

## EVOLUTION OF THE CONCEPT OF COMPULSORY LICENSING: A CRITICAL ANALYSIS OF KEY DEVELOPMENTS BEFORE AND AFTER TRIPS

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### ABSTRACT

*Patents provide monopoly rights to patent holders. There are safeguards in patent regime to ensure that exclusive right of the patent holder is not misused. Compulsory licensing is one of the safeguards provided under TRIPS using which patent granting state may allow a third party to exploit the invention without patent holder's consent upon terms and conditions decided by the government. This concept existed since 1623 and was not introduced by TRIPS for the first time. But this mechanism has undergone significant changes especially in post-TRIPS era. History of evolution of compulsory licensing is one of the least explored areas of intellectual property law. This paper undertakes an analysis of different phases in the evolution of the compulsory licensing mechanism and sheds light on reasons behind developments especially after TRIPS.*

**Keywords:** Compulsory licensing, TRIPS flexibilities, Paris Convention, Berne Convention, Rome Convention, Doha Declaration, WTO Waiver Decision

### INTRODUCTION

The notion of Intellectual Property Rights is based on the principle that the person who made an intellectual contribution must have an exclusive right to enjoy the fruits of his labor. It sounds quite logical, but the monopoly right provided to the inventor is not only in direct conflict with the competition laws but also has implications with regards to human rights law. Thus, there is a need to provide safeguards to ensure that this exclusive right of the patent holder is not misused.

Compulsory licensing of patents is one such safeguard under which government of the state that granted the patent could allow a third party to use the patent without consent of the patent holder on payment of a reasonable royalty or remuneration to the patent holder. It is "a statutorily created license that allows certain people to pay a royalty and use an invention without the patentee's permission" (Bryan, 2004). This safeguard is particularly useful with regards to pharmaceuticals especially in the instances of public health crisis when underprivileged states have no other option but to dilute the patent in order to improve access to affordable essential medicines to their poor citizens with limited purchasing power.

After the industrial revolution in the West, the technologically advanced countries felt the need for international standards regarding protection of intellectual property rights. Their efforts could not bear the desired fruits until the end of the cold war between the capitalist and communist blocks. Towards the end of the twentieth century, they linked trade with IPRs protection and succeeded in negotiating an international treaty which was imposed on the third world subject to the provision of an extended period for implementation of the treaty obligations. The primary objective of TRIPS Agreement was to provide stringent intellectual property protection to protect the interests of the multinationals in the technologically advanced world. Problems of the third world were therefore not given due consideration. Though compulsory licensing and parallel importation were included as safeguards, these

were just exceptions to the general stringent patent protection for all products including pharmaceuticals.

Compulsory licensing safeguard, initially provided under TRIPS, had no practical significance for least developed countries (hereinafter LDCs) which lacked manufacturing capacity of their own because the pharmaceutical products manufactured under compulsory license could only be sold in the domestic market. With the outbreak of epidemics and pandemics like HIV/AIDS in Africa, the outcry by NGOs and human rights activists succeeded to draw attention of the world community towards practical problems faced by the LDCs (lacking manufacturing capacity) despite the flexibilities provided in the TRIPS. Changes were made in the existing system under Doha Declaration 2001, and WTO Waiver Decision 2003 to address the problems of the LDCs by allowing export of generics produced under compulsory licensing to these countries.

Now, theoretically, safeguards are available to the poorer countries and WTO member states have included the compulsory licensing provisions in their municipal laws. But practically, these provisions are seldom used owing to numerous implications including economic and political pressure.

### MEANING OF COMPULSORY LICENSING

“Compulsory license<sup>1</sup> is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder’s consent” (Paris Convention, 1883). In simple words, “compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government” (Jain, 2009). The government, however, pays a royalty to the patent holder in order to compensate them for the use of their patent without their consent (Durojaye, 2011). In other words, “Compulsory license means a non-voluntary license issued by the state to a third party, without the authorization of the patent holder, on the condition that the licensee pays reasonable remuneration to the right holder in return” (Kuanpoth, 2004). A compulsory license or a non-voluntary license may also be defined as “an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state” (Arnold, 1993). The licensee enjoys the right to manufacture, sell or import the patented product. These acts are otherwise covered by the exclusive rights of the patent holder (Arnold, 1993).

No doubt, patents are necessary to promote innovation. If the government does not ensure patent protection, no firm would have an incentive to develop new products. If other firms are allowed to copy the same products, there would be no monopoly and prices would automatically come down. But this price control is at the cost of innovation. Patent is therefore an imperfect but necessary instrument to encourage innovation (Hollis, 2002). But when monopolistic patent rights are conferred on the products which are essential for human life, they can have adverse effects on the socio-economic development of the country that grants patents. An obvious result of patents may be an increase in price and decrease in supply of the patented products as the patent holder enjoys monopoly (Kuanpoth, 2008).

World Trade Organization<sup>2</sup> (hereinafter WTO), in its Doha Declaration<sup>3</sup>, recognizes the right of access to affordable medicines. Life-saving medicines may be beyond the purchasing

<sup>1</sup> The birth of the concept of compulsory licenses is linked to the obligation, introduced by the United Kingdom (UK) Statute of Monopolies in 1623. Compulsory licensing has been reported to be popular in Britain as early as 1850s. Later it was recognized by the international community through Paris Convention of 1883.

