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Flexibility of the TRIPS  
Agreement with Regard to  
Patent Protection

Master Thesis

20 Points

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**International Intellectual Property Law**

**Spring 2002**

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# Preface

To my parents whose love and comfort encouraged me to complete this academic pursuit.

# Acknowledgment

I hold it as a great honour to participate in the master programme on Intellectual Property and Human Rights, which is cooperated by WIPO and Raoul Wallenberg Institute. It is a pleasure to express my gratitude to all the persons who helped me in pursuing my study and research. First, I devote my very particular thanks to the WIPO Academy Director, Professor Mpazi Sinjela, RWI Professor Gudmundur Alfredsson, and Professor Zhang Naigen of Fudan University. I would like to extend my words of appreciation to Librarian Lena Olsson, Lecturer Ulf Linderfalk and all the staff from the institute. Finally, I am indebted to Lund University for financing my study and living in Sweden.

Pan Xichun

1 June 2002, Lund

# Abbreviations

|        |   |
|--------|---|
| AB     | Appellate Body  |
| DSB    | Dispute Settlement Body   |
| DSU    | <i>Understanding on Rules and Procedures<br/>Governing the Settlement of Disputes</i> |
| EC     | European Community  |
| ECJ    | European Court of Justice   |
| EU     | European Union  |
| FDI    | Foreign Direct Investment   |
| GATS   | General Agreement on Trade in Services  |
| GATT   | General Agreement on Tariffs and Trade  |
| GSP    | Generalized System of Preferences   |
| ICJ    | International Court of Justice  |
| IP     | Intellectual Property   |
| IPRs   | Intellectual Property Rights  |
| LDC    | Least Developed Country   |
| MFN    | Most Favoured Nation  |
| MNC    | Multinational Corporation   |
| PCIJ   | Permanent Court of International Justice  |
| R&D    | Research and Development  |
| TRIPS  | <i>Agreement on Trade-Related Aspects of<br/>Intellectual Property Rights</i>         |
| UN     | United Nations  |
| UNCTAD | UN Conference on Trade and Development  |
| UPOV   | <i>International Convention for the Protection of<br/>New Varieties of Plants</i>     |
| USTR   | United States Trade Representative  |
| VCLT   | <i>Vienna Convention on the Law of the Treaties</i>                                   |



|        |  |
|--------|--|
| WIPO   | World Intellectual Property Organization |
| WTO    | World Trade Organization                 |
| WHO    | World Health Organization                |
| UNHCHR | UN High Commissioner for Human Rights    |

# 1 Introduction

The legality of modern institutions relies on justifications. The will of oligarchs is no longer persuasive to civil society. Democratic representation, government, law, etc, try to justify their establishment on the acceptance by the reasoning inherent in human mind. Intellectual Property Rights (IPRs), which take the form of property rights guaranteed by the monopoly privilege, are also keen to seek justification as enthusiastic as other institutions do.

Western political and economic culture provides basic justification for IPRs both in the deontological way by Locke's Labour Theory and Hegel's Liberty Theory, and in the consequentialist way by economic utility theories. Since the theoretical basis as the premise of the justification is not without question, the conclusion is also sceptical, especially to the developing and least developed countries who are mainly of non-western political culture. The attitudes of them towards the IPRs are half support and half fear in light of different effects of IPRs protection.

However, the economic globalisation promoted by international trade does not want to leave the developing and least developed countries alone and let them to make their own legislations and policy choices according to their developing levels. Instead, globalisation calls for the international harmonization of IPRs protection.

The task of harmonization is achieved by several international IPRs conventions, through national treatment principle and few substantive provisions. However, the landmark treaty in this field is the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (the TRIPS Agreement),<sup>1</sup> adopted by the Uruguay

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<sup>1</sup> *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*, adopted on 15 April 1994, LT/UR/A-1C/IP/1.

Round negotiation of the World Trade Organization (WTO). The TRIPS Agreement is not satisfied with non-discrimination treatment but also establishes substantive protection standards as well as enforcement mechanism. Therefore, the aim of the Agreement seems to be ambitious as to the very different IPRs protection levels of the members.

How did the Agreement achieve the compromise of all members? In addition to incorporating the pre-TRIPS IPRs conventions, including their methods to limit the exclusive rights conferred to the IPRs holder, the TRIPS Agreement seeks a solution from the trade-off among the rest on the agenda of negotiation round, *e.g.* agricultural products, textile and tropical products. As the Agreement provides the availability, scope, and duration of IPRs protection, it also limits the exercise of these substantive rights for the purposes of balancing private rights and public interest, as well as balancing the demands of Intellectual Property (IP) import and export countries.

However, even embodying the limitation on the protection, there is still no consensus on certain issues such as the subject matter of protection, the international exhaustion of IPRs, the status of biotechnologies, the novelty and non-obviousness standards of patentability. These areas also extend to the exact scope of exclusive rights, as well as the exceptions to the rights. For instance, it is disputable whether a country must declare a national health emergency to invoke compulsory licensing. When the hot issues could not be resolved during the negotiation, the TRIPS negotiators adopted a drafting technique to achieve the general agreement, that is, leaving these issues open-ended and allowing a certain level of flexibility in interpretation and application.

In the regime of the TRIPS Agreement, flexibility occurs as a way of permitting agreement without full resolution in hard legal cases, providing no specific content

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for many labels of IPRs issues and offering neither objective nor positive definitions for many notions of IPRs. Consequently, although there may be certain convergence on basic rights granted, the precision of the protection conferred by the Agreement remains unclarified. Under the Agreement, applicability of the TRIPS-mandated rights can be interpreted more or less expansively depending on the role ascribed to the specific list of examples (representative or exhaustive) and the requisite level of novelty imposed. This outcome is precisely what would be expected in an international agreement driven by parties having enough negotiating leverage to force agreement but inadequate power to prevail fully. Disagreements are sufficiently masked to permit signing an accord.

Inspired by the Doha Ministerial Conference of the WTO, which reaffirmed and clarified certain flexibility in the TRIPS Agreement, this thesis undertakes to explore the flexible areas inherent in the text of the TRIPS Agreement with regard mainly to patent protection. The purpose of this exploration is to provide the law-makers of different countries, especially developing and least developed countries (LDC), a framework as to the interpretation and application of the Agreement.

A main challenge to the present thesis is how to justify the flexible interpretation and application in the light of international obligation conferred by a treaty, and how to show a good faith in the process of interpretation and application. Therefore, most arguments during the exploration of flexibility are very keen to defend their legality under international law. As a matter of fact, arguments in this thesis are not merely to clarify which areas in the TRIPS Agreement leave room of flexibility to the members, but also to draw a boundary line of the flexible room and point out where there is a non-flexibility zone.

# 2 Dialectics and Harmonization of IPRS

## 2.1 Dialectics of IPRS

### 2.1.1 Controversy of the Justification of IPRs

Justification of an institution is usually double-folded: deontological and consequentialist.<sup>2</sup> A deontological justification is provided when it is shown that it enforces certain rights which persons acting within the scope of a certain institution are entitled to; a consequentialist justification of an institution arises when it is shown that its working brings about valuable consequence, like well-being, efficiency, etc.<sup>3</sup> The deontological justification of IPRs can be derived from John Locke's Labour Theory of property acquisition and Hegel's Liberty Theory of self-identity. The consequentialist justification of IPRs lies on the economic utility. Controversy exists in both way of justification and challenges the legality of the IPRs.

Locke's Labour Theory can be regarded as the union of two basic themes. First, everyone has a property right in the labour of his own body. Second, the appropriation of an unowned object arises out of the application of human labour to that object.<sup>4</sup> Therefore morally, a person has a natural right to possess IP,

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<sup>2</sup> For the deontological and consequentialist justificatory theories, see Raz, Joseph, *The Morality of Freedom* (Oxford: Clarendon Press, 1986), ch. 11.

<sup>3</sup> For instance, the 17<sup>th</sup> century's theory of natural rights offers a deontological justification of human rights, according to which human rights are derived from human nature. On the other hand, the 19<sup>th</sup> century's utilitarianism can be seen as an instance of a consequentialist justification, which provides grounds for legal institutions by arguing that the working of such institutions produces the greatest happiness of the greatest number.

<sup>4</sup> Locke, John, "The Second Treatise", *Two Treatises on Government*, ed. Laslett, Peter, (Cambridge: Cambridge University Press, 1970), p. 305-306.

which is the product of his brain. Society is obliged to reward person to the extent that he has produced: as one sows, so should one reap.

However, this justification suffers from some difficulties. If the intelligent labour employed by a person does not offer the total value of an IP product but merely adds some new value to an existing product, like innovation, the Labour Theory does not explain the ownership over the whole product.<sup>5</sup> The history of science, technology and literature illustrates that people cannot make any invention, innovation or literal works without the intellectual heritage from ancestors. In many events, they develop a small step but achieve the whole right over the IP.

Hegel's Liberty Theory holds that property is, among other things, the means by which an individual could objectively express a personal, singular will.<sup>6</sup> Civil Society is an environment in which an individual aspires to establish a unique place of liberty, and property is the vehicle by which one's self-identity is acknowledged by others who are similarly striving for self-identity. The individual and society is in a relationship that is at least partially adversarial and civil society is a constraining environmental for individuals aspiring to establish unique moral meaning. An individual tries to establish and protect his self-identity through voluntary exchange of property, which represents the individual's will. Society is thus very limited in its right to prevent an individual's fair accumulation, holding, and dispensation of property. The needs of a society *per se* would not justify taking an individual's property — including property in the form of ideas — without fair compensation.

However, many non-western political cultures do not assume an adversarial relationship between individual and society. Islamic and some African cultures go so far as to define self-identity not according to individual liberty but according to

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<sup>5</sup> Nozick, Robert, *Anarchy, State, and Utopia* (New York: Basic Books, 1974), p. 174.

<sup>6</sup> "In Property, a person exists for the first time as a reason". See Hegel, Georg W. F., *Philosophy of Right*, translated with notes by Knox, Thomas M. (Oxford: Oxford University Press, 1942), p. 235-236.

the individual's relationship with and contribution to the society.<sup>7</sup> Therefore, a right is not a function for individual good, and the concept of property is hence different: if individual's liberty is not the basis for self-identity, then the moral foundations of property rights must rest somewhere else.

The consequentialist justification of IPRs lies on the economic motivation. IPRs, especially patent, grant a right holder a temporary monopoly over the use of the invention or the reproduction of a work, and prevent competitors from sharing or using their knowledge without payment. This enables the right holder to recoup his labour and secure his economic interests and, thus encourage the research and creative act. The degree of protection afforded to IPRs has an impact on the profits gained by the inventors and writers, and without the protection of the IPRs, much research and creativity would not be carried out.<sup>8</sup>

But this is also only partly true. No doubt less creative activity would occur without IPRs, but how much less and in what areas? In the centuries before the patent system was established or enforced, inventive and creative work had also flourished. Empirical evidence shows that protection of patent is needed not so much to promote inventions,<sup>9</sup> but to provide an incentive to engage in costly research and development (R&D) activities which turn pure knowledge into innovative products or process that can be used in industry. Further more, from the economic point of view, the IP product often has the characteristics of a public good.<sup>10</sup> That is, the value of a patent will not be diminished by the

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<sup>7</sup> African philosophy of self-identity could be summed up as, "I am because we are, and because we are therefore I am." See Mbiti, John S., *Africa Religions and Philosophy*, 2<sup>nd</sup> edition (Greenwood, 1992).

<sup>8</sup> Spector, Haracio M., "An outline of a Theory Justifying Intellectual and Industrial Property Rights", *Intellectual Property*, ed. Drahos, Peter, in *The International Library of Essays in Law and Legal Theory*, ed. Campbell, Tom D., 2<sup>nd</sup> Series (Aldershot: Dartmouth and Ashgate, 1999), p. 536-537.

<sup>9</sup> Gutterman, Alan, and Brown, Robert, *Intellectual Property Laws of East Asia* (Hong kong, Singapore: Sweet and Maxwell Asia, 1997), p. 16-21.

consumption of the patented product or process, and the marginal cost of disseminating knowledge is often zero. Consequently, from the standpoint of efficiency, the optimal allocation of resources requires that such goods have a zero price. It is true that long-term social benefit of technological development requires the protection of the IPRs, but it may also entail social costs, including the consumer's benefit and later comer's benefit from free riding.

IPRs are supposed to encourage information to be disclosed to the public and thus to increase society's pool of ideas and knowledge. For example, the condition for the application of a patent is that patented inventions have to be disclosed, allowing others to study the invention even while its patent is being protected. This helps the progress, dissemination and transfer of technology. After a certain period, the protection of exclusive rights expires. This means that the invention becomes available for others to use, which avoids re-inventing the wheel and contributes to build a new foundation of human knowledge. But sometimes the holder of an IPR prefers to impede its dissemination and application. In general, the broader the scope and the longer the duration of the IPRs, the stronger the incentive for creating IP products and the weaker the incentive for disseminating and applying them.

The consequentialist justification of IPRs also argues that countries with strong patent systems typically experience more rapid economic growth and development.<sup>11</sup> Some economists claim that the level of economic development is closely correlated with the existing level of IPRs protection, and many developing countries that failed to implement IPRs protection systems experienced a correspondingly low level of economic development, as well as a slow evolution in the size and complexity of their local markets<sup>12</sup>. These findings suggest the need

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<sup>10</sup> For the analysis of public good character of IP, *see* Cooter, Robert, and Ulen, Thomas, *Law and Economics*, 3<sup>rd</sup> edition (Addison Wesley Longman, 2000), p. 128-138.

<sup>11</sup> Rapp, Richard T., and Rozek, Richard P., "Benefits and Costs of Intellectual Property Protection in developing Countries", *Journal of World Trade*, Vol. 24 (1990), p. 75-81.

<sup>12</sup> Gutterman and Brown, *see above* note 9, p. 16-21.



for further reforms to existing law as a precondition to continued growth. But in their research, there is a serious discrepancy between the cause and the effect. Is it the protection of the IPRs that enhances prosperity or prosperity enhances the protection of the IPRs? No economist has answered this question convincingly.

### **2.1.2 The North-South Debate on IPRs Protection**

The controversy of the justification of IPRs, together with the different development levels of the North (technologically advanced countries) and the South (countries in the process of industrialization), lead to the divergences on availability, scope and duration of IPRs protection between them. The latter group has often limited the scope of protection granted to foreign IPRs as part of its catching-up strategies. Even the current developed countries may also experience the same policy choice of limited IPRs protection when they were not so developed. As noted in a report by the Office of Technology Assessment of the U.S. Congress, when the U.S. was still a relatively young and developing country it refused to respect foreign IPRs on the grounds that it was freely entitled to use foreign works to further its social and economic development.<sup>13</sup>

The latter's unwillingness to strengthen the protection of IPRs stems from the fact that at a stage when the technological capacity of a particular country is weak, and its enterprises are not able to take significant advantage of the incentive provided by the IPRs protection, the benefits gained from such protection may be outweighed by the disadvantage of not being able to acquire and adapt foreign technology without reference to its right holder, or to import new IP products and processes from alternative or cheaper sources.

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<sup>13</sup> U.S. Congress Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronic Information*, OAT- CIT-3002 (Washington. D.C.: U.S. Government Printing Office, 1986), p. 228.

A short survey of the North-South debate for different IPRs protection policies could contribute to the understanding of the gap between these two groups. The argument of the North for a strong protection of IPRs can be summarized as following:

a. Increased inbound investment and technology transfer. One of the most logical and practical advantages for developing countries to enhance IPRs protection is inbound investment and technology transfer from foreign firms. In the past, concerned about the adequacy of the protection that would be afforded to the transferred technology, foreign firms limited their technology exports to developing countries by allowing only older generation technology or outdated product lines to be transferred.<sup>14</sup> Once stronger IPRs protection is enacted, it can be expected that foreign firms will increase the flow of new technologies to developing countries, either in the form of direct investment or in the form of technology transfer. Otherwise, due to the increasing cost of R&D, the multinational corporations (MNC) will no longer be willing to invest in countries that fail to offer sufficient IPRs protection.<sup>15</sup>

b. Increased flow of new products. The availability of the protection of IPRs for new products increases the flow of products, especially into the developing countries, thereby increasing the welfare of the population. For example, it has been argued that the decision of countries such as India to deny the product patent protection for innovation in the food, drug and chemical industries results in foreign and domestic forfeiture of pharmaceutical research and development

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<sup>14</sup> Wolfhard, Eric “International Trade in Intellectual Property: The Emerging GATT Regime”, *University of Toronto Faculty of Law Review*, Vol. 49 (1990), p. 106, 118. Primo Braga, Carlos A., “The Economics of Intellectual Property Rights and the GATT: A View From the South”, *Vanderbilt Journal of Transnational Law*, Vol. 22 (1989), p. 243-264. See also, Pamela, Smith, “International Patent Protection and United States Exports: Evidence in the Data”, paper submitted to the Conference on International Relations of Intellectual Property: Challenges at the Turn of the Century, Washington D.C.: The American University, 24-25 April (1995).

<sup>15</sup> “Interview with Brazilian Official on Pharmaceutical Patent Protection”, *World Intellectual Property Report*, Vol. 5 (1991), p. 128.

benefits, since then fewer new products are available on the market.<sup>16</sup> If this proposition is true, the effect in the pharmaceutical area is of particular concern, as the overall level of health in the developing and least developed countries will ultimately suffer.

c. Improvements in local knowledge base. A strong protection of IPRs improves the knowledge base concerning technical development. Such an improvement follows from increased imports, licensing activities and patent application filings in the local market. Technical information cannot be derived simply from reviewing foreign patent application or from pirating foreign products. The person-to-person communication that follows from investment activities provides a powerful training and educational tool for the local workforce. An improved knowledge base is of great use to local firms in negotiating the terms of licenses with foreign firms. In addition, it provides a greater appreciation for the availability of alternatives and the underlying utility of the licensed subject matter.

d. Reduced enforcement and transaction costs. Welfare gains of the right holder are realized through a reduction of transaction costs attributable to surveillance, verification, compliance and enforcement of IPRs. These activities are currently provided on a unilateral basis, and would become the shared responsibility of all parties to bilateral or multilateral agreements. An additional reduction would occur in the transaction costs attributable to reliance upon pirated foreign technology.<sup>17</sup>

However, the South become sceptical when the North asserts that strong protection of IPRs is the proper means to insure economic development. Some of the concerns of the South regarding IPRs protection can be summarized as follows:

a. Lack of perceived benefits. Although certain developing countries have nurtured their own domestic industries, most fail to recognize any potential

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<sup>16</sup> Rapp and Rozek, *see above* note 11, p. 75-81.

