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COMPULSORY LICENSING OF PATENTED PHARMACUETICALS UNDER TRIPS: A BLESSING FOR DEVELOPING COUNTRIES

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Abstract
Patents are granted to incentivize innovation by conferring exclusive rights upon inventors, particularly in capital-intensive sectors such as pharmaceuticals. However, this exclusivity may conflict with public interest when patented products—especially life-saving medicines—are priced beyond the reach of large segments of the population. To address this concern, the TRIPS Agreement incorporates the mechanism of compulsory licensing under Article 31, permitting the use of patented inventions without the consent of the patent holder under specified conditions. This paper examines the concept of compulsory licensing as an exception to patent exclusivity, analyzing its legal framework under TRIPS and its significance for developing and least-developed countries. It explores the scope, subject matter, and conditions for the grant of compulsory licenses, emphasizing the flexibility accorded to WTO members in determining grounds such as public health emergencies and national necessity. The study highlights how compulsory licensing serves as a vital tool to balance private patent rights with public welfare by fostering competition, reducing drug prices, and improving access to essential medicines. Ultimately, the paper underscores compulsory licensing as a crucial instrument for achieving equity in global healthcare while remaining consistent with international intellectual property obligations.
Keywords: Compulsory Licensing, TRIPS Agreement, Pharmaceutical Patents, Access to Medicines, Public Health in Developing Countries

INTRODUCTION

A patent is a right granted to a person who has invented a new and useful article or an improvement of an existing article or a new process of making an article. Patents are granted as an incentive for pharmaceutical companies to invest in drug development, as it is an expensive venture that requires millions of dollars being spent without returns. And when a miracle drug is finally produced, patenting and exclusive manufacturing rights allow these companies to make sufficient profits to justify their previous investments, as well as to invest in future innovations. Thus patent is an exclusive right available with the inventor or in the case of companies the originator. But, there is an exception in the form of compulsory license wherein the patented object may be used without authorization of patent holder.

"Compulsory licensing 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". Article 31 of TRIPs agreement deals with the concept of compulsory licensing. Compulsory license is therefore interference in the exclusive rights of the patentee of the invention. iArticle 31 provides for a distinct balancing act, establishing a government's right to issue compulsory licenses,' while attempting to safeguard the rights of the patent-holder whenever possible. Also this article allows the members to determine the grounds for granting compulsory licensing. This particular article of TRIPs agreement has greatly favored the developing nations as it allows the

governments of these nations to grant compulsory licenses in circumstances when it becomes necessary to do so for addressing public health emergencies. In addition, a close study shows that the article provides certain specific grounds for grant of compulsory licenses, but it not put any limits or restricts these grounds and they may depend and vary according to nations. Compulsory licenses can be taken like a breath of relief for developing countries which are unable to cope with the high costs of patented products, especially pharmaceutical products as many of these are life-saving drugs. Compulsory licensing engenders competition, thereby reducing prices of medicines. Each WTO member also has the right to determine what constitutes a national emergency or other circumstances of extreme urgency to issue compulsory licensing.

I. COMPULSORY LICENSE

A compulsory license permits a nation (or a third party authorized by the nation) to use a patented invention to use without the permission of the patent owner in exchange for payment of a government-determined royalty. The license is compulsory in that it is forced upon the patent owner. In addition the patent owner is required to accept the government's compensation which is likely far less than the patent owner could obtain in a free market. A compulsory license, however, never "breaks" a patent, as the patent is still valid and in force. Thus, the patent owner can continue to exclude all others besides the government-authorized licensee from the patented invention.ii

As applied to international intellectual property rights, it allows governments to grant licenses for patent use in situations where the patent-holder is either not using the patent within the country or is not using it adequately. Although compulsory licensing is not a new concept, it recently has received considerable attention as pharmaceutical companies and activist groups seek to advance their respective political agendas over the right to drug access for lifethreatening diseases. When governments issue compulsory licenses, the result is often a sharp decrease in prices, similar to the introduction of other competitive forces like generic drugs. For this reason, many developing nations argue for the right to issue compulsory licenses for pharmaceuticals that are normally very expensive for their citizens.

