Food & Medicine: If it is in the interest of public health, and if the medicine is made available to the public in insufficient quantity or quality or at abnormally high prices, the Minister of Health may grant a special ex-officio-license.

Germany: [n.99]



Food & Medicine: Germany recently granted its first compulsory license in a pharmaceutical case, in over 40 years. Judgment of 7 June 1991--3 Li 1/90 (EU) concerning a patent for a polypeptide with antiviral properties. § 24 of German Patent Act as translated provides: If the [...] patentee refuses to permit the exploitation of the invention by another [...] offering to pay reasonable compensation and to furnish security therefore, that person shall be given authority to exploit the invention if permission is indispensable to the public interest.

Greece: [n.100]

Non Working Provision: If a period of 3 years has elapsed since patent grant or 4 years has elapsed since patent application, the invention has not been worked in Greece sufficiently to cover local demand, and there is no justification for this non working, the entity requesting the license is in a position to work the invention, this entity notified the patentee one month prior to the institution of legal proceedings as to their intentions, then a compulsory license may be issued.

Dependent Patent: May be granted to the extent necessary to allow the later patentee to use his invention, (earlier patentee may cross license).

Food & Medicine: For imperative reasons of public health, if the invention has been insufficiently exploited to satisfy local needs a license may be granted to exploit said invention.

Guatemala:

Non Working Provision: 1 year after grant if inadequately worked or if working interrupted for any 3 month period.

Dependent Patent: Owner may apply for a License of Authority. Compulsory license will be granted to the extent necessary to exploit the patented invention, patentee will receive adequate compensation in an amount fixed by either the parties or the Court.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Note: in Guatemala only processes for the manufacture of foods and medicines are patentable.

Guyana:

Non Working Provision: 3 years after grant if inadequately worked.

Haiti:

No Provisions

Honduras: [n.101]

Non Working Provision: If not worked within 1 year of grant, or if the enterprise or industry is abandoned for more than 1 year after having been established, the patent lapses.

Hungary: [n.102]

Non Working Provision: 4 years after filing or 3 years from grant, (whichever is later). Importation of the patented products is considered working.

Dependent Patent: Compulsory license will be granted to the extent necessary to exploit the patented invention, patentee will receive adequate compensation in an amount fixed by either the parties or the Court.

Misc.: For reasons of national defense.

Iceland:

Non Working Provision: 5 years after grant if inadequately worked, or 3 years after grant if needed to work another patent.

Dependent Patent: The patentee is granted a patent of dependence and may only practice the invention with the consent of earlier patentee.

India: [n.103]

Non Working Provision: 3 years after grant for inadequate working.

Note: in India a statement must be filed each year informing the Patent Office as to the extent of working, if any, of a patented invention.

Dependent Patent: May obtain a license, must cross license on reasonable terms.

Food & Medicine: The royalty terms of a license concerning a patent relating to foods, medicines or drugs will in no case exceed 4% of the net ex factory sale price in bulk of the patented article.

Indonesia: [n.104]

Non Working Provision: 3 years from the date of patent grant, a compulsory license application may be filed on the ground that while it was feasible to execute the patented invention commercially, the patent holder had not done so. The individual requesting a compulsory license must be capable of executing the invention and said execution must be deemed beneficial to a great part of the community.

Note: If the patent is not executed within 4 years from date of issuance, said patent will be canceled. Also, if the government is of the opinion that implementation of the patent is important for the States defense and security, it may execute the patent itself.

Iran:

No Provisions

Iraq:

Non Working Provision: 3 years after grant if not adequately worked or working discontinued for 2 years.

Dependent Patent: If working the invention is of great importance to the industry, and if the owner refuses to license on reasonable terms, a compulsory license may be granted. If the earlier patent is of greater importance, the earlier patentee may be granted a compulsory license.

Ireland:

Non Working Provision: 3 years after grant or 4 years after application date if inadequately worked.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Israel: [n.105]

Non Working Provision: 3 years after grant or 4 years after application date if inadequately worked.

Dependent Patent: May be granted to the extent necessary to allow the later patentee to use his invention, (earlier patentee may cross license).

Food & Medicine: Compulsory licenses granted at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a medicine or in the production thereof;
2. a process for producing the substance set forth in (1) supra; and
3. any device usable for medical purposes.

Italy: [n.106]

Non Working Provision: 3 years after grant or 4 years after application date, (whichever is later) if inadequately worked, or if working interrupted for any 3 year period, without justification.