<sup>17</sup> Wolfhard, *see above* note 14, p. 117.

advantages flowing from granting greater IPRs protection. Less prosperous countries lack the resources necessary for domestic R&D and implementation of a new patent within a developing country has led to few inventions and fewer relative benefits. Moreover, developing countries may be unable to bear the loss of consumer, which is the result of the higher prices stemming from the monopolization associated with the beginning stages of IPRs development. Finally, these countries may be unable to bear the start-up and maintenance costs associated with the development and enforcement of new IPRs, although initially these costs generally accrue to foreign innovators.

b. Under-utilization of inventions and lack of stimulus for “local-specific” products. One of the arguments of the North made in favour of granting the strong protection to IPRs is its effect of increasing flow of new products and technologies. However, *e.g.* the patent products need not to enter the foreign market in which the patent was granted. Rather, the patent may simply be used as a means of preventing others from making or selling the product in that market. As a result, in many cases, the patent system actually leads to the under-utilization of inventions in the patent granting countries.<sup>18</sup> On the other hand, developed countries create a majority of the patentable inventions and technologies. Therefore most of the patents granted in developing countries are issued to foreigners. The largest proportion of inventions covered by patents are included, not by the availability of patent protection in the developing countries, but rather by the domestic patent system of the right holder or in conjunction with patent systems in other developed countries. As a result, a developing country cannot expect that implementation of a patent regime will induce foreign innovations to focus their development efforts on new products and technologies that meet the special needs of the developing countries.

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<sup>18</sup> Mesevage, Tomas, “The Carrot and the Stick: Protecting U.S. Intellectual Property in Developing Countries”, *Rutgers Computer and Technology Law Journal*, Vol. 17 (1990), p. 443.

c. Unavailability of essential commodities and damage to autonomy. Developing countries have, in most cases, adopted some form of IPRs protection. However, much resistance existing to the establishment of a uniform global standard is simply to conform to the request of developed countries. For instance, Indian officials have often expressed a high degree of indignation at the suggestion that they pursue a course undirected by their own programme of self-reliance and specific needs. Also, the Chinese government has suggested that “the level of protection for IP should keep pace with the economic development of the country concerned”.<sup>19</sup> Furthermore, regarding the local attitudes toward private property rights, many countries believe that certain products and technologies must not be included in any IPRs protection regime. The most common examples are in the area of pharmaceutical and chemical products. As the Director of the Philippine Bureau of Patents recently stated, “developing countries have a need requiring special preferential attention on patent systems — such as on medicine — to make it affordable to the poor people”.<sup>20</sup> Similarly, Chinese officials believe that pharmaceutical products “are produced for the health of people”.<sup>21</sup> Accordingly, reproduction should be permitted in order to make the essential commodities more available. In some countries, the markets for these essential commodities may actually be controlled by the local governments.

d. Mixed effect of other factors. Implementation of a patent system does not itself alone guarantee that foreign investment and technology transfer will increase. A variety of political, legal, cultural, social and economic factors impact on the perceived risks of undertaking a particular inbound investment transaction and, thus, on the level of foreign investment and technology transfer. For example, a patent life is of little value in a country where the lack of expendable capital

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<sup>19</sup> See above note 15, p. 145-146.

<sup>20</sup> “Asia-Pacific Countries Agree to Cooperate on Patent Issues”, *World Intellectual Property Report* Vol. 4 (1990), p. 53.

<sup>21</sup> “China Calls Special 301 Designation Unacceptable, Says Trade Will Suffer”, *World Intellectual Property Report*, Vol. 5 (1991), p. 146.

impedes the purchase of patented goods. Also, the ability of the patent holder to successfully commercialise any product depends, not only on the competitive environment, but also on the ability to effectively market the patented product.

### **2.1.3 Domestic Legislation and International Harmonization**

According to the analysis above, the justification and strong protection of IPRs is not without scepticism. Some maintained that infringements of IPRs constituted a straightforward matter of piracy and theft, just like the infringement of tangible property rights. However, the nature of IPRs is proprietary rights granted by monopolistic privileges. Therefore, the protection of IPRs is effected by different social situations and is more of a policy matter. The core task of the domestic legislation in this field is to adjust the tension between the private rights of IPRs holder and the public interest of a society, and the tension between the promotion of creativity and the decrease of social costs for the IPRs protection. Legislators attempt to strike a dialectic balance between these concerns at the domestic level. The result of the balancing depends on whether, in a given point of time, economic policy places more emphasis on efficiency, aimed at increasing aggregate wealth, or on equity, aimed at the redistribution of knowledge and wealth. The availability, scope and duration of IPRs protection respond to the trade-off between the private interest and public good, as well as the trade-off between economic efficiency and social welfare.

However, the harmonization of different IPRs protection at the international level faces more tasks than the domestic legislation. It seems fairly evident that IPRs protection of same level does not make same sense for all countries in a certain period. The impacts of enhanced IPRs protection upon developing countries may vary significantly. There is no *priori* strong evidence that these countries will

necessarily benefit from a reform of their IPRs systems.<sup>22</sup> The evidence which has been put forth regarding the relationship between IPRs and economic development is unconvincing.<sup>23</sup> When seeking an optimal balance between the need for monopoly and the benefits of free access to knowledge, the governments also take into consideration the national competitive capacity in IP area and the redistributive affect of international harmonization. In formulating their IPRs policies they must reconcile static efficiency considerations (which imply that knowledge should be free) with the longer-term objective of encouraging innovation and technological progress.

There is no unique answer to this conundrum. Whether a given policy of IPRs protection is optimal or not depends on the objectives and circumstances of countries and the economic sectors involved, and thus conflicts of interest between countries can easily occur.<sup>24</sup> Therefore, the international IPRs conventions face a common task when they seek to harmonize different IPRs protection: how to harmonize the controversial rationale of IPRs protection and different national interest.

## 2.2 Harmonization of the Paris Convention

The history of multilateral harmonization of IPRs protection can be traced back over 100 years. In 1883, 11 countries met in Paris and signed the Paris Convention<sup>25</sup>. This has since been followed by a number of IPRs conventions in

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<sup>22</sup> Correa, Carlos M., and Yusuf, Abdulqawi A., *Intellectual Property Rights and International Trade: The TRIPS Agreement* (London: Kluwer Law International, 1998), p. 96.

<sup>23</sup> In fact, the rise of Japan and other “technology importers” appears to support the utility of alternative strategies, at least while the country is in a relatively early stage of development.

<sup>24</sup> Hoekman, Bernard M., and Kostecki, Michel M. *Political Economy of the World Trading System: From GATT To WTO* (Oxford: Oxford University Press, 1995), p. 145-147.

<sup>25</sup> *Paris Convention for the Protection of Industrial Property*, adopted on 20 March 1883, last revised on 14 July 1967, UNTS Vol. 828, p. 305.

different IPRs fields, including the 1886 Berne Convention<sup>26</sup>, 1961 Rome Convention<sup>27</sup>, and the 1989 Washington Treaty<sup>28</sup>. Since 1967, the Paris, Berne and Rome Conventions have all been administered by the World Intellectual Property Organization (WIPO), a specialized agency of the United Nations (UN), based in Geneva.

### **2.2.1 Non-Discrimination Provisions**

The harmonization of the Paris Convention on IPRs protection is based on the principle of national treatment. Articles 2 and 3 of the Convention contain the principle of national treatment, under which, each country of the Paris Union is bound to protect the IPRs of the nationals of other countries in a manner as it protects its own nationals' IPRs.<sup>29</sup> The national treatment applies to all the nationals of the countries of the Union, both natural persons and legal entities. It also extends to the nationals of countries outside the Union, provided they are domiciled or have an industrial or commercial establishment in a country of the Union. This principle excludes any possibility of discrimination to the detriment of nationals of other countries of the Union and any requirement of reciprocity of protection. That means, suppose a given country has a longer duration of patent protection than another country of the Union, the former country will not have the right to provide that nationals of the latter country will only enjoy a shorter duration of protection as provided in the law of the latter country, if the patent is in the territory of the former country. This principle applies not only to codified

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<sup>26</sup> *Berne Convention for the Protection of Literary and Artistic Works*, adopted on 9 September 1886, last revised on 1 July 1967, UNTS Vol. 828, P. 221.

<sup>27</sup> *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations*, adopted on 26 October 1961, UNTS Vol. 469, p. 43.

<sup>28</sup> *Treaty on the Intellectual Property in Respect of Integrated Circuits*, adopted on 26 May 1989, ILM Vol. 1484, p. 28.

<sup>29</sup> Article 1(1) of the Paris Convention provides that “the countries to which this Convention applies constitute a Union for the protection of industrial property.”



law, but also to the practice of the courts and to the practice of the administrative offices.

Under the principle of national treatment, each country retained its sovereignty in determining its own level of IPRs protection. The Paris Convention respects the regulation diversity of different countries of the Union, except in few provisions including substantive protection. No international harmonization is made out on the availability, scope and duration of the patent rights. Therefore the task of international IPRs harmonization does not raise serious problem in the Paris Convention. As to the domestic legislations which existed before the entry into force of the Convention, countries have little obligation to modify them in the substantive aspects. As to the legislations after the Convention, the domestic balance of the public and private interest is still the focus of the legislators, and little international obligation imposed by the Convention has been taken into consideration.

### **2.2.2 Limitation on Rights**

The Paris Convention also embodies few substantive standards of protection, which include: the right of priority (Article 4), independence of patent (Article 4*bis*), the right of the inventor to be mentioned (Article 4*ter*), failure to work and compulsory license (Article 5*quater* and 5A), patents in international traffic (Article 5*ter*), Grace Period for the payment of maintenance fees (Article 5*bis*) and inventions shown at international exhibitions (Article 11). In these substantive protection areas, the main method the Convention adopted to resolve the controversy of IPRs protection in the process of harmonization is to limit the rights of IPRs holder.

Articles 5*quater* and 5A provide the compulsory license as a remedy of the abuse of patent right, the main purpose of which is to ensure that the exercise of

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patent right is not inconsistent with the justification of its protection. Compulsory licensing is defined generally as the granting of a license by a government to use a patent without the patent holder's voluntary permission. Article 5A(2) provides grounds for the granting of compulsory licence, that is, "each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work".

The main argument underlying the provisions requiring the working of an invention in the country where the patent was issued is the consideration that, in order to promote the industrialization of that country, patents for invention should not be used merely to block the working by others of the invention in the country or to control the importation of the patented product; they should rather be used to introduce the use of the new technology into the country. A compulsory licence may not be applied for, on the ground of failure to work or for insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; and the compulsory license shall be refused if the patent holder justifies his inaction by legitimate reasons. Such a compulsory licence shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-licence.<sup>30</sup>

However, there is no provision as to what constitutes a "legitimate reason" of the inaction of a patent holder. Whether a patent holder can really be expected to work his patent is first of all an economic consideration and then also a question of time. Working in all countries of the world is generally not economically reasonable. Therefore, it is recognized that immediate working in all countries is impossible and that several factors require to be considered with regard to working. For example, a pharmaceutical company may not market a drug in a specific country because the cost-benefit analysis would not yield a favourable

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<sup>30</sup> The Paris Convention, Article 5A(4).

result and would harm the company. In addition, it is unclear whether failure to work includes instances where the pharmaceutical company does market a drug in a developing country, but keeps the prices high and unaffordable to a majority of the population. So the concept of “failure to work” remains unclear and the “legitimate reasons” are subject to the further illustration of domestic law. What’s more, the language of Article 5A(2) goes as this: “for example, failure to work.” Therefore, failure to work is not the only ground of abuse of rights and grant of compulsory license.

Article 5A(3) also provides that “forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licences would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory licence”. What can be derived from this provision is that if the compulsory licence does not provide sufficient remedy to the abuse of right, another form of remedy could be forfeiture. The difference between compulsory license and forfeiture is: after the grant of compulsory license the patent holder still maintain the title of ownership of the patent, and is entitled to get adequate compensation; but after the forfeiture, the former right holder lose the title of the ownership of the patent and no claim to compensation will be satisfied. Therefore, forfeiture is both a form of remedy and a sanction to the abuse of right.

## **2.3 Harmonization of the TRIPS Agreement**

### **2.3.1 Incorporation of IPRs into the WTO Agreements**

IPRs became a trade issue and were incorporated into the WTO Agreements for a number of reasons. Ideas and knowledge have been an important part of trade.

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Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved. Even products that used to be traded as low-technology goods or commodities now contain a higher proportion of invention and design in their value — for example brand name clothing or new plant varieties. At the same time, the growing capacity of manufactures in developing countries to penetrate distant markets for traditional industrial products has forced the developed countries to rely more heavily on their comparative advantages in the production of IP goods than in the past. As a result, international trade in goods embodying IP has increased substantially in recent decades.

Against this background, a number of industrialized countries, concerned with the erosion of the competitiveness of their industries, increasingly felt that inadequate protection of IPRs in technology-importing countries reduced their competitive advantage in the IP goods. They called for stronger IPRs protection. However, the existing conventions cannot fully satisfy the requirements of the exporters of IP goods because of certain alleged shortcomings.

First, the membership is not universal. For example, while 162 countries signed the Paris Convention, only 88 signed the Berne Convention, and only 32 countries signed the Rome Convention. The U.S. had not sign the Berne Convention until 1988. The result is that there exists differing level of protection of IPRs around the world.

Second, the obligations or the standards of protection required by most of these conventions are considered by some to be insufficient. Most of them only impose a national treatment obligation and generally do not specify minimum levels of protection that signatories must provide to a particular IPR. For example, the Paris Convention does not specify what types of products must be eligible for patent protection. There exists neither the condition of patentability, nor the non-discrimination provision with regard to the field of technology. Also, it does not stipulate the minimum duration of patents, nor does it define the scope of the

exclusive rights. Although focusing on the industrial property, the Paris Convention does not seek an agreement on trade secrets (undisclosed information). Protection of computer software and sound recording was needed in the view of the industrialized countries, but their protection under the copyright regime is also not enough.

Third, many of the conventions are viewed as being void of adequate provisions relating to dispute settlement and enforcement. Usually, they do not oblige signatories to enforce the relevant IPRs laws within their respective jurisdictions. They also do not provide for adequate international dispute settlement when signatories fail to meet the minimum standards which they have agreed to uphold. Although in theory, most of these conventions would allow a signatory state to bring a complaint before the International Court of Justice (ICJ), this has never occurred in practice. The lack of effective dispute settlement mechanism is then matched by a corresponding lack of sanction for violations. Consequently, disputes were frequently addressed through bilateral channels, with trade sanctions of the developed countries. The U.S. played a particularly prominent role in using unilateral sanctions or threats of sanctions to deal with IPRs infringements. The two main instruments used were Section 337 of the U.S. *Tariff Act of 1930*, and Section 301 of the *Trade Act of 1974*, as amended by the *Omibus Trade and Competitiveness Act of 1988*.<sup>31</sup>

Although there existed these alleged problems, it is difficult to negotiate new substantive amendments of those conventions within the divergent views between the North and South. When a group of developed countries proposed an amendment to the Paris Convention so as to establish certain minimum standards of protection and increase its enforcement obligations relating to patents, a group of developing countries responded by proposing instead a weakening of the Convention's obligations in some areas. While preparatory meetings and negotiations continued on these proposed amendments for over years, in the end

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<sup>31</sup> Hoekman and Kostecki, *see above* note 24, p. 146-147.

neither view prevailed and consequently the Convention remained unaltered and its basic problem remained unresolved. With little fruit for their efforts towards the expansion of the IPRs protection standards and enforcement through international IPRs conventions, the U.S. and other main industrialized countries resort to the WTO as a new forum for IPRs issues.

It should be noted that the *General Agreement on Tariffs and Trade-1947* (GATT-1947) already contained some provisions which indirectly addressed certain IPRs issues. For example, Article III4 of the GATT-1947 required contracting parties to extend national treatment for imported goods. Article XX(d) allowed contracting parties to take measures necessary to secure compliance with laws relating to the protection of patents, trademarks and copyright. There are also some previous attempts within the GATT to address more IPRs issues. Until the Uruguay Round, these efforts had generally gotten no better success than the efforts within the WIPO. For example, the issue of counterfeit goods was subject to some discussions during the Tokyo Round, but no agreement could be reached prior to the completion of the round. After the Tokyo Round had been completed, the U.S., with the support of the EC, Japan and Canada, persisted with the counterfeit goods issue and during the 1982 GATT Ministerial Conference attempted to have the GATT's developing work plan expanded to include issues relating to counterfeit goods. In spite of the strong opposition voiced by some developing countries, the 1982 Ministerial Declaration did provide for some work to be done on IPRs aspect, but in the area of counterfeit goods only.<sup>32</sup>

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<sup>32</sup> See *Ministerial Declaration of Thirty-Eighth Session*, adopted on 29 November 1982, GATT, *Basic Instruments and Selected Documents* (BISD) 29S/, p. 19. This was soon followed by a U.S. proposal that the next round of trade negotiations should not be limited to issues solely related to counterfeit goods but should also be expanded to include discussion of all trade-related IPRs.

Although the trade argument was perhaps as old as the international regime on IPRs itself,<sup>33</sup> the arguments made by the proponents of new rules and disciplines on trade-related aspects of IPRs in the 1980s was very striking.<sup>34</sup> The main reason for the lack of success of these proposals was that treating IPRs as a trade issue was novel in many respects, since standard setting in the area of IPRs was traditionally done within the framework of the WIPO. Due to the different development period and IPRs policy, the developed countries' motive confronted the resistant of the developing countries initially. They hold a sceptical attitude toward the motivation of the developed countries, particularly when the firms in the developed countries claimed that monopoly rights in the new foreign markets, such as in LDC, are necessary to recover their R&D costs. On the contrary, developing countries feared that large MNC would secure global monopolies, and thereby would charge exorbitant prices for their goods. Lacking the scientific and financial infrastructures necessary to create patent-induced innovations, developing countries are far more interested in technology transfer than in the encouragement of domestic innovations. Not surprising, the motive of the developed countries was confronted by the resistant of the developing countries.

With regard to patents, for example, developing countries have always emphasised on local working requirements. They allow parallel imports and greater scope for compulsory licensing in the absence of local working, for the purpose of strengthening economic development and social welfare function of the exclusive rights granted to patents. Therefore, developing countries have little or no interest in creating a system that impedes their own ability to appropriate new technologies and products developed by foreign innovators.

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<sup>33</sup> Indeed, promotion of international trade figured prominently in the letter of invitation on the First International Congress for the Consideration of Patent Protection held in Vienna in 1872.

<sup>34</sup> This was reflected in the *Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese and United States Business Communities*, and in the statement of Yeutter Clayton before the US Congress: *An Agenda for the New GATT Round*. See Carrea and Yusuf, *see above* note 22, p.81-92.