<sup>2</sup> The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. It intends to supervise and liberalize international trade. The organization officially commenced on January 1, 1995 under the Marrakech Agreement, replacing the General Agreement on Tariffs and Trade (GATT).

power of common masses in many developing and underdeveloped countries due to patent protection enjoyed by the pharmaceutical products. The availability of life saving medicines becomes even more uncertain in case of national emergency. In such situations, the national governments may avail the flexibility provided under WTO regulations by using the provision of compulsory licensing. It may, however, be noted that a national emergency is not the only ground for the issuance of compulsory license. Doha Declaration on Public Health 2001 provides freedom to member states to determine grounds of compulsory licensing (Janodia, 2006). In the absence of international norms and standards for this practice, the grounds for granting compulsory licensing vary from country to country depending on laws of each state.

Compulsory licensing obviously involves breaking of the exclusive right of the patent holder. The purpose behind breaking of the patent right is to change the terms of bargaining between the buyer and the seller. For instance, if the government is a buyer and the patent holder is a seller, and the parties fail to negotiate a reasonable price of the product, compulsory licensing provisions provide for an arrangement using which the government may dilute exclusive patent right of the patent holder and license some other firm to sell the same product. Compensation is, however, paid to the patent holder in exchange for use of his patent (Convention for the Protection of Performers, 1961). Thus, compulsory licensing, by stimulating generic competition, strengthens the bargaining position of the government resulting in lowering of prices (Hollis, 2002). Compulsory licensing is therefore yet another necessary evil. It is a violation of the rights of the patent holder. But this violation sometimes becomes necessary in order to improve availability of essential products at affordable prices. It is pertinent to note that access to drugs or to deal with emergency public health situations is not the only reason for grant of compulsory license. It can be used as a policy mechanism to deal with anti-competitive practices, non-working of the patent, or other undesirable behavior of patent holders (Convention for the Protection of Performers, 1961). Compulsory license not only forces the patent holder to use his invention for the benefit of the society but also boosts generic industry of the country granting such license (Sterckx, 2004).

## **HISTORICAL BACKGROUND OF COMPULSORY LICENSING**

### **Pre-WTO Period**

The concept of compulsory licensing is not new. It has a long history. The English Statute of Monopolies 1623 is one of the earliest legal instrument in which concept of compulsory licensing was incorporated. The concept became popular in the United Kingdom as early as 1850s. With the passage of time compulsory licensing provisions became a typical feature of almost all patent systems.

Patents have been an important part of intellectual property even before the eighteenth century though patent laws at that time were not complex (Drahos, 3). However, traditionally, for most of the states, enforcement of patent laws was not a priority and consequently they had weak patent regimes. In the 1980s, when the technology-focused industries grew in the advanced world, intellectual property emerged as a trade concern and states started to realize the importance of enhanced global intellectual property protection (Bird, 2009).

Congress of Vienna for Patent Reform 1873 was the first international patent convention. After a debate on the costs and benefits of providing monopoly rights to patentees, the convention endorsed the principle of patent protection in order to preserve incentive for

<sup>3</sup> The November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.

innovation. The convention also allowed compulsory licensing -as a safeguard against potential abuse of monopoly rights- in situations where the public interest should require it. Compulsory licensing was therefore accepted as a “strategic compromise” (Chien, 2003). However, this convention, prescribing only minimum standards, was not popularly accepted (Holbrooke & Holmer, 674). Moreover, the Congress of Vienna for Patent Reform did not produce any binding legal instrument (Holbrooke & Holmer, 674). It, however, led to the first major international intellectual property convention that was held in Paris after ten years in 1883 (Zischka et al., 5).

Prior to World Trade Organization (WTO), World Intellectual Property Organization (hereinafter WIPO), established in 1967 with an aim to protect intellectual property and to encourage the creative activity, was sole centralized international agency that governed intellectual property rights. The WIPO’s aim is to bring harmony in intellectual property legislation and procedures of member states (Yosick, 2001). Under the WIPO regime, not only various new treaties were concluded but also some old treaties were revised in Stockholm Revision Conference (Gontijo, 2005) convened in 1967 keeping in view the advancements in technology. Paris Convention for the Protection of Industrial Property 1883 and Berne Convention for the Protection of Literary and Artistic Works 1886 are the most notable out of these treaties.

Patent holder’s right to control price, usage, and supply was recognized globally much earlier, but recognition of this right was confined to patentee’s home country (Gumbel, 2008). Countries lacked power to protect hard work of their citizens from infringement in other countries. The primary objective of the Paris Convention was to develop a system at international level using which inventors could protect their innovations globally (Paris Convention, 1878). Article 5(A)(2) of the Paris Convention provided for involuntary licensing in order to prevent abuse of exclusive patent rights (Gumbel, 2008), for instance, failure to work (Bondy & Saggi, 2012). Purpose of allowing the member states to grant compulsory licensing was to solve the problem of underutilized patents (Foed, 2000). Article 5(A) (4), however, provides that compulsory license must be refused if the patentee has legitimate reasons to justify his inaction. This right to avoid a charge of abuse was given to the patentee in 1925 when Article 5(A) of the Paris Convention was revised at The Hague (Reichmann & Hasenzahl, 2003). Moreover, the license must be non-exclusive and non-transferable (EU & Members States, 2006).