Dependent Patent: If concerning an important technological improvement a compulsory license may be granted, it may be granted on the condition of a cross license.

Note: Both patents must actually be granted before compulsory licensing provisions may be initiated.

Jamaica:

No Provisions

Japan: [n.107]

Non Working Provision: 3 years after patent grant or 4 years post filing if inadequately worked or if needed to work another patent. Importation of the patented products is considered working.

Dependent Patent: If needed to work the invention a compulsory license may be granted, the earlier patentee may obtain a cross license.

Jordan:

Non Working Provision: 3 years after grant if inadequately worked.

Korea, Republic of: [n.108]

Non Working Provision: If 4 years has passed from application date of the patent and one of the following conditions is satisfied:

1. not worked in Korea for 3 or more years, and such non working was not caused by a justifiable reason;
2. not worked on a considerable commercial scale for 3 or more consecutive years without any justifiable reason or has not satisfied the domestic or export demand thereof;
3. patentee has unreasonably refused to grant a license and has thereby caused a loss to an industry, to the state, or to the business of a domestic resident.

Where the patented invention has not been continuously worked in the Republic of Korea during a period of 2 years or more from the date of the arbitration decision resulting in a compulsory license, the Administrator of the Office of Patents Administration may cancel the patent right either ex officio or upon the request of an interested person. While the Act now defines working to include importation, there is some doubt as to whether the KIPO will count importation alone as working.

Dependent Patent: If a patentee wishes to obtain a license and the other party refuses to grant such a license without cause, and if the invention covered by the junior patent constitutes a substantial technical advance as compared with the senior party's patented invention or registered utility model, then the patentee may demand a trial for granting a nonexclusive license within the scope of what is necessary to work the patented invention. A cross license may be granted.

Misc.: A non exclusive compulsory license may be required if the working of the patented invention is necessary in the public interest.

Kuwait:

Dependent Patent: If the invention is of great importance, a compulsory license may be granted.

Lebanon:

No Provisions

Lesotho: [n.109]

Non Working Provision: 4 years from filing date or 3 years from patent grant, (whichever is later) if the invention was not sufficiently worked a compulsory license may be granted to an entity which proves its ability to work the invention.

Libya:

Non Working Provision: Can be ordered at any time.

Luxembourg:

Non Working Provision: After 3 years.

Malawi:

Non Working Provision: If patent not sufficiently worked within 3 years.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Malaysia: [n.110]

Non Working Provision: 3 years after patent grant if the invention is not being worked without any legitimate reason, or the level of working does not satisfy public demand.

Dependent Patent: If the invention is an important technical advance in relation to the invention claimed in the earlier patent, a compulsory license may be granted to the extent necessary to avoid infringement of the earlier patent.

Malta:

Non Working Provision: If not worked in 3 years.

Mauritius:

No Provisions

Mexico: [n.111]

Non Working Provision: If not worked in 3 years of issue, or 4 years from application filing, if working suspended for more than 6 months, if working fails to meet national demand, or if export markets exist which are not being supplied by working the patent. Importation constitutes working. Prior to granting the compulsory license the Secretariat shall give the patent owner the opportunity of working the patent within a period of 1 year from the date of notification.

Monaco:

Non Working Provision: If not worked within 3 years of grant.

Mongolia: (Draft version) [n.112]

Non Working Provision: If not worked within 5 years from date of grant, without justifiable reason.

Morocco:

No Provisions

Namibia:

Non Working Provision: If not worked within 2 years.

Nauru:

No Provisions

Netherlands: [n.113]

Non Working Provision: 3 years after grant if not adequately worked.

Dependent Patent: Patentees are bound to license and cross license, but only to the extent required to use the licensee's patent. Patentee is not required to license a European patent until the period for opposition has ended. A compulsory license granted on the grounds of dependence shall not terminate if the dependent patent lapses through no fault of the owner.

New Zealand: [n.114]

Non Working Provision: At any time for foods and medicines; revocation of patent after 2 years if licensing not satisfactory.

Dependent Patent: 3 years after the date of sealing a patent any person interested may obtain a compulsory license if the working of an invention which makes a substantial contribution to the art is hindered and if the patentee refuses to license the required patent. This may be subject to a requirement to cross license.

Note: There do not appear to be any compulsory licensing decisions in New Zealand in this area.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Nicaragua:

No Provisions

Nigeria:

Non Working Provision: 3 years from grant or 4 years from application date if inadequately worked. Importation of the patented products is considered working.

