CHAPTER-III
TRIPs AGREEMENT AND OTHER INTERNATIONAL AGREEMENTS

3.1. INTRODUCTION

Markets are explored under the shield of Liberalization, Privatization and Globalization (LPG). Trade between different countries is considered to be the ‘World Trade’ in support of International trade, many economists said that trade between the countries would be mutually beneficial if one country could produce one commodity at an absolute advantage over the other country and the other country could, in turn, produce another commodity in an absolute advantage over the first this is due to the reason of Industrial development and innovations the consequence of which has paved the path for mutual dependence on each other as a family and hence the world has become “Vasudeve kutumbakam” (world is like a family).

The term globalization means integration of economics and societies through cross country flows of information, ideas, technologies, goods, services, capital, finance and people and is used in the limited sense of economic integration leaving cultural, social and political dimensions, which can happen through the three channels i.e. trade in goods and services, movement of capital and flow of finance by influencing market integration efficiency and industrial organization. Globalization has been fueled by important changes in technology generation, adoption, and diffusion, including major advances in communications and transportation. This eliminated some of the geopolitical barriers to world integration, and by the process of economic deregulation and liberalization in many countries. The codification of trade rules under the World Trade Organization (WTO) and its predecessor, the General Agreement on Tariffs and Trade (GATT), is one of many possible economic examples. Strong disagreements on the scope and content of the Agreement emerged during the Uruguay Round negotiations, both between developed and developing countries and among developed countries themselves. The Implementation of the Agreement and its review under the “built-in agenda” has also been contentious with regard to many aspects. The conclusion of the Uruguay Round is looked in two angles. One is the political economy angle

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which envisages a surrender of Third World Country’s (including India) sovereignty and the re-emergence of economic imperialism through the guise of world trade agreements. The other angle is that the Third World Economy is over-protected resulting in technological backwardness. If their economy is to be developed then their industrial sector must upgrade technology to international standards. In its original form GATT is a treaty about trade in goods. Political economy crept in with the inclusion of agriculture, subsidy, services, Intellectual Property Rights, investments, environment, social issues, intellectual property rights, etc., in trade agenda, some of which are extraneous to trade.

### 3.2 THE FORMATION OF WTO

The International Trade Organization appeared as WTO (World Trade Organization) on the world scenario and agreed to by 125 countries on April 1994 at a conference in Marrakesh which concluded the strenuous Uruguay round of the GATT negotiations after more than seven years of bargaining. The new body took shape on 1st January 1995. The WTO is the highest body to make rules and regulations for international trade and also regulates the dispute settlement under its rules by providing forum to the members for speedier dispute settlement mechanism. There was a delay for a period of 50 years in the birth of this new body as there was an opposition from the U.S to a World rule making body in the field of trade. As the U.S felt that the rules would go against their own interests and would amount to a loss of Sovereignty for the trade super power. However, the very same United States saw the need for a fully empowered world body in mid 80’s to frame and enforce a law to combat rampant intellectual property piracy the world over and the US has put it’s might behind the Uruguay round, the scope of negotiations widened well beyond the original Punta del Este declaration. The WTO is said to be the youngest international organization which was established on 1st of January 1995. In the real sense, the WTO was established through the Marrakesh Agreement establishing the WTO, which was signed on 15th of April 1994 at Morroco. The WTO is also known as a successor of the GATT, which was signed by 23 countries including India at Geneva in the year 1947. The history for the GATT is very amazing. After the First World War, the western countries suffered

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losses in various terms, such as human resource loss, monetary loss etc. The situation was critical after 1918, i.e. after the First World War. Due to this some countries started thinking of some international organization, which would help to foster trade and relation in the world. When the thought was in the process, another setback event took place known as the ‘Great Depression’. This actually occurred in the year 1929 and continued for a decade, i.e. 1939. The thought of starting an international organization generated after the First World War was executed at top priority by some countries. When this thought was in the process and still under discussion, the second crucial event happened popularly known as the ‘Second World War’.

The thought of creation of an international organization reached its peak and finally, one conference gave birth to three international organizations i.e. the ‘World Bank’, the ‘International Monetary Fund’ and ‘International Trade Organization’. This conference is known as “Brettonwood Conference”. These Brettonwood Twins immediately started working on their objectives. However, the third the ITO (International Trade Organization) was postponed. Four more conferences were to be conducted for it. The first two conferences were held only to complete the draft for the ITO. The third conference was held at Geneva for continuation of the drafting work. Actually, this conference was divided into two phases. In the second phase 23 countries came together and signed an agreement, which became the world-renowned agreement subsequently known as the GATT. This agreement was signed in the year 1947 and hence called as the GATT 1947.

The primary objective of the WTO is to bring uniformity, certainty and transparency in world trading system by restraining the members from invoking arbitrary and unilateral trade policy measures. The Preamble of the WTO Agreement states its objectives as “raising the standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for optimal use of the world’s resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development”. The WTO also aims at progressive liberalization of world trade and services and protection of intellectual property rights. The agreements include legal instruments which are
integral part of the agreement and are binding on all the members referred to as “Multilateral Trade Agreements” which are binding on all the members and the agreements which are known as “Pluri-lateral Trade Agreements” are not obligatory on the members who have not accepted them. The multilateral agreements included the agreements on Agriculture, Textiles and clothing, Agreements on Technical Barriers to Trade, Agreements on Trade related Investment Measures (TRIMS), Intellectual Property Rights (IPR), Industrial Products, Subsidies, Anti-dumping rules, government procurement, Balance of Payments Provisions, Safeguard Action and Coherence in Global Policy Making were the major ones.

3.3 TYPE OF AGREEMENTS

GATT Agreements are of two types, bilateral and multilateral agreements

3.3.1 Bilateral (Plurilateral) Agreements

Trade Agreements on bilateral basis were entered by a number of countries under the agreements for imports and exports and are fixed by the contracting countries. Each country to an agreement binds itself to imports from the other given quantities of specified commodities at stipulated prices every year or for a number of years. The agreements are similar to that of a trade which is carried under the barter system in olden days. Bilateral agreements are entered by the countries to bring about a balance in their payments with other countries. Sometimes arrangements are made according to which the deficit country is allowed credit terms for the purchase of goods up to certain limits. Other purpose of this agreement is to provide the countries an outlet for their surplus output and also to provide access to a scarce material available in the other country. They are based on the principle of economic treaties among market economies under ‘Friendship – Commerce-Navigation’ treaties recently a number of bilateral treaties were completed under ‘economic co-operation agreements’ which provided a loose framework for developing trade between market and non-market economies. Under the bilateral agreements countries tended to negotiate only with trading partners who were ‘principal suppliers’ of particular commodities. So this developed a desire to multilateralise the tariff negotiations in the GATT. Some of

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the plurilateral agreements in the GATT are: (i) Agreement on Trade in Civil Aircraft, (ii) Agreement on Government Procurement, (iii) International Dairy Agreement, and (iv) International Bovine Meat Agreement.

3.3.2 Multilateral Agreements

Multilateral Agreements are concluded usually in regard to trade in specific commodities among countries that are major producers and buyers of these commodities. The object of these agreements is to regulate the production, prices, trade and marketing practices in relation to these commodities. To safeguard the interests of both producers and consumers and to control the flow of trade between countries, agreements are concluded among countries interested in the commodities. An agreement of this type provides for the quantity that will be exported by such participating exporting country and the quantities that importing countries will purchase. The upper and lower prices are agreed upon so that the producers and consumers both have a fair deal this agreement offers a degree of certainty to both which is not there without it. The basic object is to expand the market. The GATT is one of the multilateral trade agreements and each country has a separate schedule which lists its own commitment of bindings which is appended to the GATT Agreement and incorporated into it by reference in Article II of the GATT. The WTO system as it has emerged from the Uruguay Round now consists of the following main substantive Agreements:

I. Multilateral Agreement on Trade in Goods including the General Agreement on Tariffs and Trade (GATT 1994) and its associated Agreements

II. General Agreement on Trade in Services (GATS)

III. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)

The legal instruments that now form the WTO system are:

1. Marrakesh Agreement Establishing the World Trade Organization
2. Multilateral Agreements
3. Trade in Goods
4. General Agreement on Tariffs and Trade (GATT 1994)

Apart from these substantive agreements there are associated agreements which are mentioned as under:
1. Uruguay Round Protocol GATT 1994
2. Agreement on Agriculture
3. Agreement on the Application of Sanitary and Phytosanitary Measure (SPS)
4. Agreement on Textiles and Clothing
5. Agreement on Technical Barriers to Trade (TBT)
6. Agreement on Trade Related Investment Measure (TRIMs)
7. Agreement on Implementation of Article VI of GATT 1994 (Anti-dumping)
8. Agreement on Implementation of Article VII of GATT 1994 (Customs Valuation)
9. Agreement on Pre shipment Inspection (PSI)
10. Agreement on Rules of Origin (ARO)
11. Agreement on Import Licensing Procedures (AILP)
12. Agreement on Subsidies and Countervailing Measures (CSM)
13. Agreement on Safeguards (AOS)
14. General Agreement on Trade in Services (GATS)
15. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)
16. Plurilateral Trade Agreements
17. Agreement on Trade in Civil Aircrafts
18. Agreement on Government Procurement

3.4 THE MAIN DIFFERENCES BETWEEN THE GATT AND THE WTO

The GATT was provisional. Its contracting parties never ratified the General Agreement, and it contained no provisions for the creation of an organization. The WTO and its agreements are permanent. As an international organization, the WTO has a sound legal basis because all members have ratified the WTO Agreements, and the agreements themselves describe how the WTO is to function. The WTO has “members.” GATT had “contracting parties,” underscoring the fact that officially the GATT was a legal text. The GATT dealt with trade in goods. The WTO deals with

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6 The GATT was a negotiating platform whereas the WTO is an institutional body. The term ‘WTO’ is used to refer to any one of four distinct things: (1) the WTO as an organization (i.e. its member states, acting collectively), (2) the WTO secretariat, (3) the WTO Agreement, or (4) the WTO dispute settlement mechanism. The Objectives and organization of WTO. Available at www.WTO.org visited on 25th April, 2010.
apart from trade in goods also the trade in services and intellectual property as well. The WTO dispute settlement system is faster and more automatic than the GATT system. Its rulings cannot be blocked. The WTO has introduced a trade policy review mechanism that increases the transparency of members’ trade policies and practices. Before the Uruguay Round, the GATT itself did not deal with the level of IPRs protection although it contains some provisions of relevance in Articles III, IX and XX (d). Under these provisions, measures which would otherwise be inconsistent with the GATT could be taken (subject to certain conditions) to secure compliance with laws or regulations relating, among others, to intellectual property rights. These provisions were hardly discussed until the GATT ministerial meeting in 1982 brought up the problem of counterfeit goods in international trade. Some countries, particularly the United States of America appeared to be influenced by the perception that their competitiveness, dependent on technology and creativity, was not adequately protected worldwide by existing rules on Intellectual Property. This led them to argue for inclusion of Intellectual property matters into the Uruguay Round, hence the adoption of the TRIPs agreement.

3.5 OBJECTIVES OF THE WTO

The main objective for the creation of the WTO is “to help free, fair and predictable trade flows". This objective carries various functions of the WTO. The above mentioned objectives can be divided as follows—

(a) To help Free Trade Flow
(b) To help Fair Trade Flow
(c) To help Predictable Trade Flow.

3.6. FUNCTIONS OF THE WTO

The main objective of the WTO is to achieve fair, predictable and free trade flows for carrying the objectives it will do:

(i) Administering trade agreements,
(ii) Acting as a forum for trade negotiations,
(iii) Settling trade dispute,
(iv) Reviewing national trade policies,

(v) Assisting developing countries in trade Policy issues through technical assistance and training program.

As per Article III, the WTO will facilitate the implementation, administration and operation, and further the objectives of this agreement and of the Multilateral Trade Agreements and will also provide the framework for the implementation, administration and operation of the Plurilateral Trade Agreements. The WTO will also provide the forum for negotiations among its members concerned with the multilateral trade relations in matters dealt with under the agreements of GATT. The WTO may also provide a forum for further negotiations among its members concerning their multilateral trade relations, and a framework for the implementation of the results of such negotiations as may be decided by the Ministerial Conference. The WTO will administer the understanding on Rules and Procedures governing the settlement of disputes. The WTO is the highest authority to administer the Trade Policy Review Mechanism (TRPM). The WTO will cooperate as appropriate, with the International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (IBRD) and its affiliated agencies to achieve greater coherence in global economic policy-making.  

3.7 STRUCTURE OF WTO

The WTO consists of the following bodies:

The various bodies that work for the WTO are The Ministerial Conference, The General Council, The Dispute Settlement Body, The Trade Policy Review Body, the Council for Trade in Goods, Services and the council for TRIPs which are assigned with different works for smooth functioning of the WTO.

a. Subsidiary Bodies

The Council for Trade in Goods, the Council for Trade in Services and the Council for TRIPs shall establish subsidiary bodies as required. These subsidiary bodies shall establish their respective rules of procedure subject to the approval of their respective councils. The various committees are The Committee on Trade and Development, the committee on Balance of Payments Restrictions and the committee on Budget, Finance and Administration.

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8 Article III of GATT Agreement.
9 Article III of GATT Agreement.
b. Bodies provided under the plurilateral Trade Agreements

This body shall work in accordance with the institutional framework of the WTO. These bodies shall keep the General Council informed of their activities on a regular basis.

3.8 PRINCIPLES OF THE WTO TRADING SYSTEM

The basic principles of WTO are contained in the original GATT Act, 1947. These are still operative in the form of GATT 1994 which updates the GATT 1947. The Principles are

1. Transparency

WTO aims at maintaining transparency in international trade relations by obligating members to notify changes in the trade regulations, technical and other standards well in advance in turn this ensures the exporters in planning the business and safeguards them against unnecessary hardships. Every member is required to publish promptly laws, regulations and administrative ruling of general principles pertaining to the classification or valuation of goods for customs, rates of duties affecting sale, distribution, transportation, insurance, warehousing and inspection of goods to enable the governments to acquaint with them.

2. Most Favored Nation Treatment

MFN means that every time a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from its WTO trading members. All members are to be treated equally equal opportunity should be provided to all the countries in the matters of trade and business without any kind of discrimination.

3. National Treatment

Imported and locally –produced goods should be treated equally once the foreign goods have entered the market. The same should also apply to foreign and domestic services, and to foreign and local trademarks, copyrights and patents. The member country shall not extend protection to domestic industry through application of internal taxes and other charges, laws, regulations and requirements affecting imports. Only those internal taxes and regulations as applicable to domestic products can be imposed on imports.

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4. The Free Trade Principle (Optimal Utilization of World resources)

Lowering trade barriers is one of the most obvious means of encouraging trade. The barriers concerned include mainly customs duties or tariffs and measures such as quantitative restrictions like import bans or quotas that restrict quantities selectively.

5. Dismantling Trade Barriers

Physical restrictions on the import and export of goods are specially prohibited under GATT. Tariffs should be used to control the import and protect domestic industry. These quotas of import and export licenses are specially named as quantity restrictions. The multilateral trading system is an attempt by governments to make business environment stable and predictable. In the WTO, when countries agree to open their markets for goods and services, they “bind” their commitments. These bindings amount to ceilings on customs tariffs. The countries cannot exceed the bound rates under any circumstances. Article II sets out the requirements and implications of the schedules in which each WTO member specifies the precise tariff commitments that have accepted. Again under Paragraph 1 (b) of the article establishes the basic requirements that “Ordinary customs duties” shall not be higher than the levels specified in the schedules. Article II :1 (c) provides for preferential tariff imposition limited to territories recognized and preferential under Article I the exception to which exceptions are provided under Article II thus taxes and equivalent to those imposed on local goods can be levied on imported goods. In the same manner antidumping duty, countervailing duty, safeguard duty, protective duty can be imposed for neutralizing subsidies and protect the countries interest. Other provisions deal with provisions to ensure that import monopolies do not result in the defeat of the bound rate commitments.

6. Rule Based Trading System

The WTO stands for rule based trading system. The core principle of non-discrimination goes a long way towards meeting the objectives of rule based trading system and in case of disputes it has to be settles under DSB.

7. Special and Differential Treatment for Developing and Least Developed Countries

The WTO recognizes the need for positive policy efforts to help developing countries especially LDCs reap the full benefits of trade liberalization which is set out by the Preamble of the WTO Agreement. The special and differential treatment
provisions for developing and least developed countries run across the whole range of agreements covered by WTO. There are certain concessions for developing and least developed countries which are in the form of waiver or deferral of obligations, transfer of technology, flexibility in application of technical and Phyto-sanitary standards by the developed countries. Para 2 of Article XI sets out terms and conditions for accession to WTO. The least developed countries are required to undertake commitments and concessions commensurate with their individual development, financial and trade needs or their administrative and institutional capabilities.

8. The Competition Principle (Restricting monopolies and promoting consumer interests)

The WTO system is dedicated to open and fair competition. The reduction of tariffs and eliminations exercises goes hand in hand with measures to reduce or eliminate subsidies to provide fair competition between foreign and local goods to increase efficiency and consumer welfare. The aim of the WTO also aims to promote consumer interests by promoting competition in market which ensures the availability of alternate goods at the cheapest price. Hence trade flows across the border are not restricted because of unnecessary trade regulations.

9. Environmental Protection (Improving Quality of Life)

The preamble to the WTO Agreement includes direct references to the objectives of sustainable development and to the need to protect and preserve the environment. Agreement on technical barriers to trade and sanitary and physiosanitary measures explicitly take into account the use by governments of measures to protect human, animal and plant life, health and the environment. The agreement on subsidies and countervailing measures treaty as a non-actionable subsidy government assistance to industry covering up to 20 percent of the cost of adapting existing facilities to new environmental legislation. Similarly, both TRIPs Agreement and GATS contain environment related provisions.

3.9 MAJOR AGREEMENTS OF WTO

The important agreements arrived at the Uruguay Round of negotiations are on agriculture, sanitary and physiosanitary measures, textiles and clothing, technical barriers to trade, trade related aspects of investments measures, anti-dumping, custom valuation, pre-shipment inspection, import licensing procedures; subsidies and countervailing measures, safeguards, general agreement in trade in services,
trade related aspects of intellectual property right etc. Out of these major agreements are as follows:

1. Trade in Agricultural Commodities and Trade Related Policies affecting Agriculture,
2. Textiles and Clothing,
3. Technical Barriers to Trade,
4. Trade Related Aspects of Investment Measures (TRIMs),
5. Trade in Services and
6. Trade Related Aspects of Intellectual Property Rights (TRIPs).

3.10. TRIPs AGREEMENT

The World Trade Organization (WTO) and the TRIPs Agreement was created in the framework of the General Agreement on Tariffs and Trade (GATT) and agreed upon in 1994. The TRIPs Agreement is undoubtedly the most significant development in intellectual property in recent years, perhaps even in the 20th century, together with the creation of the World Intellectual Property Organization (WIPO) at the 1968, Stockholm Conference.\(^\text{11}\) TRIPs, which set the minimum standard for IPR protection among the WTO members, became final after many negotiations between 1986 and 1994. The first proposal that had similarities with the final TRIPs Agreement was tabled by the EC in March 1990, and was entitled “Draft Agreement on Trade-Related Aspects of Intellectual Property”.\(^\text{12}\) The US closely followed with a very similar draft, which also carried the same title. Consultations between the two had probably preceded the tabling of both documents. Many countries disagreed with the proposals in full or in part, filing additional proposals. What the developing countries were especially concerned about was the inclusion of pharmaceutical products in the agreement.\(^\text{13}\)

In June 1990 the Chairman of the negotiations put forward a draft called “Chairman’s draft” or “Composite draft text”, which included and combined all of

\(^{11}\) D Gervais, The TRIPs Agreement: Drafting History and Analysis (1998) at 3 (D Gervais, the TRIPs Agreement). Along with the creation of WIPO, the 1968 Conference also adopted revised Berne and Paris Conventions.

\(^{12}\) Document MTN.GNG/NG11/W/68, cited in D Gervais, The TRIPs Agreement at 15.

\(^{13}\) F M Abbott, “The Doha Declaration On The TRIPs Agreement and Public Health: Lighting A Dark Corner At The WTO” (2002) 5 JIEL 469 (F M Abbott, “The Doha Declaration”).
the suggested proposals. The developing countries opposed an all-encompassing agreement on intellectual property, especially as they felt that the proposal by the Chairman adopted an overall structure that was very similar to that of the EC and the US proposals. During further discussions it was clear that the question of protection of pharmaceutical products through patents was one of the major issues to be resolved. However, with a new draft of TRIPs presented by the Chairman, the reactions were mainly positive and although pressure still existed for changes, few amendments were made before the final TRIPs Agreement was adopted at Marrakech in 1994. Regarding pharmaceutical patents, the two parties mainly opposing the agreement were India and the American pharmaceutical industry. Although it was not a party to the transition rules (subsequently amended), which stretched the transition periods for least developed countries (LDCs) even further, India was, and still is, concerned about restrictions on compulsory licensing of patents, found in TRIPs, Article 31. It seems evident that the two could not have found a draft with which they were both satisfied. In the Agreement, the American pharmaceutical industry was a powerful lobbyist.

The TRIPs Agreement is a comprehensive international intellectual property agreement negotiated by WTO members during the Uruguay Round of trade negotiations (1986-1994). It consists of 73 Articles in VII parts. The Intellectual Property rights are private rights, and are guided by the framework of principles, rules and disciplines dealing with the Intellectual Property rights. Intellectual property right was not part of the GATT till the Uruguay round. It was introduced in the Uruguay round and strongly pressurized by the developed countries (mainly USA) to make it a part of WTO agreement. Which is presently known as Trade Related aspect of Intellectual Property Rights (TRIPs) Intellectual Property was opposed by some developing countries to be a part of the WTO. However, their

16 The least developed countries have until 2016 to implement the TRIPs Agreement. See the Doha Declaration on TRIPs and Public Health, para 7.
opposition could not prevent IP from being part of WTO. The TRIPs was finally signed at MARRAKESH on 15th April, 1994 by 125 member countries.