Any nation any issue a compulsory license consistent with TRIPs because TRIPs imposes no limitations on the type of country that can utilize this procedure. A country of any level of economic status (as well as any type of government) is equally entitled to use a compulsory license under TRIPs. Compulsory licensing is a fundamental tool that developing countries may use in certain conditions to ensure that poor people have access to necessary medicines. This measure may produce positive social effects. Compulsory licensing engenders competition, thereby reducing prices of medicines.iii The TRIPs agreement does not refer to the widely accepted notion of compulsory licenses. On the other hand, it provides for a certain set of conditions and set of limitations for granting of such licenses. Article 31 provides as:

Other Use without Authorization of the Right Holder

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:

- Authorization of such use shall be considered on its individual merits;
- 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 a 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;
- 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 noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- Such use shall be non-exclusive

- Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- 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;
- the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- 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;
- 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;
- 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;
- 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:
- 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;
- the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
- the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent. " iv

II. SUBJECT MATTER OF COMPULSORY LICENSE

Under TRIPS, any patent may be subject to a compulsory license. Although there are a dozen subparts to the relevant TRIPs provision concerning compulsory licensing (Article 31), none of these contain provisions that limits the type of inventions that may be licensed. The 2001 Doha Public Health Declaration lends additional support to this conclusion. Scholars generally consider this document an appropriate interpretative tool. Importantly, Doha Declaration clearly affirms "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted."

Of particular importance to the issue of access to medicine is that any and all drug patents may be subject to compulsory license under TRIPs because no subject matter is excluded. Of course, nations need not permit any compulsory license at all, but, if they do, drug patents are definitely within the range of inventions that may be subject to them.v

This is another relaxation provided for in TRIPs that goes a long way in helping developing countries as they can grant compulsory licenses according to their needs without having to worry about any repercussions. In the case of patented pharmaceuticals which are very expensive and usually out of the reach of most of the population in developing countries and least developed countries, this inclusion of all subject matter for grant of compulsory license in accordance of the needs of such nations, proves to be very beneficial.

III. CONDITIONS OR GROUNDS FOR GRANT OF COMPULSORY LICENSES

Article 31 allows members to determine the grounds for granting compulsory licensing. Article 31 sets forth a series of guidelines member nations must respect prior to implementing compulsory licenses.

Section (a) notes that authorization of compulsory licensing should be considered on its merits. This means that decisions cannot involve sets of patents defined by its subject matter, title-holder or otherwise. However, this would not be an impediment to establish parameters for granting of compulsory licenses regarding, for

instance, certain categories of products that are needed to express a specific need. In addition, Article 31 (a) would not prevent a member from authorizing the use of several patents relating to a given product or process. vi

Section (b) conditions the granting of compulsory licenses on an initial attempt to obtain authorization by the patent holder through commercial terms and failure to obtain an agreement within a reasonable amount of time. This provision makes compulsory a prior negotiation with the title-holder. The determination of what the 'reasonable terms and conditions' are is left to national laws. Article 31 allows, nevertheless, for exceptions in cases of :

- national emergency or other circumstances of extreme urgency;
- public non-commercial use;

licenses granted to remedy anti-competitive practices.

In the case of national emergency or other circumstances of extreme urgency, the title-holder should be notified as soon as reasonably practicable. In the case of government use, moreover, he should be informed when there are demonstrable grounds that his patent is or will be used.

Section (c) limits the use of the compulsory licensing scheme to the purpose for which it was initially authorized. This clause may imply the limitation of the license, both in terms of scope and of duration. However, noting will prevent a potential licensee from asking for and being granted a license covering all the claims of a patent and extending until its expiry. For a licensee that has to undertake investments in production or marketing it will be often essential to obtain a license for the lifetime of the patent.

Section (d) notes that the compulsory license will not be exclusive.

Section (e) notes that it will not be assignable. The only exception recognized to the above conditions is only that part of the enterprise or goodwill has exclusive power or is assigned, that uses it.

Section (f) prescribes that use of the license shall be predominantly for domestic market use.vii This limitation – which may not be applied in connection with licenses to remedy anticompetitive practices – implies that a compulsory license or government use cannot be given exclusively or principally for exportation. The vague wording used does not provide specific guidance as to when the domestic market is to be deemed 'predominantly' supplied. National laws may adopt different standards in this respect, based on sales value or volume. viii This condition is a little ambiguous as there was a difference in its interpretation by developing and developed countries. While developing countries took its meaning as implying that nothing in TRIPs agreement prevented members from granting compulsory incenses to supply foreign markets. On the other hand, other members i.e. majorly developed countries treated it as a barrier to such supply. This uncertainty led to the adoption of paragraph 6 of Doha Declaration. And this further led to the amendment to TRIPs agreement including Article 31bis to TRIPs agreement which incorporated WTO decision of 30th August 2003. It addresses the issue of countries having insufficient manufacturing capacity and cannot ensure access to medicines even if they granted a compulsory license, since they would not be able to find a source for their importation.