Paris Convention was controversial because of its uncertainty and broad provisions. “Abuse” of the patent, for instance, is a vague undefined term that is open to broad interpretation. Paris Convention leaves key terms to be defined by the member states (Cottierr et al., 2012). Paris Convention, however, contributed towards evolution of minimum international standards regulating intellectual property protection. Despite its demerits, Paris Convention as a whole was a successful treaty that has survived for such a long time<sup>4</sup> without any substantial change and the number of countries that became party<sup>5</sup> to it is also impressive.

Berne Convention for the Protection of Literary and Artistic Works 1886 is another important international treaty that was revised by WIPO. Article 11 of the Berne Convention provided for compulsory licensing in case of broadcasting and related rights. Similarly, Article 13 of the Berne Convention provided for compulsory licensing in case of recording of musical works (Jain, 2009). There was a difference of opinion between developing countries and developed world at Stockholm Revision Conference convened in 1967. India, for instance,

<sup>4</sup> Paris Convention is still in force as of February 2013.

<sup>5</sup> There were only 11 original signatories of the Paris Convention. Now it has more than 170 contracting member countries making it one of the most widely adopted international treaties.

argued that there should be no barrier to grant of compulsory license if situation or circumstances demanded this. Developed countries like the United Kingdom opposed compulsory licensing arguing that poor countries could not be provided economic assistance at the expense of authors (Chung & Sun, 2006). Due to lack of compromise between two blocs, the Stockholm Protocol failed to provide explicit compulsory licensing provisions. Compulsory licensing provisions were disturbingly ambiguous, extremely complicated with overly strict conditions for grant of compulsory license and could hardly serve the purpose desired by the third world countries seriously lacking administrative and legal infrastructure to avail the flexibility.

Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations 1961 is another important treaty in this regard. Rome Convention recognizes the grant of compulsory licensing without mentioning any conditions for the grant thereof. Article 15 of the (Rome Convention) merely states that “Compulsory licenses may be provided only to the extent to which they are compatible with this Convention”. Although ambiguities are there in these conventions yet they show that the concept of compulsory licensing was recognized in the intellectual property rights conventions well before TRIPS Agreement (Jain, 2009).

In order to centralize international trade issues, the General Agreement on Trade and Tariffs was created in the 1940s. The GATT is an international agreement with 92 states as contracting parties. These states participate in multilateral trade negotiations with an aim to expand international trade, raise world welfare by reducing uncertainty associated with commercial transactions between different states, and to prevent economic discrimination between nations (Arnold, 1993). Under GATT, further trade negotiations were held in Uruguay between 1986 and 1994. As a result of these rounds, World Trade Organization was established as a separate and viable organization with members from developed, developing and least developed nations. GATT deals with trade in goods, whereas WTO deals with trade in services and intellectual property related to trade and investment issues (Gontijo, 2005).

### **Post-WTO Period**

Post-WTO period saw much more rapid progress with regards to intellectual property laws in general and compulsory licensing in particular. Some of the important developments are briefly discussed as under:

#### **TRIPS Agreement**

The WTO, in December 1994, approved an important treaty the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which came into effect on January 1, 1995. Primary objective of TRIPS Agreement was to minimize the distortions and impediments to global trade by giving due importance to protection of IPRs (Arnold, 1993). It provided for minimum standards to harmonize divergent domestic laws of the WTO member countries and provided mandatory rights for right holders (Kuanpoth, 2008). It required all WTO member states to adopt regulations relating to IPRs as laid down in the treaty (Hunter, et al., 2009).

TRIPS Agreement did not repeal Paris Convention. Rather it incorporated Paris Convention under its Article 2(1)<sup>6</sup> and both apply on equal footing. TRIPS, however, provided for higher standards of intellectual property protection and it is difficult to reconcile Article 27(1)<sup>7</sup> of

<sup>6</sup> Article 2(1) stipulates that: “In respect of Parts II, III, and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention (1967)”.

<sup>7</sup> Article 27(1) stipulates that: “...patents [can] be granted for any invention, whether products or processes, in all fields of technology...[and] patent rights enjoyable without discriminations to the place of invention, the field of technology and whether products are imported or locally produced”

TRIPS with Article 5(A) of the Paris Convention (Temmerman). The TRIPS Agreement, under Article 27(1), provides that the signatory states are obliged to protect any innovations, whether products or processes, in all fields of technology.

Before 1995, when TRIPS Agreement was not concluded, almost 50 countries had excluded drugs from patentability (Ebomoyi, 2010). But TRIPS Agreement prohibited any such exclusion (Barton, 2004). To enjoy protection, the invention must fulfill three conditions namely, “it must be new, it involves an inventive step, and it is capable of industrial application” (Kongsombut, 2012). Moreover, TRIPS Agreement, under Article 28, provides the patent holders exclusive rights to prevent third parties from making, using, offering for sale, selling or importing patented products without consent of the patent holder.<sup>8</sup> These monopoly rights are provided to the patent holders for a period of twenty years (Jain, 2009).