Dependent Patent: If the 2 inventions serve different industrial purposes a compulsory license may be granted to the extent required to practice the invention, if the industrial purposes are similar a cross license will be required.

Food & Medicine: The Federal Commissioner for Trade may provide for the grant of a compulsory license if the patented product or process is declared to be of vital importance to the defense or economy of Nigeria, or for public health. This could include:

1. any drugs or pharmaceutical preparations, substances and materials; and
2. any plant, machinery or apparatus, whether fixed to the land or not after importation.

Norway: [n.115]

Non Working Provision: 3 years from grant and 4 years from application date if inadequately worked.



Dependent Patent: Junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Misc.: When required for important public interests.

Pakistan: [n.116]

Non Working Provision: 4 years from application date if demand is not being met to an adequate extent and on reasonable terms, and the patentee is unable to give satisfactory reasons for his default.

Panama:

No Provisions

Paraguay:

Non Working Provision: If not worked for any 3 year period.

Peru: [n.117]

Non Working Provision: 3 years after grant or 4 years after application if inadequately worked, or if working interrupted for any 1 year period, unless force majeure can be shown.

Dependent Patent: A license may be granted to the extent required to practice the invention, the national office will fix the terms of the agreement.

Food & Medicine: Patents relating to public health or national development requirements may be the subject of a compulsory license at any time.

Philippines: [n.118]

Non Working Provision: 2 years from grant if patent not worked on a commercial basis, and if there is no reasonable explanation for this non-working; if the demand for the patented article in the Philippines is not being met to a reasonable extent and on reasonable terms; if due to the refusal of the patentee to grant a license the establishment of new trade or industry in the Philippines is being prevented or unduly restrained; if it relates to food or medicine or the article is necessary for public health or safety. It is noted that the bulk of applications concern food or medicine. In each of these cases the

petitioner must prove that he has the capability to work the patented product. Working is defined as the manufacture and sale. Importation does not constitute working.

**Dependent Patent:** So long as the invention serves a different industrial purpose, or concerns an important technological improvement, a compulsory license may be granted to the extent required for working the invention.

**Food & Medicine:** If the patented product or process is deemed of vital importance to the country's defense or economy or public health, compulsory licenses may be granted by the National Economic Development Authority. This may occur prior to the expiration of the normal working period of 2 years from grant. As stated above, any person may apply for a compulsory license 2 years from the date of patent grant if the invention relates to food or medicine, manufactured products or substances which may be used as food or medicine, or an invention which is necessary for public health or safety.

**Note:** The 2 year time period is in contravention to the Paris Convention.

**Poland:** [n.119]

**Non Working Provision:** 3 years from grant or 4 years from application date, (whichever is later) if the invention is not worked sufficient to meet the needs of the national economy.

**Dependent Patent:** May be granted if the compulsory license is needed to apply an invention subject to an earlier patent.

**Misc.:** If needed for the realization of tasks specified by economic plans.

**Note:** The Patent Office compulsory license decision will specify the method and amount of payment. After 2 years the license terms may be changed at the request of an interested party. All licenses are non-exclusive. During the past 20 years only 2-3 of such licenses have been granted per year, with only approximately 2 of these cases involving foreign patents.

**Portugal:**

**Non Working Provision:** 3 years from grant if inadequately worked, if working interrupted for any 3 year period, or if needed to work another patent.

**Romania:** [n.120]

**Non Working Provision:** 4 years from application date or 3 years from grant if not sufficiently worked.

Misc.: In the interests of national defense or State security.

Russia: [n.121]

**Non Working Provision:** If an invention or industrial design is not exploited within 5 years following the date of publication of patent grant, or if a utility model is not exploited within 3 years from the date of publication of patent grant, and if there is no justifiable cause for the nonexploitation, an individual willing and able to exploit the invention may file suit with the Patent Court of the Russian Federation for an involuntary license.

**Dependent Patent:** If the patentee may not use the invention, utility model, or industrial design without infringing the rights of another patentee, he has the right to require the latter to conclude the license agreement.

Rwanda:

No Provisions

Slovenia: [n.122]

**Non Working Provision:** If the patentee does not work, or does not sufficiently work the patented invention, and this nonworking is not justified, or if the demand is primarily satisfied through importation, then a compulsory license may be granted.

