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Compulsory Licensing under Patent Law in India with Reference to Natco v/s Bayer Case

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Abstract

The grant of patent follows with certain aftermath like the exclusive authority of the inventor leading to a high price of the invention and where the invention is something meant for the public at large it still remains out of reach. Thus, with changing times and advancement in technology concept of compulsory license is evolved. Compulsory licensing has been likened to the existence of a willing buyer against an unwilling seller by forcing a patentee to license the invention, a country can ensure that the patent does not exist on its books just to manipulate or otherwise restrict the development and marketing of the invention by one of the country's own citizens. Compulsory licensing is a fundamental tool that developing countries may use in certain conditions to ensure that poor people have access to necessary medicines and such other necessity. This measure shall produce positive social effects and promotes social well – being to the extent that it obviates the drawbacks of a patent system and creating an efficient tool for access to the necessary inventions e.g. drugs, medicines etc. In this paper we have explained the impact of the judgment in Natco v/s Bayer case and its significance for developing countries in the field of compulsory licensing.

Keywords: *Generic medicines, Kidney cancer treatment, Compulsory license issue, Intellectual Property Appellate Board, Bayer Corporation, Natco pharma limited, Sorafenib tosylate.*

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1. INTRODUCTION

A patent is a document issued upon application by a government office which describes an invention and creates a legal situation in which the patented invention can normally only be exploited with the authorization of the owner of the patent.

From the point of view of a developing country, a patent is a guarantee by the State to an inventor that his invention will be protected for a certain number of years, to allow him to exploit the invention for economic benefits. In exchange, the inventor must disclose his invention so that the State's citizens can benefit from the invention, and its store of knowledge will be enriched to facilitate further creativity. This kind of exchange juxtaposes immediately the opposing objectives of two parties, the inventor and the State. At best, their alliance, animated by opposing interests, will result in mutual satisfaction as both achieve their respective goals. At worst, the alliance will be broken and the respective goals of the parties, forgotten. The international framework integrating the world economies make it almost impossible for one party or both to simply walk away.[1] And presently In India 'patent' means a patent for any invention granted under Patent Act. [2]

As patents allegedly fuel inventive genius so does there are techniques which lead to fire. It is to be noted that a patent is a right of personal property and can be dealt with by assignment, mortgage, license etc. In Modern times, the burning issue is that of compulsory licensing, thus determining its meaning. A license is a permission by one person to another to do or continue to do something which would, in the absence of such permission, be unlawful. [3]

2. THEORY OF COMPULSORY LICENSE

Compulsory licenses are generally defined as "authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent."[4]

Compulsory licensing has been likened to the existence of a willing buyer against an unwilling seller. The might of the government is put to bear on the unwilling seller to enable a transaction to go through. By forcing a patentee to license the invention, a country "can ensure that the patent does not exist on its books just to manipulate or otherwise restrict the development and marketing of the invention by one of the country's own citizens."[5]

Compulsory license provisions may broadly be classified according to four theories: the adequacy of supply theory, the public interest theory, the worked-in-the country theory and the interdependence of patents theory[6] :

A. The Adequacy of Supply Theory.

The demand for an invention product may be so great that a patent holder may not be able to supply the market with the patented product. Consequently, it may be forced to grant a license to someone in the same business, most likely, a competitor. Under this theory of adequate supply,

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[1] Compulsory Licensing and Pharmaceuticals: Emerging Issues in Philippine Trade by Ma. *Rowena R. Gonzales*

[2] Sec. 2(m), Patents Act, 1970

[3] Mitra's Legal Dictionary

[4] Scherer & Watal *supra* note 3, at 12.

[5] Carolyn S. Corn, *Pharmaceutical Patents in Brazil: Is Compulsory Licensing the Solution?* Boston University International Law Journal, vol. 9 p. 93 (1991), quoting from *International Patent Protection: An Integrated Solution to the Inadequate Protection Problem,* 29 Va. J. Int'l. L. (1989) p.538.

[6] Ibid. pp. 668-672.

the inventor's right to the economic benefits of his intellectual creation may be reduced in favor of the accessibility and availability of the goods to the public.

B. Public Interest Theory

Similar to the adequate supply theory, this theory limits compulsory licenses to cover patented products/processes which are considered vital to the public. The licenses issued following this theory commonly involve inventions relating to public health, welfare, or national defense.

C. Worked-in-the-Country Theory

Many compulsory licensing provisions require that an invention be 'worked' in the country. The interpretation of 'work' varies from country to country ranging from the set-ting up of a manufacturing plant to the use of the patented product.

D. ***Interdependence of Patents Theory***

This theory recognizes that an earlier patent may have to be used for another patent to be exploited. The State allows such use by giving a compulsory license to the inventor of the second patent. The theory is designed to facilitate the use of an improvement or new use over a prior invention, the patent of which still exists.