Since the beginning of the 21st century, the globalization trend of world economy has become more and more obvious. Mutual permeation and interdependence between countries in politics, economy, society, and culture and so on are deepening day by day. Even in the legal system, which has the strongest characteristic of national sovereignty, permeation and harmonization are underway without notice. Because patent system is the combination of technical, economics and law, the international convergence and harmonization of patent system are more active and advanced than in any other fields. Since 1999, the harmonization of international patent system advocated by developed countries has become the mainstream of the intellectual property rights field. TRIPs agreement is divided into 73 Articles which speaks about all forms of Intellectual Property and their protection. Intellectual Property is divided into two major parts known as Industrial Property and Copy Right and related Rights. TRIPs consists of patent, trademark, copyright, industrial design, geographical indication, undisclosed information etc. as a form of Intellectual Property.

Jagdish Bhagwati, a highly regarded economist and free trade advocator considers that IPR should have never been included in the WTO agenda. He claims that: “Intellectual property protection is not a trade issue; and the WTO ought to be about lowering trade barriers and tackling market access problems that will often go beyond border measures to internal regulations: a thorny issue”. In this sense, TRIPs can be considered a successful strategic accomplishment that imposes and ensures a high minimum IPR standard in every country that wants to benefit from the WTO multilateral trade system. The purpose of TRIPs with respect to patents is to “…strike a balance between the long term social objective of providing incentives for future inventions and creations, and the short-term objective of allowing people to use existing inventions and creations.”

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The TRIPs Agreement negotiations were highly contentious, and the perspectives of developed and less developed countries on the role of intellectual property protection and enforcement remain far apart. Debate over the claim to intellectual property can be traced back to the beginnings of IP protection. It has varied over history and among societies depending upon their perspectives on real property. The positions taken by various nations in recognizing the intangible asset is somewhat different in different countries which reflect their differing cultural, philosophical, historical, economic and political points of view regarding the need for strong IP protection as well as their public policy and health needs and stage of development in the field of technology, innovation and industrial development. TRIPs Agreement consist of two parts Part I consists of general provisions and basic principles. Member countries are obliged to enact domestic legislation to give effect to the provisions of the TRIPs Agreement, which defines “intellectual property” as “all categories of intellectual property that are the subject of Sections 1 through 7 of Part II” of the Agreement, namely copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits, and protection of undisclosed information (trade secrets) (Article 1). \(^{21}\)

Further, the TRIPs Agreement provides that Members shall comply with their obligations concerning intellectual property rights under existing treaties (Article 2). These treaties that must be complied with are specified as the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (Rome Convention) and the Treaty on Intellectual Property in Respect of Integrated Circuits (IPIC Treaty).

In previous treaties concerning intellectual property rights, since there were only provisions establishing national treatment, problems would sometimes arise where persons from specific countries would be awarded greater protection than the country’s own nationals. Although this kind of occurrence was not usual, it was sometimes granted as a tradeoff in return for other items as a result of bilateral

\(^{21}\) Introduction to TRIPs Agreement, Japan Patent Office Asia-Pacific Industrial Property Center, JIII.
negotiations between countries. Therefore, in the TRIPs Agreement, both national treatment (Article 3) and most-favored-nation treatment (Article 4) were provided as basic principles. Although most-favored-nation treatment was stipulated in GATT previously, this applied only to “goods”, in other words imported and exported products, whereas in the TRIPs Agreement it came to be applied to “persons” as the holders of intellectual property rights, that is, both natural and legal persons.22 Part II of the TRIPs Agreement provides standards concerning the availability, scope and use of intellectual property rights.

3.11 THE NATURE AND ROLE OF INTELLECTUAL PROPERTY

One of the main problems that our post-TRIPs world was facing lies in coming up with a consensual definition for IPR that suits the realities and necessities of every member in the international community. Intellectual Property encompasses a broad scope of rights that are clustered in a modern legal institution which intends to stimulate innovation and creation by offering the prospect of a monetary reward that allows a titleholder to recover investments in research and development (RandD) and possibly make a profit, as well as, exclusive rights to prevent third parties from making commercial use of the knowledge without authorization. Hence, IPR titleholders benefit from dual advantage, they are not only entitled to own and sell their innovations and creations, but also to control their use after the first sale, creating an intellectual monopoly not only over the product or process, but also over the manner in which they are commercialized after being incorporating into the free circulation of goods in the market. It is reasonable to assert that intellectual property is a legal creation that is provided in order to meet certain goals that aim mostly at fostering innovation and creativity, as well as, improving the wellbeing of people in societies. IPR did not always exist as we know them today (prior to the creation of the modern nation-states), and hence, do not correspond to rights that transcend our social contracts (states) and are not inherent to the dignity of our human nature. Human beings are entitled by their nature to certain rights, such as the right to life, liberty, security, private property, among others, that should never be violated. However, intellectual property can be considered a sui generis kind of ownership, which is not an end in itself, but more a

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22 Introduction to TRIPs Agreement, Japan Patent Office Asia-Pacific Industrial Property Center, JIII
means to promote individual growth, but also and more importantly societal well being. Nevertheless, several reasons have been claimed in favour of states granting IPR. In this sense, they are exclusively granted in order to meet specific economic conditions that should be beneficial for society as a whole. These goals can be achieved by newer and newer inventions; the inventions are having their own role.

**Importance of Inventions**

1. Inventions play an important role in Promotion and disclosure of technology innovation.

2. Transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare.

3. Monetary retribution for innovative research. The rational in this condition can be found in the difficulty that patent producers may encounter in trying to recover their fixed costs of R&D, when the product or process that embodies the new invention is readily copy able.

4. Promotion of foreign direct investment. If countries protect innovations by granting patents, this would make them more attractive for foreign investors that hold IPR abroad. The latter would increase direct foreign investment, which would stem from counties where new patented technologies are originated. However, foreign investment through this avenue is usually only delivered when patents are granted based on the condition that the owner will actually use or exploit the scope of the invention in the country that issued the patent ownership title.

Stressing more on the fact that intellectually property is as a private good rather than a public one seems to be driving the global policy agenda of the post TRIPs system. Furthermore, the TRIPs successful strategy is being internationally entrenched by what Peter Drahos has called the Global Intellectual Property Ratchet, which depends on the following propositions:

1. The entrenchment in international agreements of a principle of minimum standards (WTO).

2. A process of forum shifting to venues that are more adequate to promote higher IPR standards: from the World Intellectual Property Organization (WIPO) to the WTO.

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23 Peter DRAHOS, Expanding Intellectual Property’s Empire: the Role of FTAs. [online] Available at: <http://www.bilaterals.org/IMG/doc/Expanding_IP_Empire_-_Role_of_FTAs.doc>
3. Co-ordinating bilateral and multilateral IPR strategies (signing FTAs with higher IPR standards than TRIPs).

The reason for the conclusion of the TRIPs Agreement may be explained on two grounds. First, the need to provide a stronger Intellectual Property protection to business communities of industrialized countries, which had been complaining that they suffered huge economic loss as a result of piracy and counterfeiting. Second, the need to overcome the shortcomings of the existing IP conventions that failed to provide effective means of enforcement of intellectual property rights. The TRIPs Agreement, unlike prior IP conventions, provides an effective dispute settlement mechanism. Countries failing to comply with the TRIPs Agreement standards could be subjected to trade retaliation if the dispute settlement mechanism of the WTO has determined the existence of a case of non-compliance with the Agreement. The TRIPs Agreement, *inter alia*, aims to:

(a) Harmonize intellectual property rights protection by providing with the minimum standards that should be adopted by member states;

(b) Enhance and broaden the scope of protection of patents by:

(i) Reducing the scope of various restrictions and safeguards which used to be incorporated by national laws to protect the public interest and control abuse of a right by the patentee,

(ii) Expanding the scope of duration of protection by, for instance, requiring that patent protection shall be available in all fields of technology (Article 27(1) and making duration of a patent 20 years (Article 33),

(c) Providing a mechanism that ensures effective enforcement of rights; violation of IPRs and failure of member states to provide with an effective enforcement of the same will entail severe consequences such as loss of trade rights and imposition of sanctions.

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25 It has been said that “US business communities have estimated that worldwide losses suffered by US corporations owing to IP “theft” runs to the tune of around US$43 billion to US$61 per annum” (see Blakeney (1996) and McGrath (1996)).

26 See Article I of the TRIPs Agreement. The Agreement is sometimes referred as a minimum standard agreement. It establishes minimum requirements that should be complied with in protecting intellectual property.

27 See Article 64 of TRIPs.
3.12 LEGAL PROTECTION OF INTELLECTUAL PROPERTY RIGHTS (IPR)

The modern protection for intellectual property rights developed first as national legislation in developed countries, followed by international agreements such as the Paris Convention28, the Berne Convention29 and other co-operations, eventually leading to the TRIPs Agreement30.

3.12.1 Meaning of IPRs and their protection

An intellectual is a person who uses his or her intellect to work, study, reflect, speculate on, or ask and answer questions with regard to a variety of different ideas. Cultural “intellectuals” are persons with notable expertise in culture and the arts, expertise which allows them some cultural authority, and who then use that authority to speak in public on other such matters. Intellect is defined as- "Capacity for thinking and acquiring knowledge, especially of a high or complex order; mental capacity, a particular mind or intelligence, especially of a high order, a person possessing a great capacity for thought and knowledge, minds collectively, as of a number of persons or the persons themselves31."

‘Intellectual Property’ is a generic term that probably came into regular use during the twentieth century. This generic label is used to refer to a group of legal regimes, each of which, to different degrees, confers rights of ownership in a particular subject matter. The subject matter of these rights is disparate. One striking feature of intellectual property is that, despite its early historical links to the idea of monopoly and privilege, the scope of its subject matter continues to expand. A definition of intellectual property that moves beyond lists or examples and attempts to deal with the essential attributes of intellectual property has to focus on two elements: the property element and the object to which the property element relates. Intellectual property rights are often described as intangible rights. The idea behind this classification is that the object of the right is intangible. All property rights place the right holder in a juridical relation with others. The key difference between rights of real property and intellectual property rights is that in the latter case the object of the right is non-physical. One can think of it as an abstract object

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28 Paris Convention for the Protection of Industrial Property 1883.
29 Berne Convention for the Protection of Industrial Property 1886.
31 A Handbook on Laws Relating to Intellectual Property Rights in India,(2007), Published by Committee on Trade Laws and WTO, The Institute of Chartered Accountants of India ICAI Bhawan, Post Box 7100, Indraprastha Marg, New Delhi-110 002. INDIA.
rather than a physical object. It is possible that one can ‘own’ the abstract object without owning a particular physical manifestation of the abstract object. All societies have had to devise norms for regulating the ownership and use of different kinds of information. Historically, this has been especially true of religious information. One can thus identify customary equivalents of intellectual property. But the western intellectual property tradition is rooted in the idea that intellectual property rights are positive rights created by the state for the benefit of the commonwealth. Within Thomist political theory the validity of positive law was itself to be judged by the axioms of natural law. The norms of positive law had to converge with the divine design which natural law communicated to men. The rules of positive law then met the test of validity, not by being a mirror reflection of some metaphysical counterpart, but rather by whether or not they contributed to the overall divine plan. Conceptually speaking, this allowed someone working within the natural law tradition to recognize the right of a state to modify property rights through the enactment of positive law.

3.12.2 The Traditional Concept of IPRs

The theoretical justification for intangible property has traditionally been grounded on two main theories of property. The first is John Locke’s labor theory of property. The second is the utilitarian doctrine. The basic concept of the modern patent system in particular is however predominantly based on the utilitarian theory. The utilitarian theory is rooted in the traditional western view of property, which emphasizes private property and its importance in development. The conventional justification of the patent system based on this approach is that the inventor and investors are rewarded for their time, work and risk of capital by the grant of a limited but strong monopoly of exploiting the invention. The system guarantees a limited exclusive term in return for the inventor’s disclosure of the details of the invention. The approach is seen as benefiting society by stimulating investment, creating employment and ensuring supply of technology based goods and services. In addition, the system is seen as ensuring a continuous process of knowledge creation and data building which is crucial for technological advancement.

In the pharmaceutical industry, the accumulated knowledge is considered invaluable as a basis for further research in the continuing efforts to deal with the persistent and emerging challenges in disease management. The Canadian philosopher Will Kymlicka suggests that utilitarianism conforms to our inner sense of social responsibility; that is, the idea that the well-being of humans matters, and moral rules must be subjected to tests for their consequences to human beings. The utilitarian approach weighs the long-term development of society against the short-term drawback of assigning exclusive exploitation rights to the inventor. It is true that IPRs can induce creativity and the production of some intellectual products, increasing the immediate availability of products, particularly in the fields requiring long training and/or high research costs. However, this does not necessarily imply a long-term benefit of economic progress. If the purpose of IPRs were simply to induce creativity and production, then this is easily achieved. However, a system based on such assumption would say nothing about the rights of other people to use this information except under the monopoly conditions. If the purpose of the system is to make the lives of people better, then one must look at the effects that the grant of IPRs has on all people. Consequently, although an inventor’s rights must be recognized in any IPRs scheme, the rights must be juxtaposed with the interests of society. In short, one must ask whether the institution of IPRs is just when it provides benefits to a select few. In the global economy access to advantages produced by IP protection is based on financial resources, which one would naturally expect in a competitive economy. Such a system is satisfactory when one is concerned about the distribution of non-essential items, that is, objects that do not affect people’s well-being. Traditionally the patenting of inventions such as chemicals, food products and pharmaceuticals has however been associated with high prices.

3.12.3 General Provisions and Basic Principles of IPR under TRIPs Agreement

Intellectual property rights as a collective term includes the following independent IP rights which can be collectively used for protecting different aspects of an inventive work for multiple protections and includes Articles 1 to 8 of the TRIPs Agreement provide the basic general principles of this Agreement. The members are under an obligation to give effect to the provisions of this Agreement. Members desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of
intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade; In this regard they agreed upon having the following in the mind they framed the new rules and disciplines concerning the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions with an intention to make provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights; the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems; the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and transitional arrangements aiming at the fullest participation in the results of the negotiations; there is a need for recognizing a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods along with the protection of underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives 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. Members shall accord the treatment provided for in this Agreement to the nationals of other Members. Nothing in this Agreement shall derogate from existing obligations that members may have to each other under Paris Convention, Berne Convention, and the Rome Convention. Each Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection of Intellectual Property. The object is the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and

34 Article 1 of TRIPs Agreement.
35 Article 2 of TRIPs Agreement
36 For the purposes of Articles 3 and 4, “protection” shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.
users of technological knowledge and in a manner conducive to social and
economic welfare, and to a balance of rights and obligations.\textsuperscript{37} 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\textsuperscript{38}.

1) Copyright and Related Rights (Articles 9 to 15)

Provisions are included regarding clarification of the relation to the Berne
Convention (Article 9), protecting the copyright of computer programs and
compilations of data (Article 10), rental rights (Article 11), the term of protection
(Article 12), and protection of performers, producers of phonograms (sound
recordings) and broadcasting organizations (Article 14). Regarding the protection of
computer programs and compilations of data, there had been moves led by
developed countries to improve their copyright system so as to afford protection to
these rights through copyright law, but there were no clear provisions in the Berne
Convention. The TRIPs Agreement therefore made express provision for the
protection of computer programs and databases using copyright. Further, the Berne
Convention permits other countries to provide for a limited right of reproduction,
provided that such reproduction does not conflict with a normal exploitation of the
work and does not unreasonably prejudice the legitimate interests of the author
(Article 9(2)). In fact, many countries’ copyright laws permit the private copying of
works by the user, and therefore it is not a violation of copyright to reproduce CDs
and records etc. for personal enjoyment. However, due to the existence of rental
businesses that are predicated on private copying, this leads to a decrease in CD and
record sales and copyright holders are denied their proper benefits. Therefore,
countries have recognized rental rights, which enable copyright holders to license
the rental of their works and claim remuneration for this. The TRIPs Agreement
obligates Members to establish rental rights at least regarding computer programs
and films. The copyright protects original literary, dramatic, musical and artistic
works and cinematograph films and sound recordings from unauthorized use.
Unlike the case with patents, copyright protects the expressions and not the ideas.

\textsuperscript{37} Article 7 of TRIPs Agreement
\textsuperscript{38} Article 8 of TRIPs Agreement
There is no copyright in an idea. In the case of original literary, dramatic, musical and artistic works the period is counted from the year following the death of the author. In the case of cinematograph films, sound recordings, photographs, posthumous publications, anonymous and pseudonymous publications, works of government and works of international organizations, the period is counted from the date of publication. India is a member of the Berne Convention for the Protection of Literary and Artistic Works of 1886 (as modified at Paris in 1971), and the Universal Copyright Convention of 1951. Though India is not a member of the Rome Convention of 1961, the Copyright Act, 1957 is fully compliant with the provisions of the Rome Convention. Two new treaties, collectively termed as Internet Treaties, were negotiated in 1996 under the auspices of the World Intellectual Property Organization (WIPO). These treaties are called the ‘WIPO Copyrights Treaty (WCT)’ and the ‘WIPO Performances and Phonograms Treaty (WPPT)’. These treaties were negotiated essentially to provide for the protection of the rights of copyright holders, performers and producers of phonograms in the Internet and digital era. India is not a member of these treaties as yet.

2) **Trademarks (Art 15 to 21)**

Any sign, or combination of signs, capable of distinguishing the goods or services of one undertaking, shall be capable of constituting trademark. Trademark includes personal names, letters, numerals, figurative elements and combination of colors as well as any combination of such signs. Members may require, as a condition of registration, that signs must be virtually perceptible. Actual use of a trademark shall not be a condition for filing an application for registration. Members shall publish the trade mark either before the registration or after registration so as to provide an opportunity for petitioners to cancel the registration if found not genuine. The registered mark provides the owner an exclusive right to prevent all third parties not having the owner’s consent from using in the course of trade identical or similar signs for goods or services which creates or likely to create the confusion. These rights shall not prejudice any existing prior rights.

The Paris Convention makes provision for the independence of each country in the protection of trademarks (Article 5), the protection of well-known marks (Article 6(2)), the protection of state emblems etc. (Article 6(3)), the assignment of marks (Article 6(4)), the protection of marks registered in other countries (Article
6(5)), the protection of service marks (Article 6(6)), the protection of collective marks (Article 7(2)), and the protection of trade names (Article 8). The TRIPs Agreement supplements these provisions with extra provisions concerning protectable subject matter (Article 15), rights conferred (Article 16) and the term of protection (Article 18), etc. There are two international treaties governing Trademarks - the Madrid Agreement Concerning the International Registration of Marks and the Madrid Protocol. In India, the Trade Marks Act, 1999 was passed on 30th December 1999 and came into force on 15th September 2003. Before commencement of this Act, the Trade and Merchandise Marks Act, 1958 governed the protection of trademarks in India, which has now been replaced by the Trade Marks Act. The Trade Marks Act, 1999 is in coherence with the provisions of the TRIPs Agreement. The new Act provides for registration of trademarks for services in addition to goods, and has increased the period of registration and renewal from 7 years to 10 years.

3) Geographical Indications

Section 3 Part II (Article 22 to 24) of the TRIPs Agreement contains the provisions for minimum standards in respect of geographical indications. Geographical Indications of Goods are defined as that aspect of intellectual property which refers to the geographical indication referring to a country or to a place situated therein as being the country or place of origin of that product. Typically, such a name conveys an assurance of quality and distinctiveness which is essentially attributable to the fact of its origin in that defined geographical locality, region or country. Under Articles 1 (2) and 10 of the Paris Convention for the Protection of Industrial Property, geographical indications are covered as an element of IPRs.

In India, the Geographical Indications of Goods (Registration and Protection) Act, 1999 came into force with effect from 15th September 2003. This Act seeks to provide for the registration and protection of Geographical Indications relating to goods in India. The Controller General of Patents, Designs and Trade Marks is also the registrar for the Geographical Indications, and the Geographical Indications Registry is located at Chennai.
4) Registered (Industrial) Design (Art. 25 and 26)

Agreement contains the provisions for minimum standards in respect of Industrial designs. Industrial designs are an element of intellectual property. Industrial designs refer to creative activity, which result in the ornamental or formal appearance of a product. Design rights refer to a novel or original design that is accorded to the proprietor of a validly registered design. But it does not include any mode or principle or construction or anything which is in substance a mere mechanical device.

India has already amended its national legislation to provide for these minimal standards. The essential purpose of the Designs Act, 2000 is to promote and protect the design element of industrial production. It is also intended to promote innovative activity in the field of industries. The present legislation is aligned with the changed technical and commercial scenario and conforms to the international trends in design administration.

Under the Designs Act, the designs would not include any trade mark, as defines in the Trade Marks Act or property mark or artistic works as defined in the Copyright Act. Protection of IC layout design and Protection of undisclosed information the duration of the registration of a design is initially ten years from the date of registration, but in cases where claim to priority has been allowed the duration is ten years from the priority date. This initial period of registration may be extended by further period of 5 years on an application before the expiry of the said initial period of Copyright. The proprietor of a design may make an application for such an extension as soon as the design is registered.

5) Layout Designs of Integrated Circuits

Articles 35 to 38 of Section 6/Part II of the TRIPs agreement contain the provisions for protection of rights in respect of Layout Designs of Integrated Circuits.

The basis for protecting integrated circuit designs (Topographies) in the TRIPs Agreement is the Washington Treaty on Intellectual Property in Respect of Integrated Circuits, 1989. India is a signatory to this international agreement.

