

THE CURIOUS CASE OF COMPULSORY LICENSES IN PATENTS

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I. INTRODUCTION

The TRIPS Agreement outlines in its Preamble a very crucial objective for its member countries directed towards recognising the inherent nature of Intellectual Property Rights as –private rights¹ and at the same time also seek to achieve the underlying –public policy objectives¹ of the respective national systems. *Article 7* that outlines the –objectives¹ of the TRIPS also reiterates the need to strike a balance the rights and obligations of the right-holder of an IP and the welfare of the society. In order to give effect to this provision, the member-states have been conferred with enormous flexibility in so far as they adopt their national laws to –protect public health and nutrition and promote the public interest in the socio-economic and technological development¹. Thus, the above two provisions indicate that in order to effect the –balance of rights principle¹ members have been granted a wide space while they shall incorporate the TRIPS mandate in their national laws.

Patent Rights confers upon its right- holders exclusive monopoly to use, sell, manufacture and import their product and process patents to the exclusion of a third party until the expiry of the term of patent. Thus, it provides an incentive for the innovation which is a contribution to the society in lieu of which they agree to disclose their patent in the public domain once the term is over and they have reaped the benefits of their labour. However, at times it may be so that such exclusive rights fail to fulfil the public interest thereby thwarting the very purpose of its grant or such rights may be used in a manner detrimental to the public interest itself. It is under these circumstances that the State has the authority to grant –Compulsory Licenses¹ (hereinafter shall be used as –CL¹) to parties interested in the utilisation of the patent invention to serve the public interest and this becomes all the more important when the patent relates to life-saving drugs, as providing the same to the public is the underlying objective of the welfare state which pledges tend to the health and wellbeing of the members of its society. These are such licenses that are issued by the State to a government agency, a

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¹Article 8, TRIPS Agreement

company or any other interested party to use the patent without the patent holders' consent². Thus, it enjoins upon a third party the right to work the patent to the advantage of the public in a manner that best suits and fulfils the purpose of an invention of a life-saving drug. Thus, this flexibility empowers the States to end the monopoly rights enjoyed by the patent holder in case of his failure to fulfil the public policy objective and this flexibility becomes all the more important in the context of third world countries when they are faced with the dilemma of combating the public health crisis which is at stake due to unaffordable patent drugs³. Under these circumstances it becomes important to forgo the patent rights in a drug so as to give the rights of making generic copies of the same.

II. RATIONALE BEHIND GRANT OF COMPULSORY LICENSES

The concept of compulsory licensing is not an absolutely new concept, but surely it has come to gain a lot of relevance under the Patent Laws in the present times, especially with the pharmaceutical groups and generic drug manufacturers as far as the question of ensuring the availability of necessary drugs for life-threatening diseases to the public and their commercial agendas are concerned. When these drugs are made available by the Government, there occurs a considerable reduction in the prices of these drugs as compared to the price at which they are made available by the patent holders by way of exporting it to the countries that are in need of the same. The Government gives the rights to manufacture these drugs and make available to the public to the generic manufacturers in their own country and this is a big reason why the developing countries are bent upon issuing the rights of compulsory licenses for patents on pharmaceuticals that are quite expensive for their citizens.⁴ Compulsory license („CL“) is seen as one such tool adopted by the government to enter the market in order to rectify the problem of market failure by mitigating the rigours of –abuse of the dominant position by arbitrary refusal to deal or license ll.⁵

²To quote, E. Durojaye, — Compulsory licensing and access to medicines in post Doha era: what hope for Africa? *Journal of Intellectual Property Law*, (vol. 18, no. 2, pp. 35, Spring 2011), cited in Md. Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An analysis of arguments*, International Journal of Social Science and Humanity p.1(Vo l. 3, No. 3, May 2013) (available at- <http://www.ijssh.org/papers/239-D00013.pdf>)

³ Md. Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An analysis of arguments*, International Journal of Social Science and Humanity p.1(Vo l. 3, No. 3, May 2013) (available at- <http://www.ijssh.org/papers/239-D00013.pdf>)

⁴Sara M. Ford, *Compulsory Licensing Provisions under TRIPS: Balancing pills and patents*, p.7 (American University International Law Review, vol, 15, issue 4, article 5, 2000) (available at- <http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1278&context=auilr>)

The rationale behind granting patents is that they shall encourage innovation by providing incentives to the patent holder in the form of exclusive monopoly rights. However, this grant is not without its own costs and is accompanied with problems like abuse of monopoly rights by the patent holder, use of patents to block inventive activity by the third parties, diversion of productive activities disproportionately towards patentable activities, and the considerable amount of investment in maintaining a patent system. It is these costs that have resulted in the usage of the CL policy by Governments around the world and has been accepted as a –Strategic Compromise. ⁶