**Dependent Patent:** If the working of the later patented invention is of special importance for the economy or is in the public interest with respect to meeting the social needs of health service or national defense, then a compulsory license may be granted. If such a license is granted, a cross license may also be issued.

**Note:** An application for a compulsory license may not be filed until 3 years after patent grant, or 4 years after application, whichever is later.

South Africa:

**Non Working Provision:** 3 years from grant or 4 years from application date, (whichever is later) if inadequately worked, needed to work another patent, or for foods, plants or medicines.

**Dependent Patent:** Commissioner may grant a compulsory license, which may only be used to work the patent.

Spain: [n.123]

Non Working Provision: 4 years from application date or 3 years from grant if not worked. So long as a certificate of working has been filed with the Registry of Industrial Property, it shall be presumed that the patented invention is being worked in the form required by Section 84 of the present law.

Dependent Patent: May be granted to the extent necessary to allow the later patentee to use his invention, so long as the invention has distinctive industrial objectives or represents considerable technical progress in comparison with the earlier patent. The compulsory license is only to be sufficient to allow working of the dependent invention. The earlier patentee may obtain a cross license.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Compulsory cross licenses for patents concerning chemicals and pharmaceutical processes and products. The grant of compulsory licenses for inventions relating to the public health.

Misc.: For reasons of public interest; i.e., when the initiation, increase or generalization of working the invention, or improvement of the conditions in which it is worked, are of paramount importance for public health or national defense.

Sri Lanka:

Non Working Provision: 3 years from application date if inadequately worked.

Sudan: [n.124]

Non Working Provision: 3 years from patent grant, or 4 years from application date, (whichever is later) a compulsory license may issue if the working of the invention does not satisfy on reasonable terms the demand for the product, if working within the Democratic Republic of Sudan is being hindered due to importation of the patented invention, or if due to the patentee's refusal to grant licenses on reasonable terms the establishment or development of industrial or commercial activities in the Democratic Republic of Sudan is unfairly and substantially prejudiced.

Dependent Patent: If the invention concerns an important technological improvement or will effect a different industrial purpose, a compulsory license may be granted.

Food & Medicine: Should the patented item be declared of vital importance for the defense, economy, or public health a compulsory license may be granted. This may occur prior to 4 years from date of application or prior to 3 years from date of patent grant.

Sweden: [n.125]

Non Working Provision: 3 years from grant and 4 years from application date if inadequately worked.

Dependent Patent: Junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Misc.: When required by public interests of extreme importance.

Switzerland: [n.126]

Dependent Patent: When the invention serves a different industrial purpose or represents a great advance a compulsory license may be granted. If the inventions serve the same industrial purpose a cross license may be required.

Non Working Provision: After 3 years from patent grant and 4 years from filing the application, any person capable of justifying a legitimate interest may apply to the court for the grant of a license to use the invention, if at that time the patentee has not sufficiently worked his invention in Switzerland and is unable to justify his failure to do so.

Misc.: Compulsory licenses may be granted when to do so would be in the public interest.

Syria:

No Provisions

Taiwan:

Non Working Provision: If invention is not properly put into practice after 4 years from patent grant, the Patent Office may, upon request from an interested party grant special permission to such party for putting it into practice. Compensation shall be decided by the Patent Office. If this invention is not practiced within 2 years from the rendering of

permission, and there are no proper reasons for such non use, the Patent Office may revoke the patent at the request of an interested party.

Dependent Patent: If the invention is a manufacturing process which would promote the public welfare, the Process Patentee may ask the Patent Office to fix the appropriate compensation to permit the product to be processed through the patented process.

Tangier Zone:

Dependent Patent: Junior patentee may obtain a compulsory license, senior patentee may obtain a cross license.

Thailand: [n.127]

Non Working Provision: 3 years from grant if not worked properly.

Dependent Patent: If the invention is important, or can satisfy the people's need, if the right of another patentee will not be unreasonably damaged, and if the applicant cannot reasonably exercise his invention without the license, a license may be granted.

Note: Applicants for the compulsory license must first attempt to seek licenses from the patentee before applying for same with the Director, General.

Misc.: A compulsory license may be granted in order to carry out any service for public consumption or which is of vital importance to the defense of the country or for a search for natural resources or the agriculture or industrial development or for any other public service.

Trinidad/Tobago:

No Provisions

Tunisia:

No Provisions

Turkey:

Non Working Provision: 3 years from grant if inadequately worked, or if working interrupted for any 2 year period.