3. THE CURRENT TREND

It is now a decade since the World Trade Organization (WTO) adopted the "Declaration on the TRIPS Agreement and Public Health" at its 4th Ministerial Conference in Doha. The Doha Declaration reaffirmed the right of WTO member states to apply the legal flexibility of compulsory licensing—which is a state licensing the use of a patented innovation without the permission of the patent title holder—to pharmaceutical patents under the WTO's Trade-Related Aspects of Intellectual Property (TRIPS) Agreement[7]. It also led the TRIPS Council to announce a waiver allowing states lacking strong drug production capacity to import generics under compulsory licensing[8].

Giving effect to the declaration, progress is made in increasing pharmaceutical access in the poorest countries, particularly with the global antiretroviral treatment scale-up, yet such improvements also relate to increased philanthropic activity, public–private partnerships, and bilateral aid.

"If we believe men have any personal rights at all as human beings, they have an absolute right to such a measure of good health as society and society alone is able to give them" [9]

Compulsory licensing is now giving shape to the above jurisprudential aspect and thus leading to a healthier world.

So in the race of brewing better medical facilities are entering the giants of pharmaceuticals, fighting over the patented rights.

India granted its first ever compulsory license to Natco against Bayer's patent on drug nexavar on March 09, 2012 under Natco v. Bayer.

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[7] World Trade Organization (2001 November 20) Declaration on the TRIPS agreement and public health. Available: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[8] World Trade Organization (2003 September 1) Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. Available:http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

[9] By Aristotle

4. NATCO V/S BAYER

An application was filed by Natco against Bayer's patent on drug Nexavar which is a patented generic medicine – 'sorafenib'[10] , which resulted in the grant of permit to Natco for the marketing and manufacturing of its generic version on following terms[11]:

1. The right to make and sell 'sorafenib' is limited to applicant i.e. no sub-licensing is permitted.
2. The compulsorily licensed drug product can be sold only for treatment of liver and ceral cancer.
3. The royalty shall be paid at a rate of 6%
4. The price is set at Rs. 74/- per tablet which equals Rs.8880/- per month a course of 120 tablets
5. The commitment by applicant to provide drug for free to at least 600 'needy and deserving' patients per year.
6. The compulsory license is not assignable and non-exclusive , with no right to import drug
7. No right to licensee to represent publically or privately that the product is same as Bayer's Nexavar.
8. Bayer shall have no liability for Natco's drug product.

5. LICENSE JUSTIFIED

The controller found justification for compulsory license on three grounds, detailed as follows:

1. **Reasonable requirements of Public are not satisfied**[12]: The applicant alleged that there were approximate 20000 liver cancer patients and approximately 9000 kidney cancer patients, thus assuming 80% demand i.e. 23000 bottles of drug per month to satisfy this demand. But the evidence on record shows that no supply was made to India in 2008, only 200 bottles were supplied in 2009 and No import in 2010 made the availability of the drug to only 2% of eligible patients, thus, not satisfying the reasonable requirements[13] of public at large.
2. **Non-availability at reasonably affordable prices**[14]**:** The controller found that the drug is exorbitantly priced and is also out of reach of public at large. The price quoted in the decision as being Rs.2,80,248/- per month and Rs.33,65,136/-per year as opposed to Rs.8800/- per month from Natco. Moreover the availability of drug was restricted to the metropolitan areas and was not uniformly available throughout the country and that too in a frequent short supply. The controller enunciated an Indian-centric philosophy that the mandate of law is not just to supply the drugs in market but to make it available so that a substantial portion of public is able to reap the benefits of the invention. Also, it was declared that :
   The invention is a 'life saving drug' and not a 'lucky item'.
   The above aspect of decision was illustrated by controller's calculation that at Bayer's price, a common man would take 3-5 year wages to afford the one month's supply of the drug and so in order to construe a reasonable price predominantly with reference to the public the license was granted.

[10] The drug is for the treatment of kidney and liver cancers in advance stages. Presently, the drug is imported to India after being manufactured in Germany.
[11] See the controller's decision available at www.ipindia/nic.in/iponew/compulsory-license-12032012.pdf
[12] Sec.84(1)(a), Indian Patent Act,1970
[13] The requirement of drug was necessitated to at least 8842 patients.
[14] Sec.84(1)(b),Indian Patent Act,1970

3. **Non-working in India:**[15] As the Natco advanced an argument that the Bayer had 'worked' the patented invention extensively in other countries but not in India while having the industrial capacity to produce it here as well and the minimal working was not enough but the term "worked in the territory of India" is not defined under Indian Patent's Act, so the controller construed it with regard to "various International conventions, the Patents Act and legislative history. In this light, the controller reached the decision after considering the relevant provisions of the Paris Convention, TRIPs Agreement and Patent Act, where Article 27(1) of TRIPs[16] and Article 5(1) (A) of Paris convention[17] supported the interpretation that failure to manufacture supports grant of compulsory license.