Thus, when the inventor fails in its endeavour to satisfy public demands the Government resorts to CL, which is –an involuntary contract between a willing buyer and an unwilling seller imposed or enforced by the state. ⁷ The Government however pays the royalty to the patent holder in lieu of using their patent without their consent. They are an abrogation of an IP right- an extra ordinary legal instrument- whereby the State allows itself or the third party to have access to, to produce, use or sell the IP protected product or process without the consent of the patent holder and hence are mandatory and involuntary compulsory licenses granted to prevent the misuse of monopoly rights conferred on the patent holder. ⁸

III. SCOPE AND APPLICATION OF COMPULSORY LICENSES

A. UNDER THE TRIPS AGREEMENT-

Article 30 under the TRIPS Agreement provides for incorporating limited exceptions upon the exclusive use of the rights that are conferred upon the right- holder. One such exception is what has been provided under Article 31 that provides for certain other uses of the patent without the authorisation of the right-holder. This Article doesn't expressly use the term –compulsory licensing but the same is an implied power conferred upon the governments of the respective countries. There are certain specific conditions under which the same may be granted without the permission from the right- holder. In the cases of –national emergency, or other cases of extreme urgency or in cases of public non-commercial use (i.e. government

⁶To quote, Hellen and Eisenberg, Can Patents Deter Innovation? The anticommons in biomedical research, 280 SCI. 698 (1998) cited in, Collen Chien, *Cheap Drugs at What Price to Innovation: Does CL of pharmaceuticals hurt innovation*, p.5 (available at- <http://www.btlj.org/data/articles/vol18/Chien.web.pdf>)

⁷To quote, J. Arnold, International CL: The rationales and reality, IDEA: The Journal of Law and Technology, 33 (2)(1993) 349, cited in, Radhika Gupta, *CL under TRIPS: How far it addresses public health concerning developing countries*, Journal of IPR, vol.15 (NALSAR University of Law, p.2, September, 2010) (available at - [http://nopr.niscair.res.in/bitstream/123456789/10211/1/JIPR%2015\(5\)%20357-363.pdf](http://nopr.niscair.res.in/bitstream/123456789/10211/1/JIPR%2015(5)%20357-363.pdf))

use),^l licenses for the use of the patents may be granted by the government, however, information and some form of notification regarding the same ought to be given by the government to the right-holder. The existence of these specific circumstances can be said to have magnified the legitimacy of every complying governments' right to resort to CL whenever it was required by its domestic self- interest.⁹

The conditions under which the same may be granted are as follows:

Such other use may be permitted only when the proposed user has failed in his endeavour to get such authorisation after having voluntarily made efforts to obtain authorisation from the right-holder on such terms and conditions that are reasonable and just. However, this may be waived in cases of emergency or public non-commercial use.

Such uses are non-assignable and non-exclusive. Thus, the purposes for which they have been obtained cannot be further transferred or retransferred to a third person and are such licenses that don't exclude the right-holder from its usage.

The grant of such use shall not be made without the payment of a considerable amount of remuneration to the right-holder whose are suspended for a certain specific duration. The same may stand terminated once the purpose for which the same was granted ceases or is unlikely to recur.

The most important clause under Article 31 is clause (f), which states that such use shall be authorised for the purposes of supply to the domestic market of such authorising member state, thereby restricting the use of CL having a good manufacturing capacity. The licensees are obliged to supply a predominant part to their domestic markets, thereby limiting its capacity to export the medicines to countries with public health needs. At the same time, it restricts the countries with low or no manufacturing capacity to derive benefit from this provision except when the same is necessary to curb anti-competitive practices¹⁰.

There are five such uses that are permitted under Article 31 namely: licences for public non-commercial use by the government; licenses granted to third parties authorised by the

⁹To quote, J. Watal, *IPR in WTO and Developing Countries* (Boston: Kluwer Law International, 2002): at 33-44 cited in, Comment by J. Reichman, *CL of Patented Pharmaceutical Inventions: Evaluating the options*, p.2 (available at- http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2747&context=faculty_scholarship)

¹⁰Radhika Gupta, *CL under TRIPS: How far it addresses public health concerning developing countries*, Journal of IPR, vol.15 (NALSAR University of Law, p.2, September, 2010) (available at- [http://nopr.niscair.res.in/bitstream/123456789/10211/1/JIPR%2015\(5\)%20357-363.pdf](http://nopr.niscair.res.in/bitstream/123456789/10211/1/JIPR%2015(5)%20357-363.pdf))

government for public non-commercial use; licences granted to remedy a practice which has been determined after administrative or judicial process to be anti-competitive; and licences arising from a dependent patent. The TRIPS Agreement does not, however, limit the grounds to these five and the countries are therefore left with a very broad scope of action in regard to the grounds on which they can grant compulsory licences.¹¹ Also, the decisions regarding the judicial validity of such licenses may be adjudicated upon by the bodies that may be assigned for the said purpose by the member state itself. With regard to the decision of its termination, the members are at liberty to specify the conditions under which the same shall stand terminated.