Section (g) authorizes use of compulsory licenses only during the time that the circumstances for its creation still exist, and "competent authority" shall have the power to review the continuation of the compulsory licenses.ix The essential problem is that the factors contributing to the legitimate need to issue compulsory licenses are not fully developed within the text of Article 31. Without clarity in the language, nations are likely to evade the issue of compulsory licensing, fearful of the unknown.x

Section (h) ascribes proper payment to the patent holder, based on the economic value of the compulsory licensing scheme.xi The word used is "adequate" which is not clarified but may be understood to mean that the title-holder should be able to obtain a remuneration comparable to what it would have obtained in a voluntary license. Another manner of treating is by taking into account factors such as the subsidies or other contributions that the titleholders eventually received to develop the invention, the degree to which the development costs have been amortized and R&D commitment of the patent owner.

Section (i) notes that the decision to authorize compulsory licenses is subject to judicial review and Section (j) explains that the payment to the patent holder is also subject to judicial review by a "distinct higher authority in that member".

Finally, Section (k) comments that special consideration should be given in cases where the patent holder is engaged in anti-competitive acts.xii

IV. INTERPRETATION OF ARTICLE 31 FAVOURING DEVELOPING NATIONS

Without expressly defining the perimeters of the categories in Article 31, there is great room for different interpretation of the ambiguous terms surrounding the issuance of compulsory licenses. Amidst the backdrop of multiple urgent problems present in developing nations, the leaders must develop a unique approach to compulsory licensing. Taking into account their domestic laws concerning intellectual property fights, it is realistic to expect that the actions of developing nations will support the immediate concerns of their population's needs in formulating a new policy. Developing nations are likely to argue for a broad interpretation to pave the way for easier implementation of compulsory licensing. The arguments of developing nations facing staggering health challenges support the idea of morality in international trade practices. Developing nations generally believe that the economic injury complained of by the pharmaceutical companies in developed nations should have no bearing on the right to receive adequate health care. For these nations, compulsory licenses should be available for any health concern where there exists a pharmaceutical capable of either curing or postponing the disease. Thus, they believe that the moral exception argument should dictate the broad use and implementation of compulsory licenses under the TRIPs Article 31. The justification for the developing nation's perspective would likely arise out of the exclusions noted in Article 27 of TRIPs. Article 27 provides exceptions for patents in cases where Members wish to protect public order and morality, including the protection of human life. In this case, the purpose for utilizing compulsory licenses for AIDS pharmaceuticals is as simple as saving lives. In fact, this was the position that the South African government adopted in the recent dispute. As mentioned earlier, the express purpose of the Medicines and Related Substances Control Amendment Act was to protect the health of the public. Thus, as phrased, it is impossible to divorce the Act's economic implications from its moral imperative.22

Due to the non-specific language employed in international instruments, national legislations decide the degree of flexibility in the conditions for compulsory licensing. Many terms have been left undefined, for example, 'public non-commercial use', 'national emergency', 'extreme urgency', 'adequate remuneration', etc. which can have varied interpretations. TRIPS provides no clear guidance on how nations are to implement these provisions. For example, while TRIPS specifies that remuneration shall be determined taking into account the economic value of the authorization, it nowhere defines 'economic value' nor prescribes a method to calculate it. TRIPS does not specify at what level a compulsory license can or should be authorized. According to Bryan Mercurio, four main areas which are not satisfactorily resolved are:

- the scope of diseases and products covered under the exception;
- countries that would be eligible to use the system;
- ensuring adequate remuneration; and
- safe-guarding the system against diversion of drugs into other markets.

The ambiguity in the provisions can serve as a tool to promoting access to drugs and can enable experimentation with different patent schemes to serve this cause. Under TRIPS, it is possible for developing countries to define the content of the standards imposed, the singular requirement of international law being that this is done in good faith. Developing countries should utilize this opportunity to tailor domestic legislation in a way that promotes local inventiveness by, for example, permitting lower standards of inventiveness, preventing broad claims, protecting improvements as separate inventions, employing a liberal test for nonobviousness, etc. Undefined words and phrases may be interpreted according to local requirements and may be flexibly applied. For example, Thailand authorized compulsory license for the drug Plavix under the provision for 'public non-commercial use,' under Article 31 of TRIPS, rather than the provision on 'national emergency or other situation of extreme urgency.' Developing countries should craft domestic legislation in a way that benefits their immediate societies. The fact that these loopholes can be exploited to the advantage of the developing countries is also evident from the pre-TRIPS situation. The heavy dependence on protection afforded by national legislation pre-TRIPS resulted in a number of disparities, but they actually benefitted the developing nations. They not only allowed for the possibility and right to tailor the patent system as per respective needs of the state, but also facilitated access to technology. Hence, a balancing act is possible through a careful policy making on administering price controls, setting royalties in compulsory licensing system, or determining length of domestic patent protection.

