

## Short Communication

# A study of Natco v. Bayer case: its effect and current situation

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### ABSTRACT

Patent right provide the monopoly to the patentee over the manufacture, sell and import of the products. In the absence of such right to the patentees, the infringement of the same will not be penalized and their work will not be awarded, but there are certain conditions when the government can forcefully take away the rights of the patentee and give it to the third party for the sale and manufacture of the same. This article focuses on the case analysis of the grant of compulsory licensing, introduced in India with the case of Natco Pharma. Ltd. v Bayer Corporation, its effect and the present scenario.

## 1. INTRODUCTION

### Compulsory Licenses

Compulsory License as a mechanism is allowed by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) – the international agreement which establishes intellectual property rights, including patent rights. Patent protection can be overcome through the use of Compulsory Licenses, which enables other companies to produce a patented product without the permission of the patent holder. A compulsory license creates an exception to the monopoly created by patent protection and acts as a legal counterweight to combat the adverse effects of patents. TRIPS empowers the state to make use of compulsory license according to its own discretion. Thus, the state can rightfully resort to the use of compulsory license in order to meet health requirements of the country's population [1].

## 2. CASE REPORT

### 2.1 Background of the case

The history of compulsory licensing can be traced back to the

UK Statute of Monopolies in 1624, which ruled out monopolies associated with Patent, and stated that grants should not be mischievous to the State or hurt trade. The UK recognized compulsory licensing in terms of non-working and stipulated rules to prevent patents from not being worked commercially [2].

TRIPS agreement states that “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”[3]. The agreement allows compulsory licensing as part of the agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term “compulsory licensing” does not appear in the TRIPS Agreement. Instead, the phrase “other use without authorization of the right holder” appears in the title of Article 31. Compulsory licensing is only part of this, since “other use” includes use by governments for their own purposes. Compulsory licensing and government use of a patent without the authorization of its owner can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder [4].

In 2001, WTO Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In particular, concerns had been growing that patent rules might restrict access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, including HIV, tuberculosis and malaria. The Doha Declaration states that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted [5].

The currently the system of compulsory licensing for patents, in India can be found in chapter XVI of the Patents Act 1970, under the sections 82 to 94 which complies with the decisions made in the above mentioned international agreements. *Natco v Bayer* is the case which granted compulsory licensing in India post TRIPS agreement.

## 2.2 Highlights of the case

Bayer Corporation (to be referred as patentee) is the American subsidiary of Bayer AG, a German multinational chemical and pharmaceutical company. It manufactured a drug called ‘Sorafenib’ (Carboxy Substituted Diphenyl Ureas) used in treating advanced stage cancer in kidney and liver. Patentee obtained a patent for the same in United State and India, also in many other countries including countries of European Union. It was granted patent in India in the year 2008 after examining the various provisions of the Indian Patent Act, 1970. Meanwhile in 2005 patentee developed a drug named Naxavar (to be referred as ‘drug’) for the treatment of Renal Cell Carcinoma RCC (kidney cancer) and subsequently got approval for the hepatocellular carcinoma HCC (liver cancer). Patentee got approval for importing and marketing the drug in India until 2008, when it was finally launched in India.

Indian generic pharmaceutical company, Natco Pharma Ltd. (Hereafter to be referred as applicant) was incorporated on 19th September, 1981 in Andhra Pradesh as a Pvt. Ltd. Company as Natco Fine Pharmaceuticals Pvt. Ltd. and became a deemed Public Company with effect from 1st July, 1992 under Section 43A of the Act. Subsequently, it changed its name to Natco Pharma. Ltd.

The application for the compulsory licensing of Naxavar [6] by applicant was filed before the Controller of Patents in 2011 under section 84 of Patent (Amendment) Act 2005 [7]. Applicant claimed that Bayer’s patented drug not been made available to the public at a reasonably affordable price and that the reasonable requirements of the public had not been met. It further argued that Bayer had failed to work the patent in India within the specified three years period [8].

In the judgment of the same, licence was granted to applicant against which patentee appealed to Intellectual Property Appellate Board (IPAB) which was rejected [9]. 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 [10], and flagged the major issues based on the three-pronged test laid out in section 84(1) of the Act [11]. In granting the compulsory

License to Natco, the controller took account of the fact that Bayer had priced Naxavar at ₹ 2.85 lakhs for a month’s course, whereas Natco planned to sell its generic version, for just ₹ 8,900.