The pharmaceutical patent protection, however, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals. It does not work well in developing and least developed countries because of different factors, affordable access to medicines being the most important of them.

Keeping in view the practical implications of patent protection in third world countries, TRIPS Agreement provides mechanisms to poorer countries to override patents through legitimate means. It contains arrangements such as ‘parallel importation’<sup>9</sup> and ‘compulsory licensing’ which are exceptions to the stringent patent protection (Durojaye, 2011). Even though the word ‘compulsory license’ has never been used in the TRIPS Agreement, the exclusive rights to the owner of patents are specifically subject to compulsory licensing under the Agreement. Article 30 of the TRIPS Agreement provides:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Under Article 31, TRIPS Agreement provides an exception to the monopoly rights of patent owners (Holmer, 676). Instead of listing or defining situations in which compulsory license may be granted, it only sets out certain conditions for the issuance of non-voluntary license. Leaving the matter to the signatory states, TRIPS Agreement imposes safeguards to avoid abuse of rights. The specific terms therefore vary from country to country. The signatory states decide each case of granting a compulsory license on case-by-case basis. It would be against the essence and spirit of Article 31 of TRIPS Agreement if a person becomes legally entitled to get a compulsory license automatically upon fulfillment of certain conditions (Jain, 2009).

There is a condition that proposed user must have made reasonable commercial efforts to negotiate with the owner of the patent for permission to use the patent for a reasonable period of time (TRIP Agreement, Article 31(b)). However, this condition of prior negotiation with

<sup>8</sup> TRIPS Agreement, Article 28(1)(a).

<sup>9</sup> A parallel import is a non-counterfeit product imported from another country without the permission of the intellectual property owner. Parallel imports are often referred to as ‘grey product’. The practice of parallel importing is often advocated in case of software, music, printed texts, and electronic products and occurs for several reasons. It involves bringing in products from a third party in another country at relatively inexpensive price. The companies set different prices for the same product in different countries. The purchaser from a third party other than the manufacturer can take advantage from this fact. For instance, according to a study in 1998, the price of Smithkline Beechman’s version of Armoxil was \$8 in Pakistan, \$14 in Canada, \$16 in Italy, \$22 in New Zealand, \$29 in the Philippines, \$36 in Malaysia, \$40 in Indonesia, and \$50 in Germany. Certainly, the actual production cost is same for any market but the logic of price difference is to allow an elevated price to recover costs of research and development from the developed world. There may be various other reasons for price difference in different countries. For more details, visit <[http://en.wikipedia.org/wiki/Parallel\\_import](http://en.wikipedia.org/wiki/Parallel_import)> [ accessed 11date April, 2012].

the owner of the patent may be dispensed with in the cases of national emergency, or situations of extreme urgency, or for public non-commercial use.

The TRIPS Agreement makes a provision that the owner of the patent must be provided an adequate royalty as a matter of right (TRIP Agreement, Article 31(h)). Remuneration is decided on the case-by-case basis depending on the economic value of the authorization. In order to determine whether or not any decision of granting a compulsory license was legally valid and to provide an opportunity to the patent owner to prevent abuse of his right, TRIPS Agreement obliges the signatory states to a judicial review or other independent review (TRIP Agreement, Article 31(i)). The reviewing authority must be a higher one having the power to reverse, vary or annul the original decision of the license granting authority.

There is also a provision in the TRIPS Agreement which allows compulsory license in the case of dependent patents. "A dependent patent is one that can be used only after infringing an earlier existing patent." Consequently, both parties cannot make effective use of the innovation; invention of the second party violates patent of the first party and first party is also barred from using the second party's improved innovation. Therefore the improved invention would not be used if the parties fail to reach a licensing agreement. As a result, the community would not be able to reap the fruits of the innovation. Compulsory licensing provisions may be invoked to force the parties to either allow use of the patent after receiving remuneration agreed upon between the parties or cross-license their patents to ensure working of the patent (Yosick, 2001).

It must be noted that an extended period of time was granted to the developing and least developed countries to conform to TRIPS Agreement. An extended period up to January 1, 2000 was given to developing countries during which they were not required to conform to most of the provisions of the TRIPS Agreement. The least developed countries were given an initial transition period up to January 1, 2006. In November 2005, however, the WTO member countries agreed on further extension until July 1, 2013, or to date an underprivileged state is no longer included in the category of least developed countries, if that occurs before the end of the deadline (Jenkins, 2006). A further extension in the deadline until January 1, 2016 was given to the least developed countries by the TRIPS member nations (Bird, 2009). This, however, remains a fact that the least developed countries despite being lawfully allowed to manufacture generics until 2016, cannot do it realistically owing to the fact that they have no manufacturing capacity.