V. INDIAN LAW ON COMPULSORY LICENSING

The Patents Act, 1970, as amended in 2005, dedicates Chapter XVI to the, Working of Patents, Compulsory Licenses and Revocation. The Act clarifies that the limit of Compulsory Licensing covers patented products as well as patented processes. The Indian Patent Act gives a pointer to the objects of compulsory licensing and requires that while granting a compulsory license, the general conditions in the section have to be focused on the working of patents.

The Indian law provides for the grant of a compulsory license under Section 84, aiming to prevent the abuse of a patent as a monopoly and to make way for commercial exploitation of invention by an interested person. Under this section, any person can make an application for grant of compulsory license for a patent after a period of three years, from the date of grant of that patent. The grounds that may be vouched to apply for the same include:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied;
- The patented invention is not available to the public at a reasonably affordable price.
- The patented invention is not worked in the territory of India.

Section 89 too specifies and clarifies the general purposes of grant of the compulsory license as elucidated under Section 84. The purposes include:

- The patented inventions are worked on a commercial scale in the territory of India without any undue delay and to the fullest extent that is reasonably practicable; and
- The interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

Also, Section 84 (6) specifies that the Controller shall take into account the following factors while considering the application for Compulsory License:

- The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patent or licensee to make full use of the invention;
- The ability of the applicant to work the invention to the public advantage;
- The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted; and whether the applicant has made genuine efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.

Section 90 of the Act also empowers the controllers to settle the terms and conditions for compulsory licenses, which include financial concerns such as royalty and remuneration to the patentees.

Section 92A, puts forth the provision for export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector and in certain exceptional, to address public health issues. Such country has to either grant compulsory license for importation to the manufacturer of the pharmaceutical product or issue a notification for importation into that country. However, in the circumstances of National Emergency or Extreme urgency or public non- commercial use including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno deficiency virus, tuberculosis, malaria or other epidemics, to avoid any delay, the compulsory license will be granted, immediately under section 92 (3) under the terms and conditions that the articles manufactured under the patent shall be available to the public at the lowest prices.2

VI. BENEFITS OF COMPULSORY LICENSES FOR DEVELOPING NATIONS

In respect of developing countries, there are many advantages of granting compulsory licenses, namely:

Firstly, patents, especially on pharmaceuticals, are harmful to developing and underdeveloped countries lacking their own domestic and technical infrastructure; patents may become an impediment in economic

[2] Midha, Suchi & Midha, Aditi, *Compulsory license: Its impact on innovation in Pharmaceutical Sector*, 223 (International Journal of Application or Innovation in Engineering & Management, Vol. 2, Issue 6, June 2013) Available at www.ijaiem.org

growth of such countries and availability of necessities to population of such countries. Threat of non-voluntary licensing may be helpful in negotiating a reasonable price of the needed drug acceptable to both the patent owner and the government. Secondly, opposition of compulsory licensing by advanced countries may raise thoughts of "neocolonialism" because patent protection disproportionately favors advanced countries as developing countries have much fewer patents to protect. Thirdly, compulsory licensing of pharmaceutical patents sometimes becomes inevitable to save lives of the populace by ensuring accessibility of drugs at affordable prices; it can be used to break up monopolies and cartels, which are some of the abuses of patent rights. Fourthly, sometimes delay in development of important technology is caused due to deadlocks between the improver and the original patentee. Compulsory licensing can be used as an effective tool to resolve these deadlocks by pressurizing the original patentee to come to the terms of an agreement with the improver. It can therefore help in generating rapid technical progress. Fifthly, compulsory licensing becomes inevitable to deal with the situations of "patent suppression". By incorporating an effective mechanism of compulsory licensing, governments of developing countries may pressurize the patent holders to work the patent to maximum national advantage. Sixthly, compulsory licensing might be necessary in situations where its refusal may prevent utilization of another important invention which can be significant for technological advancement or economic growth. Seventhly, the proponents of compulsory licensing argue that compulsory licensing does not discourage research and development because the costs incurred on research are recovered from sales of the patented products in the advanced states of the world having stringent patent protection. Eighthly, it is argued that compulsory licensing plays a vital role in developing and fostering a local generic pharmaceutical industry. Lastly, apart from economic arguments, use of compulsory licensing to protect the public interest can be defended on social justice grounds; strict adherence to patent protection can hardly be recommended at the cost of human lives.[xiii]