B. UNDER THE INDIAN PATENT LAW

In India too, the provision for grant of CL has been made in order to restrict anti-competitive practices and to strike a balance between rewarding the patentees and simultaneously inventing and making new products especially drugs that are to be made available to a large population at cheaper and affordable prices. *Chapter XVI Sections 82 to 94*¹² were inserted under *the India Patent Act, 1970 vide the 2002 Amendment* and *Section 84* specifically provides for the grant of CL after the lapse of 3 years from the date of grant of patent on an application (accompanied with the statement about the nature of interest involved) being filed by an interested person before the Controller of patents on any of the following grounds:

That the reasonable requirements of the public are not being met with respect to the purposes for which the new patented invention has been devised; or

That it is not being made available to the public at reasonably affordable prices; or

It is not being worked within the territory of India.

Clause 7 of this section further clarifies that the reasonable requirements of the public shall be deemed to have not been satisfied if any existing trade or industry or the development and establishment of the same is getting hampered; or the demand of the invention has not met to an adequate extent or on reasonable terms; or no supply is made to the export market; or such terms and conditions have been imposed upon the licensee that cover situations of exclusive

¹¹ J. Sulander, *The Role of CL in Improving Access to Medicine in the Developing Countries*, p.7 (LW 556 Intellectual Property Law 2001/ 2002) (available at- [https://www.kent.ac.uk/law/ ip/resources/ip.../2001.../Diss-Sulander.doc](https://www.kent.ac.uk/law/ip/resources/ip.../2001.../Diss-Sulander.doc))

¹² *Indian Patent Act, 1970*

grant back or package licensing; or if the patent is not being worked in India on a commercial scale.

Section 83 clause (b) and (f) are of immense importance in the context of CL as far as the working of the patented invention is concerned as these two clauses make it clear that patents shall not be granted to enable the patentees to enjoy monopoly for importing the patented article; and patents are granted to ensure its availability to the public at reasonably affordable prices. Thus, the term –has not been worked in the Indian Territoryl *u/s 84(1)(c)* excludes from its ambit the imports of such patented drugs. Thus, CL cannot be granted only for the purpose of importing the drugs such that the patentees start abusing and monopolising their exporting rights and derive huge undue benefits. Here, it is important to note that under Article 27.1 of the TRIPS, importation of the goods are included in the definition that constitute –use of patentsll, whereas Article 5B of the Paris Convention allows lack of local use as a ground for issuing CL. In India, however, there seems to be a difference of opinion as far as the inclusion of the condition of importation within the ambit of the term –working of patentsll is concerned. Some argue that it should include importation as not every company shall be able to establish its manufacturing industry in India and this would eventually affect the prices of the drugs. On the other hand, there is the view that the same should be remain excluded as India being a hub for generic drug manufacturers it shall keep the opportunity open for these local manufacturers to collaborate with the patentees for manufacturing it in India on terms of licenses and thereby reduce the manufacturing cost and the price of the drug.¹³

However, before the acceptance of the application for grant of CL, the Controller has to keep in mind the nature of the invention and the ability of the applicant to work the invention; the reasons for failure on the part of the patentee to do the same; or unsuccessful attempt by the applicant to obtain voluntary licenses from the patentee.¹⁴

Section 89 provides that the grant must be made to ensure that the invention is being worked on a commercial scale in the Indian Territory and the interest of any other person who is working upon an invention for the time being in India should not be prejudiced. *Section 94*

¹³*World Intellectual Property Review*, Vikarant Rana, *Patents and Compulsory Licenses*, p.2(India Focus, September/October 2011) (available at- [http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5CPatents%20and%20Compulsory%20Licensing%20\(WIPR%20Sep-Oct%202011\).pdf](http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5CPatents%20and%20Compulsory%20Licensing%20(WIPR%20Sep-Oct%202011).pdf))

¹⁴Section 84(6), *Indian Patent Act, 1970*

states that the CL may be terminated once the purpose for which it was granted ceases or doesn't recur again.

The Patent Amendment Act, 2005 has inserted Section 92A that provides for CL under exceptional circumstances for the purpose of exporting the patented invention. It states that CL shall be made available for the purposes of manufacture and export of patented drugs to such countries that have insufficient or no manufacturing capacity to address public health problems, provided that the country who is importing such drugs has notified its consent for the same. This was included after the conclusion of the Doha Declaration on Public Health.¹⁵ However, the Section fails to define what constitutes 'public health problems' and as such provides the exporting country with immense leeway to grant CL to the importing country even when there are no any emergency situations. This in turn shall adversely affect the rights of the patentee and allow the generic companies of the exporting countries to make undue commercial gains.¹⁶ Also, this provision confers immense powers upon the Controller to whom the application for the same has been made to decide upon the terms and conditions of such grant and also doesn't prescribe the amount of royalty or remuneration that is to be paid in lieu for such grant.