However, for pharmaceuticals and agricultural chemicals, the TRIPS member nations that were yet to provide patent protection on January 1, 1995 were under two obligations. Firstly, these countries were under an obligation to receive patent applications from inventors from January 1, 1995; they could, however, delay their decision to grant or not to grant patent until the end of the extended period. The aforementioned obligation is under article 70, paragraph 8 of the TRIPS Agreement which is also called 'mailbox' provision because it allows states to receive and store the applications. Secondly, if a state allowed marketing of such products during the extended period, the state was under an obligation to provide exclusive marketing rights to the patent applicant for five years, or until a judgment was made on the application for the grant of patent. This obligation was, however, subject to certain conditions. This provision is found in Article 70, paragraph 9 of the TRIPS Agreement (Jenkins, 2006).

Article 31(f) of the TRIPS Agreement puts an important limitation on the use of involuntary license. Article 31(f) of the TRIPS Agreement stipulates that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (TRIP Agreement, Article 31(f)). A narrow interpretation of this provision suggests that non-voluntary license can be used only for consumption of the product within the

country. It cannot be used for export of the product manufactured under compulsory license. As a consequence, the access to essential life-saving medications may remain an unattainable dream in the countries which lack pharmaceutical manufacturing capacity or ability to reverse engineer the needed pharmaceutical product.<sup>10</sup>

This provision has a twofold effect on developing and least developed countries. Firstly, the countries having insufficient or no manufacturing capacity cannot import drugs from countries that produce and export generic drugs, thus, denying availability of essential pharmaceuticals to their masses. Secondly, this restriction of the domestic market restricts the flexibility of developing countries which have the capacity to manufacture drugs to boost their economy by authorizing the export of compulsory licensed drugs. If a developing nation with enhanced technology such as India, Brazil, South Africa and the like has invoked compulsory licensing and is able to produce generic drugs, it still cannot supply the compulsory licensed drugs to other countries because of the domestic market limit provided in the Article 31(f) (Durojaye, 2011).

According to another interpretation of Article 31(f), the purpose of this provision may not be to prohibit the grant of compulsory licenses for the purpose of exporting the products manufactured under compulsory license, but to put a limitation on such export; it may mean that compulsory licensed goods should not be allowed to be exported in competition with the owner of the patent (Lowenfeld, 2002). Article 31(f), however, remained an obstacle for underprivileged states to obtain affordable generic medicines from the developing countries which have the capacity to manufacture cheaper generics.

The controversy between developed and poorer countries with regards to interpretation of Article 31(f) is indicative of the fact that TRIPS provisions are not capable of exclusive interpretation (Jain, 2009). This issue of limitations put by Article 31(f) was raised at Doha, Qatar in 2001 (Janodia et al., 2008). However, compromise between developing and developed countries in this regard could be reached in 2003 and was adopted in WTO General Council's Decision.

Taken together, TRIPS provided relatively stringent worldwide norms of patent protection which best suited the advanced countries and research based pharmaceutical industry (Reichman, 2009). No doubt, TRIPS Agreement contains safeguard provisions for developing and underdeveloped countries. However, implementation in practice of these provisions has never been easy for the developing and underdeveloped countries. The developing countries managed to obtain some rights at international level; due to various factors like a threat of economic and political pressure (for instance, withdrawal of foreign aid or tariff benefits (Shaffer, 2006), or even threat of trade sanctions from certain developed countries (Janodia et al., 2008), they have not been fully able to actually invoke and use these legal rights.

Ellen't Hoen, senior advisor on intellectual property for UNITAID<sup>11</sup>, aptly says that "while most countries' national legislation contains provisions for use of compulsory licensing, it does not mean countries use it in practice" (Chami & Kintu, 2011) Implementation of provisions regarding compulsory licensing is fraught with challenges, heated legal battles and

<sup>10</sup> The manufacturing capacity here means the capacity to manufacture a specific product, and not the general capacity to manufacture pharmaceutical products.

<sup>11</sup> UNITAID is an international facility for the purchase of drugs against HIV/AIDS, Malaria and Tuberculosis. It was founded in September 2006 on the initiative of Brazil and France. The organization's principal strength is the negotiation of low prices for drugs on the basis of its strong financial means. For details visit <<http://www.unitaid.eu/>> ,[accessed 16 April, 2012].



multiple litigations and is severely opposed and criticized not only by the developed countries but also by pharmaceutical companies.

Tedious and cumbersome procedure to obtain a compulsory license is another reason for rare use of compulsory licensing provisions. If a country wants to avail TRIPS flexibility of compulsory licensing, the judicial and administrative procedure may take nearly three years to obtain the license (Udupa, 2006).

It is pertinent to note that though the provisions relating to non-voluntary licensing are safeguard provisions, Article 31 of TRIPS permits all WTO member countries to issue non-voluntary licenses. Its application is not restricted to least developed or the poorest countries (Outterson). Practically, in most of the developed countries, general compulsory licensing provisions are rarely invoked. According to a study conducted a decade ago, Switzerland has never invoked compulsory licensing provisions; Japan has invoked eight times since 1960; France invoked three times since 1953, Canada invoked general (non-pharmaceutical) compulsory licensing provisions eleven times since 1935. Compulsory licenses are granted more frequently in countries which in their national laws provide for special compulsory licensing provisions for pharmaceutical and food patents. (Gottschalk, 22). Even where compulsory licensing provisions are rarely or never used, it is reasonable to assume that the presence of such provisions has significance in the patent system. Owing to the threat of compulsory licensing, patent owners negotiate licenses that they would otherwise refuse to negotiate.