A consensus had not been achieved until the time of September 1986, when a ministerial meeting called to finalize the agenda and initiate the new round of negotiation. Strongly supported by the developed countries led by the U.S., the Ministers were finally able to reach agreement on a negotiating mandate for “trade-related intellectual property issues”.<sup>35</sup> By the time of the Brussels Ministerial Meeting in the November 1990, a proposal led by India, Brazil, Egypt, Argentina, and Yugoslavia sought to draw a firm distinction between the work on trade of counterfeit goods and that on the IPRs more broadly defined. They were willing to co-operate on the former but opposed the latter. The first order of priority of poor countries was to ensure that unilateral measures to protect IPRs did not cause barriers to legitimate trade. There was a general concern that greater protection of IPRs would strengthen the monopoly power of MNC, and detrimentally affect poor populations by raising the price of medicines and food. As IPRs create market power, developing countries sought assurances that action could be taken against the abuse of monopoly rights by IPRs holders. However, another proposal which supported an integral part for including both issues, was advocated by the developed countries.

The result of the enthusiastic promotion of developed countries and the compromise of developing and least developed countries is the adoption of the former’s proposal with some modification by the latter’s proposal, with a final act called the *Agreement on Trade-Related Aspects of Intellectual Property Right*. As one of the most significant achievements of the Uruguay Round negotiation, the TRIPS Agreement was signed by 124 members together with other multilateral trade agreements and the *Marrakesh Agreement Establishing the World Trade Organization* (the WTO Agreement). It is the first comprehensive IPRs agreement ever executed by most trading nations of the

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<sup>35</sup> *Ministerial Declaration on the Uruguay Round*, GATT, adopted on 20 September 1986, BISD 33S/19 (1986), p. 25-26.



world which establishes minimum standards for practically all categories of IPRs.<sup>36</sup>

### **2.3.2 The Solution of the TRIPS Agreement**

The TRIPS Agreement marks a departure from previous IPRs conventions in that it not only inherits the principle of national treatment, but also provides the “most-favoured-nation” treatment (MFN). That is, the obligation to extend, with some limited exceptions, the advantages granted to one member to all the other members. These principles are meant to end discrimination, both between foreigners and nationals and between nationals of different countries, which arises when IPRs are granted only to the nationals of the country that pressed for them, as for example in the case of the recognition of pharmaceutical patents in South Korea.

What’s more, the Agreement also goes much farther to require the harmonization of substantive standards of IPRs among members. At the same time, members agreed to offer fair and equitable enforcement of those substantive rights by providing effective action against any act of infringement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These fundamental differences in the approach of harmonization are notable examples of the deepening of international IPRs law. To an ever-increasing degree, the domestic IPRs laws of most members are being directly affected by international trade negotiations.

As analysed in Section 2.1, the harmonization of different IPRs protection at the international level faces the task to balance different levels of IPRs protection, including the controversial rationale of IPRs protection and different national interest. The harmonization of pre-TRIPS IPRs conventions is not so ambiguous,

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<sup>36</sup> Correa and Yusuf, *see above* note 22, p. 93.

so the limitation on rights by compulsory license and forfeiture more or less meets the requirement of balance. However, the harmonization of the TRIPS Agreement expands to the substantive areas such as availability, scope and duration of the protection. Merely limitation on rights is not sufficient and further solutions are necessary to balance the different interest as a counterpart of the improved IPRs protection.

The solution of the TRIPS Agreement in this aspect is unique as it is not only built in the text of the Agreement itself, but also built outside the Agreement and in the context of the Uruguay Round package of WTO. That means, during the negotiation, the cross-field exchange of interest happened and benefit gained in other fields partly traded-off the loss in IPRs field. Another unique characteristic of the solution of the TRIPS Agreement is that it leaves some hot disputed topics unresolved in the text of the Agreement, and allows certain limited flexibility in the interpretation and application of the different members. The following part this sector devotes to overview how did the TRIPS Agreement balance the different interest in the process of international harmonization. Further analysis of the flexibility of the Agreement is the main task of next chapter, but the other solutions serve as a background and context of the analysis.

### **2.3.2.1 Incorporation of the Paris Convention**

Article 2 of the TRIPS Agreement entitled “Intellectual Property Conventions” establishes the basic link between the TRIPS Agreement and the other IPRs conventions. It provides:

1. In respect of Parts II and IV of this Agreement, Members shall comply with Articles 1-12 and 19 of the Paris Convention (1967).
2. Nothing in Parts I to this Agreement shall derogate from existing obligations that Members may have to each other under the Paris

Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

This provision incorporates into the TRIPS Agreement some provisions of the Paris Convention, as amended in 1967. Through this incorporation, the above-mentioned provisions of the Paris Convention are made applicable to those states that have ratified the TRIPS Agreement even they had never become parties to the Paris Convention. Therefore, the TRIPS Agreement not only incorporates the non-discrimination and few substantive provisions, but also embraces the limitation on rights conferred by the Paris Convention, for instance, compulsory license for failure to work or other reasons, and forfeiture measures.<sup>37</sup>

### **2.3.2.2 Trade-off**

During the negotiation of the TRIPS Agreement, the initial resistance of the developing countries was clear and strong. However, unlike the WIPO negotiations where countries had to consider only the direct arguments for or against higher standards of protection, the WTO negotiations would allure developing countries to look into what they would gain in other fields by offering concession on IPRs. Although the IPRs-incorporation approach was initially resisted by the developing countries,<sup>38</sup> the convergence of various factors and political pressures led them to acquiesce in the establishment of higher IPRs standards in the framework of the WTO.

The trade-off were made between the TRIPS and the rest of the agenda of the Uruguay Round negotiation. These areas include, *e.g.* agricultural products, textiles, and tropical products, where the developed countries offered more market access to developing and least developed countries. Trade-off also occurred in other areas, although it is not possible to identify specific linkages of

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<sup>37</sup> See above, p. 14.

<sup>38</sup> Even after the adoption of the *Ministerial Declaration on Uruguay Round* in 1986, which placed the topic on the agenda of the Uruguay Round negotiations, the resistant of the developing country members still existed.

the agenda formally. For instance, the U.S. government started to make effective IPRs protection a precondition for access to the U.S. market under the Generalized System of Preferences (GSP) for developing countries. Reversals on the MFN treatment may give rise to non-developing countries in the 1980s in their attitudes towards inward protection of the IPRs. Foreign Direct Investment (FDI) also played a role in inducing the acceptance of the Agreement, because to attract FDI in certain high-tech sectors requires strong protection and enforcement of IPRs. As a counterpart, interest groups in developing countries also existed that favoured stronger protection of IPRs, *e.g.* those domestic IP-creating or IP-using industries where the transfer of technology generally requires FDI, which is generally conditional on the existence of strong protection of the IPRs. Therefore, the membership in the WTO may increase the credibility of domestic economic reforms in developing countries by reducing the uncertainty of trade regimes, providing a more open trading environment, and additional incentives to FDI.

At the same time, with the inclusion of trade-related IPRs issues in the framework of the WTO, trade sanctions in this area can only be taken so far as the retaliation has been authorized by the WTO. The multilateral framework of the WTO comes to be perceived by the developing countries as less evil than bilateral concessions, which means the increased trade security for trade relations under the WTO agreement.<sup>39</sup> The security is safeguarded by the dispute settlement procedure of the WTO.<sup>40</sup>

In summary, the acceptance of the TRIPS deal in the Uruguay Round by the developing countries stemmed from a mix of fear, motivation and compromise. They feared that without the multilateral mechanism, they would be increasingly

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<sup>39</sup> For unilateral sanctions, *see above* note 21. Actually, by the threat of trade retaliation for inadequate IPRs protection, the U.S., and later the EC, were able to induce significant changes in the IPRs laws of many developing countries.

<sup>40</sup> Primo Braga, *see above* note 14, p. 255.

vulnerable to unilateral sanction by the U.S. and the EC.<sup>41</sup> At the same time, a growing perception existed that IPRs laws also had benefits in terms of allowing participation in creative activities, providing consumer with access to new products, and giving industries better opportunities of obtaining cutting-edge technologies.<sup>42</sup> They increasingly felt that stricter IPRs protection might also in their interest, if only because it was a necessary component of a more general move towards a market economy.<sup>43</sup> Potential cross-field trade-off further enlarged the scope for negotiation and compromise. As exchange for the acceptance of the Agreement, poor nations and transition economies could seek more open market for their agricultural and tropical products, as well as better market access for their textile exports.

Developing countries realised that IPRs impose social costs on them. Although the costs is, to varying degrees, offset by the prospects of enhanced market access and the relief from unilateral trade sanctions, *inter alia*, to adopt a stricter IPRs protection also takes time, especially in the areas where no protection was established at all. Therefore, developing countries insisted on a long transitional period during which changes in domestic legislation could be implemented, as well

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<sup>41</sup> The threat of unilateral sanction was used to push developing countries to support the TRIPS negotiation at the Uruguay Round. The countries placed on the Priority Watch List of the U.S in 1989 in this effort included India, Brazil, Taiwan and Thailand, which all opposed the inclusion of IPRs protection in the Uruguay Round in general and in TRIPS in particular. The action against Brazil and India, two of the biggest members of the developing country coalition, the group of seventy-seven countries, played a major role in splitting the coalition and in securing acquiescence to TRIPS by developing countries. The IP Coalition (the main lobby power in the U.S. in favour of the TRIPS Agreement) also suggested that the U.S. should condition debt forgiveness to Latin American countries on adequate patent protection.

<sup>42</sup> It is important in this connection that developing countries were not really a cohesive bloc on the TRIPS issue. Some of the poorer countries had tightened their domestic protection of IPRs unilaterally so as to attract FDI and technology transfer or as a response to the threat of the U.S. action, feared to be undercut by competitors in other developing countries. This can be seen from the fact that over 40 developing countries unilaterally strengthened their IPRs regimes in the 1990s. *See* Mansfield, Edwin, ‘‘Intellectual Property Protection, Foreign Direct Investment, and Technology Transfer’’, discussion paper No. 19, Washington, D.C.: The World Bank and International Finance Corporation (1994). Available at <<http://www.ifc.org/economics/pubs/dp19/dp19.pdf>>.

<sup>43</sup> Hoekman and Kostecki, *see above* note 24, p.152-153.

as the technological cooperation to implement the high IPRs standards. The inclusion of transitional arrangement and technological cooperation provision allure the final accept of the Agreement by the developing and least developed countries.

### **2.3.2.3 Limitations**

Another solution of the TRIPS Agreement to harmonize different rationales and interests of members was to set limitation on the protection of IPRs in addition to the already existing limitations inherited from the Paris Convention. This is mainly promoted by the developing countries who are more sceptical and reluctant to the strong protection of IPRs. During the negotiation of the Agreement, a “Group of 14” developing countries submitted a proposal to highlight the importance of the public policy objective underlying the national IPRs systems,<sup>44</sup> the necessity of recognizing those objectives at the international level, and the need to specify some basic principles which could subsequently elucidate the application of any standards established in the TRIPS agreement. They insisted on the need to respect and safeguard national legal systems and traditions on IPRs, in the light of the diverse needs and levels of development of countries participating in the IPRs negotiations.

The limitation on the protection of patent in the TRIPS Agreement includes: limitations on patentability subject, limitation on right conferred to the patent holder, and the duration of protection. The next chapter will further explain these limitations in detail.

### **2.3.2.4 Flexibility**

However, even having embodied the limitations on the protection, there is still no consensus on certain issues such as the precise subject of protection, international exhaustion of IPRs, the status of biotechnologies, the novelty and non-

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<sup>44</sup> Proposal submitted by a group of 14 developing countries during TRIPS negotiations in the Uruguay Round negotiation, submitted on 14 May 1990, MTN.GNG/NG11/W/71.

obviousness standards of eligibility for patent protection. These areas also extend to the exact scope of rights, as well as the exceptions of the exclusive rights, *e.g.* it is disputable whether a country must declare a national health emergency to invoke compulsory licensing.

When such hot issues could not be resolved during the negotiations, the negotiators adopted a drafting technique to achieve the general agreement on the convention. That is, they left these issues open-ended and allowed a certain amount of flexibility in interpretation and application. Flexibility occurs as a way of permitting agreement without full resolution in hard legal cases, where the meanings of the key terms are disputed. The Agreement does not provide in specific content of many labels of IPRs issues and does not offer an objective or positive definition for many notions of IPRs. Consequently, although there may be some convergence on basic rights granted, the precision of the protection remains unclear. Under the Agreement, applicability of the TRIPS-mandated rights can be interpreted more or less expansively depending on the role ascribed to the specific list of examples (representative or exhaustive) and the requisite level of novelty imposed. This outcome is precisely what would be expected in an agreement driven by parties having enough negotiating leverage to force agreement but inadequate power to prevail fully. Disagreements are sufficiently masked to permit signing an accord.

All of these unclear areas give developing and least developed countries certain room to develop the practice which is consistent with their developing level. The WTO Director-General Mike Moore stated that “TRIPS Agreement plays a vital role in tackling the problems like crisis of disease facing developing countries. It strikes carefully-negotiated balance between providing IP protection and allowing countries the flexibility to ensure that treatments reach the world’s poorest and

most vulnerable people. Countries must feel secure that they can use this flexibility and the work started in the TRIPS Council should reinforce that security’’.<sup>45</sup>

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<sup>45</sup> Moore, Mike, “Intellectual Property and Access to Medicines”, the statement issued on the TRIPS Council’s special discussion on 20 June 2001. Available at <[http://www.wto.org/english/news\\_e/news01\\_e/dg\\_trips\\_medicines\\_010620\\_e.htm](http://www.wto.org/english/news_e/news01_e/dg_trips_medicines_010620_e.htm)>.



# 3 Flexibility of the TRIPS Agreement

The exploitation of the flexibility of the TRIPS Agreement in this thesis is made in two dimensions: horizontal and vertical dimensions. Horizontal dimension of the TRIPS Agreement covers the general issues that constitute the legal framework of the interpretation of the Agreement, and affect all fields of IPRs. Provisions in this dimension where the flexibility could be exploited are: the purposes and objectives of the Agreement reflected in the preamble and Articles 7 and 8; exhaustion of rights in Article 6; anti-competitive measures in Articles 31 and 40; suspension of non-violation complaint in Article 64; and transitional period in Part VI. Meanwhile, the exception to these flexible fields is the national treatment and MFN in Articles 3 and 4, where there is no flexibility allowed. Vertical dimension of the TRIPS Agreement with regard to patent protection is included in Section 5 of Part II (Articles 27 – 34). Provisions in this dimension where flexibility exists are mainly concerned about: patentability; rights conferred to the patent owner; exceptions of the exclusive rights and conditions on patent applications; use without the authorization of the right holder; transitional arrangement and the “mailbox” system.

## 3.1 Flexibility in Horizontal Dimension

### 3.1.1 Interpretation Framework: Objectives and Principles

The *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU) of the WTO states that the WTO’s dispute settlement system serves “to clarify the existing provisions of the Agreements in accordance with

the customary rules of interpretation of public international law.”<sup>46</sup> It is now established in international law that the *Vienna Convention on the Law of the Treaties* (VCLT) is the authoritative statement of the customary rules in international law for the interpretation of treaties.<sup>47</sup> As such, it is binding even on those states which are members of the WTO but have not ratified the VCLT. The interpretation authority of the VCLT has also been accepted by the WTO panels and Appellate Body. It was first noted in *US — Standards for Reformulated and Conventional Gasoline* case.<sup>48</sup> The Appellate Body subsequently confirmed that the VCLT is a codification of customary international law, and therefore binds all States. In the case of *Japan — Taxes on Alcoholic Beverages*, the Appellate Body ruled that both Article 31 and Article 32 of the VCLT have attained the status of a rule of customary international law. The rules of treaty interpretation spelt out in the VCLT have also been applied in disputes specifically dealing with the interpretation of the TRIPS Agreement, e.g. in *India-Patent Protection for Pharmaceutical and Agricultural Products* (India Mailbox) case,<sup>49</sup> and *Korea-Dairy Products* case.<sup>50</sup> There have been numerous other rulings from panels or Appellate Body of the WTO which confirmed the application of the VCLT to the interpretation of the WTO Agreements including the TRIPS Agreement.

Article 31 of the VCLT states:

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<sup>46</sup> *Understanding on Rules and Procedures Governing the Settlement of Disputes*, Annex 2 of the WTO Agreement, adopted on 15 April 1994, LT/UR/A-2/DS/U/1, Article 3.2.

<sup>47</sup> *Vienna Convention on the Law of the Treaties*, adopted on 23 May 1969, UNTS Vol. 1155, p. 331.

<sup>48</sup> Report of the Appellate Body, WT/DS2/AB/R (29 April 1996), p 17.

<sup>49</sup> Report of the Appellate Body, WT/DS50/AB/R (19 December 1997), para. 46.

<sup>50</sup> Report of the Appellate Body, WT/DS114/R (17 March 2000), para. 7.26

(1) A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

(2) the context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annex:

... ..

The preamble of the TRIPS Agreement acknowledges that the IPRs are private rights. At the same time, it recognizes the underlying public policy objectives of national legal systems for the protection of IPRs, including developmental and technological objectives. It also recognizes the special needs of the LDC members in respect of the maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base. Of particular significance are Articles 7 and 8 on the objectives and principles of the Agreement. Article 7 provides that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Furthermore, Article 8 provides that:

#### Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which

unreasonably restrain trade or adversely affect the international transfer of technology.

The importance of the general provisions and basic principles contained in the preamble and Articles 7 and 8 of the TRIPS Agreement exists in the horizontal dimension. That means, they are relevant to all the subsequent provisions in the specific fields of IPRs because they establishes the interpretation framework that must guide the decision-making process of the dispute settlement body (DSB) constituted under the DSU, and eventually the application of the Agreement by the national courts stressed in Section VI. Therefore, the preamble, Articles 7 and 8 provide a general framework of interpretation and application of the Agreement, and constitute the legal basis for the members to reserve domestic control of IPRs policy.

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the objectives and purposes of the Agreement as expressed, in particular, in its text. What's more, the interpretation of the TRIPS Agreement should also be viewed together with the agreements relating to the TRIPS Agreement. Article 31.2 paragraphs a and b of the VCLT provides that the context of the treaty shall also comprise any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty, and any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

The WTO's numerous trade agreements, including the TRIPS Agreement, were negotiated and concluded as a single package, with all WTO members agreeing to all the treaties. Therefore, all of the other Agreements negotiated at the conclusion of the 1986-1994 Uruguay Round of trade negotiations are agreements "relating to" the TRIPS Agreement that were made "in connection"

with the conclusion of the Agreement. The chief significant agreement in this context is the *Marrakesh Agreement Establishing the World Trade Organization* (the WTO Agreement), the founding treaty to which all the other multilateral WTO agreements — and in particular the GATT-1994, the *General Agreement on Trade in Services* (GATS) and the TRIPS Agreement — are annexed. The provisions of the WTO Agreement are clearly parts of the “context” within which the terms of the TRIPS Agreement must be interpreted.