1. Protection in accordance with Treaty on Intellectual Property in Respect of Integrated Circuit. (Art.35)
2. Protection shall extend to layout designs as such and to the industrial articles that incorporate them. (Art.36)

3. Bona fide purchasers of products involving infringing layout designs shall be liable to pay compensation to the rights-holder after. (Art.37)

4. Term of protection is a minimum of 10 years notification. (Art 38)

In India, the IPRs on the layout designs of integrated circuits are governed by the Semiconductor Integrated Circuits Layout-Design Act, 2000.

Under this Act, a layout-design shall be considered original if it is the result of its creator’s own intellectual efforts and is not commonly known to the creators of layout-designs and manufacturers of semiconductor integrated circuits at the time of its creation. But a layout-design, which is not original, or which has been commercially exploited anywhere in India or in a convention country; or which is not inherently distinctive; or which is not inherently capable of being distinguishable from any other registered layout-design, shall not be registered as a layout-design. But if a layout-design which has been commercially exploited for not more than two years from the date on which an application for its registration has been filed either in India or in a convention country shall be treated as not having been commercially exploited. The registration of a layout-design shall be only for a period of ten years counted from the date of filing an application for registration or from the date of first commercial exploitation anywhere in India or in any country whichever is earlier. No person shall be entitled to institute any proceeding to prevent, or to recover damages for, the infringement of an unregistered layout-design.

6) Protection of undisclosed information

Undisclosed information is to be protected against unfair commercial practices, if the information is secret, has commercial value and is subject to steps to keep it secret. Secret data submitted for the approval of new chemical entities for pharmaceutical and agrochemical products should be protected against unfair commercial use and disclosure by governments.

Article 39 of Section 7 Part II of the TRIPs agreement elaborates on the protections of trade secrets. A trade secret or undisclosed information is any information that has been intentionally treated as secret and is capable of
commercial application with an economic interest. It protects information that confers a competitive advantage to those who possess such information, provided such information is not readily available with or discernible by the competitors. They include technical data, internal processes, methodologies, survey methods used by professional pollsters, recipes, a new invention for which a patent application has not yet been filed, list of customers, process of manufacture, techniques, formulae, drawings, training material, source code, etc. Trade Secrets can be used to protect valuable “know how” that gives an enterprise a competitive advantage over its competitors.

The Agreement provides that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by or used by others without their consent in a manner contrary to honest commercial practices. Further, parties are required to protect against unfair commercial uses, undisclosed or other data obtained as a condition of approving the marketing of pharmaceutical or of agricultural chemical products.

There is no specific legislation regulating the protection of trade secrets. India follows common law approach of protection based on contract laws.

7) Patents (Art 27-34)

Section 5 Part II of the TRIPs Agreement (Article 27 to Article 34) contains the provisions for standards in respect of the Patents.

A Patent is an exclusive right granted by a country to the inventor to make, use, manufacture and market the invention that satisfies the conditions of novelty, innovativeness and usefulness Members are required to comply with the Paris Convention for the Protection of Industrial Property.

Introduction of Patent Law in India took place in 1856 whereby certain exclusive privileges to the inventors of new inventions were granted for a period of 14 years. Presently, the patent provisions in India are governed by the Patents Act, 1970. The Indian Patents Act is fully compatible with the TRIPs Agreement, following amendments to it; the last amendment being in 2005 by the Patents (Amendment) Act, 2005.

Product patents in the field of pharmaceuticals and agro-chemicals have been introduced by deleting Section 5 of the Patents Act. Those inventions which
are considered a mere discovery of a new form of a known substance or mere
discovery of a new property or new use will not be considered patentable.

The term of every patent is now for 20 years from the date of filing. The
filing date of a patent application and its complete specification will now be the
international date of filing for the patent as per the provisions of the Patent
Cooperation Treaty.

A provision has also been introduced in the Patents Act to enable the grant
of compulsory licenses for the export of medicines to countries with limited or no
manufacturing capacities to meet emergent public health situations. The law
effectively balances and calibrates intellectual property protection with public
health concerns and national security. This provision is in line with the Decision of
the WTO of 30 August 2003 on the Implementation of Paragraph 6 of the Doha
Declaration on the TRIPs Agreement and Public Health.

3.13 PATENTS IN THE TRIPs AGREEMENT

Patents shall be granted for any inventions, whether products or processes,
in all fields of technology, provided they are new, involve an inventive step and are
capable of industrial application. No discrimination in respect to place of invention,
Exceptions available for diagnostic, therapeutic and surgical methods of treatment
for humans or animals, as well as plants and animals and essentially biological
processes for the production thereof.

1) Patentable Subject Matter (Art.27)

1. Subject to the provisions of paragraphs 2 and 3, 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. (1)
Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of
this Article, patents shall be available and patent rights enjoyable without
discrimination as to the place of invention, the field of technology and whether
products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their
territory of the commercial exploitation of which is necessary to protect ordre
public or morality, including to protect human, animal or plant life or health or to

39 http://www.wto.org/english/tratop_e/TRIPs_e/t_agm3c_e.htm#5
avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude 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. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

2) Rights Conferred (Art. 28)

Exclusive right to owners against third party for using subject matter including process of patent, without his consent (Art.28)

1. A patent shall confer on its owner the following exclusive rights:

   (a) Where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing (2) for these purposes that product;

   (b) Where the subject matter of a patent is a process, to prevent third parties not having the owner’s consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

3) Conditions on Patent Applicants (Art. 29)

Inventions shall be disclosed in a manner, which is sufficiently clear and complete for a skilled person in the art to carry out the invention. (Art. 29)

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for
carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.

4) Exceptions to Rights Conferred (Art. 30)

Limited exceptions to the exclusive rights provided such exception do not conflict with normal exploitation of the patent. (Art.30) 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.

5) Other Use without Authorization of the Right Holder (Art. 31)

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

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

(b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) The scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
(d) Such use shall be non-exclusive;

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

(f) Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

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

(i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) Where such use is authorized to permit the exploitation of a patent (“the second patent”) which cannot be exploited without infringing another patent (“the first patent”), the following additional conditions shall apply:

(i) The invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
(ii) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

6) Revocation/forfeiture is subject to judicial review. (Art 32)

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

7) The term of Patents (Art.33)

The term of protection shall be at least 20 years from the date of application.

8) Process Patents Burden of Proof (Art. 34)

Reversal off the burden of proof in civil proceedings relating to infringement of process patents is to be established in certain cases. (Art.34)

1. for the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.

Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) If the product obtained by the patented process is new;

(b) If there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.
3.14 Basic Patent Obligations of TRIPs

Under TRIPs, WTO members are required to provide patent protection for essentially all inventions, whether a product (such as a medicine) or a process (such as method of producing the chemical ingredients for a medicine)\(^{40}\). The TRIPs Agreement also includes exceptions to these obligations, specifying certain conditions under which Member governments do not need to recognize patents\(^{41}\).

To qualify for a patent, an invention must satisfy three criteria of eligibility: novelty, inventive step and industrial applicability\(^{42}\), Patent protection has to be granted for a minimum of twenty years from the date the patent was filed\(^{43}\).

The TRIPs Agreement requires that WTO Members not to discriminate in their patent regimes between different fields of technology, place of invention, or place of production\(^{44}\). For example, India, which did not recognize product patents for pharmaceuticals prior to TRIPs but did provide patents for other products, has an obligation to grant patents to pharmaceutical products as in other fields of technology by 2005.

In addition to basic obligations, TRIPs specifies exceptions, or “flexibilities,” to patent protection. There are two broad categories of exception: (1) allowance for governments to provide limited exceptions to patent rights; and (2) ability of a government to override patent rights. With regard to the first exception, Article 30 of TRIPs states that “members may provide exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties.”\(^{45}\) Some countries and public health groups have interpreted this provision to allow export of the generic versions of patented

\(^{40}\) TRIPs, Article 27.
\(^{41}\) Article 27.2 and 27.3 of TRIPs specify three conditions under which WTO members can refuse to grant patent protection. First, a government may refuse to issue a patent for an invention if the invention is contrary to public order or morality. Second, a government can exclude patents for diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms). Finally, a government can refuse to patent biological processes for the production of plants or animals (other than microorganisms).
\(^{42}\) TRIPs, Article 27.1
\(^{43}\) TRIPs, Article 33.
\(^{44}\) TRIPs, Article 27.1.
\(^{45}\) TRIPs, Article 30.
medicines and other inventions to address the health needs in importing countries. However, the developed countries, the European Communities in particular, have interpreted the Article more stringently to mean that the “legitimate interest” of the patent owner to include economic benefits gained from market exclusivity provided by the patent.

Second, under limited circumstances, TRIPs allows WTO Members the option of overriding the market exclusivity of patents, more commonly known as granting “compulsory licenses” to non-patent holders. “Compulsory licensing” refers to granting a license to an entity other than the patent holder to manufacture a patented product without the patent holder’s permission. Compulsory licensing is not a new practice; TRIPs seeks to discipline its use.

TRIPs Article 31 details the procedures and circumstances under which WTO members can use patented inventions “without authorization of the right holder.” Article 31, as commonly believed, and does not explicitly state that a situation of “national emergency” or extreme urgency must exist for a country to use Article 31 flexibilities. The situation of national emergency or extreme urgency must exist only if a Member government wants to waive the requirement of negotiation with the patent holder before granting compulsory licenses. Though it does not use the term “compulsory licensing,” Article 31 is generally understood as disciplining the practice. It sets out the requirements including consideration of each case separately, attempts to negotiate with the patent holder, specificity of time

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46 India, Pakistan and other developing countries made a proposal to the WTO in 2001 to interpret Article 30 of the TRIPs Agreement in a manner that allows countries to export medicines and other inventions in order to address the health needs in importing countries. Public health groups comprising Heath Action International, Doctors without Borders and Consumer Technology Project endorsed this approach in the 1999 “Amsterdam Statement to WTO Members on Access to Medicine.” Oxfam has also urged the WTO to consider an interpretation of Article 30 that is similar to the one proposed by India and other developing countries.

47 Many developed countries have long included in their patent laws provisions permitting compulsory licensing under specified conditions. The U.S. has led the world in issuing compulsory licenses to restore competition when violations of the anti-trust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred. Article 31 (k) of the Agreement states that “Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.” The United Kingdom and Canada provide leading examples of compulsory licensing of patented drugs without a finding that the anti-monopoly laws have been violated. Threat of compulsory licensing is often used as a bargaining tool to bring down the price of patented products, as the United States did with Cipro and Brazil did in with regard to ARVs. See F.M. Scherer and Jayashree Watal, “Post-TRIPS Options for Access to Patented Medicines in Developing Nations,” Journal of International Economic Law (2000), pp.913-939.
and purpose, and adequate remuneration for the patent holder. Significance of the Authorization (Art 31):48

a) The requirement that each authorization shall be considered individually (i.e., authorizations cannot be automatic – e.g., a law allowing the issuance of a compulsory license for failure to domestically produce a patented product after a specified period is prohibited);

b) The requirement that prior to issuance of a compulsory license an issuing country must try to negotiate with the patent holder to obtain the patented product. Specifically, Article 31(b) states that the country must make “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and those efforts have not been successful within a reasonable period of time.” The requirement to negotiate may be waived “in the case of national emergency or other circumstances.

c) The requirement that use be time limited, and for a specific purpose; the scope and duration of such use shall be limited to the purpose for which it was authorized…;

d) Such use shall be non-exclusive;

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

f) Any such use shall be “authorized predominantly for the supply of the domestic market of the Member authorizing such use;” This stipulation that majority of the production must stay in the domestic market of the producer and cannot be exported to disadvantaged countries without domestic capacity.

g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur…;

h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; the patent holder must be compensated for the lost economic returns. However, “adequate remuneration” is an undefined term subject to interpretation, along with the determination of economic value.

48 TRIPs, Article 31.
i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

1) Time frame for implementation of Obligations

TRIPs set out a differentiated schedule of implementation for developed countries, developing countries, and the least developed countries (LDCs)49.

a) January 1, 1996: All TRIPs obligations came into force in developed countries.

b) January 1, 2000: End of the general transition period for developing countries to apply the TRIPs provisions.

c) January 1, 2005: End of extra transition period for developing countries to apply the TRIPs provisions in areas of technology not patented at the time of TRIPs enforcement.

d) January 1, 2006: End of transitional period for LDCs to apply the TRIPs provisions, except in pharmaceutical patents.

e) January 1, 2016: LDCs must be TRIPs-compliant in all areas, including pharmaceuticals. This further has been extended up to 2023.

Once the transition period expires for a country, it is obliged to provide comprehensive patent protection for both pharmaceutical products and processes used to make those products. Any use of patented inventions without the authorization of

49 In the WTO, least developed country members are those recognized as least developed countries by the United Nations. Forty-nine countries are currently designated by the United Nations as least developed countries (LDCs). The current criteria are: (1) low national income (per capita GDP under $900 for countries now joining the list), (2) weak human assets (a composite index based on health, nutrition and education indicators), and (3) high economic vulnerability (a composite index based on indicators of instability of agricultural production and exports, inadequate diversification and economic smallness). Different thresholds are used for addition to, and graduation from, the list of LDCs. A country qualifies for addition to the list if it meets inclusion thresholds on all three criteria, and if its population does not exceed 75 million.
patent-holder will require compulsory licensing. In addition to the general transition periods, developing countries were given additional periods to comply with specific patent obligations. In particular, the “transitional arrangements” specified in Article 65 allows developing countries that did not provide patent protection in a particular area of technology when the TRIPs Agreement came into force up to 10 years to introduce the protection, or until January 1, 2005. 

For pharmaceuticals and agro-chemicals, developing countries and LDCs eligible for the ten year transition period have to comply with two obligations. First, under Article 70.8 of TRIPs the country must allow inventors to file patent applications beginning January 1, 1995. The patent application need not be considered until the end of the transition period. This is known as “the mailbox rule.”

If a product that has been the subject of such a patent application obtains marketing approval before the decision on the grant of the patent is taken, there is an obligation under Article 70.9 to grant exclusive marketing rights (EMRs) to tide over the gap. EMRs must be granted for five years, or until a decision on product patent is taken, whichever is shorter. If LDCs were bound to grant EMRs, the value of the concession made by the Doha Declaration to LDCs would be very limited, since access to medicines and other products could be effectively blocked for at least five years. But on June 27, 2002 TRIPs Council decision provides LDCs the opportunity to waive the EMR requirements with respect to pharmaceuticals until January 1, 2016 which has been further extended up to 2023.

Both Articles 70.8 and 70.9 have a direct impact on the LDCs. As a non-LDC developing country that did not recognize pharmaceutical patents pre-1995, India is obliged to establish the “mailbox” and EMR systems before they provide patent protection for pharmaceuticals in 2005. As a LDC, Uganda is also responsible for creating a “mailbox” system. The case of Nigeria is not very clear because as a non-LDC developing country, Nigeria would have been obliged to follow both Articles 70.8 and 70.9. However, even prior to 1995, pharmaceuticals were patentable under the Nigerian national laws and several patents have been granted under its provisions for pharmaceutical products in the past.

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50 TRIPs, Article 65.4.
51 TRIPs, Articles 70.8 and 70.9.
3.15 TRIPs AGREEMENT AND PATENTS ON MEDICINES AND DRUGS

The TRIPs agreement addresses seven main categories of IP rights and several supplementary aspects of IP rights to name but a few, are: Copyright and related rights; patents; trademarks and service marks; geographical indications; undisclosed (confidential information) or trade secrets; industrial designs; and layout designs of integrated circuits.52

Following the TRIPs agreement, it became compulsory for all WTO members to apply laws in their country to give effect to the agreement. Where a country fails to comply accordingly, it faces sanctions that could alienate it from the rest of the world economy. In the same vein, all developed and developing members of the WTO are required under TRIPs Article 63 to notify to the TRIPs Council of the laws giving effect to the TRIPs Agreement in their countries.53

Pursuant to Article 1 of the TRIPs agreement, individual member countries are free to determine the appropriate method ‘for implementing the Agreement within their own legal system and practice’. Article 1 professes to reaffirm the well established principle of MFN and National Treatment of the WTO/GATT. These principles are supposed to eradicate discrimination. Article 6 allows member countries to provide for the international exhaustion of rights and, therefore, to admit parallel imports if they so wish. This principle is relevant in that it seeks to protect consumers’ interests in all the member countries.

According to Bruce Lusignan54, “Parallel importation is based on the legal idea of exhaustion, which allows a rights holder to get remuneration by selling a product, but only for the first time. After this, the buyer has the right to use the product and even resell it. Economically, this ability provides additional local competition for the holder and helps to drive down costs … therefore, a company can charge drastically different rates for residents of different countries, but TRIPs

54 Patents and Developing Countries: How International Law Inhibits the Third World (SUID 05333167) ENGR 297B – Ethics of Development in a Global Environment (Winter Quarter 2005: 11 March 2005)
does not prohibit a competing company from buying the goods in the cheaper markets and then exporting it to the countries facing higher prices”.

Article 7 provides that “sound policy should strike a balance between the right to exclude and the right to use innovations.” This provision is intended to allow IP right owners to fully exploit the profits of their intellectual creation. The provisions are without prejudice to other provisions of the TRIPs agreement namely; the powers of governments to enforce parallel imports; exceptions to exclusive rights; and compulsory licenses. In respect of compulsory licenses, critics argue that TRIPs does not specify when this measure may be invoked, however, most clauses for this purpose in national statutes include: national emergencies; extreme urgency; and, the remedy of anti-competitive practices. It is unclear whether such national measures would violate or comply with Article 7 of the TRIPs agreement.

Article 8 of the Agreement, provides that; “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…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 provisions of Article 8 seek to facilitate legislative limitations to exclusive rights, as well as the enactment of legislative provisions concerning compulsory licensing of certain IP rights.

However, Article 31 specifies that such use can be resorted to only if certain preconditions are fulfilled. These requirements are such that they in effect reduce the scope for granting compulsory licenses. Article 30 allows exceptions to patent rights, including use for research, teaching, and improvement. This means that developing nations, for example, can dissect technology to educate their own populace and improve development. The laws in each country, however, must

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55 Compulsory licenses are authorizations granted by a government or a judge permitting the use of a piece of intellectual property without the consent of the title-holder.
specify the exceptions. Unfortunately, few developing countries have done so and thus they have little experimentation\textsuperscript{56}.

The TRIPs Agreement makes dispute between WTO Members in respect of the TRIPs obligations subject to the WTO’s dispute settlement procedures. In addition the Agreement provides for certain basic principles, such as national and most-favored-nation treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IP rights do not nullify the substantive benefits that should flow from the Agreement.\textsuperscript{57} The various proposals have no recognized source and only the participants directly involved know how and why certain provisions were adopted or not as the case may be. Hence, the TRIPs negotiations can be considered the most non transparent negotiations conducted to date on IP rights. The result is that the contracting parties now lack the background information necessary for interpreting the proposed rules or for understanding better the background, premises and intent of the adopted text\textsuperscript{58}.

The TRIPs agreement makes relatively few concessions to developing countries. Developing countries and countries in the process of transformation to a market economy were allowed until 2000 to comply with the agreement. In addition, if a country is required by the TRIPs agreement to extend patent protection to new product and technology areas not covered by local IP legislations, it was allowed to delay compliance until January 2005. Developing countries taking advantage of this further delay are required to notify the TRIPs Council under the terms of Article 70, such notifications had been received from: Argentina, Cuba, India, Pakistan, Jordan, Uruguay, Egypt, United Arab Emirates and Turkey. Similarly, ‘least-developed’ countries were allowed to delay until 2006 to comply with the entire TRIPs agreement, with the exception of the general obligations of national treatment and MFN treatment of the GATT/WTO. With regard to pharmaceuticals, the 2006 deadline for less-developed countries were extended to 1 January 2016 at the Doha Ministerial Conference of 9-14 November 2001\textsuperscript{59} this further has been extended up to 2023. Irrespective of the grace period given to the

\textsuperscript{57} Ibid
developing and less-developed countries for compliance with the TRIPs agreement, Article 70.8 and Article 70.9 require that they must establish an administrative means for preserving novelty and priority for patent applications during the transitional period. They are also obliged to provide a system for granting exclusive marketing rights for such products and/or processes\(^{60}\).

The express text of paragraph 7, second sentence, exempts LDCs from the obligation to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement, and the obligation to enforce rights provided for under those sections. By its express terms, paragraph 7, second sentence, does not address obligations under Article 70:8 and 70:9 of Part VII of the Agreement. In the absence of some contrary understanding reached at Doha, Article 70:8 would appear to continue to apply, and require least developed Members to maintain “mailbox” application mechanisms that allow for the receipt and retention of pharmaceutical patent applications until coverage is provided under local law. Pharmaceutical patent applications received before January 1, 2016 would have priority dates preserved and be reviewed under patentability criteria as of the priority date. Patent protection would be available for the remainder of the patent term counted from the priority date.

Where a contrary understanding not reached at Doha, Article 70:9 also appear to apply. If so, exclusive marketing rights should be granted to the patent applicant for a maximum period of five years following marketing approval of the pharmaceutical product in the least developed country, provided that a pharmaceutical patent has been granted and marketing approval has been obtained by the patent applicant in another Member. A pharmaceutical patent applicant with exclusive marketing rights in a least developed Member has the effective equivalent of patent rights because, while it may not have exclusive rights to make or import the covered drugs, it presumptively will be able to prevent the marketing of generic equivalents, and it may thereby control the local market. Exclusive marketing rights may be even more burdensome to LDCs than patents if they are understood not to be subject to the same exceptions (e.g., Article 30, TRIPs Agreement) to which patents are subject, or to compulsory licensing (Article 31, TRIPs Agreement).

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The Doha Declaration confirmed the right of developing countries to use compulsory licenses to override patents on medicines, in order to allow generic drug manufacturers to produce cheap versions of patented medicines. Sadly, the Ministers in Doha failed to agree on how to solve the problem of how those developing countries without the domestic pharmaceutical manufacturing capacity could effectively use the compulsory license. This became to be known as the Paragraph 6 problem, named after the paragraph dealing with this issue in the Doha Declaration 61.