United Kingdom: [n.128]

Non Working Provision: 3 years from grant if inadequately worked and if the patent application was filed prior to June 1, 1978.

Dependent Patent: 3 years after the date of sealing a patent any person interested may obtain a compulsory license if the working of an invention which makes a substantial contribution to the art is hindered and if the patentee refuses to license the required patent. This may be subject to a requirement to cross license.

United States of America:

As a remedy in antitrust cases, Atomic Energy Act, Clean Air Act, 28 U.S.C. § 1498(a).

Uruguay:

Non Working Provision: 3 years from grant if not worked.

Venezuela: [n.129]

Non Working Provision: 3 years after grant or 4 years after application if: there is a scarcity of industrial production of the patented invention; or the patented product is not distributed, sold or imported in levels sufficient to satisfy the market in competitive conditions of quality and price; or if working is interrupted for any 1 year period.

Dependent Patent: Applicant must prove the need to use the other patent, and prove that they were unable to obtain a license from the patent owner under reasonable conditions. The license will be nonexclusive and the licensee must pay the owner of the patent adequate compensation.

Misc.: Compulsory licenses may be granted for reasons of public interest, national security, in cases of emergency, to assure free competition and to avoid abuses on the part of the patent owner or abuses due to a dominant market position.

Viet Nam: [n.130]

Non Working Provision: A compulsory license may be granted if the patent holder has not utilized, in the absence of justifiable reasons, the invention, or the extent of his utilization has not met the socio-economic development of the country.

Misc.: A compulsory license may be granted where the Chairman of the State Committee for Science and Technology considers it necessary to utilize the protected invention for the needs of national defense and security or of prevention and treatment of human disease and other vital public interests.

Yugoslavia (Serbia): [n.131]

Non Working Provision: 3 years from grant if inadequately worked, if working is interrupted for any 3 year period, or if needed to work another patent.

Dependent Patent: An application for compulsory license may be submitted 4 years after the filing date or 3 years after the registration date, (whichever is later), and may be granted if it is shown that the patent cannot be used without the license, and the invention represents a significant technical progress of special importance to the economy.

Food & Medicine: An official license may be granted if the patented invention is of general social interest for health purposes.

Zaire:

No Provisions

Zambia:

Non Working Provision: Immediately for food or medicine, otherwise 3 months after grant if inadequately worked.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.

Zimbabwe:

Non Working Provision: 3 years from grant or 4 years from application date if inadequately worked.

Food & Medicine: Any interested party may apply to the Patent Office for a license, at any time after the patent is sealed, if the patent concerns:

1. a substance capable of being used as a food or medicine or in the production of food;
2. a process for producing the substance set forth in (1) supra; and
3. any invention capable of being used as or as part of a surgical or curative device.



## APPENDIX B [n.132]

### ARTICLE 30: EXCEPTIONS TO RIGHTS CONFERRED

PARTIES may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

### ARTICLE 31. OTHER USE WITHOUT AUTHORIZATION OF THE RIGHT HOLDER

Where the law of a State provides for use of the subject matter of a patent, other than that set forth supra, without the authorization of the patent holder, including use by the government, or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of use shall be considered on its individual merits;
- (b) prior to application for use, the applicant must have made unsuccessful efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions. This requirement may be waived by a State in situations of extreme urgency or national emergency. In a case of this nature the patent holder shall be notified as soon as reasonably practicable. Additionally, in the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the patent holder shall be informed promptly;
- (c) the scope and duration of use shall be limited to the purpose for which it was authorized;
- (d) use shall be non-exclusive;
- (e) use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) use shall be authorized solely for the supply of the domestic market of the State authorizing such use;
- (g) authorization for use shall be subject to termination if the circumstances which led to its grant cease to exist and are unlikely to recur; the competent authority shall have the authority to review, on motivated request the continued existence of these circumstances;
- (h) the patent holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision pertaining to the authorization of such use shall be subject to review by a distinct higher authority in that State;
- (j) any decision relating to the remuneration provided in respect to such use shall be subject to review by a distinct higher authority in that State;

(k) States are not obliged to apply the conditions set forth in paragraphs B through J above, where the use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct a practice of this nature may be taken into account in the determination of appropriate remuneration in such cases;

(l) where such use is to permit the exploitation of a dependent patent the following additional considerations apply:

(i) if the dependent invention is an important technological advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent may obtain a cross license on reasonable terms to use the invention claimed in the second patent;

(iii) the use authorized in respect of the first patent shall be nonassignable except with the assignation of the second patent.