In particular, the preamble of the WTO Agreement provides a further textual basis for interpreting the TRIPS Agreement in a fashion that is “consistent with States’ obligations under international law”. In the preamble, WTO members do not state that trade is an end itself, but rather assert that it serves as a means to an end. Specifically, WTO members recognize “that their relations in the field and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income, ... while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and enhance the means for doing so in a manner consistent with their respective needs and the concerns at different level of economic development”; and recognized “further that there is a need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development”.

Other related instruments include the WTO’s Ministerial *Decision on Measures in Favour of Least Developed Countries*, adopted as part of the final act of the Uruguay Round and its numerous annexed agreements. In that decision, the Ministers recognized the plight of the LDC and the need to ensure their effective

participation in the world trade system, and to make further measures to improve their trading opportunities. Therefore, they decided that:<sup>51</sup>

... if not already provided for in the instruments negotiated in the course of the Uruguay Round, notwithstanding their acceptance of these instruments, the least-developed countries, and for so long as they remain in that category, while complying with the general rules set out in the aforesaid instruments, will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs, or their administrative and institutional capacities.

Furthermore, the WTO Ministers agreed that the rules set out in the various agreement and instruments and the traditional provisions of the Uruguay Round should be applied in a flexible and supportive manner for the LDC. To this effect, sympathetic consideration shall be given to specific and motivated concerns raised by the LDC in the appropriate Councils and Committees.<sup>52</sup>

Another related agreement, the GATT, has accepted social interest through restrictive interpretations of the exceptions listed in Article XX, which allows the balancing of social objectives, such as public health and protection of the environment on one hand and free trade on the other hand. Since the *US – Shrimp Turtle Case* the exception has been recognized. A central issue in this case was whether exhaustible resources in Article XX(g) include endangered species. In answering this question, the WTO Appellate Body examined the question of whether an endangered species is an exhaustible resource under Article XX(g) by referring to international environmental law. The Appellate Body ruling, in effect, allowed members to take action to protect exhaustible natural

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<sup>51</sup> *Decision on Measures in Favour of Least-Developed Countries*, Annex 4 of the WTO Agreement, adopted on 15 April 1994, LT/UR/A-2/DS/U/1, para 1.

<sup>52</sup> *Ibid*, para 2(iii).

resource in a manner that respects the context of public international law. Therefore, the agreements under the WTO are not isolated from the regime of public international law, such as human rights and environmental protection, which are for the purpose of social interest and public good.

Furthermore, Article 31(3) of the VCIL also provides that the context of a treaty should also be taken into account, which includes:

- (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions.
- (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.
- (c) Any relevant rules of international law applicable in the relations between the parties.

At the first WTO Ministerial Conference in 1996, the member countries adopted the *Singapore Ministerial Declaration*. It stated that in pursuit of the goal of sustainable growth and development for the common good, the members were renewing the commitment to a system that was “fair, equitable and more open.” The members also recalled that the WTO Agreement contains provisions conferring differential and more favourable treatment for developing countries, including special attention to the particular needs of the LDC.<sup>53</sup>

As a summary, the purposes and objectives of the TRIPS Agreement are embodied in the text of the Agreement, especially in the preamble, Articles 7 and 8, the context of the Agreement including the related and subsequent instruments and practice. They constitute the framework of the interpretation and then the application of the TRIPS Agreement. All these text and context analysed above

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<sup>53</sup> *Singapore Ministerial Declaration*, adopted on 13 December 1996, WT/MIN(96)/DEC/W/, para. 6, 13.

disclose the concern of the members on the balance of private rights and public interest, and the various economic developing levels of members. They constitute the legal basis for the further exploration of the flexibility of the Agreement for the purpose of public good or the interest of developing and least developed country members.

### **3.1.2 Exhaustion**

IPRs protection is primarily national legislation, with each country creating and enforcing its own IPRs exclusive within its jurisdiction. The IPRs holders must therefore seek protection and enforcement in the territory of each country individually. As a result, the IPRs holder may hold a set of parallel national IPRs covering the same IP in a variety of jurisdictions. According to the principle of exhaustion of IPRs, once the IPRs holder has firstly sold the product covered by the IPRs, he cannot thereafter have any control on the later stages of the marketing of the product. The IPRs are deemed to have been exhausted after the first sale.

There are different legal systems under the issue of IPRs exhaustion. Some states follow a rule of national exhaustion, which is limited in the territory of a state. National exhaustion has no effect on parallel IPRs under the jurisdiction of other states, each of which continues to be fully enforceable in its own jurisdiction. As a result, the holder can separately invoke each parallel IPR in different jurisdictions against the import, use or release of even authorized products first sold in another jurisdiction.

The other states adopt an international IPRs exhaustion policy, which treats a first sale in any jurisdiction as automatically exhausting the holder's parallel IPRs in all other jurisdictions. Under this approach, a product may move freely anywhere in the worldwide market following any first sale. For example, when a patent holder



in a country sells the patented product, the buyer is free to use it in any way he likes, including selling it and exporting it to another country. Presuming that a product patented in country A is sold to buyer in country B. A person in another country C imports it for sale in country C where this product is also patented. Since the patent right has been exhausted in country A after the first sale, the patent holder cannot stop the export of the product to country C, which can be considered legal even without the authorization of the patent holder. This process has been called “parallel import” to distinguish it from the normal import of the product with the authorization of the patent holder. If the patent holder in country A normally sells the patented goods at a higher price in country C, the parallel import from country B may push the prices down, whereby the consumers will benefit.

A third option is regional exhaustion, by which rights are completed within a group of countries in a certain region, thereby allowing parallel trade among them, but are not exhausted between regional countries and non-regional countries. A typical example of this case is the EU, which adopts exhaustion policy in all fields of IPRs within the region but bars parallel imports coming from the countries outside its territory.

The policy choice of the international exhaustion problem is decided by the balance between the interest of consumer and right holder. Proponents of international exhaustion argue that permitting parallel imports protects the local consumers against artificially high prices through increased domestic competition, the very efficiencies envisioned by the free-trade principles on which the WTO is predicated. The rule would also encourage exports of low-cost local production, therefore fostering efficient international resource allocation. Opponents of international exhaustion argue that global market segmentation can have positive economic effects. It maximizes IPRs incentive to inventors and investors by allowing them to generate maximum return from each national market according

to the parallel protection. Specially, a non-international-exhaustion eliminates the risky resources of cheaper parallel imports back into national or premium market. Additionally, consumer non-price interest, such as adequate quality control and availability of local service and support, is protected by the elimination of the third-party parallel imports.<sup>54</sup>

Exhaustion policies vary widely in national legislations. Logically, developing countries, which are mostly IP-importing countries, prefer to adopt international exhaustion policy to protect their domestic consumers. However, the U.S. patents and copyrights holders are protected against parallel imports. Preference of non-international exhaustion by the U.S. is to maximize the return of domestic IPRs holders since it is an IP-exporting state. Some other IP-exporting countries like Japan, permits parallel imports in patented and trademarked goods unless they are explicitly barred by contract provisions. So it is more open to parallel imports than the U.S.. New Zealand and Australia have recently removed restrictions against parallel imports of copyrighted music and videos. Germany, Finland and Norway also adopted an international exhaustion policy. In these countries, national markets generally have higher prices for IP goods, domestic consumer will benefit from the price-competition provided by parallel imports from lower cost “foreign” jurisdictions. Therefore, the flow of wealth to the IPRs holder is offset by the consumer loss from the lack of parallel import competition in the domestic market. The above analysis demonstrates that the exhaustion policy depends on the calculation of the surplus of the right holder and loss of consumer. The net wealth left after the offset by conflicting interest plays a dominant role in the policy making.

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<sup>54</sup> Maskus, Keith E., and Lahouel, Boulder M., “Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement” (Revision, 1999). Available at <[http://www.worldbank.org/research/abcde/washington\\_12/pdf\\_files/maskus.pdf](http://www.worldbank.org/research/abcde/washington_12/pdf_files/maskus.pdf)>.

Other than the divergence on economic interest, the lack of agreement on international exhaustion issue also arises from the controversy on moral justifications of IPRs.<sup>55</sup> An IP creator's activity can be seen as bestowing Locke's labour-based natural rights or as an exercise of Hegel's personal liberty. It could also be viewed as an interaction with, and confirmation of, a jointly owned cultural heritage, the enhancement of national pride and community, the exercise of a usufruct rights in a trust granted by ancestors for the benefit of the present and future beneficiaries, or a contribution by the individual to the common heritage of mankind. The wide diversity of Eastern common heritage and collectivism versus Western individual incentive viewpoints partly illustrates the international exhaustion versus non-international exhaustion rule.

Even among the Western world, the different importance attached on moral rights also affects the exhaustion policy. Moral rights are predicated on natural or Hegel's rights of the authors as creator of the work. These systems, associated most strongly with France, provide extensive post-sale involvement of the authors in decisions concerning distribution and use of the work. As a consequence, exhaustion analysis under the moral rights approach differs dramatically from the economic utility "incentive to invent" justification. The latter, viewing the author's creation as an economic product, can readily accommodate first sale exhaustion based on a demonstration that additional incentive is not required. The former, which grants the author a right to protect the self-expression and personal identity manifested in the creation, provides little justification for curtailing or eliminating this control even after the first sale.

Therefore, despite the efforts of the U.S. negotiators in the Uruguay Round to incorporate a global standard of national exhaustion into TRIPS, it was impossible to reach such an agreement. The different policies of members and different

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<sup>55</sup> Although the protection of IPRs by the TRIPS Agreement is limited on economic rights, the moral justification of exhaustion underlies the debate of different systems, and helps to understand why the exhaustion issue is excluded from the Agreement.

underlying justifications of these policies are strong enough to leave the international exhaustion expressly unresolved in the TRIPS Agreement. Article 6 of the Agreement reflects the ultimate inability to agree. It provides that:

For purpose of dispute settlement under this agreement ... nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

As a result, the effect of the provision is to leave each member the freedom to establish its own exhaustion policy without challenge, subject to the national treatment and MFN provisions of Articles 3 and 4.<sup>56</sup> In this area, the only thing clear is that only after the legally first sale the IPRs could be exhausted. Counterfeiting and infringement goods could never exhaust the IPRs. Although Article 6 appears to have been accorded only a passing reference in the Agreement, it has an important implication for the limitation on the exclusive rights of the IPRs holder. It is a strong tool to protect the interest of consumer and IP-importing countries, and to ensure the availability of industrial and agricultural inputs as well as essential drugs at competitive prices, which is for the stake of public interest.

### **3.1.3 Control of Anti-Competitive Practices**

IPRs, by conferring exclusive rights to individuals, empower the right holder to appropriate the full market value of the protected subject matter. In this context IPRs, especially patent, could serve both as an incentive for the creation, use and exploitation of those intangible goods and as a stimulus to competition in a well functioning free market economy. Yet the exploitation of exclusive rights beyond the appropriate reward of creative activity could give rise to anti-competitive behaviour. Through the exploitation of the exclusive rights, right holders may

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<sup>56</sup> *Declaration on the TRIPS Agreement and Public Health*, adopted on 14 November 2001, WT/MIN(01)/DEC/2.

block the transfer of technology or distort the trade by different ways, especially by license. Therefore, the objective of public policy in this area has thus been to set the general principles that should guide the control of undesirable behaviour and seek to mediate the conflict between competition and IPRs.

The balance always begins by asking whether the restrictive practice under IPRs law results in excessive profits to IPRs holder or merely permits the holder to realize the reward appropriate to the creative work and investment. Two extreme doctrines confront each other. One is that the antitrust laws reign supreme. Under this doctrine an exploitation of IPRs is deemed illegal if it violates any aspect of anti-trust law; no privilege is accorded to IPRs. The other doctrine is IPRs statute reign supreme. Under this doctrine the anti-trust laws cannot render the right holder's exploitation illegal; the right holder has an absolute privilege to violate the anti-trust law.

Consequently, there exists interface between IPRs and competition law. The former solve the fundamental appropriability problem arising from investment in information and designate boundaries within which competitors holding IPRs may exercise their exclusive rights. The latter aims at curbing excessive exploitation of IPRs beyond the boundaries provided by the IPRs. Structured properly, the two regulatory systems complement each other in striking an appropriate balance between needs for innovation, technology transfer, and information dissemination.

Various country situations have lead to various legislations on the relationship between IPRs law and competition law. In the U.S., the basic approach is both of them share the common purpose of promoting innovation and enhancing common welfare. So there is no presumption that IPRs create market power in the anti-trust context. Instead, it is acknowledged that IPRs could serve as pro-competitive aim. The general test is to analyse a licensing restraint under the ‘rule

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of reason” treatment. That is, to inquire whether the restraint is likely to have anti-competitive effects and, if so, whether the restraint is reasonably necessary to achieve the pro-competitive benefit which outweighs those anti-competitive effects.<sup>57</sup>

In the EU, the relationship between IP licensing and anti-trust law are adjusted by Article 85 of the Treaty of Rome and related regulations<sup>58</sup>. Article 85 prohibits all the agreements that may affect trade or distortion of competition within the common market. Prohibitive provisions are automatically void unless exempted by the Commission. Article 85(3) permits that some agreement could be exempted if it contributes to improve the production or distribution of goods or to promote technical or economic progress. As to the patent licensing, the Commission has issued a block exemption, which give exemptions to bilateral, exclusive manufacturing licences with anti-trust effects which will violate Article 85(1) if not exempted. In 1996, the Commission passed a new regulation No. 240/96 on the application of Article 85(3) of the Treaty to certain categories of technology transfer agreements, which replace the previous one and harmonize and simplify rules governing licensing agreements in order to encourage the dissemination of technical knowledge in the community and to promote the

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<sup>57</sup> The “rule-of-reason” test was recommended in the 1995 *Antitrust Guidelines for the Licensing of Intellectual Property* jointly issued by the U.S. Department of Justice and the Federal Trade Commission, and respected by domestic judgments unless the restraint is unlawful *per se*. U.S. courts concluded in many cases that a restraint’s nature and necessary effect are so plainly anti-competitive that it should be treated as unlawful *per se* without an elaborate inquiry into the restraint’s likely competitive effect. Among the restraints *per se* unlawful are naked price-fixing, output restraints, and market division among horizontal competitors, as well as certain group boycotts and resale price maintenance. To determine whether a particular restraint in a licensing shall be given *per se* or “rule-of-reason” treatment, the Guidelines states that the Agencies will assess whether the restraint in question can be excepted to contribute to an efficiency-enhancing integration of economic activity. If there is no efficiency integration of economic activity and if the type of restraint is one that has been accorded *per se* treatment, the agencies will challenge the restraint under the *per se* rule. Otherwise, the agencies will normally apply a “rule-of-reason” analysis. Guidelines, p. 16.

Available at <<http://www.usdoj.gov/atr/public/guidelines/ipguide.htm>>.

<sup>58</sup> *Treaty Establishing the European Economic Community* (The Treaty of Rome), adopted on March 25, 1957, UNTS Vol. 298, p. 3.

manufacture of technically more sophisticated products. The regulation lists a number of obligations that are commonly found in licensing agreements but not normally restrict competition.

In most developing countries, the control of patent licensing practices was subject to special regulations dealing with transfer of technology transactions. Policy has evolved to a more strict application and enforcement of IPRs guided by the concern of improving the investment environment and attracting more technology transfer. In this respect, some countries provide for a certain degree of exemption for the licensing of patent.

Although there exist different addresses of the relationship between the IPRs and anti-trust laws in the domestic level, mainly through the anti-trust law, there has been no international regulation resolving this issue because of the lack of international anti-trust instrument. Several efforts to harmonize international anti-trust law, *e.g.* the Draft International Code of Conduct adopted by the UN Conference on Trade and Development (UNCTD),<sup>59</sup> did not see any success in this field. As a result, the anti-trust behaviour is under the territorial control while the IPRs protection are internationalised by the adoption of international conventions. However, with the deepening of globalisation and international trade, transaction anti-trust behaviours have prospected, especially those anti-trust behaviours enlarged by the exclusive rights granted as patent. Therefore, there had been a gap between the prosperity of international IPRs protection and the lack of international anti-trust regulation. The gap was enlarged by the adoption of the TRIPS Agreement, which seeks the further international protection of IPRs, with a unavoidable possibility of the abuse of exclusive rights.

Naturally, during the negotiation of the TRIPS Agreement, there was a general concern that greater protection of IPRs would strengthen the monopoly power of

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<sup>59</sup> *Draft International Code of Conduct on the Transfer of Technology*, adopted on 5 June 1985, TD/CODE/TOT/47 (1985), and *Negotiations on an International Code of Conduct on the Transfer of Technology*, Report by the Secretary-General of UNCTAD, TD/CODE/TOT60 (1995).

MNC, and detrimentally affect poor populations by raising the price of medicines and food. As IPRs create market power, developing countries sought assurances that action could be taken against the abuse of monopoly rights by IPRs holder. In particular, they feared that suppliers would be placed in a stronger position to restrictive conditions on the licensing of technology which would distort international trade.<sup>60</sup> Therefore, the inclusion of anti-competitive issue in the final text of the Agreement was the result of the proposal from developing countries to prevent the abuse of exclusive IPRs.

One of the general principles established by Article 8(2) of the TRIPS Agreement is the right of states to adopt appropriate measures “to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain the trade or adversely affect the international transfer of technology”. As a further particularization, Article 40 is another indication that IPRs may be exercised abusively. Thus, the Agreement reserves the rights of nations to adopt and enforce anti-trust laws in order to limit the exercise of IPRs (especially in licensing) in ways that harm competition or unduly limit the creation and diffusion of technology.

However, the address of competition by the TRIPS Agreement is not direct.<sup>61</sup> It refers to national law, with regards to both policy determination and implementation. Thus it allows members to take appropriate measures, provided that they are consistent with the provisions of the Agreement to prevent the abuse of IPRs by right holder or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.<sup>62</sup>

The open-end of the TRIPS Agreement in dealing with anti-competitive practices are evident in the text of the Agreement. The language of Article 40 is essentially

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<sup>60</sup> See above note 44.

<sup>61</sup> The issue was not dealt with in the same detail as the standards on the availability, scope and term of IPRs.

<sup>62</sup> The TRIPS Agreement, Article 8(2).



prescriptive and no precise definition of anti-competitive practices is provided. An important feature of the Agreement is that the evaluation of restraints on competition depends on the “relevant market” and therefore often has to be carried out on a case-by-case basis.