Paragraph 6 problem concerns the provision of TRIPs Agreement which allows the grant of compulsory licenses to override patents, so that generic manufacturers may produce their cheaper versions of patented drugs. However, countries with insufficient or no domestic manufacturing capacity in pharmaceuticals are faced with a problem because there are no generic manufacturers to produce the drugs domestically. An option for these countries is to grant compulsory licenses for the import of such drugs. Critics believe that, this was an intentional act by the developed countries to further control and exploit the developing and less-developed countries. It is also argued that compulsory licensing is geared towards underdevelopment of the developing countries’ health care systems. The reason is that Article 31(f) of the TRIPs Agreement requires that the production of generic drugs under a compulsory license is largely for the supply of the domestic market which means that the lesser fraction may not be sufficient for the needs of the importing country or countries 62. In or about 2003, the members of the WTO agreed to a waiver of the Article 31(f) limitation on export which lifts the requirement of Article 31(f) that pharmaceutical products produced under compulsory license shall be “predominantly for the supply of the domestic market” 63.

With the waiver in force, it means that a predominant portion or even the entire amount of production under compulsory license could be exported to a country wishes to import 64. In the decision, WTO members agreed that the waiver will last until the article

is amended. The legal problem for exporting countries was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members’ shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.

The decision actually contains three waivers:

1) Exporting countries’ obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries.

2) Importing countries’ obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.

3) Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.

Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining patent systems, particularly in rich countries. They include measures to prevent the medicines from being diverted to the wrong markets. And they require governments using the system to keep all other members informed, although WTO approval is not required. At the same time phrases such as “reasonable measures within their means” and “proportionate to their administrative capacities” are included to prevent the conditions becoming burdensome and impractical for the importing countries. After that, several potential exporting countries changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under compulsory license. Norway, Canada, India and the EU have formally informed the TRIPs Council that they have done so. The 2003 waivers were interim; the ultimate

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goal was to amend the TRIPs Agreement itself, and a decision to do this was reached in December 2005, accompanied again by a chairperson’s statement. The amendment a direct translation of the waivers enters into force when two thirds of members accept it.

The relationship between public health and the TRIPs Agreement had been examined in 1996 by the World Health Assembly, which addressed the subject in a resolution on the Revised Drug Strategy. Subsequent resolutions adopted by the World Health Assembly in 2001, addressed the need to evaluate the impact of the TRIPs Agreement on access to drugs, local manufacturing capacity and the development of new drugs.

Since one of the key objectives of the patent system is to reward innovation by allowing innovators to charge “higher prices” for protected products, it has been argued that a fully functional patent system would result in an inverse relationship between the cost of such products and affordability of access. Some have gone further to suggest that the global intellectual property system is facing a crisis of public legitimacy as citizen groups around the world are raising questions, for example, on how patents may be blocking the access of ordinary people to medicines.

While a stronger patent regime may provide the incentive (noted by the World Bank to be “marginal”) for pharmaceutical firms to discover new treatments for some “third world” diseases, there is an urgent need to consider corresponding enhancements in access to medicine.

The TRIPs Agreement refers to the substantive provisions of the Paris Convention for the Protection of Industrial Property (Articles 1 through 12, and

66 WHO was mandated “to report on the impact of the work of the WTO with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate” (Resolution WHA49.14, 25 May 1996).

67 Resolutions WHA54.10 and WHA54.11.

68 The UN Sub-Commission for the Promotion and Protection of Human Rights also pointed out the “apparent conflicts between the intellectual property rights regime embodied in the TRIPs Agreement, on the one hand, and international human rights law, on the other”, including human rights to food, health and self-determination (Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second session, Agenda item 4, The Realization of Economic, Social and Cultural Rights, Intellectual Property Rights and Human Rights).

69 See Lall and Albaladejo, Indicators of the relative importance of IPRs in developing countries, paper prepared for the UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, April 2002, at pages 2-3.


Article 19), and provides that Members must comply with those provisions of the Paris Convention, even if they are not party to that Convention (Article 2(1)). Therefore it is said that the TRIPs Agreement adopts a “Paris Plus” approach.

“The future evolution of the international patent system should provide an appropriate balance between the rights of inventors their investors and the general public, while at the same time taking into account the implications for the developing world”.72

In recent years, major concerns have been expressed by some developing countries that the implementation of effective intellectual property regimes may “affect their efforts to improve public health … particularly if the effect of introducing patent protection [is] to increase the price and decrease the choice of sources of pharmaceuticals.” 73 The controversy generated by the “unprecedented public health challenge of the humanitarian calamity of HIV/AIDS”74 serves to highlight tensions that patents on some pharmaceuticals “may be hampering governments’ attempts to deal with urgent policy issues” by “unacceptably impeding access to affordable healthcare, thus frustrating public health programs.”75 This outcry is but another manifestation of broader underlying tensions and imbalances that exist between the developed and developing worlds.

Specifically, the declaration (a) recognized that compulsory licensing could be used to procure critical drugs, at each member’s discretion; (b) acknowledged that each member is free to adopt the desired mode of exhaustion of IPRs (which bears on whether parallel imports are allowed into a country or not); (c) recognized that developing countries with insufficient drug manufacturing abilities would face difficulties in taking advantage of compulsory licensing, and thus instructed the Council for TRIPs to find a solution to this problem; and (d) extended until January 2016 the deadline for LDCs to implement IPR protection for pharmaceuticals and

73 See CIPR report, at p 29.
75 See WIPO Patent Agenda: Options for Development of the International Patent System (A/37/6) at Annex I p 28. See, for example, the recent outcry by a consortium of non-governmental organizations in Kenya over the high cost of AIDS drugs. This has called for a consideration of the following: “How does a mercilessly globalizing world balance the 3Ps - Pharmaceuticals, Patents and Profits - with the right of patients to access essential drugs? See Odour Ong’wen, Crocodile Tears: How ‘TRIPS’ Serves West’s Monopoly, the East African, March, 12 2001.
test data now which has been extended to 2023. Hence to address and balance the issues exceptions have been framed in the form of DOHA declaration.

“Developing countries should not be deprived of the flexibility to design their IP systems that developed countries enjoyed in earlier stages of their own development, and higher IP standards should not be pressed on them without a serious and objective assessment of their development impact … We need to make sure that the IP system facilitates, rather than hinders, the application of the rapid advances in science and technology for the benefit of developing countries.”76

3.16 THE DOHA DECLARATION FLEXIBILITIES TO PROTECT PUBLIC HEALTH

1) Exhaustion of rights

Exhaustion of rights – refers to cases in which intellectual property rights are deemed exhausted after first sale of the protected product by the right holder or with his consent. During the TRIPS negotiations, the international exhaustion of IP rights, in other words, the problem of parallel importing of genuine products was discussed, but the arguments of each country were different and a conclusion could not be reached. Therefore, the TRIPS Agreement provides that except for the national treatment and Most Favored-Nation provisions, the Agreement shall not address the issue of the exhaustion of intellectual property rights (Article 6).

Accordingly, the TRIPS Agreement did not contain any provisions relating to the international exhaustion of intellectual property rights or the parallel importing of genuine products, and these issues are left to be dealt with by the domestic laws of each Member. The context for this issue has also been provided by the Paris Convention. Article 5A of the Stockholm Act of the Paris Convention clarifies that “failure to work” or commercial exploitation or “insufficient working” of a patent constitutes an “abuse” of patent rights. In the event of an abuse of the patent rights arising from non-working or insufficient working, the patent granting authority was given the powers to issue a license to anyone who was willing to “work” the patent.

The Commission on Intellectual Property Rights (CIPR), which was instituted by UK Department for International Development, was equally supportive of the compulsory licensing system. In its report “Integrating Intellectual

Property Rights and Development Policy”, the Commission emphasized that “developing countries should establish workable laws and procedures to give effect to compulsory licensing and provide appropriate provisions for government use”\textsuperscript{77}. The CIPR recommended that developing countries should adopt effective compulsory licensing mechanisms which include straightforward, transparent and fast procedures that do not suspend the execution of the license. Moreover, the CIPR emphasized that developing countries should fully exploit the flexibilities within TRIPs for determining compulsory licensing, as well as for non-commercial use by the government, including production for export.

Article 6 of the TRIPs Agreement provides that nothing in the Agreement will be considered to address the subject of exhaustion of IPRs for purposes of dispute settlement. Although virtually all Members understood Article 6 to allow each of them to adopt its own policies and rules on the subject of national and international exhaustion, there was sufficient concern over interpretative questions raised by certain Members that the Doha Declaration on the TRIPs Agreement and Public Health made clear that each Member is allowed to adopt its own policies with respect to exhaustion, without being subject to dispute settlement.

The concept exists because of a fundamental difference between intellectual “property” and tangible (or physical) property. That is, IP is embodied in goods and services, but it is not the goods and services themselves. Generally speaking, when a tangible product (such as a can of soda) is sold and transferred, the seller has no further claim on the product, and the buyer can dispose of it as he or she wishes. The holder of an IP right (such as a trademark), on the other hand, generally does not give up his or her right to the IP when a product that embodies it is sold and transferred. The IP holder continues to hold the IP right. The “exhaustion” question concerns whether that right can be used to control the further disposition of the product.

WTO Members have not agreed on uniform rules regarding whether exhaustion of IPRs should have a “national” or “international” character. Under a doctrine of international exhaustion, if a product is lawfully placed on the market in one WTO Member, the holder of a “parallel” IP right in another Member is not able to control its importation or resale based on that parallel IPR. Under a doctrine of national exhaustion, the lawful marketing of the product in one WTO Member does

\textsuperscript{77} Commission on Intellectual Property Rights (2002), p. 44.
not affect the rights of a “parallel” IP holder in another Member, and the IP holder in the other Member may use its parallel IPR to block the importation and further disposition of the product. Some WTO Members follow a rule of international exhaustion, and some a rule of national exhaustion. It is not uncommon for Members to have different exhaustion rules with respect to different types of IPR.

While Article 6 and the Doha Declaration establish beyond doubt that each Member is entitled to allow international exhaustion and so-called “parallel importation” of IPRs protected goods, this does not mean that an exhaustion policy will never be challenged in WTO dispute settlement. This is because the term “exhaustion” is not self-defining, and a Member might bring a claim against another Member asserting that it has adopted an unreasonable definition of the concept of exhaustion.\(^7\)

Articles 7 and 8 of the TRIPs Agreement refer to the objectives of the Agreement and to principles that generally apply to its interpretation and application. Article 7 confirms that the IPRs are intended to reflect a balance between the interests of private stakeholders that are relying on IP protection to provide an incentive for creativity and invention (and investment in those activities), and society that is expected to benefit from access to creations and the transfer and dissemination of technology. Article 8:1 indicates that Members may adopt, inter alia, measures necessary to protect public health and nutrition, provided that those measures are consistent with the Agreement. The Article 8:1 formulation may assist in the defense of so-called non-violation nullification or impairment claims, if these are eventually permitted under the Agreement. In more general terms, the usefulness of Article 8:1 in dispute settlement is limited by the requirement that measures be consistent with the Agreement, in contrast to the formulation of Article XX of GATT 1994 and Article XIV of GATS, each of which makes provision for measures that are necessary and otherwise “inconsistent” with the Agreement. The formula set forth in Article 8:1 is controversial. Article 8:2 acknowledges the right of Members to take action against anticompetitive practices relating to IP, also with the proviso that such action must be consistent with the Agreement. The role of Articles 7 and 8 in dispute settlement has so far been

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\(^7\) Dispute settlement, WTO 3.14 TRIPs, United Nations, New Geneva.2003
limited. These provisions have been invoked as an aid in interpretation, but have not exercised an identifiable influence on the outcome of cases.

When South Africa tried to take advantage of the flexibilities embodied in TRIPs, drug companies took the South African Government to court in 2000 to challenge the pharmaceutical legislation. After an intense international campaign backing the South African Government and strong pressure from South African civil society especially the Treatment Action Campaign\(^79\) the issue finally was discussed in the WTO on 20 June 2001. Subsequently, the Doha Declaration was drawn up in November 2001, which confirmed that TRIPs “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all”\(^80\).

It is submitted that the TRIPs Agreement and public health is far from closed. Even after the passing of the DOHA Agreement on access to generic medicines in most of the poor countries, serious differences on the interpretation and implementation difficulties under the TRIPs Agreement is likely to persist on the question of balancing the IP issues and public health policy to re-establish the WTO legitimacy. The DOHA declaration was designed to respond to concerns about the negative impacts of the TRIPs Agreement on access to medicines.\(^81\)

In April 2001, Zimbabwe, on behalf of the African Group, demanded that the TRIPs Council convened a special session on access to medicines. The resulting June 2001 meeting provoked stark positioning by the United States\(^82\) and European Union\(^83\), who jointly advanced pro-PhRMA positions. However, it also resulted in a strong platform by developing countries that evolved with later submissions to include the following points:

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\(^80\) Declaration on The TRIPs Agreement And Public Health, 20 November 2001, WT/MIN(01)/DEC/2.

\(^81\) Declaration on TRIPs Agreement and public health.WTO ministerial conference, fourth session DOHA, adopted on 14\(^{th}\) November, 2001.


\(^83\) Communication from the European Communities and Their Member States, IP/C/W/280 (June 12, 2001).
(1) Developing countries have a broad spectrum of public health concerns, not just HIV/AIDS, and they are particularly concerned about the lack of research on so-called neglected diseases;

(2) Patents raise prices and thus impede access to medicines;

(3) Developing countries should be free to use existing TRIPs flexibilities including compulsory licenses and parallel importation without being threatened by developed countries;

(4) Least developed members need an extension of transitional periods beyond 2006;

(5) Developing countries need to be able to source generic medicines from exporting countries despite the “predominately for domestic use” rule in Article 31(f) of the TRIPs Agreement, preferably through an Article 30 limited exception; and

(6) Developing countries need assurances that data protection rules in Article 39.3 would not impede registration of generics.84

The Doha Ministerial Conference succeeded in agreeing a Declaration and a Work Programme for further negotiations,85 but its impact remains to be seen. Like the WTO, it does not specifically address consumer interests, but contains provisions that impact on consumers. Some issues on the Doha Agenda like compulsory licensing under TRIPs (Section 5.6) or investment liberalization (Section 5.9).

The Doha Declaration will have very specific application in the field of public health later. In a more general sense, the Doha Declaration affirms the right of Members to take advantage of the flexibility inherent in the TRIPs Agreement, and affirms and clarifies the meaning of provisions relating to compulsory licensing and parallel importation. The Doha Declaration authorizes an extension to least developed Members regarding the implementation and enforcement of pharmaceutical patent protection, the scope of which may well become the subject of dispute settlement.

The right to import is governed by the principle of rights exhaustion under which a patent holder may lose or exhaust certain rights. The principle covers three scenarios:

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84 Developing Country Group’s Paper, IP/C/W/296 (June 29, 2001); Draft Ministerial Declaration – Proposal from a Group of Developing Countries, IP/C/W/312 (Oct. 4, 2001).

85 WT/MIN(1)/DEC/1, 14. November 2001, Ministerial Declaration and Work Programme
First, national exhaustion entails the limitation of the right of goods circulation in a country. If the patent owner accepts the marketing of his (or her) product in a country, national exhaustion forbids any export of the product to another country.

Second, regional exhaustion calls for the limitation of the right of circulation of the product in a region. If the patent owner agrees to market his (or her) product for example in the European Union (EU), regional exhaustion would limit the product’s circulation within the EU. Export of a product from one member country to another member country would be lawful. On the other hand, exports from a member-country to a country outside the EU would be prohibited.

Third, international exhaustion does not call for any limitation on the flow of the product. Once the patent owner has accepted that his (or her) product be marketed in a country, international exhaustion authorizes its export to any other country.

The TRIPs agreement does not give any prescription concerning the principle that members may choose: “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights” (Article 6). Members have free scope to specify the principle of exhaustion that they wish to adopt in order to fight against anti-competitive practices and promote public health. There are animated debates about the principle members should adopt. On the one hand, international exhaustion is viewed as a means that may enable members to fight against anti-competitive practices and facilitate people’s access to treatments by proceeding with Parallel Imports (PI). On the other hand, it may be feared that international exhaustion may induce firms to opt for a single price strategy for fighting against PI. In this way, firms prevent undesirable parallel exports from countries where a product is marketed at low price to countries where the product is marketed this time at higher price. Rationally, this single price would be close to the one prevailing in developed countries, whence an upward revision for developing countries. Finally, some recommend national exhaustion\textsuperscript{86}.

The Doha Ministerial mandates negotiations in the following areas:

\textsuperscript{86}Samira Guennif, From TRIPs to “TRIPs Plus” provisions. Patents protection and public health promotion in developing countries: raising the stakes for drugs accessibility. Paper presented at a conference, Globelics, Dakar, University of Paris, October, 2009.
1. The examination of the scope and modalities for the application of no violation complaints. (Article 64.2 of the TRIPs Agreement).

2. Implementation of mechanisms for enforcement and monitoring developed countries obligations to provide incentives to their enterprises in order to generate technology transfer (Article 66.2).

3. Negotiations to extend protection of geographical indications to other products other than wines and spirits. (According to articles 23 and 24 of the TRIPs Agreement).

4. Interim suspension of granting patents that do not fulfill article 15 of the Convention on Biological Diversity (CBD).

5. Extension of the implementation period of the TRIPs Agreement for least developed countries.

6. Operationalization of articles 7 and 8 of the TRIPs Agreement.

7. Clarification that no patents should be granted on life.

8. Amendment of article 27.3b in the light of the principles of the CBD and the international undertaking, as well as several issues linked to farmers rights, food security, patentability of life, and protection of indigenous innovations.

The Declaration further mandates review in the following:\n
1. Review of Article 27.3(b) (farmers’ rights, patentability of life forms)

2. Review of 71.1 (Examining new developments)

3. Relationship between TRIPs and the CBD

4. Disclosure

5. Prior informed consent

6. Equitable benefit sharing

7. Protection of traditional knowledge

8. Sui generis protection, IPRs or no IPRs

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87 According to the Ministerial text, paragraph.19, the TRIPs council is instructed to pursue its work programme under article 27.3b, article 71.1, and paragraph 12 of the Ministerial Declaration “to examine, inter alia, the relationship with the Convention of Biological Diversity and the protection of traditional knowledge…”. We welcome the direction the Ministerial Declaration provides to the TRIPs Council in undertaking its work by focusing on “the objectives and principles set out in articles 7and 8 of the TRIPs agreement” as well as “the development dimension”.

All the suggestions to be implemented taking into account of the development dimension of the member countries.

The French patent law provides an interesting example of a patent law that differentiates the treatment of pharmaceutical products on public health grounds. It provides that:

“Where the interest of public health demand, patents granted for medicines or for processes for obtaining medicines, for products necessary in obtaining such medicines or for processes for manufacturing such products may be subject to ex officio licenses in accordance with Article L. 613-16 in the event of such medicines being made available to the public in insufficient quantity or quality or at (abnormally high prices) by order of the Minister responsible for industrial property at the request of the Minister responsible for health."

Moreover, public health is not a “field of technology”, but a problem area that may be addressed with products originating in different technological fields, such as equipment, software, diagnostic kits, medicines, and a large variety of devices used for medical treatment.

3.17 POLICY OPTION: FLEXIBILITY IN THE TRIPS AGREEMENT

Article 27.3(b) of the TRIPs Agreement in its current form accommodates the following flexibilities and interpretations:

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) Given the existence of a sui generis protection system on the national level, countries may decide to exempt plants and plant varieties entirely from patent protection. This includes patent protection for both products and the immediate products of patentable processes. No mention is made in TRIPs of patents for plant parts (cells, proteins, genes, gene fragments, etc.). As parts of exemptible objects they too may be exempted from patent protection.

88 Article L. 613-16.
89 Carlos M Correa, Implications of the Doha Declaration on the TRIPs Agreement and Public Health, University of Buenos Aires, June 2002 p43.
90 Achim Seiler, Science Centre for Social Research Berlin.
c) If member states decide not to provide patent protection within their borders for inventions on the economically significant level of plant varieties, they are obliged to set up a *sui generis* protection system for plant varieties. TRIPs contain no specific provisions concerning the nature of such systems other than that they be “effective”. *Sui generis* systems give developing countries considerable latitude in adapting intellectual property rights for plant varieties to their socio-economic needs.

d) If they opt for *sui generis* protection instead of granting patents for plant varieties, countries may also join the UPOV convention in one of its two valid forms. Even though formal admission on the basis of the older 1978 version is no longer possible, Members are still free to implement a protection system compatible with the 1978 UPOV version without actually joining the association.

e) Members have the right to develop a uniform and consistent protection policy to make sure that protective instruments developed and provided for plant varieties are not subverted by other rights whose exclusivity clause might jeopardize the status of plants specifically exempted from patent protection. This is particularly important in the case of patents for micro-organisms and their components if the latter were implanted into crops by means of biotechnological procedures.

f) Members may decide to end patent protection for micro-organisms and their components once the protected object is introduced into a crop. Also, they are not obliged to redefine the cells of plants, animals or humans (or components thereof) as micro-organisms. As they implement TRIPs-provisions for their country, they also have the authority to draw their own line of separation between inventions worthy of protection and mere discoveries that deserve no such protection.

g) In their patent laws Members may include all exemptions from special protection/variety protection granted for the benefit of farmers and breeders engaged in traditional activities. They may also adjust the implementation of TRIPs provisions nationally so as not to jeopardize the obligations of other relevant agreements dealing with living matter.

h) Members may impose safeguards to prevent plant genetic materials provided or extracted under the multilateral system of the FAO Seed Treaty from being subjected to restrictive patent rights. This notably includes parts and components contained therein, even if these are present in an isolated and purified form.
i) The effects 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.

j) We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged to implement the provisions contained in Art. 27.3(b) or to enforce rights provided for under this paragraph until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition period provided for in Art. 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Art. 66.1 Of the TRIPs Agreement.