VII. DISADVANTAGES OF GRANT OF COMPULSORY LICENSING

The most important con of grant of compulsory license as advocated by developed nations is that they adversely affect innovation. Critics of compulsory licensing further argue that over 90 percent of the drugs included in the Essential Drugs List published by the World Health Organization (hereinafter WHO) are not protected by United States patents. Moreover, compulsory licenses may raise safety concerns; the consumers of counterfeit products are at risk because the inferior quality unapproved generics may contain many dangerous impurities. Furthermore, there are many diseases which are unique to the third world countries. If patent protection is ensured in these countries, it would provide an incentive to multinationals to invest in the research to investigate these diseases which would otherwise remain incurable; multinational pharmaceutical companies carry out investment on research and development after considering the potential financial gain. Uncertainty about patent protection may halt search for new drugs much needed by third world countries. Absence of business friendly legal climate may discourage patent owning firms to start any new ventures in a country that makes use of compulsory licensing provisions. In addition to this, use of compulsory license may cause trade friction with the countries which produce patented drugs. Actual occurrence of compulsory licensing is not necessary to cause this loss; sometimes even the fear of compulsory licensing has an adverse effect on trade relations between countries. Moreover, the growth of local industry in developing countries is heavily dependent on investment that comes from outside the country. The decision of a government to grant compulsory licenses may lead to the loss of foreign direct investment. In order to protect their products from compulsory licensing, the pharmaceutical companies may find a different venue for their clinical trials. Therefore, a country may lose a potential source of economic growth by issuance of compulsory licenses. Furthermore, as a result of weak intellectual property regime, a country becomes less competitive, and brain drain is an obvious result. It becomes nearly impossible for such countries to retain their human capital; the talented scientists and researchers leave the country in search of better opportunities elsewhere in the world. Another important argument against compulsory licensing of pharmaceuticals is that the pharmaceutical companies normally lower prices, even to the extent of mere cost of production, of their much needed products in the least developed countries on humanitarian considerations.

VIII. COMPULSORY LICENSING – A THREAT TO INNOVATION?

At the outset, it is important to understand that effective use of compulsory licensing provisions or otherwise limiting patent rights will not completely curb innovation. Like developed nations, it is the goal of developing nations not to prevent but to promote the development of a flourishing pharmaceutical industry. Facilitating entry of generic products has in fact a positive impact on the development of domestic pharmaceutical industry in developing nations. Since technological demands of producing an already patented product are substantially less than undertaking research to create the patented product, less technologically sophisticated enterprises are able to produce generics. This provides an opportunity for fledgling companies in the developing world with sufficiently large domestic markets. For example, India, Argentina and Turkey have developed flourishing domestic pharmaceutical industries in the last three decades, due to policies of granting no pharmaceutical product patents (Argentina and Turkey) or imposing significant limits (India). Even in Brazil, lower patent protection facilitated industrial development.10 Compulsory licensing allows generic manufacturers to lower their marginal costs by expanding their demand pool, that is, by selling in other countries. Compulsory licensing schemes can be utilized in many third world countries for a common market approach. For example, East African nations could develop an integrated compulsory licensing and generic drug manufacturing and marketing approach. Third world countries not adopting strict patent policies have proven more innovative than others who have. It was through imitation that virtually every industrialized country built up its technological capacity. For promotion of research and development, third world countries require a science and technology infrastructure—a national system of advanced education and research—which a patent system cannot provide. Many industrialized countries developed pharmaceutical industries in the absence of patent protection. Besides, development of a sound domestic industry is much more beneficial than relying on multinationals. Domestic companies are more likely to adapt and modify technologies for local use. They promote local technological infrastructure development and favour generics. Profits accumulated by domestic companies stay within the country. xiv

The effects of compulsory licensing are to increase competition, to supply the market, and possibly to reduce prices. It is considered, in certain cases, that access to the invention should have priority over the private interest of the patent-holder and his exclusive right to exploit it. In developing countries, the patent has a marginal effect in terms of encouraging innovation, with extremely negative consequences for social well-being. The analysis of the costs and benefits of compulsory licensing is essential to use it as an instrument to create public policies by developing countries. Discouraging innovation is regarded as the main risk caused by compulsory licensing. The prospect that profits obtained from exploiting the patent could suddenly disappear would reduce the incentive to invest in innovations. It would be more beneficial to profit from investments made by third parties than perform one's own research to develop a new product or productive process. It is also stated that inventors have little incentive to patent their inventions, and would rather keep them as industrial secrets . Up until now, there have been no empirical data to prove the thesis that compulsory licensing has reduced investments in R&D in developed and developing countries. Scherer concluded that compulsory licensing granted in the 40s and 50s did not limit the great progress of the North American economy in that period. The need to continue to be competitive in the future encouraged the industry to put a long-term investment plan in practice, even when compulsory licensing was granted. Shien believes that compulsory licensing affects innovation when the industry can anticipate its concession or when the market in which it will be applied shows great economic importance. The foreseeability of compulsory licensing can affect investments in markets of great importance. However, there will be reduced impact on innovation if royalties are paid according to the existing criteria for the licensing of products on the market. Moreover, it must be remembered that the market in developing countries represents little profit for the pharmaceutical industry. Data available show that the market in developing countries contributes less than 20% of the profits obtained by pharmaceutical companies. This percentage is reduced even more if the importance of each individual market is analyzed. Only a small share of the population, usually no more than 10%, has ample access to pharmaceutical products in developing countries. Adequate use of compulsory licensing in these countries would have extremely little impact on investments in R&D.