## APPENDIX C [n.133]

### ARTICLE 30: EXCEPTIONS TO RIGHTS CONFERRED

PARTIES may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

### ARTICLE 31. OTHER USE WITHOUT AUTHORIZATION OF THE RIGHT HOLDER

Where the law of a State provides for use of the subject matter of a patent, other than that set forth supra, without the authorization of the patent holder, including use by the government, or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of use shall be considered on its individual merits;

(b) prior to application for use, the applicant must have made unsuccessful efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions. This requirement may be waived by a State in situations of extreme urgency or national emergency. In a case of this nature the patent holder shall be notified as soon as reasonably practicable. Additionally, in the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the patent holder shall be informed promptly;

(c) the scope and duration of use shall be limited to the purpose for which it was authorized;

(d) use shall be non-exclusive;

(e) use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) use shall be authorized solely for the supply of the domestic market of the State authorizing such use;

(g) authorization for use shall be subject to termination if the circumstances which led to its grant cease to exist and are unlikely to reoccur, the competent authority shall have the authority to review, on motivated request the continued existence of these circumstances;

(h) the patent holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision pertaining to the authorization of such use shall be subject to review by a distinct higher authority in that State;

(j) any decision relating to the remuneration provided in respect to such use shall be subject to review by a distinct higher authority in that State;

(k) states are not obliged to apply the conditions set forth in paragraphs b through j above, where the use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct a practice of this nature may be taken into account in the determination of appropriate remuneration in such cases.

(l) where such use is to permit the exploitation of a dependent patent the following additional considerations apply:

(i) the dependent invention must be an important technological advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent may obtain a cross license on reasonable terms to use the invention claimed in the second patent;

(iii) the use authorized in respect of the first patent shall be nonassignable except with the assignation of the second patent;

(iv) a compulsory license shall be granted only to the extent necessary to exploit the patented invention;

(v) application for this license may be tendered 5 years from grant or 6 years from application of the earlier patent, (whichever is later).

(m) where the reason for such use is the non-exploitation of the patent the following additional considerations apply:

(i) an individual may apply for a nonexclusive, nontransferrable compulsory license for the use of an invention in the public interest, on the ground of failure to work or insufficient working;

(ii) said application may be made after the expiration of 5 years from the date of patent grant or if the invention is inadequately worked for any 2 year period after this date;

(iii) the application shall be refused if the patentee justifies his inaction by legitimate reasons;

(iv) forfeiture of the patent shall not be provided for except where the grant of compulsory licenses is not sufficient to prevent abuses;

(v) forfeiture or revocation of a patent will not be instituted before the expiration of 5 years from the grant of the first compulsory license;

(vi) working shall include importation of the patented product.

(n) Inventions relating to food and medicines are to be accorded no special status. A compulsory license shall be granted in the case of an invention pertaining to food or medicine only if the applicant qualifies for such a license through a differing compulsory licensing provision.

[n.82] See Generally, Baxter, *World Patent Law and Practice* (1992); and Scott, *Compulsory Licensing of Intellectual Property in International Transactions*, 11 *E.I.P.R.* 319 (1988).

[n.83] *Patents Act 1990*, chapter 12; as reported in *Industrial Property Laws and Treaties*, World Intellectual Property Organization, Volume 1.

[n.84] *Patent Law*, (*Patentgesetz 1970*), *Bundesgesetzblatt für die Bundesrepublik Österreich* § 36; as reported in *Industrial Property Laws and Treaties*, World Intellectual Property Organization, Volume 1.

[n.85] *Industrial Property Act 1965*, No. 85 of 1965; as reported in *Industrial Property Laws and Treaties*, World Intellectual Property Organization, Volume 2.

[n.86] *Patents Act, 1981--55*, Supplement to Official Gazette, December 28, 1981 and June 18, 1984; as reported in *Industrial Property Laws and Treaties*, World Intellectual Property Organization, Volume 2.

[n.87] *Patent Law*, (*Loi du mars 1984 sur les brevets d'invention*), *Moniteur belge*, March 9, 1985, p. 2774, § 31, as reported in *Industrial Property Laws and Treaties*, World Intellectual Property Organization, Volume 2; Glas, *Compulsory Patent Licensing*, 7 *EIPR* 264 (1989).