However, what constitutes a “relevant market” is not totally clear in the sense of Article 40. It could mean the market of the product or services produced with the licensed technology, but it could also mean the market of the technology itself. According to the 1995 U.S. Guidelines, relevant market refers to technology market consisted of the IP that is licensed and its close substitutes — that is, the technologies or goods that are close enough substitutes to significantly constrain the exercise of market power with respect to the IPRs that is licensed.<sup>63</sup> Under the new EU block exemption regulation, an agreement could become vulnerable if an exclusive licensee has a particular share of the market. Thus, the issue of what constitutes a “relevant market” is treated differently in domestic legislation. This is an area left to further interpretation and are subject to the “rule-of-reason” approaches indicated in the Agreement.

What constitutes “abuse” of IPRs is another unresolved issue. National laws differ on what they consider abusive practice. In the field of patent, while a few developed countries limit the concept to anti-competitive practices bordering on anti-trust violations, most countries consider the doctrine of abuse applicable only if a right holder fails to work the patent locally in due course or refuse to grant licences on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or demands excessive prices for such products. Again, the agreement leaves sufficient latitude to national legislation to define what constitutes an abuse of rights.

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<sup>63</sup> Guidelines, *see above* note 57, section 3.2.2, p. 8.

As to the illustrative list as abusive practices, the three examples cited in Article 40(2) were part of the fourteen abusive practices included in the proposal of the developing country members and were originally reflected in the UNCTAD Draft Code. Compared with the practices that are usually considered to be critical under national anti-trust laws, these examples only represent the tip of the iceberg and do not even exhaust the list of the “abuses” that are normally considered as *per se* unlawful in the U.S. courts. On one hand, non-challenge clauses are held valid or at least redeemable under some national laws. On the other hand, practices such as vertical restrictions limiting the exhaustion of IPRs, restrictions on sales or on resale prices, and restrictions on customer are not mentioned although they are proscribed by most anti-trust laws. Therefore, the examples given in article 40(2) are not exhaustive. It indicates the intent of the negotiators of the TRIPS Agreement to leave the specification of unlawful conducts to members.

Therefore, the impact of the TRIPS Agreement will partly depend on the type of competition rules that members would adopt as to anti-competitive practices. Within the broad guiding principles of Article 40, there is space for controlling particular practices constituting abuse of IPRs that have an adverse effect on competition in the relevant market. Developing countries may be encouraged to exploit the possibility of minimizing the impact of the TRIPS obligations by introducing extensive national competition law requirements. Given the lack of consensus and its attendant soft-law approach, the logical solution is to require consultations when conflicts occur. In this respect, Article 40(3) cuts two ways. It allows developing countries in particular cases to request information from developed countries that bear on alleged violator before its own government. But it also allows developed countries to demand consultation when they view the local action or regulations as exceeding the mandate of Article 40.

Meanwhile, the TRIPS Agreement also incorporates Article 10*bis* of the Paris Convention by reference. Therefore, it reinforces general principles of unfair

competition law falling within the purview of the Paris Convention.<sup>64</sup> Thus, states that continue to tolerate practices that blatantly deceive or confuse consumers with regard to foreign producers could find themselves embroiled in the dispute-settlement procedures established in the Uruguay Round.

In conclusion, from the economic point of view, IPRs involve both pro-competitive and anti-competitive elements. The TRIPS Agreement symbolizes the current thinking in the sense that IPRs are perceived as necessary for the functioning of a competitive market-based economy and right holder should be allowed to capture the surplus inherent in creative work as the safest course for ensuring competition and growth in the long run. However, diverse national situations and equity considerations may motivate a government to limit the licensor to capture his profits, as has been the case of countries of net imports of technology. Thus, these legal limitations on some practices or behaviours might be considered necessary to ensure a better balance between the licensees and the licensors incentive to innovate, as well as being beneficial to their economies. During the economic balance of the interests of innovators and importers of technology, developed countries focus on that the IPRs licenses could also be an incentive to the competition and should be free of unreasonable or discriminatory obligations. Developing countries shall attach a great importance to the provisions in the TRIPS Agreement dealing with competition, and decrease the competitive impact of the TRIPS Agreement through restrictive anti-competitive measures.<sup>65</sup>

### **3.1.4 Suspension of Non-Violation Complaint**

Article 64.2 provides that subparagraphs 1(b) and 1(c) of Article XXIII of the GATT shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement. Article XXIII of the GATT provides that if any contracting party should consider

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<sup>64</sup> See above note 25.

<sup>65</sup> Maskus and Lahouel, *see above* note 54.

that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as a result of the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or the existence of any other situation, it might raise a dispute settlement. Therefore Article 64.2 temporarily suspends the non-violation complaint with regard to IPRs issues.

According to Article 64.2, the suspension of non-violation complaint shall expire in 1999. Before the Doha Ministerial Conference, hot discussions were developed around the extension of suspension. Developing countries argued in favour of prolonging the suspension and called on the need to adopt a declaration to clarify this issue. The developed countries opposed this claim. They considered that a dispute on non-violation complaint could be submitted to the DSB in the regime of the TRIPS Agreement. In the decision of 14 November 2001 on implementation-related issues and concerns, the Doha Ministerial Conference directed the TRIPS Council to:<sup>66</sup>

continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the Fifth Session of the Ministerial Conference. It is agreed that, in the meantime, members will not initiate such complaints under the TRIPS Agreement.

Therefore, the non-violation complaint suspension is still valid nowadays. A legal implication of the suspension is the inapplicability of the “legitimate expectation” in the interpretation of the TRIPS Agreement. In the India Mailbox case, the Panel stated that “when interpreting the text of the TRIPS Agreement, the

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<sup>66</sup> *Doha Ministerial Decision on Implementation Related Issues and Concerns*, adopted on 20 November 2001, WT/MIN(01)/DEC/17, para. 11.1.

legitimate expectations of the WTO Members concerning the TRIPS Agreement must be taken into account.” The Panel found the violation of India based on the reason that it injured the legitimate expectation of the competitors of the U.S.. In the appeal of this case, the Appellate Body sustained the finding of the panel but based on other reasoning. It believed that the Panel’s invocation of and reliance on the “legitimate expectations” of members as to the conditions of competition is a hybrid of concerns stemming from the realm of violation and non-violation complaints, and as such it is an invalid tool for deciding cases involving the compliance of the TRIPS Agreement.

The Appellate Body stated that Article 64.2 of the TRIPS Agreement stipulates that only violation complaints under Article XXIII(1)(a) of the GATT will be allowed during the first five years of the TRIPS implementation, and the complaint against India falls within this timeframe and is indeed a violation complaint. Because of the nature of the complaint and the requirement in the TRIPS Agreement that only violation complaints be heard at this time, only the concepts that relate to the interpretation of the TRIPS Agreement with regard to the violation of its provisions should be applicable. The Panel’s use of the words “legitimate expectations” is an importation of the concern for “reasonable expectations” that applies to non-violation complaints, therefore it is not applicable to the interpretation of the TRIPS Agreement. Therefore, the legal consequence is that, the suspension of non-violation complaints extends to the suspension of “legitimate exceptions” derived outside the provisions of the Agreement.

### **3.1.5 Transitional Period**

Adoption of a stricter IPRs protection takes time. Moreover, given the complete absence of certain rights in many countries, enforcement of IPRs entails

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adjustment costs. Developing countries therefore insisted on a long transitional period during which changes in domestic legislation could be implemented. Some transitional arrangements to this effect are embodied in the final text of the Agreement.

The general implementation date of the Agreement for all WTO members was 1996.<sup>67</sup> However, developing countries may delay the implementation until the year 2000, except in Articles 3, 4 and 5.<sup>68</sup> This delay is also available to countries in process of transformation from centrally planned economies into market economies, which are undertaking structural reform of IPRs law and are confronted with special problems in the implementation of the corresponding laws and regulations.<sup>69</sup> Any developing country required to extend patent protection to products which are excluded from such protection by its existing laws (*e.g.* pharmaceuticals or agricultural chemicals) may delay that step until the year 2005.<sup>70</sup> Members availing themselves of these transitional arrangements are subject to a standstill requirement, *i.e.* they may not in the interim lower the degree of consistency of their laws, regulations and practice with the Agreement.<sup>71</sup> With the exception of Articles 3, 4 and 5 of the agreement, the LDC members may delay the implementation until the year 2006, and the TRIPS Council may extend such period.<sup>72</sup> In the Doha Ministerial *Declaration on the TRIPS Agreement and Public Health*, the transitional period of LDC has been prolonged to 1 January 2016 in the field of patent protection of pharmaceutical products.<sup>73</sup>

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<sup>67</sup> The TRIPS Agreement, Article 65(1).

<sup>68</sup> The TRIPS Agreement, Article 65(2).

<sup>69</sup> The TRIPS Agreement, Article 65(3).

<sup>70</sup> The TRIPS Agreement, Article 65(4).

<sup>71</sup> The TRIPS Agreement, Article 65(5).

<sup>72</sup> The TRIPS Agreement, Article 66(1).

<sup>73</sup> *See above* note 56, para. 7.

These transitional provisions have immediate effect on members, regardless of the internal constitutional mechanisms they employ to incorporate international law into domestic law system.<sup>74</sup> In contrast to Article 16(5) of the WTO Agreement and Article 72 of the TRIPS Agreement, which render reservations impracticable, for the transitional arrangement to become effective, no formal statement or reservation is required. It follows that the developing countries may avail themselves of the transitional arrangements and delay the application of TRIPS in whole or in part with the exception of Articles 3, 4 and 5 of the agreement. Therefore, subject to the standstill requirement of Article 65(6), developing countries may enact IPRs laws which are inconsistent with the Agreement in certain aspects. Consequently, no international responsibility will arise for non-compliance with the treaty standards during the transitional period.

As to the concept of LDC, the UN's list tends to be authoritative.<sup>75</sup> However, the status of developing countries is unclear. In fact, this has always been a highly arbitrary and political concept. No agreement has ever been reached on how to define developing countries. Indeed, the issue was carefully avoided. For example, when Portugal and Israel claimed developing country status in the GATT Balance-of-Payments Committee so as to be able to invoke Article XVIII(b), the Committee avoided pronouncing on the matter. It is left to countries to self-declare their status, and the WTO members can decide whether or not to treat a particular trading partner as a developing country. Assessment is in practice subject to bilateral interaction, and qualification of the candidates is sometimes not obvious.

The application of the transitional arrangement was not easy in practice. A case in point is Argentina, where the Congress intended to delay the obligation to extent

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<sup>74</sup> See below section 4.1, p. 76.

<sup>75</sup> The WTO recognizes as LDC those countries which have been designated as such by the UN. There are currently 49 LDC on the UN list, 30 of which to date have become WTO members.

patent protection for pharmaceutical products until 2003. Under the pressure of the U.S., this transitional period had to be reduced to five years although Argentina was entitled to delay patent protection for ten years according to Article 65(4). The benefits accruing from the transitional arrangements of the TRIPS Agreement were further mitigated by means of the enactment — again under U.S. pressure — of the so-called Confidentiality Law.<sup>76</sup> Despite the acknowledgement of the sustained efforts by the Argentine government to enhance IPRs protection, the U.S. administration considered that there had been “inadequate improvements” in Argentina’s patent regime since April 1996, and Argentina’s recently enacted legislation on the protection of test data submitted for marketing approval of pharmaceutical products fell short of international standards. As a result, the President determined that Argentina fails to provide adequate and effective means under its laws for foreign nationals to secure, to exercise, and to enforce exclusive rights in IP. Consequently, the U.S. government announced its intention to withdraw 50 *per cent* of Argentina’s benefit under the GSP programme.

Another difficulty in the exercise of transitional provision is the transitional arrangements in the field of pharmaceutical and agricultural chemical products, which is further provided in Article 70 paragraphs 8 and 9. The requirement under this provision is where a member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that member shall establish certain system to file the application of this type and exercise an exclusive market power. That is the so-called mailbox system.<sup>77</sup> Therefore, although the patent protection requirement is in suspension, other alternative protection requirements are to be met by the developing and least developed country members.

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<sup>76</sup> Law No. 24.766, *Boletín Oficial*, Vol. 30 (1996).

<sup>77</sup> See below section 3.23, p. 62.



## **3.2 Flexibility in Vertical Dimension**

### **3.2.1 Patentability**

#### **3.2.1.1 Availability of Patent Protection**

Article 27.1 provides that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The terms “inventive step” and “capable of industrial application” may be deemed by a member to be synonymous with the terms “non-obvious” and “useful” respectively.<sup>78</sup>

The various terms mentioned in this provision have not been defined in the text of the Agreement. In fact, there is considerable flexibility for the members to define these terms in its domestic legislation so as to reflect its own objectives in this field. For instance, if a member wishes to give protection to the interest of established innovators, it may define “invention” in a wider way, so that new innovations which approximate the earlier ones are not considered to satisfy the condition of novelty. On the other hand, if it wishes to encourage new innovators, it may define this term narrowly, thus permitting the patenting of innovations which approximate the already patented matter. Members can also use the flexibility of definitions to reflect its national objectives in balancing the interests of innovators and consumers. The subject of a patent should be an invention, and not mere a discovery of something which has already existed in nature but was not known earlier. For example, it is possible for a member to refuse patents for biological or generic material which has been in existence, though these were not known

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<sup>78</sup> The TRIPS Agreement, Footnote 5.

earlier. It has been suggested that some members could adopt high standards of patentability so that only revolutionary, as opposed to merely improving, inventions are granted patents. Another method might be to allow prior art form to defeat novelty. This could be very useful in cases in which developing country members contend that a patent claim is based on pre-existing indigenous knowledge. All of these instances would be justifiable, as there is no consensus on an international standard of absolute novelty.<sup>79</sup>

### 3.2.1.2 Exceptions to Patentability

Article 27 paragraphs 2 and 3 states that certain types of inventions may be excluded from patentability at the discretion of a member. The reasons for this exclusion could be to protect *ordre public* or morality, to protect human, animal or plant life or health, or to avoid serious prejudice to the environment. The following subjects may also be excluded from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

The presence of these exceptions reinforces the understanding in Part I of the Agreement that IPRs are qualified and be subject to competing interest that may be more important than exclusive patent rights. Since there is no definition on the *ordre public* or morality, the explanation of these Articles is reserved to the members and shall be made in accordance with their development situation and national economy. Whether or not the national interpretation and implementation

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<sup>79</sup> Reichman, Jerome H., "From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement", *New York University Journal of International Law and Politics*, Vol. 29 (1996), p. 30.

is inconsistent with the TRIPS Agreement shall be examined in the light of the purposes and objectives of the Agreement.

These exceptions are analogous to Article XX of the GATT, which also contains general exceptions to the free trade principle. Therefore, disputes on Article XX of the GATT resolved by the DSB are relevant in this respect. In the *US — Gasoline* case, the WTO Appellate Body stated that:<sup>80</sup>

Article XX of the [GATT] contains provisions designed to permit important state interests — including the protection of human health, as well as the conservation of the exhaustible natural resources — to find expression. The provisions of Article XX were not changed as a result of the Uruguay Round of Multilateral Trade Negotiations ... So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirement of the [GATT] and the other covered agreements.

It is relevant to note that plants and animals have been excluded from the obligation of patents, irrespective of their mode of production. For example, plants and animals, even though produced by modifications through genetic engineering (transgenic plants or animals) or other methods, need not to be covered by patents. However, the process for the production of plants and animals has to be given patents, if there are non-biological or microbiological.

In the field of biotechnology, as a consequence of the Chakrabarty case decided by the U.S. Supreme Court in 1980,<sup>81</sup> there was a wave of claims to patent living forms of all kinds. Therefore, the possibility in the TRIPS Agreement of excluding plants and animals from patent protection is important in this context. It can be used to prevent the private appropriation of natural resources of importance for

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<sup>80</sup> *US — Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body, WT/DS2/AB/R (29 April 1996).

<sup>81</sup> *Diamond v. Chakrabarty*, 447 US 303 (1980).

food and agriculture and for the conservation of the environment. The proposed review of this provision is after four years from the date of entry into force of the TRIPS Agreement. The opportunity of review offers developing countries a possibility to co-operate in defining permanent rules that recognize the right of national legislation to exclude the patenting of any living form.

Even though plants themselves are excluded, plant varieties have to be covered by some forms of effective protection, either by patents or by an effective *sui generis* system, or by a combination of both. The making of varieties refers to bringing about improvements by breeding techniques to create stable and uniform objects with different characteristics. This obligation does not extend to the protection of animal varieties. There is considerable flexibility for a member to introduce its own *sui generis* system.

One example of such a system is the UPOV.<sup>82</sup> The object of the UPOV is to grant certain exclusive rights to plant breeders who develop new varieties of plants. Normally, farmers provide the source material to the breeders for the development of new varieties. They are also the users of new varieties developed by the breeders. So there is a need for a balance between the breeder's rights and what has been called the farmers' privilege. But the UPOV emphasizes on the breeder's rights and sacrifices the farmers' rights, therefore this model is not preferred to by the developing and least developed country members.

It is not necessary for a member to adopt any model mentioned above, they are free to evolve their own "effective" *sui generis* system of protection. The provisions of the Biodiversity Convention also provide some guidelines in this respect.<sup>83</sup> What's more, the criteria to be applied in determining whether

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<sup>82</sup> *The International Convention for the Protection of New Varieties of Plants (UPOV)*, adopted on 2 December 1961. Earlier, the applied version was UPOV 1978. Then, a revised version, UPOV 1991, was negotiated and came into effect. UNTS Vol. 815, p. 89.

<sup>83</sup> *Convention on Biodiversity*, adopted on 5 June 1992, ILM Vol. 31, p. 818.

protection is “effective” are not defined. Accordingly, countries are free to determine the scope and contents of the rights to be granted. For instance, they could grant exclusive rights to breeders with respect to the propagating materials (that is, seeds and other materials for the reproduction of plants) of new varieties, subject to clearly stated exceptions for the re-use and eventual sale of seeds by the farmers and exceptions for the use of protected varieties by a third party in order to develop a new variety. *Sui generis* regimes can also include compulsory licences for reasons of public interest, as well as provide recognition – e.g. via a royalty or other type of remuneration – of the rights of traditional farmers that have provided breeding materials.

In working out an “effective *sui generis* system” for plant varieties, there is considerable room for co-operation and harmonization of legislation between developing countries, the majority of which have not yet adopted any kind of protection for plant varieties. They may wish to propose a *sui generis* system which corresponds to their own needs and does not follow the UPOV convention as revised in 1991, which strengthens breeders’ rights at the expense of farmers’ rights.

