OVERALL IMPACT OF COMPULSORY LICENSING IN INDIAN MARKET: THE GOOD, THE BAD AND THE NEUTRAL

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INTRODUCTION

Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. A compulsory license provides that the owner of a patent or copyright licenses the use of their rights against payment either set by law or determined through some form of adjudication or arbitration. It is one of the flexibilities in the field of patent protection included in the WTO's agreement on intellectual property — the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement [1].

According to section 84 of Patent act of 1970,

(1) At any time after the expiration of three years from the date of the [grant] of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds:

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not workable in the territory of India[2]

BRIEF HISTORY: CASE IN INDIA (BAYER V/S NATCO)

India's first ever compulsory license was granted. to M/s. Natco Pharmaceuticals Limited (Natco) under Section 84 of the Patent Act 1970 (the Act). This compulsory license was in respect of the petitioner's patented invented drug - SorafenibTosylate (compound of Carboxyaryl Substituted Diphenyl Ureas) sold under brand name Nexavar (patented drug). [3]

This patented drug is used in the treatment of patients suffering from Kidney cancer i.e. Renal Cell Carcinoma (RCC) and liver cancer i.e. Hepatocellular Carcinoma (HCC). This Drug is priced at about Rs.2,84,000/- per month and Natco was offering the same at Rs.8,800/- per month.

On 6th December 2010, Natco approached Bayer for voluntary license because Nexavar did not meet reasonable requirements of public, nor it was reasonably priced, nor it was workable in territory of India. Bayer rejected Natco's request on 27th December 2010 because it seemed more in nature of a "notice" rather than a "voluntary license". Therefore, on 29th July 2011, after the expiry of 3 years from 3rd March 2008 (the date on which patent was granted for Nexavar drug in India), Natco applied to the controller for grant of Compulsory license. On 9th March 2012, the controller while granting Compulsory license to Natco directed it to pay Bayer royalty @6% of the net sales (later increased to 7% during the hearing on 4th March 2013)

This grant of compulsory license to Natco was welcomed with mixed reactions with some finding it to be impacting positively and there were some who found it having a negative impact. There also appeared to be a section that perceived this development in a neutral manner.

In the following section, we are discussing the overall impact of India's first ever compulsory license.

THE GOOD

1. The price of generic version (of Soranib) reduced drastically (by more than 97%) as compared to the original version. The medicine which costed Rs. 2,80,000 (Bayer, the patentee) was now sold for Rs. 8,800 (Natco, Compulsory License holder) and Rs.1710 (Cipla, Infringer). Non-governmental groups reportedly welcomed the decision [4].

2. It was a relief for a lot of patients when it came to "affordability" as well as "availability" since Natco said at least 100,000 people suffer from different types of renal cell carcinoma and hepatic cell carcinoma (the types of cancer for which sorafenib is prescribed) in India. Further, every year, 30,000 new patients are diagnosed with both these diseases and nearly 24,000 patients die every year in the country [5].

3. The affordable price of drug gave advantage to entire public and was not just limited to poor people who are under Project Affected People (PAP) program.

4. The public interest is always fundamental in deciding about pricing, while granting compulsory license for medicines/drugs. Nexavar has the potential to increase the lifespan of cancer patients in final stage by 4-5 years and hence public interest was not neglected when compulsory license was granted.

5. The share price of the generic company that received the compulsory license generally increases. The share price of Natco increased from 56.23 (07/03/2012) to 59.23 (09/03/2012) when compulsory license was granted to it on 08/03/2012 [6].

6. It paved the way for a stronger and robust industry which could now meet health requirements of the country. It is argued that compulsory licensing plays a vital role in developing and fostering a local generic pharmaceutical industry [17].

7. Lower price of drug positively contributes to generic company's inherent research strength. It enables in making deep inroads in process development. Natco was able to develop different manufacturing processes and able to sell their reverse-engineered versions of multinational-patented drugs at lower prices [7]. On the other hand, Cipla (an infringer), besides selling Soranib (at Rs. 1710), announced price reductions of brain cancer drug (molecule - Temozolamide 250 mg) from Rs. 20,250 to Rs. 5,000 for a pack of five capsules and lung cancer drug (molecule - Gefitinib 250 mg) from Rs. 10,200 to Rs. 4,250 for a pack of 30 tablets [7].