[n.88] *World Intellectual Property Report*, Vol. 6, No. 2, Feb. 1992 p 27 (BNA).

[n.89] *Canadian Patent Act* § 39 (1989); but note, "[t]he Canadian Parliament gave initial approval November 18 to Bill C-91, which would extend patent protection and eliminate compulsory licensing of patented drugs;" *World Intellectual Property Report*, Vol. 7, No. 3, March 1993 p 60 (BNA).

[n.90] *Law No. 19.039 Establishing the Rules Applicable to Industrial Titles and the Protection of Industrial Property Rights*, (*Ley Num. 19.039 Establece normas aplicables a*

los privilegios industriales y proteccion de los derechos de propiedad industrial) Diario Oficial de la Republica de Chile, No. 33.877 of January 25, 1991, pp. 1 et seq, as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 2.

[n.91] Patent Law of the People's Republic of China, Adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on March 12, 1984, Amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 27th Session of the Standing Committee of the Seventh National People's Congress on September 4, 1992, Chapter VI.

[n.92] World Intellectual Property Report, Vol. 6, No. 2, Feb. 1992 p 27 (BNA).

[n.93] Ristic's Manual of Industrial Property Rights in Eastern Europe Including the People's Republic of China, Dragoslav Ristic, 1991, confirmed by Official Gazette of Yugoslavia as adopted by Official Gazette of Croatia, Articles 139-145 and amendment of 144 in article 60 of amendments, translation by Mladen Singer.

[n.94] Law on Inventions, Industrial Designs and Rationalization Proposals, No. 527 of November 27, 1990, § 20, as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 2.

[n.95] Patents Act No. 479 of December 20, 1967, as last amended by Act No. 368 of June 7, 1989, § § 45-50, (Patentlov) as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 2.

[n.96] World Intellectual Property Report, Vol. 6, No. 2, Feb. 1992 p 27 (BNA).

[n.97] Patent Law, (Patentilaki) No. 550 of December 15, 1967, as last amended by Law No. 387 of May 10, 1985, § § 45-50, as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 3.

[n.98] Patent Law, Law No. 68-1 of January 2, 1968, as last amended and supplemented by Law No. 90-1052 of November 26, 1990, Concerning Industrial Property, (Loi sur les brevets d'invention) § § 32-41; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 3.

[n.99] World Intellectual Property Report, Vol. 6, No. 2, Feb. 1992 pp 35, 36. (BNA).

[n.100] Law on Technology Transfer, Inventions and Technical Innovation, Law No. 1733 of May 7, 1987, § § 13, 14 as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 3.

[n.101] Law on Patents, Decree No. 125 of April 1, 1919, as last amended by Decree No. 314 of February 4, 1976, (Ley de Patentes de Invencion) § 8; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 4.

[n.102] Law on Protection of Inventions by Patents, No. II of 1969, as amended by Decree-Law No. 5 of 1983, § § 21-24, as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 4.

[n.103] § 146(2) of Patents Act 1970, as reported by Ahuja, Filing of Annual Working Reports for Patents in India, 45 Pat. World 33 (1992).

[n.104] Act of the Republic of Indonesia, Number 6 Year 1989, Dated November 1, 1989, Third Part.

[n.105] Cohn, Compulsory licensing in Israel under pharmaceutical patents--a political issue?, 27 Pat. World 22 (1990).

[n.106] Law on Patents for Inventions, Royal Decree No. 1127 of June 29, 1939, as last amended by Law No. 70 of February 21, 1989, and by Law No. 349 of October 19, 1991, (Regio Decreto 29 giugno 1939, N. 1127 (Testo aggiornato delle disposizioni legislative in materia di brevetti per invenzioni industriali)) § 54; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 4.

[n.107] Japanese Laws Relating to Industrial Property, Published by the Japanese Group of AIPPI, 1988 revision, Articles 83(1) and 93; Japanese Patent Law, Tetsu Tanabe & Harold Wegner, published by AIPPI Japan in 1979, § 833; Patent Law No. 121 of April 13, 1959, as last amended by Law No. 27 of 1987; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 4.

[n.108] Laws and Enforcement Decrees of Industrial Property, The Office of Patents Administration The Republic of Korea, translated by the Office of Patents

Administration, Articles 51, 59 and 60, 1988 edition; The Korean Industrial Property Laws, Korean Invention and Patent Association, Translated by Korean Industrial Property Office, Sections 107 and 138 1991 ed.; Hee Lee, Non-Working Under Korean Patent Act, 14 Pat. World 24 (1989); Seung-ho, Compulsory Licensing Procedures, 21 IP Asia 28 (1991).