### **3.2.2 Limitation on Rights Conferred**

A patent shall confer on its holder the right of making, using, offering for sale, selling, or importing the patented product or process. The Agreement allows limited exceptions to the rights of the patent holder. Article 30 provides that members 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 account of the legitimate interests of third parties.

The exceptions take into account the legitimate interests of the third parties. Not all interests protected by national legislation are deemed as legitimate under the TRIPS Agreement. In the light of the language of Article 27 and other provisions of the Agreement, a systematic interpretation of the Agreement lead to the point that merely prohibited by national law could not be necessarily legitimate unless this national law is also consistent with the provisions of the Agreement.

At the same time, as to the judgment of which interest are legitimate, the relevant source of international law should be taken into consideration. In interpreting the scope of “exhaustible national resources” as a legitimate interest protected by Article XX(g) of the GATT, the Appellate Body took a broad view of the sources of international law that could be appropriately used to articulate the relevant evolving international legal order, including “soft law” sources, such as resolutions and authoritative reports and policy statement of relevant international organizations.<sup>84</sup> Hence, according to the widely adopted international customary law and conventions, human rights including social rights and public health could also be legitimately interest of the third parties. For instance, a previous GATT panel had ruled that measures prohibiting the advertising of cigarettes were defensible under the GATT Article XX as a measure necessary to protect public health,<sup>85</sup> provided that these measures are not discriminatory.

Various qualifying terms used here have not been clarified; there may be an ample scope for differences of opinion. Clarity will emerge during the course of the application of the Agreement. Based on prevailing practices, it does appear reasonable to assume that these limited exceptions cover the use of patented

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<sup>84</sup> *US – Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R (12 October 1998), para. 128, 130.

<sup>85</sup> *Thailand — Restrictions on Importation of and International Taxes on Cigarettes*, Reports of the Panel, DS10/R, BISD 37S/200 (7 November 1990).

products or processes for scientific or technological experiments in pursuit of further scientific development. In fact, for members who wish to encourage domestic innovation, it may be desirable to provide a limited exception that patented matter may be put to experimental use without the authorization of the patent holder. It may enable domestic innovators to do experiment with this matter and bring about further improvements, particularly those suited to local conditions. A certain degree of reverse engineering (*i.e.* proceeding backwards from the patented product to learn how it has been produced) is inevitable in this process, which may be of help to new innovators working on the further development of patented matter.

### **3.2.3 Transitional Arrangements**

Because the obligations of Section 5 require some members to extend protection to products and process that were previous not protectable under their national laws, a number of transitional issues have to be addressed. Article 65.4 permits developing country members an additional transition period of compliance with the relevant obligations of the TRIPS Agreement when such members are required by the Agreement to extend product patent protection to areas of technology that have not previously been subjected to protection within their territories.

Although transitional arrangements give some members a breathing space, this space cannot be exploited unlimitedly.<sup>86</sup> A particular case in point is the India Mailbox case under the DSB of the WTO. Article 70.8 provides that a member, who did not have patent protection for pharmaceutical or agricultural products on 1 January 1995, shall establish a provisional system whereby patent applications for these products can be filed during the transition period. This is the “mailbox” system. Once the transitional period has ended, it must then review all such

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<sup>86</sup> See above section 3.15, p. 54.

applications and extend patent protection for the remaining of the patent's term, calculated from the date of the original filing. Under Article 70.9, where a product is the subject of an application under Article 70.8, a member is required to grant exclusive marketing rights for a five-year period after the product receives marketing approval, or until the patent is granted or rejected, whichever period is shorter. In order to qualify for this period of exclusivity, a patent application ought to have been filed and a patent granted for that product in another member and marketing approval obtained in such a member. These special provisions will provide protection similar to patent protection until the applicable transition period has ended and patent protection then becomes available. As of 1999, India had not passed implementing legislation or delineated procedures to accept "mailbox" applications, therefore the alternative requirement of the Agreement to patent protection in the transitional period was violated.

### **3.2.4 Use without Authorization of the Right Holder**

#### **3.2.4.1 The Legality and Grounds of Compulsory License**

Comparing the language of the Paris Convention,<sup>87</sup> the TRIPS Agreement never mentions the phrase "compulsory license" throughout its text. Yet, Article 8 of the Agreement constitutes the basis of legal justification for compulsory licence, Article 27.2 explicitly allows the exception of patent, and Article 31 clarifies the procedural safeguards of the grant and practice of use without the authorization of the patent holder. Thus, Article 31 about the use without the authorization of the rights holder is in substance analogous to the traditional term of compulsory license. This Article in particular highlights that the private rights conferred by the TRIPS Agreement are limited and qualified. They are subject to be over-ridden by the public interest where necessary and appropriate. Therefore this part of the Agreement shall be read together with the preamble and Part I, the rationale of

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<sup>87</sup> For compulsory license under the Paris Convention, *see above* section 2.22, p. 19.



which is to seek a good balance between private rights and public interest, and to prevent the abuse of exclusive rights of patent holder.

There are no specific provisions concerning the grounds on which such licences can be granted. Specific reference is made to the dependency of patents (*i.e.* when an invention cannot be used without using another invention); to licences for governmental non-commercial use; to cases of emergency use; and to remedy anti-competitive practices. But licences may be granted also for other reasons. Thus, nothing in the Agreement prevents, in effect, the granting of compulsory licences for reasons such as public interest, public health or environmental protection, subject to the conditions set out in the Agreement.

The legality of the compulsory license granted for the reason of public health was reaffirmed and clarified by the *Declaration on the TRIPS Agreement and Public Health* adopted by the Doha Ministerial Conference. It states that:<sup>88</sup>

Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

What's more, the Declaration goes a step further by recognizing that the WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Therefore, it instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.<sup>89</sup>

Compulsory license has special impact in the field of pharmaceutical patent. The concern that the social and economic costs of introducing pharmaceutical patents are likely to outweigh the benefits in the case of most developing countries suggests a cautious approach to intellectual property protection in the area of

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<sup>88</sup> See above note 56, para 5.b.

<sup>89</sup> See above note 56, para.6.

pharmaceuticals. Since under the TRIPS Agreement member countries are bound to provide such protection, compensatory measures and schemes to avoid the negative impact of monopolization of drugs will need to be devised. Such measures could include, for instance, appropriate compulsory licence systems which facilitate the access to protected technologies and raw materials. In the new framework for IPRs, this type of licence may be an important tool for preventing anti-competitive practices and for persuading title-holders to grant voluntary licences on reasonable commercial terms.

As a matter of fact, compulsory license widely exists in the domestic legislation and practice. For instance, the U.S. can issue compulsory licenses to patented products under the *Clean Air Act*,<sup>9 0</sup> *Nuclear Energy Act*,<sup>9 1</sup> for public health purpose under the *Bayh-Dole Act*,<sup>9 2</sup> as a measure for anti-competitive practices under antitrust laws, and for government use. Under 28 USC Section 1498, the U.S. government can use patent or authorize third parties to use patents for virtually any public use, without negotiation. Patent holders have no rights for injunctive relief, and may only seek compensation, not as a tort, but as an eminent domain taking. In the year of 2000, the U.S. issued several compulsory licenses for tow truck technologies. The Secretary of the Department of Health and Human Services makes the determination in cases involving the public health under the *Bayh-Dole Act*. Also, in Canada, Australia, Ireland, Italy, Germany, New Zealand and the U.K., public use provisions also provide very similar powers, as several other countries do.

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<sup>90</sup> 42 USC § 7608 (1995).

<sup>91</sup> 42 USC § 2138 (2000).

<sup>92</sup> 35 USC § 203 (2000).

### 3.2.4.2 Procedural Safeguards

Great efforts to seek a reasonable balance is illustrated by the procedural requirements from Article 31 paragraphs a to l, which is a result of the negotiation between developed countries and developing countries. The developing countries lag behind in the technical development and concerned about the access to essential products for the public interests like national security or public health. While the developed countries lead the technical development and is concerned about the profits of domestic industry, which is not only the private interest of the right holder but also the national economic and trade benefit. Therefore, to weigh the economic interest of the different parties through the provision of safeguards against arbitrary compulsory licenses are the main task of this provision.

Article 31(f) provides that “any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use”. One of the discussions before the Doha Ministerial Conference was about the scope to produce for export under compulsory licensing in order to supply a poor-country market. This was considered important because many smaller developing countries may want to use compulsory license for import rather than local production. They argued that the language “predominately for the supply of domestic market” does not absolutely exclude the supply outside the domestic market. They called for the provisions to be interpreted leniently and compulsory license to be used to develop local production — which they said is necessary for public health and technology transfer — if a patent holder does not produce the medicine in that country.

According to the general rule of treaty interpretation, as the language of the text is vague, the provision shall be interpreted in the light of the purpose of compulsory license, which is mainly for the protection of public interest or as a remedy to the abuse of IPRs. Therefore, if a compulsory license is justified as a measure respond to the public interest, *e.g.* to overcome the severe health crisis caused by

HIV/AIDS in a member, there is no rationale to export a product made under compulsory license if the health crisis is happening only within the territory of that member. While if the crisis is of a regional character, and other small countries may lack the capacity to produce such patent product locally, then the export as a supply for foreign market is reasonable. The precondition is that the price and scale of the export is not for the purpose of profit earning. Otherwise the effect of extritorial supply is not to fight against the health crisis but to redistribute the profits generated by exclusive rights.

Another situation is that the compulsory license is made as a remedy for the abuse of patent right, *e.g.* as an anti-competitive measure. Under this context, the justification is not for the public interest but to promote the technical transfer and sanction the abusive exercise of exclusive rights. In this case, the domestic supply requirement in paragraph f should be waived.<sup>93</sup>

### **3.2.4.3 Compensation**

Adequate remuneration to the right holder is provided in paragraph h as a further condition of compulsory license. The concept “adequate” needs to be illustrated by national law and practice. Legislation could limit the remuneration so as to compensate, through a royalty calculated as a percentage of net sales, for the costs actually incurred by the patentee in developing the invention, excluding the subsidies or other contributions that the patentee may have received from third parties or entities. The compensation may also be determined taking into account the average royalties paid in the particular sector by licensees which are not under the control of the licensor concerned.

There is a rich diversity of national approaches in terms of compensation in the light of economic value of the authorization of the compulsory licensing. Japan,

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<sup>93</sup> In this situation, the procedural requirement in paragraph b could also be waived and the “adequate compensation” in paragraph h could be reconsidered.

Germany, and the Philippines and other states have adopted various forms of royalty guidelines for the calculation of compensation in this situation. Japan has used rates from 2 to 4 *per cent* in the past, and Germany used 2 to 10 *per cent*.

Canada, which according to the World Health Organization (WHO) has the most extensive use of compulsory licensing for pharmaceutical products, ordered royalties around 4 *per cent*. In 1987, when Hoffmann-LaRoche requested a flat fee royalty that would have amounted to 39 *per cent* of the price of Valium before the emergence of generic competition, the Canadian Exchequer Court set an *ad valorem* royalty of 4 *per cent* on sales after the emergence of generic competition. The court provided that in setting the terms of the license and fixing the amount of royalty or other consideration payable, the relative authority shall have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention’’.<sup>94</sup>

The U.S. Patent Code includes provisions allowing the federal government to infringe valid patent when infringement serves the national interest and reasonable compensation is paid.<sup>95</sup> The requirements for reasonable compensation have been interpreted historically to imply much lower payments than the foregone monopoly profits standard imposed in private patent infringement damages cases. In *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, a majority of the Supreme Court ruled that Congress had exceeded its constitutional powers in nullifying individual states’ sovereign immunity from patent infringement suits in federal courts, provided that the states maintain their own in-state legal procedures to ensure that the patent holders’ property is not taken

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<sup>94</sup> *Hoffmann-LaRoche Ltd v. Frank W. Horner Ltd.*, C.P.R. 107-108 (1979). See Scherer, Fredric M., “the Economic Effects of Compulsory licensing”, *Monograph Series in Finance and Economic* (N.Y.U. Graduate Sch. Bus. Admin. Center for Study Fin. Ins. Monorapg, 1977), p. 47.

<sup>95</sup> 28 USC §1498 (1994).

without due process of law.<sup>96</sup> Armed with that precedent, the states might in the future seek to alleviate their escalating drug cost burdens under Medicaid by setting up patent-infringing generic drug production operations or importing drugs from no-patent jurisdictions and offering to pay “reasonable compensation” for the use of the infringed patent. Compensation substantially less than the monopoly profits foregone by the patent holders might arguably satisfy the due process requirement.

Members of the TRIPS Agreement could design their own guidelines on this issue. Whether the rate it should be manageable, there is no reason that the TRIPS Agreement demands developing countries to pay more than the developed countries do in their domestic practices.<sup>97</sup> Like other issue in Article 31, the most important is to provide a fair process for reaching a reasonable result. There is no question about the power of states to rein in patent right in order to assure affordability and access. But in the process of doing so, the patent holder shall provide sufficient evidence to claim the investment in R&D, the risk costs, and the government shall take the burden to prove that allowed justification and procedural safeguards provided in the Agreement have been met.<sup>98</sup>

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<sup>96</sup> Florida Prepaid Postsecondary Education Expense Bd. v. College Savings Bank, 119 S.Ct. 2199 (1999).

<sup>97</sup> Love, James, “Compulsory Licensing: Models For State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord”, paper prepared for United Nations Development Programme (2001). Available at <<http://www.cptech.org/ip/health/cl/recommendedstatepractice.html>>.

<sup>98</sup> For example, the firms should disclose the actual costs invested in the development of products using a standardized disclosure format, so the data should contribute to deeper public sector and citizen understanding of the actual investments in products and the economics of new drug development. This should be accompanied by data on the actual sales of that product, since its introduction, to provide more information on the returns on the actual sales of that product to provide more information on the actual returns from the company investments. *See* Trans Atlantic Consumer Dialogue’s (TACD) recent recommendations to the US and the EU on transparency in pharmaceutical economics. Available at <<http://www.tacd.org/misc/cr-health2000.rtf>>.

#### 3.2.4.4 Non-Discrimination in the Field of Technology

Read in conjunction with Article 27.1 of the Agreement, a sensitive issue related to compulsory license is the discrimination in the field of technology. Article 27 of the TRIPS Agreement states that patents shall be available and patent rights enjoyable without discrimination as to the field of technology. So the compulsory license shall also be non-discriminatory.<sup>99</sup>

A landmark case in this field is the lawsuit brought by a Pharmaceutical Industry Association and 39 of its affiliate pharmaceutical companies against South Africa regarding provisions of its *Medicines and Related Substances Control Amendment Act* of 1997. This Act explicitly authorized parallel import and compulsory license with the objective to remedy public health crisis. It granted the Health Minister the power to act in the interest of public health by ensuring that patent rights for any drug would not hinder South Africa government from issuing a license to a third party to produce the same drug, the purpose of which is to allow easier access to affordable drugs as a response to the HIV/AIDS crisis. It also allowed both cheaper imports from drug producing countries and generic substitution.

The complaint of the plaintiff was that the Act violated the right of the pharmaceutical patent holder. They claimed that:<sup>100</sup>

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<sup>99</sup> However, Article 70.6 of the TRIPS Agreement provides that “members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.”

<sup>100</sup> *The Pharmaceutical Manufacturers' Association of South Africa, et al, v. the President of the Republic of South Africa, the Honourable Mr. N.R. Mandela N. O., et al.*, High court of South Africa, Case No. 4183/98 (1998).

It is discriminatory in respect of the enjoyment of patent rights in the pharmaceutical field which discrimination is in conflict with the provisions of Article 27 of the TRIPS Agreement, an international agreement binding the Republic and to which Parliament has given effect by the promulgation of the Intellectual Property Laws Amendments Act No.38 of 1997, and consequently with Sections 231(2) and 231(3) of the Constitution.

The South Africa government's correction of its policy, serious weakness in the technical arguments of the plaintiffs together with strong pressure from domestic and international public opinion resulted in the withdrawal of the case by pharmaceutical companies. On 17 September 1999, the U.S. and South Africa reached a common understanding on the relationship between pharmaceuticals and public health. While both governments committed themselves to the TRIPS Agreement, they nevertheless acknowledged the need to address the AIDS epidemic as a public health emergency.

Although this case was settled without touching the issue of technological discrimination, the problem was still going on. A recent WTO dispute raised the discrimination issue again, which involved Canadian patent exceptions for research and testing on generic drugs used for drug registration and a Canadian patent exception that permitted stockpiling of production in anticipation of the patent expiration.<sup>101</sup> The plaintiff (EU) argued that:

Canada, by treating patent holders in the field of pharmaceutical inventions by virtue of these provisions less favourable than inventions in all other fields of technology, violated its obligations under Article 27.1 of the TRIPS Agreement requiring patents to be available and patent rights enjoyable without discrimination as to the field of technology.

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<sup>101</sup> *Canada — Term of Paten Protection*, Report of the Appellate Body, WT/DS170/AB/R (18 September 2000).



Canada referred to Article 32 (b) of the VCLT, which says the interpretation of treaty terms “should not produce manifestly absurd or unreasonable results”. It argued that the adoption of the meaning of the Article 27.1 reflected under the argument of the EU would clearly violate the rule of the VCLT. It would lead to a requirement for “across-the-board” derogations from patent rights, thus compelling exceptions where there was no practical need and reducing patent protection more than was required in all areas save those in which a balancing measure was actually required. Such an incongruous result would not be consistent with the objectives of the Article 27.1 and the intent of Article 30. The Agreement allows exceptions that are “limited” because they are not spread across all sectors of technology. Therefore, the Canadian law respected the objective, as reflected in the TRIPS Agreement, of ensuring balance, by avoiding an anti-discrimination rule which would overwhelm other important societal interests if it had to be applied “across the board”, without regard for particular circumstances.

Therefore, the argument of the EU deprived members of the ability to create appropriate solutions for specific problems on a case-by-case (or a product-by-product) basis, and instead obliged them to impose universally applicable measures which could be entirely inappropriate in most context. It required “limited exceptions” to be unlimited.

On 17 March 2000 the WTO Panel report held that the Canadian provisions were not violations of Article 27.1 of the TRIPS Agreement. However, this decision seemed to be based largely on the fact that the legislation itself did not specifically limit itself to the pharmaceutical industry, even though it was clear that this was a primary area where the legislation was having an effect. The decision includes language that declared the reasons for Article 27.1 was to prevent countries from enacting compulsory licensing laws that dealt specifically with pharmaceuticals. However, the Panel avoided an essential question: if the legislation was particular on one technical field, *e.g.* pharmaceutical product,

would it be discriminatory; or even if discriminatory, would it be permitted discriminatory justified by the specific purpose.