### **Doha Declaration on TRIPS Agreement and Public Health**

Discussion relating to public health was initiated in the TRIPS Council by African Group; many other developing countries facing similar problems also joined the discussion and supported African Group. Advanced countries had a difference of opinion with the third world countries. Based on the discussion, two different drafts were prepared; one draft was submitted by the U.S, Canada, Switzerland and some other advanced countries; another draft was submitted by the third world countries (Kongolo, 2003). The draft submitted by developing countries was adopted as Declaration on TRIPS Agreement and Public Health, with some amendments, during the fourth Ministerial Conference (a meeting of the world's trade ministers) of the WTO in Doha, Qatar in November 2001 in order to deal with the issues of public health, especially the issues resulting from epidemics like tuberculosis<sup>12</sup>, malaria and the like and the global concerns like HIV/AIDS (Jain, 2009). The members agreed that TRIPS should permit WTO member countries to take measures to protect the health of their citizens (Jenkins, 2006).

The Doha Ministerial Declaration, a statement of intent (Mathews, 2012), recognized a collective obligation to improve access to drugs for all (Abbott & Reichman, 2007) and affirmed the right of nations to use the safeguards provided under TRIPS to meet public health concerns. It declared that each member has not only the right to grant compulsory license but also to determine grounds for the grant of license and to determine what constitutes national emergency (Sterckx, 2004). Moreover, it stated that public health crisis can represent a national emergency (Barton, 2004). Paragraph 6 of the Declaration<sup>13</sup>

<sup>12</sup> Paragraph 1 of the Doha Declaration mentions HIV/AIDS, tuberculosis, and malaria. However, it is argued that Paragraph 1 of the Doha Declaration should be interpreted broadly and generously to cover other important diseases.

<sup>13</sup> Paragraph 6 of the Doha Declaration runs: "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 report to the General Council before the end of 2002".

Full text of the Doha Ministerial Declaration is available online at

doi:[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm), [accessed 12 april, 2012].

expressly acknowledged the issue faced by the WTO member countries having no capacity to manufacture generic drugs due to the restrictions put by Article 31(f) of the TRIPS Agreement. Doha Declaration allowed member nations to take possible steps to protect public health including import of the needed drugs from other countries that had the ability and willingness to help if patent holders of pharmaceutical products had no objection (Reichman, 2007) The Declaration, under Paragraph 7, also extended transition period for least-developed countries to January 1, 2016 (Kongolo, 2003).

Taken together, although the purpose or intention of the Doha Ministerial Declaration was not to amend the TRIPS Agreement in any considerable manner (Correa, 2004) but to clarify and interpret what was already stipulated in the TRIPS Agreement (Vandoren & Eeckhaute, 2003), it was a victory of the developing world against the advanced world and the research-based brand-named pharmaceutical industry. Poorer countries won important concessions through persuasive moral arguments of third world leaders and AIDS activists, bargaining tactics, and effective strategic focus. Anthrax scare of 2001 also contributed to some extent in achieving greater latitude on non-voluntary licensing because the U.S –one of the staunch opponents of compulsory licensing- considered breaking patent of Bayer and used threat of compulsory license (Cahoy, 2007) as a means of negotiating a lower price for Cipro, an anthrax antidote (Santoro, 10).

### **WTO General Council's Waiver Decision**

Doha Declaration allowed third world countries lacking industrial capacity to manufacture drugs to import the needed drugs. But it left one important issue unsolved. If a poorer country wishes to import generic drugs produced under compulsory licensing, Article 31(f) of the TRIPS Agreement, which puts a condition of the domestic market, does not allow producers of the generic drugs to export the same (Abbot & Puymbroeck, 2005).

Though consensus could not be reached on this issue, at least it was agreed in the Doha Ministerial Conference that a problem existed (Ho, 2011). Doha Declaration, under Paragraph 6, instructed the Council for TRIPS to find an expeditious solution to the problem faced by the poorer countries and report to the General Council before end of 2002. Main issue was whether or not countries having manufacturing capacity should be allowed to manufacture needed drugs under compulsory license and then export the same to least-developed countries lacking manufacturing capacity of their own. (Kongolo, 2003).

While discussing export strategies in the TRIPS Council a new issue emerged when a draft was proposed by the President of the TRIPS Council stating that Doha Declaration was not confined to only HIV/AIDS, tuberculosis and malaria. The United States refused to accept the proposal arguing that expansion of the scope of disease was an attempt to override drug patents. Developing countries, on the other hand, were of the view that the U.S. was trying to undermine the Doha Declaration by attempting to limit its scope (Sterckx, 2004). Paragraph 1 of the Doha Declaration is not limited to specific diseases or medicines and is broad enough to include even vaccines (Reichman, 2003). To confine the flexibility to listed diseases is inconsistent with the actual wording of Doha Declaration which takes into account public health problems in general (Ho, 2011).

