



COMPULSORY LICENCE OF PATENTS IN INDIA

Harish Chandra Pandey

Harish Chandra Pandey, Assistant Professor, Faculty of Law, DDU Gorakhpur University, Gorakhpur (UP).

I Introduction

The general principle governing patents strive towards mutual advantage of producers and users of knowledge goods. It is granted not only to enjoy monopoly over rights but also development conducive to social and economic welfare. Ever since compulsory licensing has emerged in multilateral rules as an obligation to member countries, it has been debated around the balance of interests between the general public and Intellectual Property rights holders. This paper analyses implications of compulsory licensing over the pharmaceutical patents and access to medicine in the light of the *Bayer-Natco* case.

Even though all World Trade Organization (WTO) members provide for the possibility of granting compulsory licences through their national laws, the grant of compulsory licences remains a rare exception especially in developing countries. Nevertheless, India has issued compulsory licence in *Natco Pharma Ltd. versus Bayer Corporation*. This issuance has re-invigorated the debate over implications of the compulsory licensing of patent on innovation and the supply of drugs to the general public at affordable price. The paper analyses compulsory licensing regime in India. More particularly, it analyses possible implications the *Natco* decision is likely to have on pharmaceuticals sector and access to medicines.

II Compulsory Licensing in India

Patent legislation is not new in India. In 1856 the first patent legislation in India came in force and was renewed in 1859 in the lines of the *British Patent Act, 1852* and subsequently it was amended from time to time in order to meet the needs of the rapidly changing scenario.¹ However in 1911 it was replaced by the *Indian Patents and Design Act* which for the first time provided for compulsory licensing of patents in case of misuse or abuse of patent rights. Under this Act, any interested person could, after the expiration of three years of the sealing of a patent, apply to the Controller of Patents for the grant of compulsory licence on grounds such as:

- (a) that the patented invention, capable of being commercially worked in India, has not been commercially worked therein or is not being so worked to the fullest extent that is reasonably practicable;
- (b) that a demand for the patented article in India is not being met to an adequate extent or on reasonable terms, or is being met to a substantial extent by importation of the patented article from other countries;
- (c) that by reason of the refusal of the patentee to grant a licence on reasonable terms, a market for the export of the patented article manufactured in India is not being supplied.
- (d) that by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent or the establishment or development of commercial or industrial activities in India is unfairly prejudiced.

After independence the Government of India appointed the *Tek Chand Committee* in 1948 to specifically examine the existing patent legislation with a view to improving it. The key suggestions were that compulsory licences could be applied for after three years, by making an application to the Comptroller General on grounds that included the following:

- i) Commerce/industry in India was being substantially affected;
- ii) Export in the patented item was absent; and

¹ Shammad Basheer and Mrinalini Kochupillai, *The Compulsory Licensing Regime in India: Past, Present and Future* 1 (JPO, Tokyo, 2005).



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iii) Manufacture or market of other patented items was adversely affected (rather than simply assert that the manufacture was taking place outside India and the applicant was able and willing to work the patent in India).² As a result of this report, the grounds for compulsory licensing widened. The main addition to the existing grounds was that a compulsory licence could be requested if:

- (a) Due to the conditions imposed upon the use of a patent or a sale of a patented article, commercial or industrial activities were being hampered.
- (b) The Government of India felt that this would be in the interests of consumers or the industrial development of the country. The government could also apply for a compulsory licence to be granted to it in order to enable private parties to work the patent.

The provision enabling the government to request a compulsory licence on behalf of private parties seems to suggest the inclusion of a ‘public interest’ ground. In this regard, the *Tek Chand* Report went beyond the 1911 Act, under which the compulsory licence provisions mainly catered to instances of patent abuse. This focus on public interest was again reiterated when the Act was amended yet again in 1952 to include Section 23CC that provided for the automatic endorsement of licences of right in respect of inventions pertaining to food, medicine or drug. However, compulsory licensing regime was also subjected to further scrutiny by the appointment of the *Ayyangar Committee* with a view to reforming patent legislation so as to further national interest. This Committee widened its scope of examination and came up with certain valuable suggestions.³ The suggestions made by the *Ayyangar Committee* went on to form the basis for the unamended *Patents Act, 1970*. In order to comply with TRIPS, the 1970 Act was amended thrice, first in 1999, then in 2002 and again in 2005⁴. The chapter XVI of the *Patents Act 1970* sections 82 to 94 deals with compulsory licensing of patents. This chapter is drafted along the lines of Article 31 of the TRIPS Agreement. The 2005 amendment introduced the product patent for pharmaceuticals for the first time in India, earlier only process patent was allowed in case of pharmaceuticals and increased the scope of compulsory licensing of patents. The Section 84(1) provides three grounds on which compulsory license can be applied for and this are:

- (a) Reasonable requirements of the public with respect to the invention are not satisfied, or
- (b) The patented invention is not available to the public at a reasonably affordable price, or
- (c) The patented invention is not worked in the territory of India.⁴

But an application for the grant of compulsory license can only be made after the expiry of 3 years from the date of the grant of patent.⁵ Clause 7 of the section 84 states the circumstances when the reasonable requirements of the public shall be deemed not to have been satisfied. Section 92 provides that in case the Central Government is satisfied that owing to the existence of national emergency or extreme emergency or public non commercial use granting of compulsory license is necessary then compulsory license may be granted at any time after the sealing thereof to work the invention but provided that a declaration to the effect is made by notification in the official gazette.⁶ The main difference between Section 92 and Section 84 is that the applicant need not wait for a period of three years to lapse before making an application for grant of compulsory licence under Section 92(1). Apart from this, Section 92(3) stipulates that the Controller has discretionary powers to decide whether to follow the cumbersome procedure under Section 87 when faced with an application for grant of compulsory licence under Section 92.⁷ In compliance of the Doha Declaration section 92 A was added by the *Patents (Amendment) Act, 2005* and this section provides that in case of countries having insufficient or no manufacturing capacity in pharmaceutical sector for a product which is required to address public health problems in that country compulsory

² *Id* .at 4.

³ *Id* .at 5.

⁴ The Patents Act 1970, Section 84 Compulsory licenses.

⁵ Section 84 (1) , The Patents Act 1970.

⁶ Section 92(1).

⁷ *Ibid*.



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license shall be available for manufacture and export of patented pharmaceutical products to that country.⁸ Given that many countries like South Africa and Kenya, which do not have manufacturing capacities on their own, are looking to Indian generic manufacturers for their drug supplies, this is a very useful provision and is relatively easy to invoke.

III The Bayer-Natco Decision

In March 9, 2012 compulsory license was granted for the first time in India to NATCO Pharma Ltd., an Indian generic drug producing company to sell and produce sorafenib (nexavar), a drug for the treatment of advanced stage kidney and liver cancer which is a drug patented by Bayer Pharmaceuticals, a German drug manufacturing company by the Controller of Patents, Mumbai. It has laid down the very foundation stone of the jurisprudence of compulsory licensing in patents with respect to pharmaceutical products in India⁹ and has principally clarified the legislative intent behind various key provisions governing compulsory licensing under the Indian *Patents Act, 1970* read together with the TRIPS providing guidance to any further construal in this direction.¹⁰ Till 12 March 2012 nothing much had been done in the post-2005 era of product patents, in terms of using these provisions; but this order is a precedent and more compulsory licensing are likely to follow. Most other countries which had issued compulsory licensing on medicines – like Thailand, Malaysia, Indonesia, Cameroon, Eritrea, Zambia, Brazil, *et. al.* – had issued them only for government use.¹¹ The Natco compulsory license is the first time a patent has been issued to a private party, and for an anti-cancer drug.¹² India is one of the few countries where issuing compulsory license for local manufacture is meaningful, because Indian industry has the capacity to back it up by actually manufacturing the medicines so licensed.¹³ The main issues in the case were those mentioned in section 84(1) (a, b, and c), *i.e.*,

- a) the reasonable requirements of the public with respect to the patented invention have not been satisfied
- b) the patented invention is not available to the public at reasonably affordable price
- c) the patented invention is not worked in the territory of India.¹⁴