In general, the issue of permitted discrimination in the field of the technology seems to be an unanswered question even after the WTO decision in the case, and pose perhaps the most difficult issue for the drafting of legislation by members. All of the contractions and tension in the Canadian case was reserved, so the substantive question will likely be revisited in the future. The U.S. compulsory licensing laws for clean air and civilian nuclear energy are facing the same difficulty. The recommendation of this thesis for members is, to adopt laws that provide for compulsory licensing under a broader title like “health”. Confronting the challenge by other members before the WTO, they could therefore make the argument that “health” is not a field of “technology”, as “health” could be related to many technological fields.

# **4 The Legal Implications of Flexibility of the TRIPS Agreement**

## **4.1 The Status of the TRIPS Agreement in Domestic Legal Systems**

The legal status of international treaty in domestic legal systems relies on the constitutional separation of powers and the nature of the treaty concerned. The latter is further determined by the factors like the intent of the parties, the constitutional separation of power and the justiciability of the treaty provisions, all of which are reflected in the language of the treaty and the states' legislation and practice thereafter. This section will discuss the nature of the TRIPS Agreement and its legal status in domestic legal systems. The analysis will illustrate how the flexibility of the Agreement imposes important impacts on its nature and legal status. Before going to the TRIPS Agreement, general discussion of the international treaty in domestic legal systems will provide a logical premise.

### **4.1.1 The Status of Treaty in Domestic Legal Systems**

As to the relationship between international treaty and domestic legal systems, the first question is whether a treaty is a part of the legal order of a state as to enable its direct application in the domestic court, or whether a specific act of incorporation or transformation is necessary for its integration into the domestic legal system. The second question is where there exists inconsistency between a treaty and domestic law, which one prevails in domestic legal order?

#### 4.1.1.1 The Application of Treaty in Domestic Legal Systems

Theoretically, as to the relation between international treaty and domestic legal systems, there are two doctrines known as monism and dualism. The monism regards international treaty and domestic law as interrelated parts of a unitary legal system. The dualism considers that international treaty and domestic law constitute two separate and independent legal orders which coexist but differ as to their subjects and sources; neither legal order has the power to establish or alter the rules of the other. Therefore, for an international treaty to be invoked and applied within the domestic courts, the state should perform a specific act of incorporation, and then the treaty rules would be applied as part of national law and not as international law.<sup>102</sup>

In the U.K, the ratification of treaty is a prerogative power belonging to the executive authorities. The automatic application of treaty provisions may lead to the result that the executive authorities could alter the British law without the approval of Parliament, which is contrary to the basic principle of constitutional law that Parliament has a monopoly of legislative power. Consequently, a treaty is required to be transformed into domestic law by legislative enactment of Parliament. An international treaty has no effect in domestic law until an act of Parliament is passed to give effect to it.<sup>103</sup>

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<sup>102</sup> Brownlie, Ian, *Principles of Public International Law*, 5<sup>th</sup> edition (Clarendon: Oxford University Press, 1998), p. 31-33.

<sup>103</sup> There are limited exceptions to the requirement of parliamentary implementation: no legislation is required for certain specific classes of treaties, namely, treaties modifying the belligerent rights of the Crown when engaged in maritime warfare (presumably because such treaties involve no major intrusion on the legislative domain of Parliament), and administrative agreements of an informal character needing only signature, but not ratification, provided they do not involve any alteration of municipal law. Significantly, these exceptions appear to involve matters unlikely to become the subject of litigation before common-law court. See Shearer, Ivan, *Starke's International Law*, 11<sup>th</sup> edition (London: Butterworths, 1994), p. 71-74.

No act of transformation is necessary in countries such as the U.S., where the Senate's approval or a law of approval by the Congress is respectively necessary for the ratification of treaty by the executive authorities. Once the treaty is internationally in force, no other legislative act is necessary for it to become part of American law. The supremacy clause gives treaty the character of municipal law which is enforceable in domestic courts at the behest of private individuals. Courts may consider a treaty equivalent to a legislative act when the treaty is self-executing. Accordingly, the distinction between "self-executing" and "non-self-executing" is decisive.<sup>104</sup>

Similarly, in Italy, it is not necessary to reproduce the rules of treaty, but an "order of performance" setting forth the intention that the treaty be performed and applied at the domestic level is necessary. The Constitutional regulation of Spain is similar as it provides, in Article 96 paragraph 1, that international treaties, legally entered into, shall be a component for their application, "as the provided formalities for becoming a component part of the domestic order upon their official publication in Spain". No act of transformation is necessary as a condition for the domestic application of treaties, "as the provided formalities for becoming a component part of the domestic juridical system are deemed fulfilled upon publication thereof".<sup>105</sup> The French Constitution also sets up the criterion of the automatic application of treaty, without the need of any other legislative act.<sup>106</sup>

In summary, the necessity for some formal domestic transformation depends upon two factors principally:

a. The constitutional and administrative practice of a particular state:

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<sup>104</sup> See below section 4.112, p. 81.

<sup>105</sup> Correa and Yusuf, *see above* note 22, p. 100.

<sup>106</sup> Pinh, Nguyen Q., Daillier, Patrick, and Pellet, Alain, *Droit International Public*, 4<sup>th</sup> edition (Paris: LGDJ, 1993), p. 224-225.

- (i) The transformation of a treaty into a domestic rule is required before it becomes binding and applicable in domestic courts, as is the case of the U.K., Ireland and Scandinavian countries, among others.
- (ii) A treaty that are not inconsistent with the constitution binds the courts without any specific act of incorporation, as is the case of the Argentina, Belgium, France, Luxembourg, Greece, German, Spain, Mexico, the Netherlands, Switzerland, and the U.S..<sup>107</sup>

b. The nature of the particular treaty:

In the countries like the U.S., no transformation is necessary. Domestic application of a treaty is determined by its nature: self-executing or non-self-executing. Self-executing treaties need no legislative implementation.

#### **4.1.1.2 Nature of Treaty: Self-Executing and Non-Self-Executing**

In general, a “self-executing” treaty can be applied and enforced directly by the courts without a prior legislative implementation. Conversely, a “non-self-executing” treaty may not be enforced in the courts without prior legislative implementation. It merely confers rights upon states or binds them to take supplementary or regulatory steps to implement the agreement. Treaty rules would not be effective by themselves and therefore may not be invoked by individuals before domestic court. It is possible that in the same treaty some provisions are self-executing while others are not. In the domestic courts of the U.S., self-executing or non-self-executing of a treaty or a treaty provision depends on the intent of the parties, the constitutional separation of power, and the justiciability of the treaty provisions.

a. Intent

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<sup>107</sup> Brownlie, *see above* note 102, p. 31-56. *See also* Shearer, *see above* note 103, p. 77-78.

Traditionally, treaties were considered as direct source of rights and obligations of states, which are the main or unique subjects on international law. Private parties were not entitled to invoke them until the contracting parties supplemented the treaty rules with domestic legislation. This conception was upheld by the Permanent Court of International Justice (PCIJ) in the *Danzig Railway Official Case*.<sup>108</sup> However, the PCIJ acknowledged that the intent of the states parties to an international agreement could be that treaty is effectively a direct source of the rights of private parties and could be invoked before domestic courts. Therefore, considering the intent of the parties as reflected in the text of a treaty, a treaty or a provision could be self-executing and a direct source of rights.

This doctrine is further explained by the domestic judicial decisions of the U.S.. In *Foster* case, the court recognized that the general rule established by the Supremacy Clause, under which treaties are enforceable in the courts without prior legislative action, could be altered by the parties to the treaty through the treaty itself. If the parties to the treaty agreed that the rights of the private parties before domestic courts were to be affected only through future lawmaking acts of the states parties — if they “stipulate for some future legislative act” — then the treaty is not “operative of itself” and accordingly cannot be enforced by the courts without prior legislation.

In certain situations, the U.S. courts went beyond the words of the relevant treaty provision and relied on negotiating history and statements made during the executive advice-and-consent process in determining whether a treaty is self-executing or not. In some circumstance, the negotiators issued declarations binding on courts, qualifying the treaty as non-self-executing. For example, in recent years, the U.S. treaty-makers qualified its consent to the ratification of a treaty with a declaration to the effect that the treaty shall not be used as a direct source of law in the U.S. courts. These declarations have been attached to

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<sup>108</sup> *Danzig Railway Official Case*, Report of PICJ (1928), Series B., No. 5.

treaties that would clearly not otherwise be wholly non-self-executing. The unilateral declarations reflected the views of the President and two-thirds of the Senate, and have been used in respect of human rights treaties and economic agreements.<sup>109</sup>

#### b. Constitutionality: Constitutional Separation of Powers

The constitutional systems of the states also determine whether the executive or the legislature power shall enact the implementation rules to enable the application of treaties. In some countries it is usually for parliaments to legislate on international trade issues and to allocate rights of private parties, while international treaties are generally negotiated and ratified by the executive authorities without an active role of legislation. The treaty-makers (executive authorities) may bypass the law-makers by lifting a subject matter from the national to the international sphere. Therefore if the treaty-makers make a treaty in the regime of the law-makers' power, this treaty is non-self-executing because of the treaty-makers' constitutional disability, and its enforcement in the domestic courts requires an implementation act of the legislative power.

For example, if the relevant treaty deals with a subject matter in which the U.S. Congress has an exclusive legislative power, the treaty will be considered as *prima facie* non-executing, irrespective of what the intention of the parties is claimed to be.<sup>110</sup> Courts sometimes consider the subject matter of a treaty to be relevant as it reflects the allocation of power. Treaties which purport to raise revenue, make conduct criminal and appropriate money are considered to fall into the power of law-makers but not the treaty-makers, so these treaties are non-

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<sup>109</sup> For example, such a declaration was attached to the *Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, GA RES No. 39/46, adopted on 10 December 1984.

<sup>110</sup> Shearer, *see above* note 103, p. 74-78.



self-executing. Treaties of friendship, commerce, extradition and navigation fall within the power of the treaty-makers and are considered to be self-executing.

### c. Justiciability

Justiciability refers to whether a treaty is judicially enforceable by private parties in domestic courts. Treaties are enforceable in the courts only if they impose obligations. Some treaties do not impose obligations but, instead, set forth aspirations. Domestic courts have found that such treaties are not judicially enforceable, because if a treaty does not impose an obligation on the defendant to treat the plaintiff in a given way, it does not give the plaintiff a correlative right to be treated. These kinds of treaties are non-self-executing.

How to draw a line between the precatory treaty and obligatory treaty is a matter of domestic law that allocates enforcement responsibility between the courts and the legislature. In the separated power systems, a precatory treaty is a political task not for the courts to perform. Therefore, in this case, the justiciability of the treaty is not decided by the intent of the parties or negotiators, but by the separation-of-power reasons. Justiciability is similar to the constitutionality in that both require judgment about the allocation of the power. The constitutionality requires a judgment about the distribution of the power to accomplish certain ends between the treaty-makers and the law-makers. Justiciability requires a judgment about the distribution of the power to enforce particular types of treaty provisions between the courts and the legislature.

Justiciability of a treaty is reflected in many factors. A treaty may be judicially enforceable to private parties when it prescribes a rule by which the rights of private parties can be determined.<sup>111</sup> The justiciability also depends on whether the treaty is “too

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<sup>111</sup> *Edye v. Robertson* (Head Money Case), 112 U.S. 580, 598-99 (1884).

vague for judicial enforcement”,<sup>112</sup> or “provides specific standards”,<sup>113</sup> or is “phrased in broad generalities”,<sup>114</sup> or “language of a broad and general nature”.<sup>115</sup> In *American Baptist Churches v Meese* case,<sup>116</sup> the court held that Article 1 of the 1949 *Geneva Convention Relating to the Protection of Civilian Persons in Time of War* was not a self-executing treaty provision because “the language used does not impose any specific obligations on the signatory nations” and “the lack of precision deprived the court of any intelligible guidelines for judicial enforcement.”

#### **4.1.1.3 The Inconsistency between Treaty and Domestic Law**

After a treaty achieves the application in domestic law, the next question is, if there exists a conflict between the treaty and domestic law, which one prevails. The supremacy clause in the U.S. constitution declares that all treaties shall be the law of the land and have equal standing with domestic law.<sup>117</sup> By virtue of that clause, treaties prevail over earlier domestic laws in case of a conflict. By the same token, however, when a subsequent legislation enacted by the Congress modifies or is inconsistent with a treaty in force, the subsequent legislation prevails. That is the “last-in-time rule”.<sup>118</sup>

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<sup>112</sup> *People of Saipan v United States Dep’t of Interior*, 502 F.2d 90, 99 (9<sup>th</sup> Cir. 1974), cert denied, 420 U.S. 1003(1975).

<sup>113</sup> *Diggs v Richardson*, 555 F.2d 848, 851(D.C. Cir. 1976).

<sup>114</sup> *Frolova v USSR*, 761 F. 2d 370, 374 (7<sup>th</sup> Cir. 1985). The court concluded that such a language “suggested that (the articles of the treaty) are declarations of principles, not a code of legal rights”.

<sup>115</sup> *United States v Noriega*, 808 F. Supp. 791, 799 (S.D.Fla. 1992).

<sup>116</sup> *American Baptist Churches v Meese*, 712 F. Supp. 756, 770 (S.D. Cal. 1989).

<sup>117</sup> *The United States Constitution*, Article VI, Clause 2.

<sup>118</sup> Correa and Yusuf, *see above* note 22, p. 101.

Other countries adhere to the supremacy of treaty over domestic law even the latter is made after the entry into force of the former. In the U.K., where a statute contains provisions which are unambiguously inconsistent with those of an earlier treaty, a British Court must apply the statute in preference to the treaty. However, where the statute is ambiguous, a presumption arises that Parliament did not intend to legislate contrary to the Queen's international obligations under a treaty, and the court may look into the treaty for the purpose of interpreting the ambiguous statutory language, notwithstanding that the statute does not specifically incorporate or refer to the treaty.<sup>119</sup> The French constitution provides that treaties when duly ratified or approved shall on publication have an authority superior to domestic laws, even if the laws were enacted after the treaty entered into force, subject to the reciprocity.<sup>120</sup> The constitution of the Netherlands provides that statutory provisions shall not apply if their application would be incompatible with self-executing treaty provisions or resolutions of international institutions.

#### **4.1.2 Nature and Legal Status of the TRIPS Agreement in Domestic Legal Systems**

This sector will apply the factors determining the nature of a treaty to the TRIPS Agreement: the intent of parties or negotiators, the constitutional separation of power, and the justiciability. These factors are reflected in the language of the Agreement as well as the related domestic practices.

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<sup>119</sup> Shearer, *see above* note 103, p. 67-74.

<sup>120</sup> *See* Article 55 of the Constitution of France, which reads as follows: "Duly ratified or approved treaties or agreements shall, upon their publication, override laws, subject, for each agreement or treaty, to its application by the other party."

Article 1 of the TRIPS Agreement on the “nature and scope of obligations” provides that:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

The Agreement grants its members the freedom to introduce flexibility to those rights under very broad terms and conditions, just as analysed in chapter 2. States are able to introduce measures to prevent IPRs abuse to avoid trade or competitive distortions and to establish exceptions to those exclusive rights, in addition to those exceptions expressly contemplated in the Agreement. The extent and scope of such measures are flexible and depend on the policy choice of members, which must be made in the light of the basic principles and objectives set forth in preamble and Part I of the Agreement. Under these circumstance, the exclusive rights that members are committed to acknowledge through their national IPRs systems are not *ab-initio* self-executing in national courts. The courts will necessarily consider the extent and scope of the exclusive rights as broadly embodied in the TRIPS Agreement, with reference to the flexibility inherent in the provisions.

The ambiguous language or general concepts referred to by the TRIPS Agreement in several instance needs to be defined or spelt out in more detail by domestic law. Nevertheless, certain standards and principles of TRIPS might have a “direct effect” on private parties who might, depending on the constitutional system of the member concerned, seek their judicial enforcement by domestic courts. These might be the TRIPS provisions establishing the term of

protection of the different categories of industrial property,<sup>121</sup> or provisions listing the effects arising from copyright, industrial designs or patent. Though members are free under these provisions to establish a longer term of protection under their domestic legislations, no further action by national legislators is needed for these standards to have a direct effect on private parties.

In this context, it is not an easy task to assert whether the members conceived the TRIPS Agreement as a whole or in part as a non-self-executing agreement. The national practices and legislation, especially carried out by the U.S. and the EU who were main promoters of the Agreements, might have a certain impact on other members.

Starting with the *Trade Agreements Acts* of 1979, which approved the GATT Tokyo Round accords, and continuing with the acts approving and implementing the US-Israel and the US-Canada Free Trade Area Agreements, there are included provisions which deny the creation of private rights of action under the agreements (except as explicitly provided for)'.<sup>122</sup> These provisions therefore purport to deny the self-executing character of the trade agreements. Similarly, the *Uruguay Round Agreements Act* of 1994, which approved the agreements concluded in the framework of the Uruguay Round negotiations of GATT and modified the domestic legislation related to IPRs in order to adapt it to the TRIPS Agreement, also deny the self-executing of trade agreements.<sup>123</sup> Section 102(b), which is devoted to adjust the relationship of the Uruguay Round Agreements and the state law, provides that no person other than the United States:

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<sup>121</sup> For example, Article 33 of the TRIPS Agreement.

<sup>122</sup> Correa and Yusuf, *see above* note 22, p. 109.

<sup>123</sup> *The Uruguay Round Agreements Act*, 108 STAT, 4809-5053, Public Law 103-465-DEC.8 (1994).

- (A) shall have any cause of action or defence under any of the Uruguay Round Agreements or by virtue of congressional approval of such an agreement, or
- (B) may challenge, in any action brought under any provision of law, any action or inaction by any department, agency, or other instrumentality of the United States, any State, or any political subdivision of a state on the ground that such action or inaction is inconsistent with such agreement.

What's more, as to the potential conflict between Uruguay Round Agreement provisions and U.S. law, the *U.S. Statement of Administrative Action to the Uruguay Round Agreements Act* asserts that the U.S. statute is intended not to conflict with the agreements themselves.<sup>124</sup> However, where a conflict cannot be avoided, the U.S. courts are legally bound to follow the later statutory law. The *Uruguay Round Agreements Act* of 1994 also reinforces the supremacy of later domestic law by establishing that nothing in the Act shall be construed "to amend or modify any law of the United States unless specifically provided for this Act".<sup>125</sup> Neither the provisions of the Uruguay Round Agreements nor the application of any such provision to any person that is inconsistent with any law of the U.S. shall have effect.<sup>126</sup>

The TRIPS Agreement and the other Uruguay Round Agreements constitute a mere confirmation of the U.S. practice as regards international treaties, particularly trade agreements, which are considered to be non-self-executing. Against this context, in the domestic courts of the U.S., provisions of the trade agreements, particularly those of the GATT and WTO, have received scant attention in trade cases.