Due to conflicting interests of the developed and developing countries, finding an agreeable solution to this dilemma was quite difficult. On August 30, 2003, as a result of two years of substantial international discussion and negotiations, a compromise was reached and adopted as Decision of the WTO General Council.<sup>14</sup> The decision is also referred to as “the

<sup>14</sup>The General Council, which is composed of representatives of all WTO member countries, exercises the functions of the Ministerial Council when the latter is not in session, as well as other functions assigned to it under the WTO Agreement.

implementation decision” (Das, 2005). It is also referred to as “Perez Motta text” after the then Chairman of the Council for TRIPS Eduardo Perez Motta of Mexico (Eeckhaute, 2003). This Decision waives two provisions of Article 31 of the TRIPS Agreement viz. paragraph (f) which put ‘domestic market’ limitation on the generic drug exporting countries, and paragraph (h) which is regarding adequate remuneration requirement. It was agreed that in special circumstances of public health crisis, a country would be allowed to grant compulsory license to another country –having manufacturing capacity- to manufacture and export the needed drug (Kongolo, 2003).

The waiver, however, is not absolute. It can be used to the extent necessary and subject to certain conditions. The state intending to use this waiver must be an eligible importing country i.e. either least developed or a developing country with insufficient drug manufacturing capacity. Moreover, the eligible importing country (other than LDCs) must give a general notification (Annex to the Protocol Amending The Trip Agreement, Article 31 bis) of intent to use the mechanism to the Council for TRIPS along with information like name and expected quantity (Article 31 bis, 2(a)(i)) of the product needed and a confirmation (Article 31 bis, 2(a)(ii)) that the country lacks manufacturing capacity (Abbott, 2005). The Council will review the notification before giving approval. In cases of an outbreak of an epidemic, this condition may cause delay in the availability of the required drug. Furthermore, the quantity of drugs that can be manufactured for export under a non-voluntary license is subject to restrictions and can only be exported to the country lacking manufacturing capacity and facing public health crisis (Das, 2005). There is a further condition on the country wishing to export compulsory licensed drugs that it would do so on a “non-commercial basis” (Durojaye, 2011).

Similarly, the exporting country shall also notify the “Council for TRIPS” of the issuance of the compulsory license along with some information like the product for which compulsory license has been issued, name and address of the licensee, the quantity of the product<sup>15</sup>, duration of the compulsory license, and the country to which the product is to be supplied (Durojaye, 2011). The exporting licensee is also required to provide the aforementioned information on a website (Article 31 bis, 2(b)(iii)).

In order to prevent trade diversion or misuse of the Waiver, the products manufactured shall be distinguished rather clearly identified from the generics which are manufactured for domestic use. The distinction can be made through distinguishable packaging or coloring or special color or shape of the product itself to distinguish it from other products in the normal supply chain (Abbott, 2005). The exporting member is required to maintain a meticulous account of pharmaceuticals prepared under the compulsory license and the importing member is required to take all possible measures to make sure that the pharmaceuticals manufactured under compulsory license are not re-exported (Das,2005). Re-export is, however, allowed among members of a regional trade agreement (Mathews, 2012).

This interim Waiver -subject to the aforementioned conditions for both the importing and the exporting countries- was adopted as a temporary solution until the amendment of TRIPS Agreement and tried to address the initial problem caused by Article 31(f). It was heralded as a success because it addressed a grave concern of the third world countries having no manufacturing capacity of their own. It, however, seems to have created more hurdles because the procedure involves bureaucratic obstacles for third world countries that want to avail the exemption. Though the mechanism is to provide prompt solution to emergency situations of public health crisis, numerous procedural requirements to ensure that the

<sup>15</sup> The objective of this condition is to discourage production and export of the product to third country markets on commercial basis.

flexibility is not abused and to avoid trade diversions make the mechanism costly and unnecessarily burdensome. The system can be made to work through political determination, coordinated planning, and skillful lawyering which third world countries normally lack.

### **Article 31bis: An Amendment to the TRIPS Agreement**

On December 6, 2005, shortly before Hong Kong Ministerial Conference, the WTO member states agreed to amend the TRIPS Agreement to incorporate the WTO General Council's waiver decision as a permanent part of the TRIPS Agreement (Thapa, 2011). The aforementioned Doha Paragraph 6 implementation agreement was submitted to the WTO and was adopted as Article 31 bis in December 2005 (Cahoy, 2007). The 6 December 2005 amendment in the TRIPS Agreement is based on the WTO General Council's Waiver Decision. Although the wording of the amendment is different, it contains almost the same elements as the Decision. Five paragraphs of Article 31bis are compatible with the text of paragraph 2, 3, 6, 9 and 10 of the Waiver Decision (Durojaye, 2011). The purpose of this amendment was to address the limitations and confusion surrounding Article 31(f) of the TRIPS Agreement. This amendment embodies a compromise because no stakeholder was able to achieve all of its objectives (Abbott & Reichman, 2007).