As a result of the product patent regime that has been introduced in India, the indigenous firms shall not be able to produce a drug, even if they manage to develop the process unless they are granted a CL. India has adopted a stricter CL regime than what is there under the TRIPS also and gives opportunity to the patentees to manipulate the process by litigation to prevent an easy licensing of their product.¹⁷

IV. COMPETITION LAW AND COMPULSORY LICENSING

The relation between competition law and CL is quite complex owing to the respective objectives that both seek to fulfil. While CL for patents in the pharmaceutical sector is granted to restrict abusive use of monopoly rights, application of competition law in the pharma sector maintains the balance between incentives for innovation and facilitates

¹⁵*NUALS Law Journal*, Dr. Raju KD, *Compulsory Licensing Provisions to Deal with Access to Patented Medicines in India* vol.6(Publication of Student Council, NUALS, Kochi, p.8, 2012) (available at - www.nuals.ac.in/web/pdf/NUALS_LAW_%20Journal%20.pdf)

¹⁶*Supra* note. 19

¹⁷Sumana Chatterjee, *Flexibilities Under TRIPS (CL): A pharmaceutical industry in India and Canada* , p.14 (available at- http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1025386)

achievement of public health objectives.¹⁸ The sole purpose behind protection of IPRs is to prevent and prohibit imitation or copying of the original product and thereby prevent use of unfair- means increasing fair market competition. Competition law helps in restricting exclusivity if the same has been used to exclude others from the competition by application of anti-competitive means. This is what is expressly restricted under *Section 83(1)(f) of the Indian patent law* which provides for general principles that shall be made applicable for ensuring effective working of patented inventions. It restricts the abuse of the patented rights by the patentee or his assignee to resort to trade practices which unreasonably restrict trade or adversely affect the transfer of technology. Thus, this provision under the Patent law restricts anti-competitive practices. In fact the goals of both IPR protection and competition law are –wealth maximization¹⁹, where the former encourages investment in innovation and is therefore incentive oriented; the latter by prohibiting anti-competitive practices ensure equal distribution of profits among all the producers and manufacturers.

The practices that are considered to be abusive use of IPR's in general and patents in particular are:²⁰

Patent pooling where two or more patentees join in and cross- license the patent so as to restrict others from acquiring it.

Tie in arrangements or product bundling where in the other product may be coupled with the patent such that the acquirer is forced to take that other product with the patent.

Royalty payment after expiry of patent

Restricting the licensee to challenge the validity of patents.

Indulging in exclusive grant back techniques wherein authorship is asked for in amendments.

Price fixation for the licensee to sell the product.

Accumulation of patents in the form of –package patents ll.

¹⁸Available at- https://www.google.co.in/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0CCsQFjAC&url=http%3A%2F%2Fwww.nlujodhpur.ac.in%2Fdownloads%2Fsymposium_report%2F9.ppt&ei=Rn4vV Lr3NY22uASlhoDoAg&usg=AFQjCNHAWuigclut-LKSnuZQrnDcxFbggw&sig2=fRGcP Qt44OWFI0z45aMmMQ

¹⁹Pankaj Kumar, *The Interface between IPRs and Competition: Indian scenario*, (Kurukshetra University, Dissertation, p.10 (available at- <http://www.slideshare.net/pankaj7379/the-interface-between-iprs-and-competition-law>)

²⁰ Research Project, *Competition Commission of India*, Abhilash Chaudhary, *Compulsory Licenses of IPRs and its effect on Competition*, p.11(GNLU)

The main object of Competition Law is prevention of anti-competitive practices and ensuring freedom and equal opportunities of trade to other participants in the market.²¹ This makes it clear that when applied to the pharmaceutical sector, the competition law shall restrict resort to anti-competitive practices by the patentee by way of increasing the prices of the patented drugs and making its affordability difficult. It is in this regard that the CL may be granted by the state to the generic drug manufacturers in the patent pharmaceutical sector to ensure availability of life-saving drugs at affordably reasonable prices and safeguard public health.

In the case of drugs, the IPR's have given rise to fewer competitors and less competitive markets. However, consumer welfare can only be realised in the case of perfect competition as therein all the producers charge the same price for same products. In order to balance the exercise of monopoly rights by the patentee and public interest competition policies have to be intelligently devised. Thus, one way in which this can be ensured is grant of CL which shall restrict anti-competitive practices by the companies which tend to damage the interests of the consumers and competitors also. Under the competition law also, grant of CL is contemplated under *Section 27* where the Competition Commission may grant the same in order to rectify the situation where exclusivity conferred by the IP has been exploited to obtain unfair leverage. Under *Section 28* also the Commission may provide for transfer of property rights including the IPR's.²² Although CL helps in engendering competition, especially in the markets where a single manufacturer abuses his dominant position, in the long run it may hurt the incentive for innovation and may prove anti-competitive. Thus, resort to CL must be the last option in order to maintain healthy competition. Only in the cases that have been provided for under the Indian patent Law under Section 84 and under the TRIPS, the CL should be granted. It might also have an adverse impact upon the FDI of the country. Article 40 of the TRIPS Agreement creates provisions for the control of anti-competitive practices in contractual licensing. This, in turn, is further reaffirmed by the provisions under Section 31 that provide for other uses of patents without the authorisation of the right-holder. A combined reading of these provisions indicate that grant of CL in patents for drugs may be discouraged by the member states in case such licensing in the IPRs restrain competition if it adversely affects the trade and impedes transfer and dissemination of technology. Thus, CL may not always be the best method to prevent abuse of monopoly rights and may in fact lead to anti-competitive practices and ultimately affect the consumers and public interest.