The argument proceeds, having shorter patent periods by granting compulsory licenses is not just inequitable but also stifles innovation in the long-term. However, critics point out that even assuming that the prices offered by drug companies are not solely profit-driven, these allegations no longer hold water. It has been proven that the biggest driving factor for innovation is, in fact, markets. Thus, given that drug companies'

point of focus is on developing the most saleable drugs rather than the most needed ones, longer patents will only serve to enhance their profits. In fact, studies have shown that barring a few exceptional circumstances, there is no link between compulsory licensing and sluggish innovation rates or a decline in R&D. One has to look at the practical considerations of using compulsory licensing, which allow legal suppression of drug patents, as a means of making drugs more affordable in poor countries. Compulsory licensing, a feature of the new TRIPs Agreement has been historically used by countries to serve the greater good of society by restricting the monopoly rights of patent holders. This initiative is neither in conflict with TRIPs, the cornerstone of the WTO's provisions on intellectual property, nor any multilateral agreement on trade or intellectual property. Lower prices in developing countries would not be a serious threat to research and development funding because they account for a small percentage of overall pharmaceutical sales.xv

IX. CASE LAWS

1. NATCO PHARMA LTD. V. BAYER CORPORATION

Natco's application for a compulsory license for Nexavar was filed before the Controller

General of Patents ('the Controller') in 2011, under §84(1) of the Indian Patents Act, 1970 ('the Act'). In a judgment delivered on March 9, 2012, the Controller granted the license to Natco, against which Bayer appealed to the IPAB. In the interim, Bayer sought a stay on the

Controller's decision but this was denied by the IPAB. Even though the IPAB's decision was largely the same as that of the Controller, they differed slightly on some aspects. Referring to the Report of the Justice N. Rajagopala Ayyangar Committee, TRIPS and the Code of Federal Regulations of the United States, the IPAB approached the dispute from a public health perspective in the context of the right to life under Article 21 of the Constitution of India, 1950 and flagged the major issues based on the three-pronged test laid out in §84(1) of the Act.

Dealing first with the technical and procedural hurdles, the IPAB dismissed Bayer's contention that they had not been heard or given notice before arriving at a prima facie determination under §87(1) of the Act. Glossing over the issue in a short paragraph, the IPAB clarified that the principle of audi alteram partem would come into play only after the Controller decided, on a prima facie satisfaction, that the case needed to be heard. Therefore, the question of serving notice for making the prime facie determination did not arise at all.

Next, they addressed the question of Natco's attempts to obtain a voluntary license. They disagreed with Bayer's contention that Natco had not made reasonable efforts to negotiate the terms of a potential license, categorically stating that once Natco's request was rejected as per §84(6)(iv), there was no obligation to make further attempts to do so. Although this finding of the IPAB seems to have been reasonable with respect to the particular facts of this case, its application elsewhere could be problematic. The order itself recognises that even though the Controller had found the language of the letter sent by Natco to be harsh, the IPAB did not believe there was any need for niceties. This line of reasoning not only seems to lower the obligation to attempt to obtain a voluntary license but also significantly impacts the nature of communication that could be construed as an 'attempt'. It could allow compulsory license applicants to successfully employ the threat of a potential compulsory license as a bargaining chip for obtaining a voluntary license on favourable terms. On the flip side, this will force patent holders to make reasonable and concerted efforts to engage in negotiations with voluntary license seekers, rather than summarily rejecting such requests without serious consideration.

On the last technical objection of Natco's failure to file evidence for its claim, the IPAB opined that there was no such specific requirement to do so under the Act. In fact, it went so far as to say that even if some evidence had not been filed, the objection should have been raised before the Controller and that this, in itself, would not be a ground for allowing the appeal. This holding of the IPAB is particularly interesting because it creates ambiguity with respect to how instances where the Controller's decision is based on incomplete facts should be treated in appeal.