As regards the question of fulfilment of Section 84(1) (a), *i.e.* reasonable requirements of the public in relation to the invention, the availability of Nexavar was shown to be sufficient for only 2% of those getting these specific cancers and there was requirement of 70000 boxes of the drug as shown by the Applicant. The Controller accepted the contentions of the Applicant and also rejected the stand of the Patentee that another drug manufacturing company *M/s Cipla* was also in the market and was selling a similar drug and as such the reasonable requirements of the public were satisfied by combining the drugs sold by that company with the drug sold by the Patentee. Since the Patentee tried his best to prevent *M/s Cipla* by instituting an infringement suit pending before the Delhi High Court and this led to the clarification by the courts that you cannot link licensing by the drugs controller for manufacture and marketing of a medicine to its patent status. TRIPS contemplates within its ambit a health sensitive patent law which may specifically provide for several grounds for compulsory licenses including the ground of lack or insufficiency of working. This ground is expressed in a number of ways such as the demand for the a patented product not being met to an adequate extent and on these reasonable terms; the reasonable requirements of the public with respect to the patented product not being satisfied and the patented product not being available to the public at a reasonable price. The decision of the Controller, thus, by reading all these considerations into the relevant provision of Section 84(1)(a) and 84(7)(a)(ii) of the *Patents Act, 1970* is in compliance with TRIPS. Regarding the next issue *i.e.* the question of the availability of the patented product at reasonably affordable price; it is worth mentioning that the price of drug in Indian market was Rs.2,80,000 a month which is far beyond the buying capacity of an average Indian. The contention of the Patentee that “affordable to the public” is required to be considered as affordable

⁸ http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (Visited on January 29,2014)

⁹ <http://ssrn.com/abstract=2072435> (Visited on January 28, 2014).

¹⁰ *Ibid.*

¹¹ S Srinivasan, “ The Compulsory Licensing for Nexavar A Landmark Order” XLVII *EPW* 10 (2012).

¹² *Ibid.*

¹³ *Ibid.*

¹⁴ See In the matter of Natco Pharma and Bayer Corporation, March 12,2012 at P .12 of the decision.



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to different classes of the public was accepted. However, the stand of the patentee that reasonability has to be construed with reference to the public as well as the patentee was rejected. It was held that reasonably affordable price has to be construed predominantly with reference to the public. Since the sales of the drug during the last four years by the patentee at Rs. 2,80,000/- for a therapy of one month constituted a fraction of the requirement of the public. Hence, it was concluded beyond reasonable doubt that patented invention was not available to the public at reasonably affordable price. Article 8.2 of the TRIPS allows members to take appropriate measures to prevent abuse of intellectual property rights. Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Many WTO countries have laws that explicitly permit compulsory licenses in situations where patented goods are not being made available at reasonable terms. For instance, the French Intellectual Property Code, specifically regarding medicines patents, states that "...products may be subject to ex officio licenses ...in the event of such medicines¹⁵ being made available to the public in insufficient quantity or quality or at abnormally high prices."¹⁶ Similarly, in the UK, the *Patents Act, 1977* allows compulsory licenses when "...demand for the product in the United Kingdom (i) is not being met on reasonable terms." Section 84(1)(b) of the Indian *Patents Act, 1970* is, thus, a TRIPS amenable ground for issuance of compulsory license to Natco by the Controller in the immediate order and as such. One of the contentious issues decided through this order has been the scope of the term "worked in the territory of India" in light of the meaning from various International Conventions and Agreements on Intellectual Property, provisions contained in the *Patents Act, 1970*, the context in which this concept appears, and also the legislative history. While attempting to give a meaning to the term consistent with Article 27 of the TRIPS Agreement, the Controller of Patents has looked into the import of the Agreement as a whole along with the intent of Article 27.1 per se. Even though the TRIPS marked a new era of obligations regarding the protection and enforcement of intellectual property, WTO members like India have retained important policy options, flexibilities and safeguards, including the liberty to determine the grounds for issuing compulsory licenses which help it to achieve a balance between intellectual property protection specific developmental priorities, including the attainment of national public health objectives. When Article 27(1) of the TRIPS Agreement is read with Article 2(1) of the TRIPS Agreement mandating compliance with the provisions of the Paris Convention by the member states including Article 5(A)(1) and Article 5(A)(2), it follows that importation of a patented invention shall not result in forfeiture of a patent.¹⁷ However, a reasonable fetter on the patent rights in the form of compulsory license is well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. This flexibility has been held by the Controller to be invoked in Chapter XVI of the *Patent Act, 1970* by incorporating a provision for grant of compulsory license upon failure to work the invention within the territory of India. Hence, on a reading of the relevant provisions of the Act in conjunction with the TRIPS flexibilities, the Controller arrived at the conclusion of the term 'worked in the territory of India' cannot be restricted to mean as 'worked in India on a commercial scale' and it is something more than that. Further, mere importation cannot amount to working of a patented invention under Section 83(b) of the Act and in view of Section 83(c) and Section 83(f) whereby a patentee is obliged to contribute towards the transfer and dissemination of technology, nationally and internationally so as to balance the rights with the obligations and this can only be achieved by the patentee either manufacturing the product in India or by granting a license to any other person for manufacturing in India. Mere importing cannot amount to working for a license as is indicated by Section 84(6) and Section 90(2) of the Act. Therefore, a combined reading of the Paris Convention and TRIPS Agreement and *Patents Act, 1970*, 'working in the territory of India' was held to mean 'manufactured to a reasonable extent in India.' Hence, in the instant case since the Patentee has failed to establish manufacturing facilities for manufacturing drugs in India even after the lapse of four years from the date of grant of patent along with the failure to grant any voluntary license on reasonable terms to anyone in India to work the invention within the territory, Section 84(1)(c) is attracted for the grant of compulsory license to the Applicant.¹⁸