²¹Section 3, 4 and 6, *Competition Act, 2002*

²²Supra note 16, P.21

V. PUBLIC HEALTH CARE AND COMPULSORY LICENSING

The Utilitarian theory of IPR states that protection and promotion of IPR must be for the purpose of ensuring greatest number of happiness for the greatest number of people. The underlying justification is a public benefit or social good that can be gained by the IPR regime that seeks to benefit the creators and innovators in the short term, but everyone else in the long run. It is in lieu of the monopoly rights conferred upon the creators that they agree to disclose their work for public use and once the term of their monopoly expires, the creation falls into the public domain so that it may be exploited by the public. Additionally, in fact, if the public benefit is diminished as a result of exercise of monopoly rights, such IPR protection shall be rejected. Thus, in patents as well, the main aim of innovation is to promote public interest and when the same is considered in the context of promotion and development of the pharmaceutical industry, the same becomes all the more objective, wherein the only objective is innovation of new medicines and life-saving drugs for the purpose of curing the diseases and epidemics that are barriers to providing good health to the public. Hence, securing public health care is the ultimate motive of patents in the pharmaceutical sector. One of the major issues that the world all over is facing is inability of the people to have access to essential medicines at reasonably affordable prices. To this end the strategy of compulsory licensing is increasingly being seen as bringing down the price of the drug therapies and thereby improving access to essential medicines. Hence, CL helps in production of generic drugs without the permission from the patent holder and helps in increasing the availability of medicine at considerably lower prices. Moreover, the prices of the medicines are determined taking into consideration the market realities and hence due to this reason again CL provides certain very undeniable social benefits in the form of providing access to essential medicines to a significant part of the population.²³

The right to health is a fundamental right and the States are under an obligation too, to provide the same. Thus, access to medicines is also indirectly related to and forms an important aspect of the right to health. Article 8 of the TRIPS Agreement reflects that the guiding principle behind implementation of the provisions of the agreement shall be *protection of public health and nutrition and promotion of public interest in sectors of vital importance to their socio-economic development*. Hence, even this point incidentally indicates that protection of public health is of vital importance and the same shall be achieved when the

²³Supra note. 15, p.11-12

essential life-saving drugs are made available to the public easily. This again indicates a positive relation between grant of CL for pharmaceutical products with the objective of securing public health care. This has been further reaffirmed by the Doha Declaration on TRIPS and Public Health of 2002 which confers upon a sovereign nation the authority to grant compulsory licenses at times of national emergency.²⁴

Survey indicates that there are over 14 million people who die every year due to infectious diseases and the HIV/AIDS pandemic exemplifies the misery. A years' treatment's cost is equal to 30 years income of people in the developing country and only a four to six months' salary of those in developed countries. ²⁵It is obviously very difficult for a considerable section of the society to manage to buy these costly medicines and they are forced to sacrifice their lives as against the meagre income that they barely manage to earn for themselves.

This might lead us to fear the fact that in case if CL helps in reducing the cost, then the same shall have its effect the quality of the medicines offered and as such, it is again the public health that shall get compromised. However, this is one such issue that cannot blame the process of CL or the generic manufacturers, but it is something that is to be kept in mind by the governments while they frame the national drug policy and must set policy standards for ensuring good quality generic medicines. ²⁶ In order to use CL as an effective tool for reducing the cost of medicines and promote health care, the ways in which it is used must be clearly defined and CL must be resorted to by the governments only under exceptional circumstances under procedures established by law. It is only a rational use and implementation of CL that shall promote technology transfer and help in production of medicines for securing vital interests of health of the population.

VI. THE NATCO-BAYER JUDGEMENT

Earlier, in 2011, there were two applications filed for the grant of -voluntary licenses. One was by Cipla for Mrecks' anti-HIV drug Isentress, and the other was by Natco from Pfizier to make and sell copies of the HIV drug. Both of these were sought on the same ground that the drugs were highly priced making it inaccessible to the patients in India. Thereafter, Natco

²⁴Para 5, Ministerial Conference, Fourth Session, Doha, 9 - 14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001

²⁵ To quote, Myhr K : *Comparing Prices of Essential Drugs Between Four Countries in East Africa and with International Prices*, (1 June 2000, p2) cited in, J. Sulander, *The Role of CL in Improving Access to Medicine in the Developing Countries*, p.3 (LW 556 Intellectual Property Law 2001/2002)(available at [https://www.kent.ac.uk/law/ip/resources/ip.../2001.../ Diss-Sulander.doc](https://www.kent.ac.uk/law/ip/resources/ip.../2001.../Diss-Sulander.doc))_

²⁶*Supra* note. 17 p. 19

Pharma was the first company in India that applied for -compulsory license²⁷ in 2008 under Sec. 92A to manufacture and export to Nepal the generic version of drugs by Roche Ltd. and Pfizer for treating lung cancer and renal cancer respectively. However, due to certain technical incongruities, the same was withdrawn²⁷.