[n.109] Industrial Property Order, 1989, Order No. 5 of 1989; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.110] Patents Act 293, 1983 and Patents (Amendment) Act 1986, § § 49,49A.

[n.111] Law on the Promotion and Protection of Industrial Property, of June 25, 1991, (Ley de Fomento y Proteccion dla Propiedad Industrial); as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.112] A draft version of the Mongolian Patent Law is currently being reviewed by the Mongolian Parliament.

[n.113] Patents Act of the Kingdom of November 7, 1910, as last amended by the Act of the Kingdom of May 29, 1987, (Rijksocrooiwet) § 34; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.114] New Zealand Patent Act § § 46, 51 (1953), as described in Brown & Grant, The Law of Intellectual Property in New Zealand, § 6.67 (1989); but note the New Zealand law in this area is currently in a state of flux. December 1, 1992, special Section 51 provisions pertaining to food and medicine were abolished; BNA Patent, Trademark and Copyright Law Daily, Nov. 6, 1992.

[n.115] Patents Act No. 9 of December 15, 1967, as amended by Acts Nos. 35 of June 8, 1979, and 2 of February 8, 1980, § § 43-50; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.116] The Patents and Designs Act 1911, Act II of March 2, 1911, as last amended by Ordinance No. XXXVIII of 1983; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.117] World Intellectual Property Report, Vol. 6, No. 2, Feb. 1992 p 27 (BNA).

[n.118] Rules of Practice in Patent Cases, Republic of the Philippines Ministry of Trade and Industry, Philippine Patent Office, Makati, Metro Manila, § 34, 1984.

[n.119] Law of October 19, 1972, On Invention Activity, Articles 18, 42, 46, and 49, Dziennik Ustaw No. 33, item 177 (1984); The Uneasy Development of Intellectual Property Law in Poland, S. Soltysinski, 4 No. 5 J. Proprietary Rts. 2 1992; Treaty of March 21, 1990, Between the United States of America and the Republic of Poland Concerning Business and Economic Relations, 1992 W.L. 25037 (Polska).

[n.120] Patent Law No. 64 of October 11, 1991, (Lege privind brevetele de inventie), § § 49-54; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.121] Patent Law of the Russian Federation, Article 11, signed on October 7, 1992, published on October 14, 1992; 6 World Int.Prop.Org. 347 (1992).

[n.122] Slovenias Law on Industrial Property, Articles 113-118, as reported in 6 World Intellectual Property Report 220, 231 (1992).

[n.123] Law No. 11/1986 of March 20, on Patents, (Ley 11/1986, de 20 de marzo, de Patentes) § § 83-90; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 5.

[n.124] The Patents Act, 1971, Act No. 58 of 1971, Chapter IX; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 6.

[n.125] Patents Act No. 837 of 1967, as last amended by Act No. 433 of 1983, (Patentlag), chapter VI; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 6.

[n.126] Federal Law on Patents for Inventions, of June 25, 1954, as revised on December 17, 1976; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 6; Walter, Compulsory Licenses in Respect of Dependent Patents Under the Law of Switzerland and Other European States, 21 IIC 532 (1990).



[n.127] Patent Act B.E. 2522, part V; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 7; 45 Patent World 11 (1992).

[n.128] Patents Act 1977, as last amended by the Copyright, Designs and Patents Act 1988; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 7.

[n.129] World Intellectual Property Report, Vol. 6, No. 2, Feb. 1992 p 27 (BNA.); Grisanti, Decision 313--A New Patent and Trademark Statute in Venezuela, Oct. The Licensing Journal 15 (1992).

[n.130] Decree on the Protection of Industrial Property Rights, promulgated by Order No. 13 LCT/HDNN 8 of the State Council of February 11, 1989; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 7.

[n.131] Law on the Protection of Inventions, Technical Improvements and Distinctive Signs of June 9, 1981, as amended by the Laws of January 17 and April 11, 1990, § § 139-143; as reported in Industrial Property Laws and Treaties, World Intellectual Property Organization, Volume 7.

[n.132] A. Dunkel, supra note 81.

[n.133] See Dunkel, supra note 81, suggested additions are italicized.