The Doha Declaration on the TRIPs Agreement and Public Health is comprised of 7 paragraphs. Three of these are preambular, and indicate the importance that WTO Members ascribe to effectively addressing public health concerns, especially epidemic disease. The fourth paragraph includes a strong decision in support of Member’s rights to take measures to protect public health and provide affordable access to medicines. The fifth paragraph clarifies provisions on compulsory licensing and exhaustion of IPRs. It affirms, *inter alia*, that the TRIPs Agreement does not limit the grounds on which Members may grant compulsory licenses, that each Member has discretion to determine the existence of a public health emergency, and that the TRIPs Agreement permits each Member to adopt its own policies and rules regarding the exhaustion of IPRs and parallel trade. The sixth paragraph places the issue of compulsory licensing for export on the agenda of the TRIPs Council, requiring that a proposal be furnished to the General Council by the end of 2002. The seventh paragraph extends until 1st January 2016 and extended up to 2023, the transition period for least developed Members to provide or enforce pharmaceutical product patent protection. Paragraph 4 is stated in terms of an agreement among WTO Ministers acting on behalf of Members. This agreement is most reasonably considered a “decision” of WTO Members under Article IX: 1 of
the WTO Agreement. This decision of WTO Members would appear to constitute an agreement on the method of application of the agreement within the meaning of Article 31(3) (a) of the Vienna Convention on the Law of Treaties ("VCLT"), and to be the substantive equivalent of an interpretation of the TRIPs Agreement.

It is implicit within the Doha Declaration that differentiation in patent rules may be necessary to protect public health. The singling out of public health, and in particular pharmaceuticals (paragraphs 6 and 7), as an issue needing special attention in TRIPs implementation constitutes recognition that public health-related patents deserve to be treated differently from other patents.

Accordingly, on November 14, 2001, WTO members unanimously approved the Doha Declaration. Designed by developing countries to counteract continuing trade threats and a crisis in medical care, the Doha Declaration emphasized the primacy of public health and the right of Member Nations to take measures designed to increase access to affordable medicines. In relevant part, the Doha Declaration states:

1. We recognize the gravity of public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and

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91 Article IX: 1 of the WTO Agreement provides in relevant part. “1. The WTO shall continue the practice of decision-making by consensus followed under GATT 1947. Except as otherwise provided, where a decision cannot be arrived at by consensus, the matter at issue shall be decided by voting. At meetings of the Ministerial Conference and the General Council, each Member of the WTO shall have one vote.... Decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast, unless otherwise provided in this Agreement or in the relevant Multilateral Trade Agreement.”

should be interpreted and implemented in a manner supportive of Members’ right to protect public health and, in particular, to access to medicines for all.

In order to give meaning to paragraph 4, however, it is possible to interpret that the intention of the Members was to indicate that in cases where there is conflict between IPRs and public health, the former should not be an obstacle to the realization of the latter. A possible reading of this paragraph is that such a conflict may arise, and this is precisely why “the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health”.

It also should be noted that paragraph 4 makes a specific reference to the issue of “access to medicines for all”, indicating that in the interpretation of the Agreement’s obligations, special attention should be given to the achievement of this goal.

Finally, paragraph 4 alludes to the implementation of the Agreement, and not only to its interpretation. Implementation takes place at the national level, but is influenced by actions taken by other governments, either in the context of bilateral dealings or in the multilateral framework. The important message of the Declaration in this regard is that the Agreement can be implemented in a manner supportive of WTO Members’ right to protect public health.

5. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in 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 licenses and the freedom to determine the grounds upon which such licenses are granted.

93 The Brazilian delegation pointed out at the Doha Ministerial Conference that “in the area of intellectual property, different readings of the TRIPs Agreement have given rise to tensions. To a certain extent, it is natural that conflicts of interests should reflect themselves in divergent interpretations of common rules. But the commercial exploitation of knowledge must not be valued more highly than human life. There are circumstances in which the conflict of interests will require that the State exercise its supreme political responsibility… Brazil promotes and upholds intellectual property rights… However, if circumstances so require it, Brazil, like many other countries, will not hesitate to make full use of the flexibility afforded by the TRIPs Agreement to legitimately safeguard the health of its citizens.” See also, e.g. ‘t Hoen (2001), p. 11; Raja, p. 2002, 14, and the Joint Statement of 14 November 2001, by MSF, Oxfam, TWN, CPT, Consumers International, HAI and The Third World Network Third World Economics, No. 268, 1-15 November 2001.
(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, 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 Most Favored Nation (MFN) and national treatment provisions of Articles 3 and 4.

According to paragraph 6, all WTO members recognized that countries with insufficient or inefficient manufacturing capacity would not be able meet their needs for cheaper pharmaceutical products by internal production even when they override patents through the issuance of compulsory licenses. Key transitional time periods in the TRIPs agreement would soon require worldwide protection for pharmaceutical products beginning in 2005, even for countries like India that had given patent only to pharmaceutical processes. This change in India’s patent law would dramatically curtail its current lawful practice of reverse-engineering drugs and then producing them for export. Instead, post-1995 generics produced in any WTO member country (except hypothetically in least developed countries) would ordinarily have to be produced pursuant to compulsory licenses. As per Article

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95 Paragraph 6 refers to compulsory licenses, but Article 31 of TRIPs refers to the broader concept of “unauthorized use,” which as a practical matter covers both compulsory licenses and non-commercial, governmental use, or “crown use” as it is called in Commonwealth countries.

96 TRIPs Agreement, supra note 7, art. 65.4. There is now an even longer transitional period for least developed countries (increased from 2006 to 2016), but the short-term prospect that any of them will become large-scale manufacturers and exporters of pharmaceuticals seems remote. See id. art. 66. See also Doha Declaration, para. 7.

97 The problem does not arise simply with respect to medicines newly patented in 2005 or thereafter. TRIPs already has a “mail-box” rule whereby developing countries are obligated to establish mechanisms for receiving, processing, and establishing “priority-in-time” for pharmaceutical patent applications. Furthermore, developing countries have to grant exclusive distribution rights to the patent applicant when certain prescribed conditions were satisfied. TRIPs Agreement, art. 70. Thus, the mailbox rule effectively precludes generic manufacturers in developing countries that do not recognize patents on medicines or product patents from producing “copies” of medicines described in pending “mailbox” applications. Stated differently, patent applicants have significant and exclusive market advantages with respect to post-1995 discoveries even before the full adoption of TRIPs in developing countries Art. 8(1), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81
31(f) of TRIPs limits production under a compulsory license “predominantly” to the domestic market this then was the essence of the production-for-export dilemma – desperate demand but no certain source of future supply.

For the 30 August Decision to be used, WTO Members need first to pass implementing legislation. In May 2004, both Canada\(^98\) and Norway\(^99\) passed legislation to allow them to export drugs under the mechanism.

The Declaration 2001 doesn’t propose explicitly which kind of medicine products should be promoted, i.e. patented medicine, or active ingredients or intermediate products and patented production processes. In general developing countries wanted wide public health-related product coverage, but most industrialized countries wanted to limit the product scope of pharmaceutical products and patented process. Therefore a compromised solution was suggested in the 1\(^{st}\) September 2003 decision of “implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health”. It defines the “pharmaceutical product” as the follows\(^100\):

“Pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

The TRIPs Agreement sets minimum levels of IP protection that governments must respect. Nevertheless, many developing countries have been pressurized into applying stricter IPR standards (termed TRIPs-plus standards). WTO accession negotiations are one of the situations in which developing countries have had to agree to TRIPs-plus provisions. Cambodia, for example, was required to forego the 2016 implementation delay granted to all LDCs by the Doha

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\(^99\) Norway, Regulations amending the Patent Regulations (in accordance with the decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a), 14 May 2004: http://odin.dep.no/ud/engelsk/p2500832/p30003923/032121-290002/dok-bn.html

Declaration and accept a 2007 deadline. Although WTO Members have declared that they will not initiate a WTO dispute with Cambodia if it uses the full delay, doubts remain\textsuperscript{101}.

According to Paragraph 7, we also agree that the least-developed country Members will not be obligated, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under this Section until 1 January 2016\textsuperscript{102}.

Finally, the Doha Declaration proposed an extension for least-developed country members concerning their obligations to grant and enforce product patents on pharmaceutical products; that and an additional waiver affecting market exclusivity for patent applications held in a transition-period “mailbox” pursuant to Article 70.9, were subsequently voted upon by the General Council\textsuperscript{103}. Accordingly, as a matter of TRIPs enforcement, countries could suspend the future operation of their medicines patent and market exclusivity schemes even where they had prematurely and improvidently granted such protections before the expiration of their transition period, January 1, 2006. If they fail to do so by suspending or amending their product patent law, however, patent-holders can continue to file and enforce patents\textsuperscript{104}. Moreover, freedom from threat of TRIPs sanctions does not relieve least-developed countries from pre-existing obligations to patent holders who can continue to protect their vested patent rights. Those rights can still be abrogated only via a compulsory license or government use.

The terms of a fair and expeditious solution for accessing medicines in countries with inadequate domestic capacity were repeatedly advanced by the

\textsuperscript{101} Oxfam International, Cambodia’s Accession to the WTO, How the law of the jungle is applied to one of the world’s poorest countries, 2003.

\textsuperscript{102} DOHA declaration

\textsuperscript{103} The additional ten-year transition period was granted on June 27, 2002. See Extension of the Transition Period under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25 (July 1, 2002), available at http://www.wto.org/english/tratop_e/TRIPs_e/art66_1_e.htm The waiver on market exclusivity was granted on July 8, 2002. See Least-Developed Country Members – Obligations under Article 70.9 of the TRIPs Agreement with Respect to Pharmaceutical Products, WT/L/478 (July 12, 2010), available at http://www.wto.org/english/tratop_e/TRIPs_e/art70_9_e.htm.

\textsuperscript{104} According to a recent study by the U.K. Commission on Intellectual Property Rights, the majority of least developed countries have prematurely granted patent protections for pharmaceutical products. Phil Thorpe, Study on the Implementation of the TRIPs Agreement by Developing Countries, Commission on Intellectual Property Rights, Study Paper 7 (2001).
Africa Group and an affiliated coalition of developing countries and NGOs. According to this pro-public health coalition, the production-for-export accord should cover a broad range of diseases and public health needs, so that medicines for multiple debilitating and deadly conditions could be accessed more cheaply. Countries should be able to import a broad range of medical products including medicines, vaccines, diagnostic tests, and other medical products. Likewise, any country should be able to make use of the Declaration’s public health provisions, even though it is undoubtedly true that developing countries have the greatest need.

To supply importing countries, any country should be eligible to be an exporter; however, there is an underlying need to fulfill the promise of technology transfer. In addition, onerous diversion rules should not be imposed to address the illusory risk of re-export and sale in rich countries like the United States and Europe that are perfectly capable of reducing or eliminating product diversion on their own. Finally, procedural requirements should be minimized, meaning that a limited exception under Article 30 of the TRIPs Agreement, as endorsed by the WHO and many other countries, was vastly superior to the proposed U.S. solution requiring hundreds of product-by-product, country-by-country compulsory licenses in exporting countries. A solution with these terms, articulating definite and enduring rights, would have been a huge step in addressing the crisis of access to affordable medicines in the developing world.

The Doha Declaration stresses that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to

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105 At www.law.suffolk.edu/faculty/visitingpast/mpatterson/globaltech/materials/African%20Group
%20statement.html; Joint Communication from the African Group in the WTO, IP/C/W/351, available at http://lists.essential.org/pipermail/ip-health/2002-june/003193.html; Communication from Brazil on behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/355 available at http://commerce.nic.in/ip_c_w_355.htm (last visited Feb. 27, 2010);

106 This is the solution expressly endorsed on September 17, 2002, by the World Health Organization: [T]he limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export medicines and other health technologies to address public health needs. WTO Council for TRIPs, Statement by the Representative of the WHO, Sept. 17, 2002, available at http://www.cptech.org/ip/health/who/who09172002.html (last visited Feb. 27, 2004). It is also the solution implicitly endorsed by the UK Commission on Intellectual Property Rights, which emphasized the importance of economies-of-scale in attracting generic producers. And, finally, it is the solution temporarily endorsed by the European Parliament to amend its medicines regulation scheme: Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country. Amendment 196 to the Directive 2001/83/EC of the European Parliament (since rejected).
protect public health and, in particular, access to medicines for all.” Moreover, it enumerates a non-exhaustive list of policy flexibilities permitted by TRIPs, including each country’s freedom to determine the grounds for issuing a compulsory license and to decide the regime of parallel imports. Finally, this declaration is not only a political statement, but due to its nature as a WTO Ministerial Declaration it can be considered as an authoritative interpretation of the TRIPs Agreement107. It therefore emerges as a crucial tool for the protection of the right to health, especially in developing countries.

The Doha Declaration on TRIPs and Public Health, in paragraph 6 of the text, called for the need to find a solution to the fact that countries without drug manufacturing capacity could not fully benefit from compulsory licensing. This is due to TRIPs stating that drugs produced under compulsory license being “predominantly for the supply of the domestic market.” This could have limited the availability of generic drugs for export, meaning that countries unable to make the drugs themselves could lose out on low prices.

In August 2003, after two years of tough negotiations, WTO Members agreed to waive the TRIPs limit on the export of drugs under compulsory license108. Although the mechanism in the 30 August Decision can already be implemented; a permanent amendment is being negotiated in the TRIPs Council. To ensure that the mechanism is only used “in good faith to protect public health,” a number of countries have agreed to forego or limit their right to use the solution. For instance, several countries have decided to limit their use as importers to situations of “national emergency or other circumstances of extreme urgency.” Asian WTO Members having done so include Hong Kong, China, Korea, Macao, Singapore and Chinese Taipei.

The 30 August Decision sets out a detailed import/export compulsory licensing mechanism that goes beyond the TRIPs main compulsory licensing criteria. In order for a country to qualify as an importer it either has to be an LDC or demonstrate that it has insufficient or no pharmaceutical manufacturing capacity. Exporting countries, on the other hand, are not subject to qualifying criteria. For the mechanism to work, two compulsory licenses are needed: one in the importing

country and one in the exporting country. Finally, there are a number of other criteria that need to be fulfilled for the license to be valid, such as notification to the TRIPs Council, posting on a dedicated website\textsuperscript{109} and the establishment of measures to avoid cheap drugs produced for low income countries being sold in rich country markets.

The extent of the U.S. blocking strategy was epitomized in its first two Paragraphs, 6 of the Doha Declaration submissions to the TRIPs Council, which proposed the following conditions\textsuperscript{110}:

1. a requirement that export licenses be limited to addressing “grave” or “urgent” public health emergencies, such as HIV/AIDS, TB, and malaria only (a previously defeated in the Doha Declaration);

2. Limits on the types of public health products to be covered by the agreement to pharmaceutical products only;

3. Limits on the sectors which might be supplied by the agreement, specifically excluding the private or “commercial, for-profit sector;”

4. Limits on the importing countries that might benefit from the agreement:
   a) No application to small market countries that theoretically have technical capacity to produce medicines but insufficient market size to achieve economies-of-scale,
   b) Strict application of the “insufficient manufacturing capacity” standard to exclude countries where production was theoretically possible but otherwise infeasible or impractical,
   c) Income limits that would exclude many developing countries, especially middle-tier countries;

5. Limits on the countries that might export (developing countries only);

6. A preference for Article 31(f) compulsory licensing solutions in the exporting State that create multiple barriers to implementation including:

\textsuperscript{109} WTO, TRIPs and Public Health dedicated web-page for notifications: www.wto.org/english/tratop_e/trip_e/public_health_e.htm

a) Prior negotiation on commercially reasonable terms with the patent holder who might impose onerous conditionality’s;

b) Costly, burdensome, and protracted individual determinations in administrative or judicial proceedings to grant each license on a case-by-case basis;

c) Dependency on the willingness of a third country to go through such burdensome procedures because of a public health need in a third country,

d) Proof both of a triggering public health need in the affected country and of technical incapacity to produce a particular medicine; and

e) Determination of the level of license compensation in the producing country rather than in the importing country and imposition of a licensing fee even with respect to imports into a no-patent country;

7. Strict anti-diversion guarantees and limitations on re-export, especially to developed countries, but perhaps even regionally between developing countries with comparable public health needs.

According to developing world critics and their allies, each of these conditions violated the letter and spirit of the Doha Declaration and each risked undermining expeditious and efficient responses to public health needs. Although the United States eventually retreated on three conditions\textsuperscript{111}, it succeeded in inserting most of them in a “compromise” text agreement prepared by Ambassador Motta, Chairman of the TRIPs Council\textsuperscript{112}. However, because it could not impose further agreement with respect to its restrictive view on covered disease, the United States unilaterally rejected the Motta compromise on December 20, 2002\textsuperscript{113}, ensuring that a Paragraph 6 solution would not be realized by the end of 2002, as promised.

\textsuperscript{111} The United States first relaxed its insistence on market segmentation, which theretofore had excluded the for-profit sector. Second, it dropped its insistence on production by developing countries only, but only after this strategy had driven a partial wedge into the developing country coalition, essentially raising questions among some African countries as to whether India and Brazil were pursuing an industrial policy option that would undermine the development of pharmaceutical capacity in Africa. Finally, it agreed to allow more efficient regional trade of generics in WTO-sanctioned regional trading groups, so long as the groups contained at least 50% least developed countries.


\textsuperscript{113} Ambassador Eduardo Pérez Motta of Mexico, who chaired the TRIPs Council, told the General Council of the WTO on December 20, 2002, that “intensive consultations had not resolved
Even though rich countries with ample productive capacity would be able to issue compulsory licenses on any grounds whatsoever pursuant to the baseline flexibilities of Article 31, poorer and smaller countries would have options to address a short list of pandemic diseases and a baker’s dozen of tropical diseases for which there were few, if any, medicines.114 Suddenly, the scales of compulsory licensing were tilted in favor of the United States and Europe, which can produce on-patent medicines domestically should they so decide, and against countries like Malawi, which have to rely on imports. These disfavored countries would, according to Northern demands, have to favor AIDS patients over people with diabetes or people with malaria over people with asthma. This imbalance seemed to violate the promise that Doha was a pro-development round and further violated one of the bedrock principles of the WTO free trade system and the TRIPs Agreement, namely that the trading system should not preferentially advantage domestic producers over importing producers.

“A number of studies have shown that patents have been used indirectly as a means of regulating or influencing not only the behaviors of other enterprises linked by restrictive clauses…but also have impact on national economic policies… relating to exports, substitution and selection of imports, price controls, employment etc., the use of lawful monopolies has, in general, had adverse effects on certain key aspects of industrial development by restricting exports of patented products by “tying” the purchase and supplies of licensed enterprises, by setting arbitrary price for products under patents or manufactured under licensing agreements, by imposing restrictions on employment of local personnel etc.”115

Moreover, the absence of sanctions or safeguards against patent abuses has worsened the situation. A study showed that in some countries such as Ghana there were no provisions for dealing with abuses of patent rights including non-use116. In other countries, there may be sanctions but inadequate and full of loopholes. To ensure

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115 UNCTAD The Role of the Patent system in the Transfer of Technology to Developing countries, TD/B/C.6/16. 1975a. p22
the exploitation of patented invention, working of invention, for instance, was considered as one of the duties of the patentee in most Latin American countries but without defining the concept precisely. As a result, working of the patent outside the country was accepted as evidence for compliance with the legislative duty.\textsuperscript{117}

In spite of the fact that compulsory license has been conceived by many countries to be the major instrument of sanction against non-working of patents, in practice it has been proved virtually of little value Furthermore, the Commission on Intellectual Property Rights in its study (CIPR, 2002) noted that developing countries have not used compulsory license though the TRIPs agreement as further elaborated by the Doha Ministerial declaration allows it. The Ministerial declaration recognizes that “each member has the right to grant compulsory license and the freedom to determine the ground upon which such licenses are granted”\textsuperscript{118} The reason for the non-use of compulsory license include the absence of the requisite administrative and legal infrastructure as well as the non availability of potential licensees having the necessary know how and capacity to exploit the patented invention without the cooperation of the patent owner\textsuperscript{119}.

3.18 DOHA DECLARATION: ANALYSIS

In the general Ministerial Declaration of the Doha Conference, Article 17 states that the WTO countries realize the importance of the implementation and interpretation of TRIPs in a manner supportive of public health. It further points to the separate declaration, the Doha Declaration on TRIPs and Public Health. The Doha Declaration does not amend the rights and an obligation laid down in TRIPs, but provides guidance for the interpretation of the relevant parts of the Agreement.

According to paragraph 1 of the Doha Declaration the member states recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/Aids, TB, malaria and other epidemics\textsuperscript{120}. The Declaration further points out the need for the TRIPs Agreement to be part of actions to address these problems, and that IP protection is important for the development of

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\textsuperscript{117} UNCTAD \textit{The Role of the Patent system in the Transfer of Technology to Developing countries}, TD/B/C.6/16. 1975a
\textsuperscript{118} WTO, 2002:25.
\textsuperscript{119} CIPR, 2002.
\end{flushleft}
medicines, but that the effects on prices is concerning\textsuperscript{121}. Therefore, the parties to the Declaration agreed that the TRIPs Agreement should not prevent measures to protect public health\textsuperscript{122}. This is developed in paragraph 4, which provides that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”. In order for countries to have flexibility in using the TRIPs agreement, paragraph 5 goes on to state, \textit{inter alia}, that TRIPs shall be read in light of the object and purpose of the Agreement, found in Articles 7 and 8 of TRIPs, and that each member has the right to grant compulsory licences and the freedom to determine the grounds for such a licence\textsuperscript{123}. When using compulsory licensing in accordance with TRIPs Art 31, the Doha Declaration further gives the member states the right to determine what constitutes national emergency or other circumstances of extreme urgency, which are conditions to issue compulsory licences. Article 5 also leaves each member free to establish its own regime for the exhaustion of intellectual property rights without challenge. On 30 August 2003, a decision was reached in the WTO regarding new rules for the export of pharmaceutical products under compulsory licences. This decision, and the debate leading up to it, and the debate which will surely follow it, derives from Article 6 of the Doha Declaration. The article, cited in full, reads: \textit{We recognize that 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. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002}\textsuperscript{124}.