It was on March 9, 2012 that the first CL was granted by the Controller of Patents in India to Natco Pharma Ltd. for the production and sale of Bayer's patented drug Sorafenib (commercially called Nexaver, priced at 2.8 lakh a month) that is useful in treating liver and kidney cancer in the Indian Territory at a 6% royalty. Earlier in 2001 when Bayer had filed an application for registration the same was granted in 2008 in the form of regulatory approval for marketing the drugs. However, it was then realised that Bayer was not satisfying the need of the patients as it had not sold the drugs in India in 2008 at all, with only largely undistributed sale in 2009 and 2010. It was against the decision of the Controller to grant the CL to Natco that Bayer filed an appeal before the IPAB, which again reaffirmed the decision of the Controller and rejected the appeal for grant of interim stay on the orders of the Controller.²⁸

A. RATIO OF THE JUDGEMENT

The decision of the IPAB was motivated by its inclination towards the public health needs and recognition of the right to health and life guaranteed under the Constitution of India. It referred to Art.8 of the TRIPS that recognises the obligation of the Member states to maintain national interests. The IPAB placed its reliance on Sec. 84(1) and held that the reasonable requirement test was not being met as it had not made sale in India and was so highly priced to be out of reach of the ordinary public. The IPAB made the following observations:²⁹

²⁷*World Intellectual Property Review*, Vikarant Rana, *Patents and Compulsory Licenses*, p.2 (India Focus, September/October 2011) (available at [http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5CPatents%20and%20Compulsory%20Licensing%20\(WIPR%20Sep-Oct%202011\).pdf](http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5CPatents%20and%20Compulsory%20Licensing%20(WIPR%20Sep-Oct%202011).pdf))

²⁸*The Economic Times*, Sanjay Vijaykumara and Divya R., *Natco's CL for selling generic copies of Bayer's cancer drug Nexaver upheld by IPAB*, Mar 4, 2013 (available at http://articles.economictimes.indiatimes.com/2013-03-04/news/37437382_1_nexavar-co mpulsory-licence-leena-menghaney)

²⁹IPAB Order Sheet, *Bayer Corp. v. UOI* (OA/35/2012/PT/MUM) para.13 (available at [https://www.pharmamedtechbi.com/~media/Supporting%20Documents/Pharmasia%20News/2012/September/IPAB%20Order%20Bayer%20Natco%20Sept%202012.pdf](https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/Pharmasia%20News/2012/September/IPAB%20Order%20Bayer%20Natco%20Sept%202012.pdf))

Bayer had only supplied the drugs to 2% of the patients as against an eligible 8842.

The fact that it costs 2.8 lakhs a month again fails the test of –reasonably affordable prices under Sec. 84(1)(b).

With regard to the interpretation of –worked in the territory the IPAB referred to the history of the TRIPS negotiations and held that it meant –manufacture to a reasonable extent in the territory if India. Bayer had failed to do this and also to grant voluntary license to anyone under S. 84(1)(c). Though S. 84(1)(c) uses the word –not worked the Act makes it clear that the grounds of S. 84(1)(a) will arise if the work is not to the extent provided in S. 84(7)(d).³⁰

The IPAB ordered the payment of royalty by Natco at 7% of the net sale made by them in India instead of the initial 6% royalty ordered by the Controller.³¹

It was held that a combined reading of S. 83 and 84 indicate that it is the patentee's duty to show and prove that the patentee has by his own supply satisfied the reasonable requirements of the public and at reasonably affordable prices.³²

The IPAB thus refused to grant stay at the order of the Controller as the same shall jeopardise the interests of the public as the right to have access to medicines is a matter of right to dignity. The Court upheld the grant of license with certain additional conditions upon the licensee.

B. INTERPRETATION ATTRIBUTED TO “LOCAL WORKING REQUIREMENTS”

The IPAB out-rightly rejected the contention of the Patentee's that importing into India constitutes working of the invention to the fullest possible extent and the same is to be read with S.83 (a) and (b) and upheld the reasoning given by the Controller. It was held by the Controller of patents that ‘working’ doesn't only mean working on a commercial sale as this shall completely negate the authenticity of the provision in S. 84(1)(c). S. 83(b) makes it clear that mere importation cannot amount to working. A combined reading of S. 83 (c) and (f) suggests that patentee is obliged to contribute to transfer and dissemination of technology which can be achieved by either manufacturing the product in India or by granting a license for the same. Provision u/s. 84(6)(ii) and 90(2) that relates to the capacity of the licensee to