¹⁵ *Ibid.*

¹⁶ *Ibid* at 7.

¹⁷ *Id.* at 8.

¹⁸ *Ibid.*



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IV Implications of the Bayer-Natco Decision

Indian pharmaceutical industry has undergone drastic change in the last fifty years, while in the fifties it consisted largely of trade in imported drugs by eighties it became dominated by major bulk drugs.¹⁹ Today Indian pharmaceutical manufacturers produce more than 250 bulk drugs relying both on original research and product adaptation. Currently India is the world's fourth largest producer of pharmaceuticals by volume accounting for around 8% of global production. The tension between the patent rights and the need for cheaper drugs is not new. There are some lessons in the decision itself which research companies should consider in order to pre-empting compulsory licensing applications. By licensing rather than by being force to license, patentees can negotiate the terms of license. Differential pricing structures may also be introduced for different sections of the society.²⁰ Also the decision will now open up the field for the generic industry to follow suit and could well pave the way for the availability of cheaper drugs for lifestyle diseases.²¹ The landmark judgment by the Indian Patent Office is now being seen as a test case by the generic industry and has significant implications for both the domestic generic industry as well as Multinational Corporation (MNCs), which spend substantial amounts on Research & Development (R&D) before they find a new drug. Experts suggest that Natco Pharma's strategy of invoking the compulsory licensing clause could well prove to be a game changer for the generic industry, which has been facing formidable barriers for a long time and it would open up the field for many domestic manufacturers to follow Natco's strategy. The country's first ever compulsory licensing approval also has significant upsides for consumers, especially the poor since it would open up the field for other generic companies to tap this route, thus forcing MNCs to rethink their pricing strategies for India and other developing countries. According to *Prof. Shamnad Basheer*, "Not only will MNCs need to revisit their pricing strategy in India, the decision will have a spin off effect in other countries like Thailand and Brazil , as well as in their home markets. "Significantly, this would lead to lowering in exorbitant prices of lifesaving cancer drug and HIV drugs. MNCs, however, feel that these licences should only be granted in case of a public health crisis. If used arbitrarily, compulsory licenses will serve to undermine the innovative pharmaceutical industry and will be to the long term detriment of the patient. It will discourage investment in new medicine for patients"²²

V Conclusion

This decision serves as a warning that when drug companies are price gouging and limiting availability, there is a consequence. In the pharmaceutical sector, the decision of the *Bayer-Natco* case is going to boost generic manufacturer of drugs and also compel the MNCs to rethink their pricing strategy and make them more open to granting voluntary licenses.

¹⁹ Rachna Bakru and Ranjan Narula , "India Grants First Compulsory License Under Patent Act" *Intellectual Property Magazine* 47 (June, 2012).

²⁰ *Ibid.*

²¹ Rupali Mukherjee , "Road To Cheaper Drugs" *The Times of India*, March 14,2012.

²² *Ibid.*