Thus, ultimately, the controller found ample jurisdiction for granting compulsory license in light of sec.83 (b) of Patent Act which states that patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article and sec.83(b) which provides that the grant of a patent right must contribute to the promotion of technological innovations .

6. SIGNIFICANCE OF THE JUDGMENT

The following points shall illustrate that the significance of this judgment is multi-fold when seen in respect of the country:

1. **Change in patentee's attitude**: This will necessarily change the attitude of the patentee and they won't be able to obtain monopoly and abuse their position. The social responsibility shall also be shouldered to them and shall be catering the same for the good of society on whole.
2. **Encouragement in Indian and Third World's Generic Industry**: The decision will encourage more companies to resort to this route. Also it furthers the chances of more compulsory licenses in India with most of the drugs being imported and not complying the "working in the territory "clause.
3. **Benefits Patients and Consumers**: The decision will have a positive impact on the patients suffering from kidney and liver cancers in India by making the drug affordable. Further, note should be taken that 600 needy and deserving patients will be provided the free medicine.
4. **Considering Differential Pricing Structure**: With the Controller seeking the question that why Bayer did not consider the differential pricing, the decision may make MNC's to consider the differential pricing structure for selling drug and setting up various parameters to determine the prices for different sections/classes of the public in India.
5. **Resolving the Blocking Issue**: Even though there is no issue of blocking in pharmaceuticals but this is quite common in other fields of technology and a classic example of same is the conflict between Marconi and De Forest.[18] In this case the Marconi was able to block improvements and thus making it impossible for the parties to end up with licensing agreements. But such an issue shall be redress able by controller at instance of either party.

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[15] Sec.85(1)(c),Indian Patent Act,1970

[16] *"Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."*

[17] *"Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses".*

[18] Marconi wireless Tel. Co. v. De Forest Radio Tel. & Tel., 236 F 942 (SDNY 1916) ; https://bulk.resource.org/courts.gov/c/US/320/320.US.1.369.373.html

6. **Setting up the Precedent for Developing World**: This is the first decision on compulsory license application in India and would act as a precedent for all possible future cases.
   The above decision is not merely restricted within Indian boundaries rather it shall also affect the third world countries and shall motivate them to adopt a similar legal provision for the benefit of people.
7. **Developing nations and the compulsory license: maximizing access to essential medicines-minimizing investment side effects:** For compulsory licensing to be an efficient tool to reduce the costs of the system of patents and provide greater social welfare, the ways in which it can be used must be clearly defined. It would be wrong to believe that compulsory licensing is a panacea for all the problems of public health faced by developing nations. Some questions are of a structural nature and need comprehensive policies which include the adoption of measures of different kinds. It must also be acknowledged that compulsory licensing is an exceptional resource which should be used by governments in exceptional circumstances, established by law. The rational use of compulsory licensing may favor the transfer of technology to produce medicines for countries in areas of vital interest for the health of the population.

Developing countries should use the alternatives offered by the TRIPs Agreement and create legal tools and public policies to exploit the potential offered by compulsory licensing to allow greater social equality in access to medicines. In this context it is absolutely necessary to maintain the flexibility established by the TRIPs Agreement for this to happen.
The pressure for compulsory licensing not to be conceded and frequent attempts to interpret the TRIPs Agreement in a restrictive manner are extremely damaging to the interests of developing countries, and preclude them from carrying out public policies that prevent death and improve the health of a considerable part of the population.

8. CONCLUSION & SUGGESTIONS

Granting compulsory license can now be never kept at bay for people has known its sweet taste. So the only plausible alternative is to make the royalties paid to the patentee such that it does not drain the interests of pharma players to play in India. The government should make effective policies and rules that can an orchestrate to a harmonious tune the cries of both the patients and the big pharma players. Only a well synchronized rule can help this happen. Certain Suggestions in this regard are:

1. The grant and exercise of patent rights should be consistent with the basic goals and interests of the society, particularly promotion and protection of public health.
2. The nations must shape their patent law according to the socio-economic needs and objectives.
3. The improvement of access to medicines requires a pro-competitive approach where by Compulsory Licensing is a good option.
4. A Legal instrument is necessary for the enforcement and redressal of disputes in the matters of patents and Compulsory Licensing.
5. Need for the revival of laws under Competition Act in India and like in other nations as well as establishment of an agency for regular reporting on progressive realization should be evolved.

Thus, 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.

Moreover, compulsory licensing promotes social well-being to the extent that it obviates the drawbacks of a patent system and creating an efficient tool for access to essential medicines in developing nations.

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