³⁰*Ibid* para.31

³¹The Financial Express, *Patent Appellate Board rules against Bayer in cancer drug case*, March 27, 2014 (available at <http://www.ableindia.in/wp-content/uploads/2014/03/patent-appellate-board-rules-against-bayer-in-cancer-drug-case-financialexpress.pdf>)

³²*Supra* note 35, para.30

work the invention also excludes imports and necessitates manufacture in India. Thus, it attributed the same logic to the patentees also.³³

C. CRITICAL APPRAISAL OF THE JUDGEMENT

The first point of incongruity rises from the fact that the IPAB decided to grant CL to Natco as it had fulfilled the pre-condition of making an attempt to obtain voluntary license. It is pertinent to note that the Controller had pointed out that the language of the application for voluntary license was harsh and this raises a serious doubt as to the nature of communication that can be termed as an ‘attempt’. Such an ‘attempt’ backed by a potential threat of CL may become a bargaining tool in the hands of the applicants seeking to obtain voluntary licenses to negotiate the terms of licenses on their own whims and fancies.

The next is with regard to the decision of the IPAB regarding the ‘reasonably affordable drugs’. Although, it took into consideration the public interest involved, but at the same time ignored other relevant consideration including the nature of drug, need for differential pricing for different sections of the society etc. From a patentees’ point of view there is enormous ambiguity with regard to the standards that shall go into ensuring the ‘affordable limit’ as drug making and innovation is equally and substantially costly.

The interpretation accorded to ‘working of the invention’ is too restrictive as manufacturing in India has been made a pre-condition for it and hence raises doubts regarding the prospects for a patentee who may supply adequately at reasonable prices.

VII. CONCLUSION

Patent protection, although imperfectly clothed, is an effective in providing an impetus to the development and invention of new products. As far as pharmaceutical patents is concerned the shall only work well in the high income countries as there the purchasing power of the people of the society is high and hence they have an easy access to medicines. Compulsory licensing thus shall prove to be a saviour for the low income countries. Undoubtedly, decisions by domestic courts in these countries, especially India, demonstrates their strong potential to re-shape global health diplomacy and also enforcing their guidelines by holding the pharmaceutical companies responsible for their corporate obligation with regard to ensuring access to medicines. Although, the rights of patentees’ do get prejudiced with such

³³*NatcoPharma Ltd. v. Bayer Corpn.* (CLA no. 1/2011) p.40-44 (available at <http://www.hkindia.com/images/compulsory.pdf>)

decisions, however a holistic approach indicates that such decisions help in reaffirming the right to have access to medicines which is an inseparable aspect of the right to health. However, at the same time, it is only its narrow and well defined application with necessary precautions that shall ensure a balance between innovation, investment and competition. The effective use of compulsory licensing as a legal weapon will certainly assist India in promoting technology transfer, and India should avoid undermining and underutilizing the compulsory licensing system just for export purpose or to increase the economies of scale. Also, if the trend of compulsory license gains momentum and is managed appropriately, it will attract a significant amount of investments, leading to an exponential increase of FDI in this sector, putting India up the line of economic prosperity.

A. IMPLICATIONS FOLLOWING THE GRANT OF CL

Just as a coin has two sides to it, the concept of CL is not without its demerits. Although it provides benefit to the people by safeguarding their health issues by way of supplying life-saving drugs at affordable prices but its long-terms benefits may not be easy to achieve. Licences should strike a reasonable balance between the Government (authoriser), the licensee (the generic drug manufacturing company-public or private) and the IP owner (the unwilling patentee). The biggest drawback of granting CL is its discouraging effect upon the patentee who may get demotivated from indulging into inventive activities. The other may be with regard to the creation of grey market that may subsequently be created due to its local supply in large quantities. The fact that it helps in generating drugs at affordable prices and secures healthcare was negated by certain experts from the Biotechnology Industrial Organisation (BIO), especially in India where the rate of interest or royalty is uncertain, issuing CL leads to demotion of invention.³⁴

The producer of generic drugs, on the other hand, may be restrained from exporting its output, if the supply is predominantly for the purposes of the domestic market. Also, the fact that CL is accompanied with the payment of adequate amount of remuneration to the patentee may eventually add on to the price of the medicine. Thus, CL cannot always be seen as the ultimate resort for the purposes of making available drugs to the people as it may subsequently discourage investments in India as well as the patent owners shall look for more business friendly legal environments. The grant of royalties is also nowhere near to the economic benefits that the patentee is able to reap by exercising his exclusive monopoly

³⁴SuvhiMidha, AditiMidha, *CL: Its impact on innovation in Pharmaceutical sector*, vol.2 (*International Journal of Application or Innovation in Engineering and Management* , ISSN 2319 – 4847, Issue 6, June 2013) (available at-<http://www.ijaiem.org/> Volume 2Issue6/IJAIEM-2013-06-20-056.pdf)

rights. In fact economically perceived, the licensee gains advantage without contributing for their share in the research and development cost of the invention. Moreover, there is a risk of supply of inferior quality medicines to the consumers as there is no regulator authority to supervise the production and manufacture of generic drugs.