Paragraph 7 of the Declaration provides, \textit{inter alia}, an extension to the transition periods for LDCs as regards the pharmaceutical products, until 2016\textsuperscript{125}. As was indicated above, one main area of debate since the Doha Conference has been paragraph 6 of the Declaration, which addresses the effective use of compulsory licensing. As the Council for TRIPs was given until the end of 2002 to

\textsuperscript{121} Ibid paras 2-3
\textsuperscript{122} Ibid para 4
\textsuperscript{123} Doha Declaration, Art 5a) and b). The objectives of the TRIPs Agreement, found in Art 7, are, \textit{inter alia}, to promote intellectual property in a manner conducive to social and economic welfare, and to a balance of rights and obligations. The principles, found in Art 8, state that members may 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.
\textsuperscript{124} Doha Declaration, Art 6, emphasis added
\textsuperscript{125} Erik Alsegård, Global pharmaceutical patents after the Doha Declaration – What lies in the future Volume 1, Issue 1, 2004 DOI:10.2966/scrip.010104.12 SCRIPT-ed Open Licence (SOL).
find a solution, it did put forward a proposal. Most countries found the proposal acceptable, with the US being the only country to object to it. On 20 December 2002, as the US made clear that they would not accept the proposal, it was obvious that the Council for TRIPs had failed in the task given to it in November 2001. With a new decision in place from August 2003, some of the problems may have been solved, but as will be developed below, there is still no solid solution and this will remain one of the main issues of debate. In further discussions, it will become evident that the wording of the other Doha Declaration paragraphs is also important and their meaning not yet entirely agreed upon.

Public spending on drugs in over three dozen countries, many in sub-Saharan Africa, is less than $2 per capita per year. The retail prices of proprietary drugs in some of the poorer countries are higher than the prices in wealthy countries, and in many developing countries these proprietary brands of drugs are the only products available. Izaak Walton once wrote: “Look to your health, and if you have it, praise God, for health is a blessing that money cannot buy.” He may have been right in his day, but times have certainly changed.

The Declaration was significant because it intended to dispel the notion that the intellectual property regime under TRIPs solely concentrates on a trade-motivated agenda and has no place for human rights concerns.

The Declaration proposed a balancing approach to the interpretation of the TRIPs Agreement. In the first four paragraphs of the Declaration it was agreed that the TRIPs Agreement had to be a part of a wider national and international action to address the grave public health problems afflicting many developing and least developed countries, especially the problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Para 3 and 4 stated that the intellectual property protection is important for the development of new medicines and reiterates the commitment to TRIPs. On the other hand the paragraphs also acknowledge the effect of intellectual property protection on drug prices and state that TRIPs should not prevent members from taking measures to protect public health.

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127 K Balasubramaniam, in Drahos and Mayne (eds), Global Intellectual Property Rights, at 100.
However, the Declaration failed to provide any substantive guidelines to the Governments on measures that could be taken to overcome the intellectual property barrier while making available cheap medicines. The Declaration left open all the possibilities that already existed under the TRIPs Agreement in the all important Para 5. Read in the context of the TRIPs Agreement, the paragraph reiterates that member States can have provisions relating to parallel importing, or use the Article 30 exception, or use the option of compulsory licensing. In relation to compulsory license the member States given a right to determine what constitutes a “national emergency”. According to Article 31(b) of TRIPs, in case of a “national emergency” there is no pre-requisite for a proposed user of the compulsory license to make efforts from the patent-holder to obtain authorization on reasonable commercial terms and conditions. Thus, if there exist, a “national emergency”, grant of a compulsory license should be relatively easy. But the Doha Declaration did not define any parameters for declaration of a national emergency and merely provided that “public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency”.

The Declaration acknowledged that the compulsory-license approach fails where a country has insufficient or no manufacturing capacities in the pharmaceutical sector. For such types of cases, it was left to the TRIPs Council in paragraph 6 of the Declaration to find “expeditious solution to this problem and to report to the General Council before the end of 2002”. But a solution was reached by the TRIPs Council only on 30-8-2003, just a few days before the Cancun Ministerial Conference, where the US feared a backlash from a strong and determined developing world. Prior to that, the US was the only country that wanted to restrict the scope of diseases covered under Para 6 of the Declaration and was not willing to agree to the proposals that wanted a specific reference to the public health problems afflicting many developing and least developing countries, especially resulting from HIV/AIDS, tuberculosis and malaria.

As to the flexibilities are concerned a different approach is taken in the TRIPs Agreement, which lays down the minimum substantive standards of protection that must be provided by WTO Members. There is a common understanding among experts that those standards were set broadly at the current
level of developed countries at the time of the negotiations of the Uruguay Round; therefore a reduction of the room for maneuver was the consequence of the inclusion of new minimum substantive standards. Developing countries, aware of the implications of this change to a new “post TRIPs era” where policy space has been reduced, are looking for a better understanding of this set of rules, to be able to implement the Treaty in a consistent manner as well as to take advantage of the options available, which might be used in the implementation of the Treaty according to their national policy choices.

In 2006, the WHO report on Public health, innovation and intellectual property rights stated that “the TRIPs Agreement allows countries a considerable degree of freedom in how they implement their patent laws, subject to meeting its minimum standards including the criteria for patentability laid down in TRIPs. Since the benefits and costs of patents are unevenly distributed across countries, according to their level of development and scientific and technological capacity, countries may devise their patent systems to seek the best balance, in their own circumstances, between benefits and costs. Thus developing countries may determine in their own ways the definition of an invention, the criteria for judging patentability, the rights conferred on patent owners and what exceptions to patentability are permitted”\textsuperscript{129}.

The concept of “flexibility”\textsuperscript{130} as applied to the obligations imposed by the TRIPs Agreement has been central to several analyses of the TRIPs Agreement\textsuperscript{131} and to the position of developing countries at the Council for TRIPs in the special sessions on TRIPs and health. Spelling out some of the available flexibility was the main objective of the Declaration.

Some experts believe that the foundation of the available flexibilities are to be found in the negotiation process of the TRIPs Agreement, where policy autonomy for implementation was agreed by Members, as trade negotiators favored an agreement with a great degree of built-in flexibility. Moreover, the term “flexibility” is contained in certain provisions such as paragraph 6 of the Preamble of the TRIPs Agreement:


\textsuperscript{130} “Flexible” means “easily led, manageable, adaptable, versatile, supple, complacent” (Visual Oxford Dictionary, p. 373).

\textsuperscript{131} See, e.g., Correa (2000a); Reichman (1997).
The meaning of the word “flexibility” as used in the Preamble is explained by Article 66.1, which reads:

“In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of...”

The famous meaning construed in context of TRIPs Agreement is defined as flexibilities as a range of rights, safeguards and options that WTO Members can exploit in their implementation of the TRIPs Agreement;

3.19 CLASSIFICATION OF FLEXIBILITIES

Flexibilities could be classified in just two categories those regarding transition periods, and “substantive” flexibilities in the TRIPs Agreement. A more detailed classification could distinguish among: (i) subject matter which qualifies for protection; which is covered under Article 27 of TRIPs Agreement (ii) scope of the protection; (iii) modes of IP enforcement; and (iv) Matters of administration.

(i) Scope of Patentability under Article 27

Perhaps the most useful way of grouping flexibilities takes into account the point in time at which Members may resort to them: (i) in the process of the acquisition of the right; (ii) defining the scope of the right; and (iii) when enforcing the right. (iv) Flexibilities in the process of acquisition of the right

The first modality of flexibilities seeks to ensure that the titles of industrial property rights are adequate and proper, in order to create legal certainty. In the area of patents, flexibilities apply to formal requirements of patentability, for instance, disclosure requirements, which can be more complete than the minimum established by Article 29.1 of the TRIPs Agreement. Using flexibility on the issue of sufficient disclosure, for example, would allow a country to require the

132 Document prepared by the Secretariat WIPO on “Patent related flexibilities in the Multilateral Legal framework and their Legislative Implementation at the National and Regional Levels” Committee on Development and Intellectual Property (CDIP), Fifth Session Geneva, April 26 to 30, 2010

133 Document prepared by the Secretariat WIPO on “Patentable related Flexibilities in the Multilateral Legal framework and their Legislative Implementation at the National and Regional Levels”. Committee on Development and Intellectual Property (CDIP), Fifth Session Geneva, April 26 to 30, 2010 p12
description of the process of making the claimed product or parts of the product; or demand that the disclosure be adapted to the technological level of the receiving country, in order to promote effective technological dissemination; or it could require disclosure of access to genetic resources, in order to ensure compliance with access and benefit sharing requirements; or it might demand disclosure of sources of public funding. In the same group of flexibilities, we find those related to substantive requirements, such as the definition of invention (inventions vs. discoveries, such as genes or gene sequences; inventions vs. small, incremental improvements such as new salts, esters and polymorphs).

(ii) Flexibilities related to the scope of the patent right

The second category consists of measures to ensure that the right is adequately framed and dimensioned having in mind the objectives of its protection: to achieve social and economic welfare and to guarantee a balance of rights and obligations (Article 7). This group of flexibilities includes the possibility of using patented inventions for experimental purposes or for obtaining data necessary for anticipating marketing approval. They also include the grant of compulsory licenses on grounds of public interest (in all its modalities, such as lack of exploitation, and abusive and anti-competitive practices). The exhaustion of patent exclusivity is within this group of flexibilities.

(iii) Flexibilities related to the use and enforcement of patent right

Right holders, in order to benefit from the full enjoyment of their rights, should be able to rely on the enforcement measures that each Member state has put in place. As an example, civil judicial procedures must be available, and judicial authorities must have the power to order an infringer to desist from an infringement and to pay adequate damages to compensate for the injury. Therefore, the third category consists of the group of flexibilities related to the enforcement of IP rights. In this regard, Member States are entitled to take necessary steps to prevent abusive and anti-competitive practices (including the preventive control of such practices in contractual licenses); and damages could be limited to those cases in which the infringer “knowingly, or with reasonable grounds to know, engaged in infringing activity”. The examples mentioned illustrate the broad range of options for Member States to set out rules that meet TRIPs obligations, while still paying attention to
national needs. Striking the right balance in each discipline is a precondition for the IP system, and particularly for patents, to support countries’ economic development.

3.20 LIMITED FLEXIBILITIES IN THE PARAGRAPH 6

3.20.1. Patentable subject matter (Article 27)

The three criteria for patentability (novelty, inventive step and industrial application) are not defined under TRIPs. Each member is free to interpret their meanings, which can determine what is patented in the pharmaceutical sector. In addition, governments can refuse to grant patents for three reasons that may relate to public health, including inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2); diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a); and certain plant and animal inventions (Article 27.3b).

The key impact is that countries can ensure that only true inventions are patented, so that far fewer products will be under patent than would otherwise be the case if the patentability criteria were not carefully defined or where the power to refuse patenting in certain cases was not exercised. The impact is that a greater number of medicines can be available in generic forms in a competitive market, which has a positive impact on prices.

3.20.2 Research and experimental use exception (Article 30)

Under this exception, countries allow the use of a patented invention for research in order to understand the invention more fully and for other related purposes. The intent of this exception is to ensure that patents do not prevent scientific research that uses existing knowledge to generate new knowledge. The research exception is important for improving the effectiveness of products or the development of better-adapted formulations. This exception fosters pharmaceutical technological progress and innovation by exempting experimentation acts for purposes such as inventing around the initial invention, improving on the invention or evaluating the invention.

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3.20.3 Compulsory licensing (Article 31)

Compulsory licensing is one mechanism by which a government may curb the monopoly power of a patent.

The effect of a compulsory license is to force the patent holder to license the invention to others in return for a royalty set by the government. A compulsory license, also referred to as a non-voluntary license, is a license granted by an administrative or judicial body to a third party to exploit a patented invention, without the consent of the patent holder. Compulsory licensing is used in public health to address a variety of situations including: high prices of medicines; anti-competitive practices by pharmaceutical companies; failure by pharmaceutical patent holders to sufficiently supply the market with needed medicines; and in emergency public health situations. In practical terms compulsory licensing can be used to bring down the prices of medicines and to ensure a sufficient supply of medicines in the market in cases where the patent holder cannot, or will not, provide sufficient supplies at the right price. It is also a critical tool in emergency situations where the patent holder cannot respond to an urgent situation.

Compulsory License system is the back bone of the patent laws for LDC and developing countries to ensure the role of domestic enterprises to provide adequate availability of patented products at competitive prices. The DOHA Agreement clarifies Article 31 of TRIPs Agreement by restating propositions that big pharmaceutical companies, in particular, had put in doubt. Paragraph 5(b) clearly states that 'each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which the licenses are granted. While including a number of procedures for granting compulsory licenses does not limit the grounds on which compulsory licenses can be granted, leaving the members to stipulate such grounds in their domestic legislations. Therefore members can grant such licenses on the ground of protecting public health beyond the three examples explicitly included in Art 31which are national emergency, public non commercial use and anti-competitive practices.

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The Implementation Agreement resolved the Article 31(f) situation by creating an exception to Article 31(f) of TRIPs that allows nations with insufficient or no manufacturing capabilities to override intellectual property protection and import generic copies of patented drugs to combat public health crises. However, in order to be TRIPs compliant, the importing Member must abide by several procedural steps, namely that the importing Member:

(1) Must notify the TRIPs Council of the “names and expected quantities of the products needed”;

(2) Must confirm that it is either a LDC or “establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question”; and

(3) Confirm that, if the “product is patented in its territory, that it has granted or intends to grant a compulsory license in accordance with [TRIPs] Article 31.”

The Implementation Agreement also outlines several procedural conditions an exporting Member must fulfill when issuing a compulsory license:

3.20.4 Conditions for Compulsory Licenses

Implementation of the Decision involves two kinds of notifications to the Council for TRIPs: a general notification about the intention to be an eligible importing member, and a specific notification about the products, quantities, and so on that the country intends to import. The notifications are for the sake of transparency and information only, and do not amount to requests for authorization.

The first notification is about the intention of a member to use the Decision, and not about its actual use. It is not a requirement for LDCs, however, which automatically qualify as eligible importing members. The notification may be unqualified, when the member does not declare any limitations to its potential use of the system, or it may be qualified, when the member voluntarily states that it will only use the system in a limited way. There is nothing in the Decision preventing a member from changing, at any time, the terms of its notification. The effect of the

137 Except as required by Article 31 (b), where applicable, there is no obligation to notify the patent owner about the intention to grant a compulsory licence and the conditions thereof. Likewise, there is no obligation to offer the patent owner the option to supply the required products under the terms and conditions established for the compulsory license, as proposed in Canadian Bill C–56 (2003).
notification is declaratory only; this means that neither the Council for TRIPs nor any other WTO body is entitled to review, approve or reject a notification and the specific terms under which it is made.

Under the second notification, the would-be importing country is bound to notify the Council for TRIPs of:

(i) The names of the needed product(s)—the generic names of the required pharmaceuticals are to be mentioned.

(ii) The “expected quantities”: the notified quantities may not exactly correspond to the quantity of product finally requested or purchased.

However, importing countries should carefully assess the quantities needed since, as mentioned below, the corresponding compulsory license in the exporting country can be granted only for a specified amount. The obligation to specify the expected quantity only applies to the notification. It does not refer to the specific terms of the compulsory license. A situation may arise in which the notified “expected” quantities may not correspond to the quantities effectively imported. This discrepancy would not affect the right to import, so long as the compulsory license was not limited to the amounts specified in the TRIPs Council notification. Moreover, there is no obligation on the importing country to determine a specific timeframe in which importation would take place.

(iii) Lack of manufacturing capacity: the requirement of establishing the lack of or insufficient manufacturing capacity does not apply to LDCs. For other countries, insufficient or no manufacturing capacity is not to be assessed in general, but for the particular pharmaceutical product(s) required. The assessment of the existence of manufacturing capacity should not be limited to technical aspects.

The Decision does not determine particular criteria or methods to establish the lack of or insufficient capacity. This is a matter of self-assessment, the outcome of which cannot be challenged by another member and cannot be subject to review, reversed or rejected by the Council for TRIPs.

(iv) Granting of compulsory license: where a pharmaceutical product is patented in its territory, the importing country must notify the Council for TRIPs that it has granted or intends to grant a compulsory license. It would be sufficient to
notify the Council that the competent authority intends to grant a compulsory license. The only condition imposed on the compulsory license to be granted is that it be “in accordance with Article 31 of the TRIPs Agreement\(^{138}\).

The grant of a compulsory license in the importing country before or after notification may be for an unlimited quantity, as long the patent is in force, and without compensation. In addition, there is no obligation in the importing country to provide compensation to the patent holder. However, the Decision does not waive the obligation of Article 31 (b) of the TRIPs Agreement for prior negotiation with the patent holder. Nevertheless, the importing country (as well as the exporting country) may apply the system on the basis of an authorization for public non-commercial use.

For such use, the obligation for prior negotiation is waived. The notification will be made publicly available by the WTO Secretariat through a page on the WTO website dedicated to the Decision. If the notification was made before the granting of the compulsory license by the importing country, there is no need to make another notification after grant of the license.

The obligations of an exporting Member under Article 31(f) of the TRIPs Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

a) The eligible importing Member(s) has made a notification to the Council for TRIPs, that:

(i) specifies the names and expected quantities of the product(s) needed;

(ii) confirms that the eligible importing Member in question, other than a least developed country

Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

\(^{138}\) A question may be raised as to whether this condition means that a compulsory license may be granted to import pharmaceutical products under Article 31 even in cases where the national legislation does not provide for such grant or for the execution of the license through importation. The adopted waiver means that a Member country will not have the right to complain against another Member not complying with Article 31 (f) or (h) but would not prevent, in principle, the patent owner from interfering with the granting of a compulsory license if inconsistent with national law.
(iii) Confirm that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPs Agreement and the provisions of this Decision;

(b) The compulsory license issued by the exporting Member under this Decision shall contain the following conditions:

(i) Only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPs;

(ii) Products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) Before shipment begins, the licensee shall post on a website the following information:

The quantities being supplied to each destination as referred to in indent (i) above; and - the distinguishing features of the product(s) referred to in indent (ii) above;

(c) The exporting Member shall notify the Council for TRIPs of the grant of the license, including the conditions attached to it.

The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.139

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139 Council for TRIPs, Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, WT/L/540 (Aug. 30, 2003) [hereinafter Implementation Agreement]. The agreement was only finalized when the Members agreed to attach a statement to the text setting out the conditions under which the measure detailed in the Implementation Agreement can be used. Among other things, the Statement: (i) “recognizes that the [compulsory licensing] system ... should be used in good faith to protect public health and [not as] an instrument to pursue industrial or commercial policy objectives”; (ii) “recognizes that the purpose of the [Implementation Agreement] would be defeated if [drugs were] diverted from the [intended] markets” and calls on Members to take “all reasonable measures” to “prevent such diversion”; and (iii) reiterates the importance of Members to seek expeditious and amicable resolutions to issues arising from the Implementation Agreement. See The General Chairperson’s Statement, WTO NEWS, Aug. 30, 2003, http://www.wto.org/english/news_e/news03_e/TRIPs_stat_28aug03_e.htm [hereinafter Chairperson’s Statement]. The Implementation Agreement was transformed into a permanent amendment of the TRIPs on December 6, 2005. This represented the first time a WTO Agreement had been amended.
While the Implementation Agreement goes some way in addressing the legal hole that existed, it is not a miracle solution and to hold it out as such would be extremely misleading.\(^{140}\)

To some, the Implementation Agreement fails to satisfactorily resolve several issues, including:

(i) the scope of diseases and product coverage;
(ii) countries that would be eligible to use the system;
(iii) ensuring adequate remuneration; and
(iv) Safeguarding the system against diversion of drugs into other markets.

Health and policy advocates, meanwhile, have also criticized the Implementation Agreement, in particular the prerequisite that a drug supplied under compulsory license must normally be clearly identifiable as a generic version.\(^{141}\)

Recently, the trend worldwide has been to restrict the use of compulsory licensing provisions. Two reasons account for this trend: pressure from pharmaceutical manufacturers and the desire to unify disparate international intellectual property laws under the General Agreement on Trade and Tariffs (“GATT”)\(^ {142}\). The long-term effect of this trend may be to shift the disparities in the treatment of pharmaceuticals from the intellectual property arena to the price regulation arena.

Clearly under compulsory licensing, the price of the same medicine will be very different in the developed and developing countries. Hence, some experts suggest using parallel imports for developing countries to diminish the negative impact of inflexible protection of IPR. In contrast, others argue for the exact opposite to ensure the incentive to innovate is not lost, and maintain that parallel trade in patented products should be banned, especially for pharmaceutical products. They attribute price differences to many factors outside the control of

\(^{141}\) For criticism, see MSF, MSF Comments on the Draft Chairman’s Statement of 21 August 2003 (Aug. 26, 2003), http://www.accessmedmsf.
\(^{142}\) Under the current text, member countries are permitted to 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...taking account of the legitimate interests of third parties General Agreement on Tariffs and Trade (Uruguay Round), Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, 33 I.L.M. 95, an. 30, (Geneva, Switz., Dec. 15,1993) [hereinafter TRIPs Agreement]. See GATT provisions, infra pan III.C.2.
global drug companies and argue that prices do not necessarily fall even with parallel imports. Such a prohibition does not require an amendment to the TRIPs agreement, however, although each country is free to prevent or permit parallel imports by establishing its own regime for the exhaustion of patent rights.