## 2.3 Effects on Indian pharmaceutical companies

This decision rose controversies and raised a question on the grant of same as the companies argued that developing such drugs means investing a lot of money in R&D, time and effort and hence they should be given the liberty to enjoy the monopolistic right over the use of same, to earn the profit and hence balancing the cost borne during R&D. The other argument which was raised, that the controller failed to provide for a reasonable and affordable price as in this case.

While the controller accepted Natco’s price, the same may not be affordable for some sections of the society. The question still remains arguable, whether the demand for the patented invention has to be satisfied by the patentee or its licensee and not by a third party in the instant case.

## 2.4 Later patents in the same course

Surprisingly, there are very few cases of compulsory licensing after the grant of license in the Bayer case. The grant of Compulsory license claim was made in the case of *Emcure Pharmaceuticals v. Roche*, for Roche’s Drug “Trastuzumab” commonly known as Herceptin. However, the Department of Industrial Policy and Promotion (DIPP) denied the Ministry of Health in proceeding with this application, which had made a request under section 92 of the Patents Act, which allows for the government to file for a license in cases of national emergency. Another very important case is BDR Pharma and Bristol Myers Squibb (BMS) where, BDR Pharma filed for a compulsory license in March 2013, for Bristol Myers anti-cancer drug “Dastanib” but the Controller rejected the compulsory license application of BDR Pharma. On 29<sup>th</sup> October, 2013 on the grounds that BDR Pharma could not make out a prima facie case for the grant of a compulsory license, because as the applicant, BDR Pharma had failed to make efforts to obtain a voluntary license from the patentee on reasonable terms and conditions.

The most recent case is that of Lee Pharma v. Astra Zeneca [11], where Lee Pharma, a Hyderabad-based Drug manufacturer, filed a CL Application in accordance with Section 84(1) of the Indian Patents Act, on 29<sup>th</sup> June, 2015. The CL application was made against one of the patented drug “Saxagliptin” used in the treatment of Diabetes Mellitus. The patent on Saxagliptin was granted to Bristol Myers Squibb (BMS) in India on 30<sup>th</sup> April, 2007 which was assigned to Astra Zeneca by way of Deed of Assignment. Lee Pharma. Alleged that Astra Zeneca had been importing the drug at less than a rupee but charged as much as ₹ 45 for each tablet, driving up the cost of therapy beyond the reach of most Indian patients. It also contended that Astra Zeneca had not made sufficient efforts to make the drug in India, running in contravention to the existing Patent laws of the country. The Controller, however found that, a *prima facie* case could not be made out for making an order under Section 84 of the Patents Act and issued his decision on the 12<sup>th</sup> of August, 2015 in favor of Astra Zeneca [12].

### 3. CONCLUSION

Patent Act, 1970 which is consistent with the TRIPS Agreement provides that the compulsory licensing should be granted only after taking the fact in account that the considerable efforts have been made by the applicant in obtaining the Licence, as in the instant case the Licence was granted soon after the single attempt made by Natco. This proves the fact that the controller have adopted the most favorable applicant approach, which is non-acceptable in other countries granting compulsory licensing.

Patent occupy a very important place in pharmaceutical companies. This decision has certainly disappointed the R&D industries. Given the time and cost in R&D and filing a cross suit for the compulsory licensing is something which companies resent to. Foreign R&D drugs companies have shown their disappointment in the decision and indicated that it could both jeopardize India's position as a potential market for the launch of new drugs and discourage innovation [13]. It would be appreciating, if there could be any other mechanism that can be found for providing the medicines with lower or at some different prices to those who cannot genuinely afford it. It is advisable if there can be genuine negotiated agreements and voluntary licensing instead of coerced ones.

A more pragmatic approach to compulsory licensing is the one taken up by Brazil. Instead of private generic companies obtaining compulsory licensing, the government studies which diseases needs intervention from the state and use the compulsory licensing as a bargain tool to get the innovator companies to come to the negotiating table. Brazil has been successful in getting various inventor companies to reduce drug prices by up to 40% [14]. This approach has provided a three dimensional benefit firstly, the government is able to make out as to which disease requires the urgent need of availability of medicines. Secondly, it helps the patentee to retain exclusive rights to the patents and lastly, it provides the public in general, medicines at a lower and affordable price.

In India the similar approach can be adopted as there already exist regulations in the same regard in the form of Drugs (Price Control) Order 2013 [15]. This can help the government in effective price control of the drug without taking away the monopolistic rights of the patentee. Also this will help in increasing the access to the medicines. Now, this is only up to the supreme court of India to draw up the lines for an effective mechanism to be followed in this sphere whereby following the standards laid down globally.

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