Moving to the substantive questions, the IPAB began, first, by examining the role of CIPLA in the dispute. CIPLA had been selling a generic version of Nexavar for the much lower price of Rs. 30,000/- per month (to Bayer's Rs. 2,80,428/- per month) since 2010 and a patent infringement suit filed by Bayer was pending against them. Given these facts, Natco contended that Bayer should not be permitted to include CIPLA's sales made in the total sales of the drug in India since Bayer alone was responsible for satisfying the reasonable requirements

of the public under §84(1)(a). Bayer countered by pointing towards the injustice that would be caused if CIPLA's sales were not taken into account for this purpose. Bayer argued that because CIPLA was selling a version of the same drug, if consumers purchased CIPLA's drug, they would obviously not be required to purchase Bayer's product. Consequently, owing to the low pricing of CIPLA's drug, Bayer's market would get affected and it would be unable to fulfill the condition of satisfying the "reasonable requirements of the public". This in turn would become a legitimate ground for a compulsory license to be issued in respect of Bayer's patented drug, thereby further prejudicing Bayer's interests. The IPAB concluded that the requirement had to be met by Bayer alone and that it could not rely on CIPLA's sales especially since it was contesting CIPLA's market presence in a separate litigation. The objective of granting a patent is to increase public access to the patented product. Consequently, the quid pro quo for patent protection is the patentee's obligation to make the patented product available to the public at affordable prices. The IPAB opined that since the patentee alone was getting the benefit of the patent, the burden of ensuring reasonable access also had to be met solely by the beneficiary i.e., the patentee and/or his licencee(s). Therefore, it held that CIPLA's presence was irrelevant for the purpose of determining the extent of Bayer's compliance with the law.

The IPAB categorically stated that Bayer had not fulfilled the requirements in §84(1)(a) by any stretch of imagination. Further, the IPAB reiterated that the patent holder's position was irrelevant in the consideration of compulsory licenses, and the affordability of the patented product for the public was the sole factor in the determination of a compulsory license application. This part of the decision is especially important not just for potential compulsory license applicants but also for future patent seekers. On one hand, this raises important questions about how exactly 'reasonable affordability' is to be defined from a public perspective. The usage of an ambiguous standard like this could increase the scope for subjectivity. On the other hand however, even without precise definitions, the emphasis on the public perspective is heartening. It illustrates yet again that the focal point of Indian pharmaceutical patent law seems to be on ensuring affordable access to the largest numbers and that the judiciary's primary consideration is that of public interest. The IPAB has sent out a clear message that it will not allow drug companies to wriggle out of compulsory licenses without actually working their patent to the advantage of the public. Indian patents are based on a quid pro quo and the IPAB seems unwilling to compromise on this aspect. In fact, even the Supreme Court seems to be viewing these issues in a similar vein. From a foreign viewpoint therefore, this is a notable assertion of India's stance and it represents a clear victory for patients and general manufacturers alike. Thirdly, on the issue of the 'working' of the drug in Indian territory, the IPAB refused to accept Bayer's plea that it was not feasible to manufacture the drug in India and that importation was the only option. Differing slightly from the opinion of the Controller, the IPAB held that the word 'worked' could have a flexible meaning based on the specific facts. However, it pointed out that any contentions regarding the non-feasibility of local 'working' had to be proven, not merely stated. In the instant case, they agreed with the

Controller that Bayer had failed to demonstrate why it could not 'work' the drug locally. Therefore, it was held to have failed the test of §84(1) in this regard.

Lastly, in order to meet the ends of justice, the IPAB modified the royalty rate payable by Natco in respect of the license and increased it by 1 per cent to 7 per cent. Although it acknowledged the UNDP recommendation to award a maximum possible royalty of 6 per cent, the IPAB also took note of the disparate profit margins of Bayer (about 14 per cent) and distributors of Nexavar (about 30 percent). Therefore, placing reliance on §90(2), it increased the royalty rate so as to allow Bayer to derive a reasonable advantage from its patent. Overall therefore, the IPAB upheld Natco's compulsory license, dismissing Bayer's appeal and modifying only the royalty rate.xvi

This is effectively India's first patent compulsory licensing order in the post TRIPS era (there have been compulsory licenses issued under the Patents Act, 1970, but these were all prior to the 2005 amendments).

In many ways, it sets the tone for future cases and will spur many other generics to resort to this route. To this extent, it will certainly be music to the ears of several patient groups and NGO's that have been battling pharmaceutical patents and excessive prices for many years now. Many have been puzzled by the lack of initiative shown by generic companies in availing of the extremely wide compulsory licensing grounds articulated in India's patent regime.

Perhaps Natco's baby steps in this regard may pave the way for a giant leap of sorts, where many more drug patents are subjected to this "stick" so as to help bring down what are by most standards, highly excessive

prices for a country like India. In fact, given that more than 90% of MNC drugs are imported into India, this order may pave the way for wholesale compulsory licenses to be issued against a wide spectrum of drugs in the near future. This interpretation of

"working" to mean "local working" (local manufacture within India) may in fact prove the most controversial part of the order and may perhaps attract a TRIPS challenge as well.