3.20.5 The possibilities of structuring the grant of CL arising from TRIPs and Paris Convention

1. Voluntary Licenses

Under this the patent laws may make the provisions keeping in mind the local requirement of the state “Any patentee may apply to the controller for an entry to be made in the register of licenses to the effect that any person may obtain license of his patented substance or technology;

The controller shall grant a license under the patent to any person who applies for such a license on such conditions, restrictions and royalty terms as may be agreed upon by the patentee and the applicant. If the patentee and applicant are unable to agree within a period of 90 days the controller shall grant the license on such conditions, restrictions and royalty terms as he may deem appropriate”.

This helps the patentee to promote his patented product in the markets of that country due to certain limitations, seeks the assistance of other persons and indirectly promotes the product.

2. Authorization for meeting government requirements Public, non-commercial use (government use) (Article 31)

The TRIPs Agreement, although not specifically mentioning government use, recognizes such use by its references to the concept of public, non-commercial use and of patents “used by or for the government”. Where the state or a state agency uses patents without the consent of the patent holder, it is, like compulsory licensing, covered under Article 31. The distinction between government-use provision and compulsory licensing primarily relates to the nature or purpose of the use of the patent. In the case of government use, it is limited to “public, non-commercial purposes”, whereas compulsory licenses can also cover private and commercial use. As with compulsory licenses, government-use orders can be used to bring down the prices of medicines, to ensure a sufficient supply, and address emergency situations.
Article 31 provides for use of patentable subject matter of patented substances for meeting government requirements. This can be achieved through government undertakings or other private enterprises authorized by the government to produce and supply. The formulation of provisos in the patent law can be made to give effect in meeting government requirements, the controller of patents will have the right to authorize the use of the subject matter of patent by the government or by the third parties on such stipulations as the government may authorize.

3. Compulsory Licence for Abuse of Patent

Generally speaking, abuse of rights as a legal concept is well-known. It means that although in theory someone might be acting within the scope of what is legally permitted (as a ‘right’), the law is infringed nonetheless because a specific situation turns out to render the chosen action to be (legally) unacceptable. A right is used, but in an illegitimate (‘abusive’) way. Without the application of the abuse of rights theory, said behavior could not or only with great difficulty be challenged. Abuse of rights thus frames the general ‘substance over form’ debate. It can be considered a counterweight of flexibility to/in positivistic legal systems.

Article 8 of TRIPs and Article 5 of Paris Convention deal with the abuse of patent rights by the patentees. These articles provide that suitable steps could be taken to remedy the abuse. The abuse arises when the patentee is charging high price for his patented product and that the relevant product is the not available in sufficient quantities to meet the domestic demands either through imports or domestic production by the patentee. The patent law may provide that after the expiration of three years from the date of sealing of a patent any person interested may make an application to the controller of patents for grant of compulsory license on any of the following grounds

a) That the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

b) That the patented invention is not available at a reasonably affordable price, or

c) That the patented invention is not being worked in the different regions of the country.

A distinction can be made here between the different kinds of criticism or reported misuses of the system. One can group them according to whom or what is affected. Then, depending on the category into which a specific instance falls, the appropriate remedy will (have to) differ. In a typology of possible ‘patent failures’, one could thus envisage three categories:

(i) Uses of (a) patent(s) considered abusive towards a specific user or group of users (e.g. certain licensing practices);

(ii) Uses of (a) patent(s) that would go against the rationale of the patent system itself (incentivizing innovation); and

(iii) Uses of (a) patent(s) that would go against higher ends (e.g. access to medicines, human rights, benefit of society as whole).

The first category is usually left to the challenge of third-parties, the second and third brings expectations for state-driven actions or redress. The patent system however strongly relies upon the challenge of private actors, i.e. competitors. Patent offices are overloaded with work and do often not check whether the patentability requirements are being met before issuing the patent.

4. Compulsory License for reason of unsuccessful attempt to obtain voluntary license

Article 31(a) and (b) of TRIPs provide for compulsory license due to unsuccessful attempt by a domestic enterprise to obtain voluntary license from the patent holder. The provisions can be included as “where the individual merits of an applicant have been determined by the controller of Patents to use the patented invention and that the proposed user has made efforts to obtain authorization from the patentee to use the patent on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

5. Determination of National Emergency and Extreme Urgency

The Doha declaration explicitly gives each member the ‘right to determine what constitutes national emergency or other circumstances of extreme emergency’ it specifies that public health crisis includes those relating to HIV/AIDS, Tuberculosis, malaria and other epidemics, can represent national emergency or other circumstances of extreme urgency. Hence, ministers reiterate the freedom to grant compulsory licenses in order to combat the public health crisis. The combination of paragraph 5(a) and (b) should enable developing countries and least
developed countries to use TRIPs compatible compulsory licensing as a tool to protect public health without fear of challenge from pharmaceutical companies.

6. Compulsory License in cases of Public Non-commercial use

Where there is requirement and an application has been made at any time after expiry of three years from the date of sealing the patent any enterprise may obtain the CL for using the patented substance to produce finished formulations from such a substance for distribution/sale on public non-commercial basis i.e. no profit or no loss basis subject to condition that the licensee shall produce a certificate to the controller stating that the goods were used for public non-commercial use. The period of such license will be as may be requested by the applicant the royalty payable to the patentee shall be decided by the controller of patent in consultation of the patentee.

7. Compulsory License to remedy anti-competitive practice Competition law (Article 40)

Article 31(K) provides for remedying anti-competitive practice. The member countries can frame proviso as where the situation of resorting to anti-competitive practice by the patentee has been determined after judicial or administrative process and that the need to remedy the practice has been notified by the government in the official gazette, the controller of patents will issue compulsory license to remedy the situation. The terms and conditions of the compulsory license will be decided by the controller of patents.

Under Article 40 of the TRIPs Agreement, it is recognized that licensing practices or conditions pertaining to IP rights that restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. Consequently, the TRIPs Agreement allows WTO members to specify in their legislation the specific licensing practices or conditions that may constitute an abuse of IP and have an adverse effect on competition in the relevant market. They may also adopt appropriate measures to prevent or control such anti-competitive practices. Countries that use this provision appropriately can ensure adequate and healthy competition in the pharmaceutical market, improving pricing and availability of needed products.
8. Second Patent for an invention involving important technical advance

Where an important technical advance of a considerable economic significance over the first patent has been justified by an interested enterprise to the satisfaction of the controller of patents, compulsory licenses can be granted.

3.20.6 Parallel Imports: Exhaustion of rights (parallel importation) (Article 6)

Exhaustion of rights under IP theory refers to the point at which the right holder loses legal control over a protected product by virtue of selling or otherwise releasing it into the channels of commerce. The rules on exhaustion determine whether the patent holder can prevent a third party from importing a pharmaceutical product where the patent holder or his licensee may have sold the product into another country where they also have a patent. A number of countries allow such imports, which are commonly known as parallel imports. These rules therefore address what is commonly referred to as parallel importation. In the context of medicines, parallel importation allows procurement agencies and treatment providers or third-party importers to import medicines from other countries where the prices are lower than the prices set in the local market by the patent holder or his licensees.

Subject to the most favored nation and national treatment provisions of Article 3 and 4, members are free to adopt their own policies concerning the exhaustion of IPR and to establish their own parallel importation system within the chosen policy this had been a disputed point of interpretation under the TRIPs Agreement. By making it clear by all the states may adopt legislation to allow parallel imports without the consent of the patent holder; the declaration greatly advances the interests of the developing countries in obtaining low cost access to pharmaceutical supplies.

3.20.7 Bolar provision/regular exception

The “Bolar exemption” became a feature of the US patent statute in 1984, following the ruling of the Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc.* This case involved a generic manufacturer (Bolar Pharmaceuticals) who had used a patented invention to test and apply for marketing authorization of its version of a patented medicine. The Court had determined that the common law “experimental use” defense only covered experimentation for scientific, not commercial, purposes, and that the
generic manufacturer’s activities therefore amounted to an infringement of the relevant patents.\footnote{WTO (2000), p 37.}

Section 271(e)(1) of the US patent law (35 USC), which provided the “Bolar” or “experimental use exception” allowed the generic firms to conduct research on patented drugs prior to the expiration of the patent, so long as the experiments were “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”. The effectiveness of the “experimental use exception” was however dependent on the interpretation of the term “reasonably related”, and not unexpectedly, this term was the subject matter of a litigation between Merck KGaA and Integra Life Sciences, which was adjudicated upon by the US Supreme Court.\footnote{As quoted in Biswajit Dhar, KM Gopakumar, in Effect of Product Patents on the Indian Pharmaceutical Industry while quoting the case of Supreme Court of the United States (2005), p. 24.}

In a significant ruling, the US Supreme Court clarified that “Section 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA\footnote{Ibid, p. 24.},” (emphasis in original) and that “[t]his necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process.” The Court held that Section 271(e) (1) applies to preclinical in-vitro and in-vivo studies intended to obtain information on the “pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals\footnote{Biswa

\textbf{3.20.8 Regulatory (bolar) exception (Article 30)}

This exception allows a potential competitor to use an invention to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term without the authorization of the patent holder. This exception is provided to ensure that generic versions of the product are available on the market immediately, or within a reasonable time, after the expiry of the patent. More rapid introduction of generics into the market leads to more rapid competition and lowering of prices. This permits the use of a patented
invention without authorization from the patent owner in order to obtain marketing approval of a generic product before the patent expires. This allows a generic product to enter the market more quickly after patent expiry, which in turn facilitates access to cheaper medicines.

3.20.9 Pharmaceutical test data protection (Article 39.3)

The most recent affronts on the rights of the developing countries like India to provide access to medicines at affordable prices to its citizens, has come through pressures brought by the US and the EU for the introduction of data exclusivity. This demand is linked to the implementation of Article 39.3 of the TRIPs Agreement, which requires WTO Members to protect undisclosed test or other data, developed with “considerable effort”, against “unfair commercial use” when such data are submitted for seeking marketing approval for products using “new chemical entities”. In addition, Members are required to protect such data against “disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.”148

While Article 39.3 is clearly intended to ensure that “undisclosed test data” was not misappropriated, the pharmaceutical industry associations in the United States and the European Union, representing the larger firms, have argued that Article 39.3 should be interpreted in a manner that provides statutory protection spanning a period of time to data submitted for obtaining marketing approval, among others.

Article 39.3 of TRIPs provides that members who require, as a condition of approving the marketing of pharmaceutical or other products that utilize new chemical entities, the submission of undisclosed test or other data, must protect such information or data against unfair commercial use if its generation involved considerable effort. In some jurisdictions, particularly the United States and the EU, this provision has been implemented by granting a time-limited exclusivity to the originator company. During this period the regulatory authorities cannot rely on the test data to register generic substitutes (commonly referred to as “data exclusivity”). The TRIPs Agreement does not, however, mandate data exclusivity as the only way to implement the provisions. Other countries allow national health authorities to rely on such test data to register generic substitutes based on bioequivalence, while prohibiting disclosure of the data to generic companies or other third parties.

148 Generally see Article 39.3 of the TRIPs Agreement Available at www.WTO.org.
An approach to test data protection, which allows regulatory authorities to rely on the data but not provide generic companies access to it, has important public health benefits. It ensures that generic producers do not need to conduct trials on compounds that have been proven to be efficacious, thus avoiding the imposition of additional costs that may be passed on to the consumer. This approach may also be important for preventing unnecessary and unethical tests, such as repeated human trials for each version of the medicine.

TRIPs provided for protection of the data submitted to governments in order to obtain approval of pharmaceutical and agrochemical products. This is known as the “Data exclusivity”\textsuperscript{149}. Article 39.3 of the TRIPs Agreement is interpreted to mean that such tests and data must be protected against unauthorized disclosure and unfair commercial use. Once a company submits the original data to the regulatory authority then others are excluded from referring to this submitted data for a fixed period of time. The regulatory authorities can rely on this data for the registration of generic substitutes after the exclusivity period expires. This interpretation of multinational companies and developed countries is however disputed widely by NGOs and developing countries.

\section*{3.21 INTELLECTUAL PROPERTY AND DEVELOPMENT\textsuperscript{150}}

The development of economies in developing countries is primarily a reflection of their indigenous technological capability and their research and innovation capability. In order to build technological capacity, developing countries require substantial transfer of basic technologies, which they may dissect and absorb into their own technological capacity. In addition, they require increased foreign direct investment and greater exports to stimulate research and development within their industries. It is theorized by developed countries that increased IPR will serve to increase technology transfer, FDI, and exports, thereby strengthening indigenous technological capability in developing countries and improving their respective economies. However, with patent protection also comes major restrictions on the ability of developing countries to use the same reverse engineering techniques used by today’s developed countries during their industrial developments limiting

\begin{itemize}
  \item \textsuperscript{149} Dr Gopakumar G Nair, TRIPs and Patents.
  \item \textsuperscript{150} Anne St. Martin, The Impact of Trade Related Aspects of Intellectual Property Rights (TRIPs) on Access to Essential medicines in the Developing World A Major Qualifying Project Report submitted to the Faculty of Worcester Polytechnic Institute in fulfillment of the requirements for the Degree of Bachelor of Science May 01, 2006 p32
\end{itemize}
developing countries’ ability to build their industries in the same manner as today’s developed countries. Moreover, patent protection is designed fundamentally to protect and stimulate innovation, and the majority of today’s developing countries do not currently possess innovative capabilities worth protecting.

3.22 TRANSITION PERIODS: (Articles 65.2; 65.4; and 66.1)

The TRIPs Agreement provides four transition periods for the implementation of its minimum standards. The first two sets of transition periods, those relating to developed countries and developing countries, lapsed in 1996 and 2000 respectively. The third, which lapsed in 2005, related to those developing countries that did not provide pharmaceutical patents when TRIPs came into force in January 1994. The fourth transitional period, that relating to LDCs, will remain in force for pharmaceutical patents and test data protection until at least 2016. It can be extended further, hence, until 2023 or later, LDCs have no obligation to provide patent protection to pharmaceuticals, including medicines and diagnostics.

LDCs that take advantage of this transition period can achieve two broad goals. They can obtain medicines at generic prices since there will be no patents in their territories. Second, by not granting patents, LDCs can also foster the development of a generic industry to supply low-cost medicines.

In fact, it is not clear that developing countries have ever issued a compulsory license for import or export of pharmaceutical products. This phenomenon seems to be due to two factors. First, when countries have threatened to issue compulsory licenses – South Africa, Thailand, Brazil --international pressure was brought to bear against them. Second, in many situations, the threat of CL was used as a negotiating tool with the patent holder, and usually led to lower prices without resort to actual issuance. Although many countries already have compulsory laws in cases of health crises or emergencies, they rarely use them for trepidation of antagonizing the intellectual property right lobby and investment community. Also, since the system is not widely used and there are social, political and economic reasons not to issue a compulsory license, countries may fear stigma for engaging in the practice. “Others said that while the deal might seem to offer new opportunities on papery, few countries that produce generic drugs would likely
be willing to risk the wrath of the wrath of the United States by repeatedly breaking patents to help their neighbors."

3.23 DIFFERENTIAL PRICING

Differential pricing entails charging different prices in different markets based on “Ramsey pricing” such that prices are inversely related to the elasticity of demand. Price differentials could be such that prices in high income countries exceed the cost of production and distribution to cover joint costs of RandD and prices in low income countries cover their marginal costs. From the view point of efficiency and equity, differential pricing can be welfare improving if more drugs can be developed and distributed in the developing countries and lower prices are charged in low income countries. The pricing system is the cornerstone of the current patent system. The 20-years monopoly granted to a patent owner is “considered necessary to encourage RandD, particularly in an RandD-intensive industry such as pharmaceuticals.” A price for a given pharmaceutical includes not only the cost of making it, but more importantly the RandD and marketing costs. Though the innovation incentive is a strong justification of the monopoly granted to the patent owner the price system has been criticized as being inefficient. As pointed out, the “current system of financing research and development for new medicine is deeply flawed by the impact of high price on access to medicine, the wasteful spending on marketing and RandD for medically unimportant product, and the lack of investment in the areas of greatest public interest and need.”

Moreover, in most of the developing countries, the current price scheme makes drugs unaffordable to consumers who desperately need it.

Differential pricing for pharmaceuticals proposed as an alternative to the current price scheme aims at reconciling access to medicine, patent rights and RandD. Basically the “price solution” for better access to medicine is framed around the idea of a differential pricing between developed and developing countries based

on the income of each country. As summed up by Danzon,\textsuperscript{155} “under a well-design differential pricing, price in affluent (and, to a lesser extent, middle income countries) exceeds the marginal cost of production and distribution in these countries by enough, in aggregate, to cover the joint costs of RandD, while the price in developing countries covers only the marginal cost”. For the differential pricing to work, an amendment of the TRIPs agreement prohibiting the parallel trade would be needed.

The development of pharmaceutical products requires enormous expenditures for research and clinical trials. On a per unit basis, these costs are generally quite large compared to the actual marginal production cost of producing the product. Unless these expenditures are absorbed by taxpayers through subsidies to research, they must be absorbed by patients, either directly or through intermediary health care organizations (which may themselves be taxpayer-supported). Typically, the patent system is used to permit a higher-than-marginal-cost price for the first generation of patients (and the relevant intermediaries), who absorb this development cost. After the product goes off patent, the price normally falls, so that future patients face a cost closer to the marginal cost of production and distribution\textsuperscript{156}.

“Competition is perhaps the most powerful policy instrument to bring down drug prices for off-patent drugs. In the United States, when a patent expires the average wholesale price falls to 60% of the branded drug’s price when there is just one generic competitor, and to 29% with 10 competitors. The concept of marginal cost is important because it reveals the value of resources used in making a product. In a competitive environment, marginal cost is close to the market price of the product. However, determining marginal cost is difficult. So other approaches to determining a price for a particular drug, including using the price of unpatented therapeutic equivalent drugs, and pharmacoeconomic analysis, have been proposed. With price at, or close to marginal costs, some essential drugs may still remain


\textsuperscript{156} Note that there are actually two kinds of “fixed costs”: those associated with research and development, and those associated with the construction of particular manufacturing plants. The “excess capacity” of a particular plant can be marketed at near marginal cost; larger amounts can be marketed only at a cost which permits recovery of incremental manufacturing capability, but need not permit recovery of research and development costs. As quoted in John Barton, Differentiated Pricing of Patented Products, Indian Council for Research on International Economic Relations, NOVEMBER, 200, p1
unaffordable to poor people. In these instances additional international financing should be considered.”

It is equitable that wealthier patients pay a relatively larger share of the research and development costs. This equitable allocation of costs can be achieved by “tiered pricing”, also called “equitable pricing,” under which patients in developed, high-income nations pay higher prices than patients in developing, low-income nations. To maintain this price difference, there must, of course, be barriers to the reverse (or arbitrage) flow of products from low-income nations to high-income nations.

Such a price differentiation appears unambiguously good, since it makes the product available to those in the developing world who would not otherwise be able to afford it, and allocates the cost of research in an equitable way, without harming patients in the developed world. But a caveat should be noted – this is a sound approach to distributing the costs of products whose development is justified by the developed world market, but it leaves little or no incentive to develop products oriented primarily to the developing world market. For these products, there must be a return from the developing world patient or, more likely, from an international subsidy.

### 3.24 THE “SPECIAL 301” AND ACCESS TO MEDICINE

Besides Free Trade Agreements setting higher standards of IP protection, the US doesn’t hesitate to take unilateral sanctions against countries failing to protect US IP rights under “Special 301” of the Trade Act of 1974. Section 301 was initially designed to “grant the President the power to take action against countries

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159 It is wise to note the precise relationship between the interests of the high-paying and the low-paying patient. If the pharmaceutical firm sets its price for a particular product in a profit-optimizing manner in the higher-price nation, that price would not be affected by the presence or absence of sales in other nations. Any receipts above marginal cost in the lower-income nations would contribute to overall profits, and would not lower costs to high-income patients. See Høsbjør Report at pp. 11–12. Note also, however, that any increase in overall profits would make drug development more appealing economically and would therefore increase the total availability of new pharmaceutical products to the world as a whole.
in response to trade complaints brought by private parties. Section 301 was further amended and a “Special 301” addressing only “violations” of US IP rights protection was added. The “Special 301” gives to the USTR the authority to take unilateral actions against individual countries that do not protect U.S. intellectual property by investigating them and imposing sanctions. “Special 301” can be actionable under two circumstances:

1) In case of a failure for a country to “enter into good faith negotiations” or to
2) To make significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights”.

Countries failing to provide adequate intellectual protection has been designated “priority foreign country”. Besides the “priority foreign country” watching list, three others categories are created by the USTR: countries “of growing concern”, countries on a “watch list” and countries on a “priority watch list”.

The threat of the “Special 301” have a big impact on the countries, especially developing countries which can stand US economic sanctions, on the exercise of their rights under the TRIPs agreement. This avoidance of the multilateral framework has direct impact on access to medicine in developing countries.

3.25 OVERVIEW OF INTERNATIONAL DEVELOPMENT IN THE FIELD OF PATENT AND OTHER INTELLECTUAL PROPERTIES

Efforts to protect intellectual property have a long history. Some analysts date the origins of intellectual property as far back as the fourth century B.C. to Aristotle; others to ninth-century China. Still others trace laws dealing with intellectual property to the system of royal privilege giving that operated in medieval Europe.

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The Venetians are credited with instituting the first properly developed patent laws in 1474, and their model spread to many other European states in the next 100 years. Modern copyright law began in England with the 1709 Statute of Anne.  

The United States Constitution, drafted in 1787, vests the Congress with power ‘to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respectful Writings and Discoveries.’ Historically, countries have adopted laws to protect intellectual property for several reasons. According to the World Intellectual Property Organization (WIPO), an independent specialized agency within the United Nations family of organizations, intellectual property regimes give statutory expression to the moral and economic rights of creators in their creations and define the rights of the public to access to such creations. The second motivation WIPO identifies is to provide incentives and rewards to inventors and creators and thereby stimulate economic and social development. Beyond these traditional rationales, governments use intellectual property laws as a means to improve the country’s competitive economic advantage. This third concern has become an increasingly dominant motive in the global economy. Often these policies favour major economic interests, particularly large multinational firms, to the detriment of protecting public access and benefits in the home country and promoting development in countries in the South.