However, after having undertaken a literature survey as to the implications of CL upon investment in R&D for developing patented drugs it is clear that CL does reduce the motivation to innovate and the consequences are graver for the drug industry that has the responsibility to meet unmet medical needs. The reasons for the same are as follows:³⁵

The process of developing drugs involves gross costs and risks and thus, patenting drugs becomes all the more essential. Thus, the drug industry shall obviously suffer if measures like CL are implemented that reduce patent protection and threaten innovation and investment.

The policy makers are hence faced with a challenge to simultaneously ensure that patent-weakening schemes that improve access to medicines should at the same time be such that they cause minimum harm to patent innovation and investment.

B. SUGGESTIONS AND RECOMMENDATIONS

The conflict of interest that is the necessary evil of grant of CL may be defeated by the following resolutions:

The grant must be made after elaborate clarifications regarding the conditions on which the same is granted. Certain parameters must be framed to determine what constitutes –reasonable terms of the license and the adequate remuneration. The TRIPS must lay down proper guidelines for the member states to follow in this regard. The rate of royalty must only be determined after considering the cost and time of R&D involved.³⁶

The patentee must be afforded a chance to be heard by the Controller and give such satisfactory reasons that may justify his failure to work the patent as stipulated.

In cases when the CL is granted during national emergency situation, the same must be granted for a specific duration and the patentee must also be duly informed within

³⁵CollenChien, *Cheap Drugs at What Price to Innovation: Does CL of pharmaceuticals hurt innovation*, p.19 (available at- <http://www.btlj.org/data/articles/vol18/Chien.web.pdf>)

³⁶Deli Yang, CL: For good or for worse, the done deal lies in the balance, p.5 (JIPR vol. 17, January 2012) (available at- [http://nopr.niscair.res.in/bitstream/123456789/13414/1/JIPR%2017\(1\)%2076-81.pdf](http://nopr.niscair.res.in/bitstream/123456789/13414/1/JIPR%2017(1)%2076-81.pdf))

a specific duration. The fact that he should be informed ‘as soon as may be practicable’ is quite vague and leads to confusion.³⁷

The generic companies must be discouraged from exploiting the process and using it merely for the purpose of generating revenue.

The threat of arbitrage must also be avoided, wherein a patented drug is imported to a market where it is priced low but then again it is re-exported to the market where it is priced high without the consent of the patent holder.

A national pricing authority should be constituted so as to avoid excessive pricing, which shall work on the basis of scientific and economic calculations.³⁸

It shall be appropriate if a list of threatening diseases is recognised that pose an increased threat to public health and the same shall be eligible for automatic CL under the law.³⁹

There must be a certain international system that should be evolved to coordinate the grant of in cross-border situations which shall monitor the conditions of fairness to both the licensors and licensee. There shall also be a system of filing complaints before a designated body so that the disputes may be resolved.

In fact the scheme of CI shall really be beneficial to all only when the concept of differential pricing is also followed so as to provide access to medicines to different sections of the society.

Most importantly CL shall not help unless issues such as healthcare infrastructure, disease diagnosis and medical insurance are also tackled as a generic version of the drug also (e.g. Nexaver that is priced at 80,000) would be beyond the reach of poor Indians suffering from cancer or any other fatal disease.⁴⁰

Thus, it can be said that CL does affect the investment in innovation to a certain extent, especially the countries that don't have manufacturing capacities and as such they have to depend upon the resources from developed countries. Under such circumstances the restriction of CL shall demotivate the patentees to invest in the R&D in these countries. It is

³⁷ *Ibid.*

³⁸ *NUALS Law Journal*, Dr. Raju KD, *Compulsory Licensing Provisions to Deal with Access to Patented Medicines in India* vol.6(Publication of Student Council, NUALS, Kochi, p.8, 2012) (available at - www.nuals.ac.in/web/pdf/NUALS_LAW_%20Journal%20.pdf)

³⁹ *ibid*

⁴⁰ Bhawna Sharma, Rishu Srivastava, *CL: Compromise or necessity*, 50 (Legal Era, May 2012) (available at - [http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5C2012-06-07-Compulsory%20License-Compromise%20or%20Necessity\(Legal%20Era\)%20in%20India.pdf](http://www.ssrana.in/Admin%5CUploadDocument%5CArticle%5C2012-06-07-Compulsory%20License-Compromise%20or%20Necessity(Legal%20Era)%20in%20India.pdf))

important that CL must only be granted when all the remedies to ensure public health care and maintaining investment in innovation have been exhausted. In fact the same should be resorted to after framing such policies that shall balance both public health needs and investment. The adverse effects on investment can be controlled and limited by framing such CL policies that are to be applied in a manner that the very rationale and basis for the grant of same is not challenged and it continues to tend to the needs of the public to have easy access to medicines without compromising the need for investment in innovating and patenting new and useful drugs.