This order may also prompt other countries, particularly developing countries to adopt similar provisions and issue similar orders. Lastly, one hopes that it prompts innovator drug companies to engage in more significant differential pricing schemes and introduce drugs at much cheaper prices in countries with a significant number of extremely poor patients such as India.

X. CONCLUSION

According to the data compiled by the UN Millennium Development Goals Project, 40 million people are infected by the AIDS virus in developing countries, with 26.6 million on the African continent. About 93% of those infected with the AIDS virus cannot afford to buy the antiretroviral medication which they need. The Joint Program of the United Nations on AIDS believed that unequal access to treatment at acceptable prices is one of the main reasons for the low levels of survival in poor nations. Although it may seem a paradigm, the problem of access to patented medicine is not limited to anti-retroviral for the treatment of AIDS, as Brook K. Baker notes. In developing countries the poor are victims of a large number of infectious diseases such as tuberculosis, malaria, respiratory infections, diarrhoea, and Chagas disease, for which there is little or no access to medication. The treatment of other illnesses such as diabetes, asthma, heart disease and mental illness is insufficient as the medication available is beyond the purchasing power of a large part of the population.xvii

This being the harsh reality, the presence of strict patent protection for medicines in particular that are usually owned by big pharmaceutical companies of developed nations whose major objective is earning more and more profits, the poor inhabitants of developing nations turn out to be the victims in the whole scenario. They are the people who are unable to afford life-saving drugs and hence in most cases die of diseases which could have been cured if only necessary medicines could be accessed. Recognizing this crisis and with an intention to provide solution for it, the first agreements on intellectual property, made in the XIX century, assigned compulsory licensing the task of solving problems created by the patent system. . It authorizes a third party to manufacture, use or sell a patented invention without the authorization of the title-holder, under clearly stated circumstances, i.e., national emergency, or when a state wants the invention to have public use on non-commercial grounds. The main goal behind grant of such compulsory license is to supply the domestic market in unusual situations. It is pertinent that nations enjoy undeniable flexibility to adopt public policies in the field of health. TRIPs agreement leaves room for the members to decide and determine for themselves that what these circumstances are that result in a national emergency, which are extremely important in the public health crises caused by epidemics or pandemics. Thus, this leeway provided by TRIPs agreement works for the favour of developing nations as they have a freedom to define such circumstances.

Developing countries that have applied TRIPs have not made full use of the flexibility of international trade law either because of lack of knowledge of their rights or because of pressure from the west. Developing countries need to inquire about the status of their domestic law provisions for compulsory licences and parallel imports and lobby to change laws if they are more restrictive than the TRIPs agreement demands. Another that needs to be considered is that if domestic governments request it, technical assistance to become TRIPs compliant is available from World Intellectual Property Organisation (WIPO). Ultimately, the right of a country to safeguard the health of its citizens partly depends on access to essential medicines and we must focus on improving this access. Medical professionals in the developing world refuse to accept the fact that their patients are dying because multinational pharmaceutical companies, with the help of their national governments, are distorting international trade law to keep the price of essential medicines high in developing countries.xviii

The Doha declaration about TRIPs and public health in 2001 maintained the flexibility of the Agreement negotiated during the Uruguay Round, which allowed the implementation of public policies that facilitate access to medications. The Doha declaration, however, did not address the possibility of the import of manufactured products through the concession of a compulsory license by other countries. It has been established, in this case, that the title-holder has the right to prevent the medication from being launched on

other markets because his rights have not expired. From this perspective, compulsory licensing aims mainly at supplying the domestic market. xix

Once it is granted, compulsory licensing does not produce the expected results due to the lack of technical ability of local industry. This problem was solved by the General Council of the WTO on August 30, 2003, by a decision that protected the flexibility of TRIPs, as it was agreed that countries that met some requirements would not be subject to the restrictions in article 31(F). The member countries of the WTO will be able to import medicines through compulsory licensing if domestic industry proves unable to supply the needs of the domestic market. This privilege is ensured to less developed members of the WTO and to any member who at any time notifies the Council of TRIPs Agreement of their intention to use the system, which is provided for in the decision of the General Council in cases of national emergency or other circumstances of extreme urgency, or in cases of non-commercial public use. The decision of the General Council established a number of safeguards to prevent medications produced through compulsory licensing for developing countries from supplying the market of developed countries. Such safeguards include, among other requirements, the form, color, and type of packaging of the products sold. The decision, which will be interpreted and implemented in good faith, will deal with public health issues and will not aim at achieving goals of commercial or industrial policies.3

The use of compulsory licensing by developing countries will contribute to cultivating the degree of competition, which will certainly cause a decline in the price of medicine. Developing countries should use the substitutions offered by the TRIPs Agreement and create legal apparatuses and public policies to exploit the prospective offered by compulsory licensing to propagate greater social equality in access to medicines.

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