Intellectual property has three customary legal domains: copyright (author’s rights), patent, and trademark. Various legal regimes have evolved over time, each of which, to different degrees, recognizes rights of ownership in a particular form of intellectual subject-matter under specific conditions for designated periods of time. Intellectual property law is constructed around an eighteenth-century paradigm of

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166 The World Intellectual Property Organization (WIPO) is responsible for the promotion of intellectual property worldwide. It acts as the secretariat for the negotiation of treaties that establish new norms in the field of intellectual property, and administers several treaties. It also conducts extensive programmes for training and technical assistance for developing countries.
the author or creator as a single, solitary figure. But this image often does not fit developments in the contemporary world. In science and technology, for example, researchers often work in large teams and collaborate across national boundaries. Scientific knowledge is additive; discoveries and inventions build on work by others conducted over a long period of time. This means that it is frequently difficult to separate out the relative contributions of various researchers.

The many legal suits by members of research teams contesting ownership and control of patents reflect this dilemma. An age of printing is often inadequate to deal with the challenges of new technologies. Intellectual property law generally assumes that there are practical limits on the ability to copy and distribute information or works of art. The advent of photocopying and audio- and videotaping began to change the balance between the owners’ and users’ rights by facilitating the reproduction and dissemination of publications outside the control of the intellectual property owner. The development of computer technology and the Internet has further complicated the protection of intellectual property. Once information is available in electronic form it can be distributed to a worldwide audience at little additional cost. The legal controversy over whether Internet sites, such as Napster, which facilitate the trading of electronic copies of music, are engaging in copyright infringement is but one indication of the need for rethinking approaches to intellectual property protection. Efforts to develop standards for electronic publications that will protect the interest of authors and the integrity of their works are another. On the other side of the issue, some corporate interests have sought new and stricter intellectual property protections which would reduce scientific and public access to resources.

The European Union, for example has passed legislation creating a sui generis form of intellectual property to protect database rights and in 1996 proposed that WIPO adopt a treaty on intellectual property protection for databases. The American scientific community vigorously opposed this draft treaty and efforts to legislate similar protections in their own country arguing that it would undermine the ability of researchers and educators to access and use scientific data.

Because the current system of intellectual property is built around the idea of originality, traditional/indigenous knowledge and art forms cannot meet the criteria for copyright or patenting.

Traditionally, intellectual property regimes sought to balance the rights of creators with the interests of the public to have access to artistic works and technology products. The very existence of intellectual property rights was originally justified on the grounds that incentives and rewards to artists and inventors result in benefits to society. However, current developments tend to weaken these balances and to skew the system in favour of a much narrower range of interests.

Commercialization has changed intellectual property from a means to provide incentives to researchers and inventors to a mechanism intended to encourage investment and protect the resources of investors. The privatization of the public domain reflects this transformation. Preserving the public domain is important because it serves as a resource for future creators and as raw material for the market-place of ideas. All these have lead to various instruments in protection of Intellectual Property Rights.

3.26 PARIS CONVENTION

The Paris Convention for the Protection of Industrial Property (“Paris Convention”) is one of the first, and arguably most important, of the various multilateral treaties protecting intellectual property. It addresses patents, marks, unfair competition whether or not implicating marks, and the related industrial property of industrial designs, utility models, geographical indications, trade names, possibly trade secrets within the context of unfair competition, but not copyright. The Convention secures for nationals, those domiciled, and those having a real and effective industrial or commercial establishment within a country party to the Convention, the important procedural advantages of national treatment and priority rights in respect of patents and trademarks. The Convention for the most part neither defines the rights it purports to protect nor guarantees any minimum level of protection for these rights. The scope and quality of the protection member nations are obligated to provide under the Convention are, in most instances, left to domestic legislation and tribunals to develop and define. While the enumerated

protections serve primarily industrial interests, the Convention allows party states to retain some protectionist legislation, in the form of limited working requirements and compulsory licenses. The lack of provisions defining minimum substantive rights and mandating enforcement of those rights is thought to be justification for the Agreement on TRIPs, a multilateral treaty that seeks to address these observed shortcomings. 

1) Reasons for the Origin of Paris Convention, BIRPI

Initially, inventions were kept secret so that it is well protected. As technology developed periodically, as a matter of national prestige the inventions were exhibited. At the Paris exhibition in 1867, Germany received the first genuine recognition as an industrial nation. During the 1873 Vienna exhibition, it was the Americans who refused to participate. The reason was that the Americans need intellectual protection of their creations from German nations so that the ideas are well protected. This led to the origin of Paris convention in 1883. This international treaty helped people of one country to protect their creations in another country, provided the other country is also a member of the convention. The main advantage is that the inventor has the right of priority of his invention. This in turn was the origin of the protection of industrial property in different countries. In 1893, in order to carry out the administrative tasks, an international organization called United International Bureaux for the Protection of Intellectual Property (BIRPI) was established in Berne, Switzerland.

In the development of patent law harmonization perhaps the most important event of the modern era was the Vienna exhibition of 1873. Prior to the exhibition considerable concern was expressed by American commentators about the state of Austrian patent law and its ability to protect exhibitors from plagiarism and piracy. In this context there was a requirement to harmonize the issues in relation to protect patents right from the pirates. “In consideration of the great inequality of the existing patent legislation, and in consideration of the altered means of international communication of the present time, there is great want of reform, and it is very

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desirable that the Governments will initiate an international understanding on the patent protection. Then after a series of conferences the Paris Convention for the Protection of Industrial Property (Paris Convention), signed in Paris, France, on March 20, 1883. There are 172 members party to Paris Convention (as on 3rd March 2008). The Paris Convention on the Protection of Industrial Property provided a rather flexible framework for the protection of industrial property, including patents. Paris Convention contains inter-alia the provisions of national treatment, right of priority, independence of patent, mention of the inventor in the patent, compulsory Licenses and the concept of an “Open Union”, with the possibility of revision and the extension of membership. Although it introduced certain common standards (e.g. independence of patents, priority right, conditions for revocation of patents and compulsory licenses) it left the determination of most aspects of patent law (including patentable subject matter, duration, rights conferred) to national laws.


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177 Article 4 of the Paris Convention
178 Article 4bis of the Paris Convention
179 Article 4ter of the Paris Convention
180 Article 5 of the Paris Convention
2) Paris Convention for the Protection of Industrial Property

The Paris Convention for the Protection of Industrial Property, signed in Paris, France, on March 20, 1883, was one of the first intellectual property treaties. It established a Union for the protection of industrial property. The Convention is still in force. After a diplomatic conference in Paris in 1880, the convention was signed in the year 1883 by 11 countries namely, Belgium, Brazil, France, Guatemala, Italy, Netherlands, Portugal, El Salvador, Serbia, Spain and Switzerland. As of December 2011, the Convention has 174 contracting member countries, which makes it one of the most widely adopted treaties worldwide. Notably, Taiwan and Kuwait are not parties to the Convention. The Paris Convention is administered by the World Intellectual Property Organization (WIPO), based in Geneva, Switzerland. The Convention applies to industrial property in the widest sense, including patents, marks, industrial designs, utility models (a kind of “small patent” provided for by the laws of some countries), trade names (designations under which an industrial or commercial activity is carried on), geographical indications (indications of source and appellations of origin) and the repression of unfair competition. India’s membership into the convention came into force on December 7, 1998. Some of the important Articles are summarized

Article 2

National Treatment for Nationals of Countries of the Union

1. Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.

2. However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any Industrial property rights.

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3. The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved.

**Article 3**

Same Treatment for Certain Categories of Persons as for Nationals of Countries of the Union

Nationals of countries outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union.

**Article 5 quarter**

Patents: Importation of Products Manufactured by a Process Patented in the Importing Country:

When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country.

Primarily, the Paris convention provided the freedom for countries to decide on the areas of patentability and duration of patents. Many countries decided not to provide patent protection for pharmaceutical products or medicines, but rather only grant patents for the processes, or the method of manufacturing each specific drug. These process patents were granted for a period of seven to ten years, but did not impede the transfer of pharmaceutical knowledge and technologies because of reverse engineering strategies used in the developing world. Granting process and not product patents allowed other nations to investigate newly invented medicines to determine their chemical structure, then work backwards and deduce step-by-step possible synthetic routes for production. Other nations could then produce a generic version of the same drug through a different synthetic route, providing their citizens access to quality drugs at an affordable costs, while simultaneously strengthening national pharmaceutical industries by the mere investigation of foreign medicines. In addition, article 5b of the Paris Convention obliged
the patent owner to work the patent in the country that grants process patent protection, that is, the product had to be manufactured in every country to which patent protection was granted. Importing of the product does not qualify as “working the product”; therefore patenting a product in a particular nation was a serious commitment to ensure the manufacturing of that product.

Finally, the Paris convention also allowed governments to issue compulsory licensing if the protected patent was not being worked in the named country and the drug was not regularly available. Under these circumstances the government that required the drug could authorize a domestic drug company to manufacture the drug after paying a compensation fee to the patent holder. However, “a compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last.” (Paris Convention, 5A4).

Many researchers note that a patent free environment was essential for the growth of pharmaceutical industries, which is reflected in the fact that the countries with today’s most successful pharmaceutical industries refused to grant patent protection on medicines until they had reached a certain standard of development. Most notably, France was the first country to introduce product patents in 1960, followed by Germany in 1968, Japan 1976, Switzerland 1977, Italy and Sweden in 1978. The United States specifically stated that it was freely entitled to foreign works to further its social and economic development, despite British retaliation (US Congress, 1986)\textsuperscript{185}.

**Article 10bis** Unfair Competition

1. The countries of the Union are bound to assure to nationals of such countries effective protection against unfair competition.

2. Any act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.

3. The following in particular shall be prohibited:

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\textsuperscript{185} Anne St. Martin, The Impact of Trade Related Aspects of Intellectual Property Rights (TRIPs) on Access to Essential Medicines in the Developing World A Major Qualifying Project Report submitted to the Faculty of Worcester Polytechnic Institute in fulfillment of the requirements for the Degree of Bachelor of Science May 01, 2006, p. 36.
1. All acts of such a nature as to create confusion by any mean whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

2. False allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

3. Indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.

3.27 THE BERNE CONVENTION

The Berne Convention for the Protection of Literary and Artistic Works, usually known as the Berne Convention, is an international agreement governing copyright, which was first accepted in Bern, Switzerland in 1886. The Convention rests on three basic principles and contains a series of provisions determining the minimum protection to be granted, as well as special provisions available to developing countries which want to make use of them.

The following are the three basic Principles:

(a) Works originating in one of the contracting States (that is, works the author of which is a national of such a State or works which were first published in such a State) must be given the same protection in each of the other contracting States as the latter grants to the works of its own nationals (principle of “national treatment”).

(b) Such protection must not be conditional upon compliance with any formality. (principle of “automatic” protection).

(c) Such protection is independent of the existence of protection in the country of origin of the work (principle of the “independence” of protection). If, however, a contracting State provides for a longer term than the minimum prescribed by the Convention and the work ceases to be protected in the country of origin, protection may be denied once protection in the country of origin ceases.

As of March 2012, there are 165 countries that are parties to the Berne Convention. India’s membership into the convention came into force on April 1, 1928.
3.28 ROLE OF WIPO IN HARMONIZING PATENT PROTECTION

1) Introduction

The role of WIPO is to promote international cooperation with respect to creation, dissemination, use and protection of works of the human mind for economic, social, cultural progress of all mankind. It enhances a worldwide balance of the creation i.e., by protecting moral, material interests of the creators and providing access to the socio-economic and cultural benefits to others. WIPO promotes protection of intellectual property and bring out cooperation among the union. In addition to these, WIPO sets norms, standards and execute legal technical assistance, registration activities for intellectual property protection to member countries. It is the WIPO; which is responsible for the formation of Patent Co-operation Treaty (PCT).

“A robust and dynamic industrial property system, and particularly the patent system, support and encourage technological innovation, bring more and better products onto the market for the benefit of people, and promote investment and technology transfer” to promote technology transfer and investment for the advancement of the public good is the goal.

2) World Intellectual Property Organization (WIPO)

The World Intellectual Property Organization (WIPO) is one of the 17 specialized agencies of the United Nations, located in Geneva, Switzerland. The Organization has External Offices at Rio de Janeiro in Brazil, Tokyo in Japan, Singapore and New York. The mission of WIPO is to promote innovation and creativity for the economic, social and cultural development of all countries, through a balanced and effective international intellectual property system. The origin of WIPO goes back to 1883 and 1886 when the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works, respectively, were concluded. Both Conventions provided for the establishment of an international bureau. The two bureaus were united in 1893 and, in 1970, were replaced by the World Intellectual Property

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188 See WIPO Patent Agenda (A/36/14).
Organization, by virtue of the WIPO Convention. The WIPO Convention, the constituent instrument of the World Intellectual Property Organization (WIPO), was signed at Stockholm on July 14, 1967, entered into force in 1970 and was amended in 1979. WIPO is an intergovernmental organization that became in 1974 one of the specialized agencies of the United Nations system of organizations. WIPO currently has 185 Member States, and 68 intergovernmental organizations (IGOs) and 232 International non-governmental organizations (NGOs) and 63 National NGOs that are accredited as observers at WIPO meetings.

(i) The Core Tasks of WIPO:

working with Member States to support a balanced evolution of international IP law administering treaties assisting governments and organizations in developing the policies, structures and skills needed to harness the potential of IP for economic development servicing global registration systems for trademarks, industrial designs and appellations of origin and a global filing system for patents delivering arbitration, mediation and other dispute resolution services promoting respect for IP providing a forum for informed debate and for the sharing of IP knowledge identifying IP-based solutions that can help confront global challenges and maximize the benefits of the IP system for all.

(ii) The Working of WIPO:

WIPO’s Member States determine the strategic direction and activities of the Organization. They meet in the Assemblies, committees and working groups. The WIPO Secretariat, or International Bureau, is based in Geneva. WIPO staff, drawn from more than 90 countries, includes experts in diverse areas of IP law and practice, as well as specialists in public policy, economics, administration and IT. The respective divisions of the Secretariat are responsible for coordinating the meetings of Member States and implementing their decisions; for administering the international IP registration systems; for developing and executing the programs designed to achieve WIPO’s goals; and for providing a repository of IP expertise to assist its members.

It has to present a program and a budget every 2 years about performance measures, budget planning for all the events of the organization which requires member state approval. It is a self financing organization and its funds are majorly used for organizing events. WIPO Arbitration and Mediation Centre was created in
1994 for the settlement of international commercial disputes arising between private parties located in Geneva, Switzerland and it has an office in Singapore

(iii) WIPO’s Goals

The strategic goals defined in WIPO’s revised Program for 2008/09 is:

i. A balanced evolution of the international normative framework for IP

ii. Provision of premier global IP services

iii. Facilitating the use of IP for development

iv. Coordination and development of global IP infrastructure

v. World reference source for IP information and analysis

vi. International cooperation on building respect for IP

vii. Addressing IP in relation to global policy issues

viii. A responsive communications interface between WIPO, its Member States and all stakeholders. An efficient administrative and financial support structure to enable WIPO to deliver its programs.

3.29 THE PATENT COOPERATION TREATY (PCT)

Basically, under the traditional patent system, the inventor has to file applications in each and every country where he wishes to possess a patent. The Paris Convention provided a great opportunity in claiming the priority date of an earlier application for the subsequent filings in foreign countries if the parent and foreign countries are members of the convention. The advantage with the Paris Convention is that, the inventor after filing a patent in his/her owns country can decide within a period of 12 months whether to file patent applications among Paris Convention countries. This in turn means that the inventor if wishes to file patent application in foreign countries; within a period of 12 months he/she has to make all the necessary arrangements of language translations, filing of patent applications in all the countries, bare fees of patent offices, attorney’s. To overcome the problem of duplication, BIRPI/WIPO came out with a new treaty called Patent Cooperation Treaty in 1970. PCT became an international cooperation treaty with respect to filing, searching, and examination of patent applications and dissemination of the technical information contained in it.
The Patent Cooperation Treaty (PCT) is an international treaty administered by the World Intellectual Property Organization (WIPO). The treaty was done at Washington on June 19, 1970. The PCT makes it possible to seek patent protection for an invention simultaneously in a large number of countries by filing a single “international application” with a single patent office (i.e. receiving Office). The PCT system simplifies the process of multi-national patent filings by reducing the requirement to file multiple patent applications for multi-national patent rights. The PCT international applications do not result in the issuance of “international patents” and the International Bureau (IB) does not grant patents. The decision on whether to confer patent rights remains in the hands of the national and/or regional patent offices, and the patent rights are limited to the jurisdiction of the patent granting authority. The PCT procedure consists of an international phase and a national/regional phase. The PCT international application process starts with the international phase and concludes with the national/regional phase. The total number of PCT filings (international patent applications filed through the Patent Cooperation Treaty) in 2010 was approximately 164,300.

3.30 PATENT LAW TREATY

The Patent Law Treaty (PLT) was adopted on June 1, 2000 at a Diplomatic Conference in Geneva. The purpose of the PLT is to harmonize and streamline formal procedures in respect of national and regional patent applications and patents. With a significant exception for the filing date requirements, the PLT provides maximum sets of requirements which the Office of a Contracting Party may apply: the Office may not lay down any additional formal requirements in respect of matters dealt with by this Treaty. This means that a Contracting Party is free to provide for requirements that are more generous from the viewpoint of applicants and owners, but are mandatory as to the maximum that an Office can require from applicants or owners. India is not a contracting party to this treaty.

3.31. CONCLUSION

To sum up in year 1995 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), became effective as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and obliged all the WTO’s member states to alter their domestic legislations and recognize a minimum standard of protection for intellectual property in all fields of technology, including
pharmaceuticals\textsuperscript{190}. Correspondingly, many countries made significant changes in the national intellectual property laws which have a direct bearing on the pharmaceutical industry. Initially the members were convinced that IPR protection is for the advantage of developing and developed countries which provides cheaper goods, transfer of technology, consumer protection and their rights would best be protected as large scale economic production would bring benefits but in reality there is a deviation on what was promised because the protection is given to all the fields of technology compromising of the moral and humanity grounds. The TRIPs widen the scope of patentable subject matter including pharmaceuticals. The minimum standards mentioned in the TRIPs agreement ensured the protection that the patent shall be granted for any inventions, whether product or processes, in all fields of technology under the conditions that they are new, involve an inventive step and are capable of industrial application without any discrimination to the place of invention or to the fact that products are locally produced or imported.

The TRIPs agreement has established detailed provisions on enforcement to make sure effective action against any act of infringement, as well as a mandatory dispute settlement process, which had a major impact on the harmonization process. In Part III of the Agreement, the provisions of section 1 (Article 41), lays down general obligations and basic principles that all enforcement procedures must meet. The following sections, which deals with civil and administrative procedures and remedies (Article 42 to Article 49), provisions measures (Article 50), special requirements related to boarder measures and criminal procedures (Article 51 to Article 61), does offer safeguards to remedy negative effects of patent protection or patent abuse, but in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access\textsuperscript{191}. The TRIPs agreement made contribution to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic social welfare (Article 7) and to permit members to adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their economic and technological


\textsuperscript{191} See World Trade Organization, “Overview: the TRIPs Agreement”, para.1. Available at: http://www.wto.org/english/tratop_e/TRIPs_e/intel2b_e.htm (Search date: 16/04/2010).
development (Article 8). The TRIPs Agreement then permits member countries to include in their legislations some flexibilities and public health safeguards. The main flexibilities built into the TRIPs Agreement are: compulsory licensing (Article 31), parallel imports (Article 6), experimental use (Article 30), Bolar exceptions (Article 30) and health sector participation in analyzing pharmaceutical patent claims (implicit in Article 8)\textsuperscript{192}.

At the end, the TRIPs agreement stipulates a number of things: patents can be provided for products and processes for at least 20 years. However, several points remain vague, left to the discretion of members: the definition of a national emergency or the principle of rights exhaustion adopted for instance.

The pre-TRIPs era saw the world have restrictive patent laws providing for process patents and non-grant of product patents in drugs and pharmaceuticals and later allow patent in both products and processes. While not all the nations have the same tone and pace in patent drugs. TRIPs attempted to harmonize the Intellectual property laws by bringing the disparities into focus and providing guidance for them by setting the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. TRIPs agreement made a substantive change and impact on the pharmaceutical patents. Before the enactment of the TRIPs Agreement, patent protection for pharmaceutical products was virtually nonexistent in many poor, developing nations, but now the WTO members have adopted the patent law protecting pharmaceutical products. Which more or less has an adverse effect on public health policy as the countries like India with huge population and lack of funding by the governmental agencies in public health sectors would prove fatal.

The utilization of the flexibilities that exists in the TRIPs Agreement is very much difficult as it has been dressed with a number of conditions the fulfillment of those stipulations is not an easy task. The countries ability to utilize those flexibilities depends on the nation’s ability to provide explanations on which ground the right of patent holder is exhausted and moreover the government has to compensate the patent holder to the fullest extent. The proper reasons to the fullest satisfaction should be given on the contrary if the reasons given are found baseless of false to such extent the flexibilities cannot be utilized and in turn the member

country has to pay for damages and loss of profit for wrongful use of flexibilities. Hence the member countries have an uphill task to utilize the flexibilities which in turn puts the developing countries into a situation where implementation of public health policies and access to medicines for all would be denied. The government has to shoulder more burdens. The public has to bear the health expenditure on their own at the cost of other expenditures required to run their families it is nothing but opt the essential and leave out the other not so essential things making things worse. Moreover the international body i.e., WTO is more interested in enforcing the multilateral agreements which have commercial benefits rather than enforcing the Human Rights especially Right to Health and some other areas such as law of wars, extradition treaty etc.