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<sup>124</sup> *Statement of Administrative Action* (SAA), H. R. Doc. 316, 103d Cong., 2<sup>nd</sup> Series, Vol. II, B(1)(d), p. 13.

<sup>125</sup> 19 USC 3512 § 102(a)(2)(A) and (B).

<sup>126</sup> 19 USC 3512 § 102(a)(1).

The case law of the European Court of Justice (ECJ) rejected the direct effect of GATT rules in the EU, basically due to the vagueness and elasticity of many of its provisions. The nature of the rules and their wording is not operative. As stated by the ECJ, the main reason to deny the direct effect of the GATT is that the negotiation was undertaken on the basis of reciprocal and mutually advantageous arrangement, which is characterized by the great flexibility in its provisions, in particular those conferring the possibility of derogation. The court also emphasised the reliance on consultation mechanisms to settle conflicts between the contracting parties and the possibility of withdrawing concessions by contracting states as additional reasons for the lack of direct effect of the GATT.

It is difficult to predict whether the ECJ would apply the same principles or reasoning contained in its decisions regarding the application of the TRIPS Agreement despite the differences that exist between the GATT and the TRIPS Agreement. It must be noted that the ECJ characterized TRIPS as an agreement setting a minimum level of IPRs protection,<sup>127</sup> member countries are free to implement more extensive protection and to determine the most appropriate method of giving effect to its provisions.<sup>128</sup> One may understand this statement as supporting that basically, the TRIPS Agreement is a non-self-executing treaty that confers a significant degree of discretion on the competent authorities to implement it and to spell out in more detail the concepts which are not defined or vaguely referred to in the text of the Agreement.

Therefore, the legislations and the court decisions of the members have further confirmed the non-self-executing nature of the TRIPS Agreement. Even in certain area where it seems to be self-executing, judging from its language, the domestic

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<sup>127</sup> Opinion1/94, adopted on 15 November 1994. The Court maintained that “The TRIPS Agreement seeks to establish a minimum level of protection of intellectual property”.

<sup>128</sup> The TRIPS Agreement, Article 1(1).

practices also render it non-self-executing according to some factors other than the language itself. At the same time, when there exists a conflict between the TRIPS Agreement and the domestic law, the supremacy of domestic law in domestic court is preserved.

## **4.2 State Responsibility under the TRIPS Agreement**

Sector 4.1 discussed the nature of the TRIPS Agreement in domestic legal order. The fact that a domestic court may not apply the Agreement directly and give a priority to domestic law in no way affects the international obligation of the state conferred by the Agreement. A domestic court which refers to domestic law, notwithstanding an inconsistent rule of international law, itself acts in breach of international law, and will, as an organ of the state, engage the international responsibility of that state. Hence, before an international tribunal, a respondent state cannot plead that its domestic law contains rules which conflict with international law, nor can it plead the absence of any legislative provision or of a rule of internal law as a defence to a charge that it has broken the international law.<sup>129</sup> This may even import a duty upon a state to pass the necessary legislation to fulfil its international obligations. To this extent, the primacy of international treaties is preserved before international tribunals.

The non-self-executing nature of the TRIPS Agreement determines that private parties cannot invoke the Agreement as source of law in domestic courts. What they can rely on is only the implementation legislation. However, if there is some inconsistency between the implementation and the treaty provisions, private parties cannot bring a lawsuit against the state on the basis of the TRIPS Agreement. What a state violates is not the rights of private parties or its domestic

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<sup>129</sup> VCLT, Article 27.



law obligation, but the international obligation under the treaty. Therefore it falls into the regime of “state responsibility”. In this section, it is argued that even in the regime of international obligation, the flexibility of the TRIPS Agreement also imposes a great impact on the realization of state responsibility of the members. Again, general international rule on state responsibility provides the premise of the argument.

#### **4.2.1 The Role of Governments in Claims under the TRIPS Agreement**

International law is unconcerned about the means, but not unconcerned about the results. The incompatibility between domestic law and international obligations engages the international responsibility of the defaulting state. International law prevails over domestic law and a state cannot plead that its domestic law exonerate it from performing obligations imposed by an international treaty, except in the exceptional case provided for in Article 46(1) of the VCLT. This exception is that, in giving its consent to an international treaty, fundamental rule of domestic law concerning constitutional competence to conclude the treaty concerned was broken and this breach of domestic constitutional law was manifest. In any event, the acts of the legislature or implementing regulations of state authorities as well as the judicial decisions, may not be considered as acts of some third party for which the state is not responsible. States may depend on their constitutional systems and enact subsequent legislations which supersede prior treaty obligations in domestic court, on the grounds that treaties as well as statutes are parts of the law of the land and consequently the “latter-in-time rule” will prevail. Though such a statute will be lawful under domestic law, it will engage the international responsibility of the enacting state, which may not be exonerated from the violation of its international obligations or from the consequence stemming from such a violation.

As to the state responsibility, the subject who possesses the right to claim state responsibility is the state of which the victim is a national. The tribunal who can settle this dispute is not the domestic court but the international tribunal appointed by the treaty. Under the TRIPS Agreement, it is the DSB of the WTO who has the competence to settle the disputes between members.

To make an inter-state claim is the right of a state, but not a duty. That means, a state has the freedom to decide whether or not to seek a negotiation with the violating state under the WTO dispute settlement mechanism, to seek a friendly-settlement, or to bring the dispute to the DSB. However, a state does not act as a representative of private parties who are the victims of the IPRs violations. It acts in its own name and for its own benefit. A state will not necessarily struggle for the benefit of the alleged victims if it is inconsistent with the general good of a state, or if the alleged victims do not have sufficient lobby power. In many circumstance, states sacrifice the interest of private parties to seek the trade-off in other sectors or merely to keep a balance with total benefit. One of the key problems was the pursuit of appropriate economic policies for the benefit of the whole state or other political or economic interest groups.

Therefore, the realization of state responsibility sometimes relies on political pressures to determine whether to pursue violations of the Agreement. Understandably, a state will not spend its limited resource on the trade problems that have little impact on the domestic economy. Before embarking on an inter-state claim, states will weigh the impact of the violation on certain industries, the political clout of those industries, and pressures from other domestic constituencies.

A state could decide not to bring a case against a particular state for political reasons or because other domestic interest would prefer to keep the law unchanged. Furthermore, intergovernmental pressure may result in cases not being

brought to the international adjudicatory body. For instance, the EU initially lodged a complaint within the WTO, which has repeatedly postponed the issue to allow the EU and the U.S. sufficient time to negotiate. There is no doubt that domestic pressure in the U.S. has led to the U.S. placing pressure on the EU not to pursue the case. In this way, the trade organization has become politicalized. Rather than adjudicating appropriate restrictions on trade, the forum is more or less hijacked by the domestic pressure and politics. Therefore, the realization of state responsibility under the TRIPS Agreement is as flexible as the Agreement itself, which is more of a political than of a legal matter.

#### **4.2.2 The Involvement of Private Parties**

The non-self-executing nature of the TRIPS Agreement determines that the Agreement has no direct effect on private parties, and private parties has no legal standing in the dispute settlement process. The involvement of the private parties in the implementation and enforcement of the Agreement is indirect. The extent of the involvement depends on the lobby power of the private parties concerned.

Examples of this would be the U.S. negotiation with Japan to open its automobile market or the negotiation with Russia regarding regional investment. Under the TRIPS Agreement, if a company in the U.S. feels that another state is violating the provisions, it must petition the U.S. Trade Representative (USTR) according to the Section 301 procedure in order to pursue a judicial remedy. The USTR must then make a decision as to whether it is worth the time and energy to pursue a remedy through the WTO.

This procedure probably operates very well for the strong companies like Kodak and IBM. But if the company affected by the violations is relatively small, lacks political influence or power, or has not suffered large losses, the USTR could, legitimately, conclude that out of the numerous trade violations it adjusts

because of the limitation of resources. The USTR's decisions have not been reviewed by the judiciary, therefore a private actor seeking dispute resolution of his claim in this manner will likely have no recourse if the USTR decides to take no action.

## **4.3 The Limitation of Competence of the DSB**

### **4.3.1 Competence of the DSB**

The WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* creates a dispute settlement body composed of all WTO members. Article 1.1 of the TRIPS Agreement grants the members freedom to choose the method to implement the Agreement in their domestic legal systems. However, it is not the member but the DSB who is the final arbiter to judge whether or not the domestic implementation of a member complies with agreement obligations. In the India Mailbox case, while the Appellate Body agreed that India could choose its method of implementation, it strongly rejected the contention that India was the final arbiter of whether or not the system of administrative instructions complied with obligations under Article 70.8. The Appellate Body stated that in order to determine whether India met its Article 70.8 obligations, the Panel did not have to decide or otherwise improperly delve into Indian law, but merely had to perform an assessment as to whether or not India's law and practices were in line with the obligations in the TRIPS Agreement. The Appellate Body was adamant that DSB of the WTO had the right to make such an assessment. It held that the Panel did not perform any improper interpretation of Indian law, because:

in this case, the Panel was not interpreting Indian law "as such"; rather, the Panel was examining Indian law solely for the purpose of determining whether India had met its obligations under the TRIPS Agreement. To say

that the Panel should have done other-wise would be to say that only India can assess whether Indian law is consistent with India's obligations under the WTO Agreement. This, clearly, cannot be so.

That means, the panel or Appellate Body established under the DSU of the WTO has the competence to interpret the TRIPS Agreement and to decide on the compliance of the implementation of the members.

#### **4.3.2 “Good Faith” Rule and Limitation of Competence**

However, the interpretation of the TRIPS Agreement made by the DSB should be in good faith according to the VCLT<sup>130</sup>. In the India Mailbox case, the Panel relied on Article 31 of the VCLT in making its decision that “good faith interpretation requires the protection of legitimate expectations derived from the protection of intellectual property rights provided for in the Agreement.” In contrast, the Appellate Body attacked the Panel's reading of “good faith interpretation” as requiring a broad inquiry into the expectations of parties, a task that to a great degree involves reverse engineering, *i.e.* taking a treaty provision and abstracting from it the expectations that likely underlie it. The Appellate Body believed that the Panel went too far in interpreting the meaning of “legitimate expectations” and strayed too far from the text of the agreement. It stated that:

The Panel misunderstands the concept of legitimate expectations in the context of the customary rules of interpretation of public international law.

The legitimate expectations of the parties to a treaty are reflected in the language of the treaty itself. The duty of a treaty interpreter is to examine

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<sup>130</sup> Article 31.1 of the VCLT establishes what has been described as the “good faith rule” of interpretation: “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” *See above* note 47.

the words of the treaty to determine the intentions of the parties. This should be done in accordance with the principles of treaty interpretation set out in Article 31 of the Vienna Convention. But these principles of interpretation neither require nor condone the imputation into a treaty of words that are not there or the importation into a treaty of concepts that were not intended.

Thus “good faith” interpretation does not include the assessment of the legitimate expectations of parties unless these expectations are grounded in the language of the treaty. The Appellate Body thus dismissed an unbounded analysis of the legitimate expectations of the parties to the TRIPS Agreement, an endeavour that would be subjective and mutable (and not in good faith) if not focused on the language of the Agreement. An analysis of legitimate expectations is a necessary component of the treaty interpretation, but only in as far as the expectations are expressed in the wording of the treaty. This holding characterized the tone of the decision of the Appellate Body. In contrast to the Panel, it focused much more on flat, formalistic treaty interpretation and looked less to the “softer” side of the expectations underlying treaty obligations.

The “good faith” rule of interpretation limits the competence of the DSB in that its interpretation of the Agreement is valid only in so far as it is grounded in the language of the Agreement. Where there is no language basis or the language is flexible, the DSB could not add new obligations on the members through an expanding interpretation. Interpretation is not a process of law-marking. The problems unresolved by the Ministers could not find answer in expert bodies. Domestic courts decline to adjudicate claims based on vague treaty provisions of constitutional clauses needing further definition or implementation by the legislature or administrative agencies. The same applies to the DSB of the WTO, including the panel and Appellate Body. They shall not clarify or judge on the flexible issues which have not been clarified by the trade negotiations or subsequent agreements.

This is the limitation of the competence of the DSB in the process of treaty interpretation, which is another legal implication of the flexibility of the TRIPS Agreement.

## 5 Conclusion and Proposal

IPRs protect the private rights of IPRs holder through the rewards to creative work and investment guaranteed by exclusive rights. The protection of IPRs also generates public benefit by promoting technology development and economic prosperity. On the other hand, IPRs give rise to customer loss and social cost. The realization of the benefit of IPRs protection depends on the economic and social condition of different countries, and the benefit of IPRs may be offset by the social cost. High level IPRs protection has different effects to the North and South. What leads to a suitable choice of IPRs policy is the balance of public interest and private rights, as well as the proper assessment of domestic developing level within a certain period.

However, after the adoption of the TRIPS Agreement, the freedom of members to make their own policy choice in the regime of IPRs decreases as the result of the substantive harmonization of the Agreement. Since the TRIPS Agreement is there and domestic legislators cannot ignore their international obligations, what can the developing and least developed countries do is to exploit the flexibility inherent in the Agreement. The objective of flexible interpretation and application of the Agreement is not to escape the international obligations, but to seek more freedom of domestic IPRs policy for the purpose of the long-term economic development and public welfare, provided that the exploitation is not inconsistent with the Agreement. As analysed in this thesis, the flexible interpretation and application in many aspects of IPRs protection, especially in patent protection, is consistent with the purpose and principle of the Agreement. In some vertical dimensions with regard to patent protection, several crucial legal notions are left undefined so that domestic legislators have the room to clarify them according to their own national interest.



The exploitation of the flexibility of the TRIPS Agreement mainly occurs in the process of national implementation. However, the legality of the exploitation has met the challenge of developed country members. Therefore, the realization of the flexibility is factually uneasy although theoretically possible. The pressure imposed by the U.S. on Argentina when it sought to invoke the transitional period of the patent protection, and the law suit brought against South Africa when it attempted to resolve its public health crisis through the measure of compulsory license, illustrated the difficulty in the exploitation of the flexibility of the TRIPS Agreement. Unilateral sanctions and threat of sanction still exist and affect the policy choice of the members whose trade and economic power are relatively weak. So it is a reasonable fear that the TRIPS Agreement may be implemented in the same way as it was negotiated. However, the arguments in the present thesis in favour of the flexible interpretation and application devote themselves to strengthen the legal power of the developing and least developed country members. For the purpose of further recognition and realization of the flexibility of the TRIPS Agreement, several proposals are set out as following:

Firstly, the multilateral dispute settlement mechanism under WTO is an appropriate and competent forum to resolve the disputes related with the interpretation and application of the Agreement. Although the ICJ is appointed by pre-TRIPS IPRs conventions as the dispute settlement body, this channel has never been used. Therefore, before the adoption of the TRIPS Agreement, unilateral sanctions had been frequently used by developed countries to remedy the alleged IPRs violations and to enforce the strong protection of IPRs. However, with the inclusion of trade-related IPRs issues in the framework of the WTO, trade sanctions in this area can only be taken in so far as the retaliation has been authorized by the WTO. Therefore, unilateral trade sanction is inconsistent with the WTO rule.

Before the possible authorization of retaliation by the WTO, developing and least developed country members could bring the case in front of the panels and appeal before the Appellate Body. As the independent expert bodies, the panels and Appellate Body shall interpret the Agreement according to the general principle and custom of international law, which is consolidated in the VCLT. The balance of public interest and private rights indicated in the preamble and Part I of the Agreement, together with other related or subsequent agreements, shall be taken into account. If the treaty provisions are vague or ambiguous in certain issues, flexible interpretation and application shall be allowed for the public interest of members, *e.g.* to resolve the public health crisis, provided that they are consistent with the Agreement. “Non-violation complaints” and “legitimate exceptions” of the developed countries without express language basis in the Agreement would not be supported. Therefore, the developing and least developed country members shall realize the advantage of multilateral dispute settlement mechanism and make full use of it to justify the exploitation of the flexibility of the TRIPS Agreement.

Secondly, the TRIPS Agreement is a living instrument instead of a static legal document. Article 71 of the Agreement provides the review and amendment of the Agreement. It states that:

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

To modify or amend the Agreement is difficult because it is almost impossible to achieve a consensus for a new proposal. However, the review of the implementation by the TRIPS Council shall be undertaken in the light of any new developments in the fields of the IPRs. Therefore, in assessing whether or not a national implementation is consistent with the Agreement, the Council shall take into consideration the development of the related issues, including the issues clarified by the subsequent WTO documents. A latest example in the field of patent is the Doha *Declaration on the TRIPS Agreement and Public Health*.

The Declaration reaffirmed “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for the purpose (of public health)”. These flexibilities include:<sup>131</sup>

- a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis,

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<sup>131</sup> See above note 56, para 5.

malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

- d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Although not an international treaty itself, the Declaration serve as the context of the interpretation of the TRIPS Agreement as it is a subsequent agreement between the WTO members. Therefore, in the review of the implementation by the TRIPS Council, measures taken in the regime of the flexibility clarified by the Declaration shall be considered as proper implementation of the Agreement.

Thirdly, the WTO is not isolated from the context of public international law. In many disputes resolved by the DSB, *e.g. Thailand — Restrictions on Importation of and International Taxes on Cigarettes* case, and *US – Import Prohibition of Certain Shrimp and Shrimp Products* case, international health law and environmental law were respected by the DSB. Therefore, a third proposal of this thesis is that the developing and least developed country members shall cooperate with each other and actively lobby the UN specialized agencies such as WHO and UN High Commissioner of Human Rights (UNHCHR). Through the resolutions adopted by these institutions, public interest such as the rights to health and culture will seek higher legal and moral status, and a general context of public international law could be created in the favour of the developing and least developed countries.

As a matter of fact, the settlement of the South African compulsory license case relied heavily on the campaign of the non-governmental organizations, the pressure of public opinion, and the moral conviction. The adoption of the *Doha Declaration on the TRIPS Agreement and Public Health* was subsequent to

the South Africa case, promoted by the workshop established by the WTO and WHO, and motivated by the general recognition of the right to health in the international community.

Developing and least developed countries have the majority of votes in the UN and its specialized agencies. Because of the similar developing level and social situation, if they are to avoid the profound North-South imbalance and to make an effective contribution to the creation of favourable legal context in international law, they need to put forward joint views in the UN and its specialized agencies. Through the establishment of a common strategy and co-ordination of their action, they can make full use of their numeral advantage, which is helpful to create a suitable context of international law and strengthen the respect of public interest in international community. Under such a context, the exploitation of the flexibility of the TRIPS Agreement will be legally and morally easier.

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