To use this mechanism, the WTO member states need to amend their national laws to permit issuance of these special licenses. For poor countries, this seems a difficult task to undertake in view of strong pharmaceutical lobby (Thapa, 2011). Article 31bis still leaves some ambiguities, for instance, it does not state formula for determining adequate remuneration. This issue of remuneration will trigger debate and even litigation whenever a country attempts to use the mechanism (Gumbel, 2008). Moreover, unnecessary administrative hurdles make Article 31bis a less effective provision for third world countries. It does not provide administratively simple, straightforward and expeditious solution to the problem. An administratively complex, expensive and time-consuming regime involving back-to-back compulsory licenses (Abbott & Reichman, 2007)<sup>16</sup> was adopted because the United States and the European Union rejected the simple and straightforward solution suggested by the developing countries (Abbott & Reichman, 2007).

The oral statement made by the WTO General Council Chairperson put further limits on the use of this mechanism. According to this statement the flexibility could be used only in circumstances of extreme urgency and not as "an instrument to pursue industrial or commercial policy objectives". The legal status of the statement made by the WTO General Council Chairperson is not clear as these words are not used in text of the amendment. It makes the Waiver more ambiguous and complex.

The provision had to be ratified by two thirds of WTO members (Seidenberg, 2008), but it witnessed lukewarm international response not only from developed countries but also from developing and least-developed countries. The developed countries were primarily against this flexibility that was against the interests of their pharmaceutical industry, but they had to agree because the negotiations between interested stakeholders failed to find any other mutually agreed solution (Shirsat, 2011). They had serious reservations that the flexibility would be abused by the third world countries and it would promote a culture of disrespect for IPRs (Thapa, 2011). Their reluctance to ratify the provision reflected the same. The poorer countries also hesitated to ratify the amendment owing to lobbying and pressure of advanced countries and multi-national pharmaceutical companies.

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<sup>16</sup> Double compulsory license does not require the remuneration to be paid twice. It is required to be paid only in the country of export; the importing country is exempted keeping in view the economic circumstances of LDCs.

An examination of TRIPS provisions reveals that compulsory licensing is of two types; normal or basic compulsory license under Article 31 of TRIPS and special Doha style compulsory license under Article 31bis of TRIPS where 'domestic market' condition is waived. If a country has adequate manufacturing capacity to make generic versions of needed patented drugs under compulsory license or the country is able to acquire the needed patented drug at a reasonable price directly from the patent holder or from any humanitarian organization, then it is not allowed to resort to special Doha style compulsory license (Berne Convention for the Protection of Literary and Artistic Works, 1979). Special mechanism is therefore reserved for special circumstances where the state is facing public health emergency and lacks manufacturing capacity of its own.

It is pertinent to note that though TRIPS provided the flexibility and Doha Declaration 2001, Waiver Decision 2003, and 2005 Amendment reaffirm WTO member country's right to issue compulsory license, the flexibility has been rarely used (Thapa,2011)<sup>17</sup> by the poorer countries owing to numerous factors. Though the WTO General Council's Waiver Decision provided interim solution in 2003 that was made part of TRIPS in 2005, not even a single country tried rather dared to invoke this mechanism (Shirsat, 2011). The factor which bar poorer countries from availing the flexibility include fear of economic consequences in the form of loss of foreign direct investment, countervailing pressures by pharmaceutical industry and governments of powerful states, fear of trade sanctions, reactions and retaliations of developed countries, lack of technical expertise, high costs of patent litigation, bilateral and regional TRIPS-Plus free trade agreements, and various other factors. A detailed discussion on these factors is beyond the scope of this work, but it has been observed that the ability to use compulsory license greatly depends on economic and political strength of a country.

## CONCLUSION

Compulsory licensing is an effective 'cost-cutting' and 'access-assuring' tool in the hands of developing and under developed countries which they may use to circumvent the patent laws remaining within the flexibilities provided by the WTO. It can be used to strike a balance between interests of patent holder and public and to mitigate the restrictive effects of patent holder's monopoly rights.

Though compulsory licensing provisions have been part of patent laws of many countries for centuries, the issue of grant of licenses came to limelight after outbreak of pandemics like HIV/AIDS. The issue of access to needed drugs was discussed at length to find a mutually agreed solution to the problem. While dealing with issues involving conflicting interests, balance of interests is the most ideal approach. The purpose of countless negotiations amongst the WTO members since 2001 was to strike a balance between interests of the patent owners and LDCs' right to public health. Despite declarations, decisions, and amendments, LDCs are still not able to guarantee their citizens access to necessary drugs owing to numerous factors.

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<sup>17</sup> The mechanism provide under Article 31bis was used for the first time in 2007 when Rwanda informed WTO of its intent to use the flexibility. Canada provided the needed drug TriAvir to Rwanda under first compulsory export license. In 2008, Nepal became the second country that attempted to use the provision. Natco Pharma, an Indian generic manufacturer, responded in this case to provide needed drug Erlotinib (Tarceva) to Nepal. This attempt, however, failed because it triggered litigation between Natco Pharma and Roche Pharmaceuticals. Natco was not able to obtain compulsory license as it decided to withdraw its application for grant of compulsory license before the case was decided. This underutilization of the mechanism shows that it is burdensome and there are barriers which prevent its use.

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