8. Hospitalization for illnesses is a major cause of indebtedness, especially for those living below the poverty line. Affordability of drugs is a key issue in India. Consumers might be able to buy generic versions of drugs at prices much lower than the original product. The resultant competition from compulsory licensing in the pharmaceutical industry would help discipline the market and keep prices in check [8].

9. Pre-empting the move to issue compulsory licenses, Multinational Enterprises (MNEs) may start following a dual pricing system wherein different prices are charged for a drug in developed and developing countries. MNEs may also sign voluntary licensing deals with domestic firms. By signing exclusive product licensing deals with domestic companies for a drug, MNEs can help avoid compulsory licensing action. Under voluntary licensing deals, MNEs have the freedom to dictate the terms at which domestic firms may sell generic versions of their drug, unlike under a compulsory licensing setup that works without the consent of the patent owner. There have already been several such deals.

   Some examples of such deals are those between:

   (a) India's Strides Arcolab Ltd. and the United States-based Gilead Sciences Inc. for a group of HIV/AIDS drugs;

(b) Pune-based Emcure Pharmaceuticals Ltd. and Swiss drug manufacturer F. Hoffman La Roche Ltd. for patented cancer drugs;
(c) United States-based Merc and India's MSD Pharmaceuticals Pvt. Ltd. and Sun Pharmaceuticals Industries Ltd for patented diabetes drugs; and
(d) Swiss drug manufacturer Novartis and Mumbai-based Lupin for a chronic obstructive pulmonary disease drug

10. India has often been called —the pharmacy of the developing world as it supplies generic medicines at low cost to many developing countries. In fact, 67 per cent of the medicines exported from India go to developing countries. Low-cost anti-retroviral drugs manufactured in India between 2003-2008 accounted for more than 80 per cent of donor-funded purchases of anti-retroviral drugs for use in developing countries. Moreover, competition in the generic drug industry has helped to lower the cost of HIV/AIDS treatment by 99 per cent since 2000 (CENTAD and CLRA, 2009; Medecins sans Frontieres, 2013). Through compulsory licensing, affordability will prevail.

11. Successful grant of compulsory license to Natco encouraged more generic companies to file for the same (Lee pharma (for saxagliptin) and BDR pharma (for Dasatinib)) with the aim to provide cheaper versions of expensive drugs [10].Not only these, a panel was set up by the Government under the purview of the Ministry of Health to assess the possibility of granting more compulsory licenses in the country. The panel, chaired by R K Jain, Additional Secretary at the Ministry of Health, recommended the application of compulsory licenses for three new anti-cancer drugs under Section 92 of the Patents Act. These drugs include Trastuzumab (or Herceptin) for breast cancer, (produced by Roche), Ixabepilone (produced by Bristol-Myers Squibb) for chemotherapy and Dasatinib for treating leukemia (produced by Bristol-Myers Squibb). Under Section 92, once the Government invokes a compulsory license for these drugs, pharmaceutical companies will be able to apply directly to the Patent Controller for permission to manufacture and sell generic versions of the patented drug at a lower price in the market. The panel zeroed in on these drugs because of the exorbitant rates at which they are sold. A vial (40 mg) of Trastuzumab costs US$ 2,480 while 60 tablets of 20 mg each of Dasatinib are priced at US$ 2340 [7].

12. A pharmaceutical drug can be introduced in the market only after conducting animal toxicity studies which are Phase I, II, and III human clinical trials generating

information and data which is submitted to the satisfaction of drug regulatory authorities. If Bolar exemption is provided instead of a Compulsory license, then generic companies can export the drug to/and conduct development studies (such as bioequivalence, bioavailability and stability studies to establish chemical and functional equivalence of their product with the originator product), generation of information and data before the expiry of the patent, i.e. during a patent's term, to launch the product in the market immediately on expiry or invalidation of the patent [14]. Through this, patients don't have to wait for cheaper/affordable generic versions to be available in market. Hence, their treatment can begin immediately.

13. Some pharma companies, under the Bolar Exemption can also pledge to provide free generic medicines to poor for life time. For example: Natco was prepared to provide medicines (Regorafenib product by Bayer) to 2000 patients free for life [15].

14. In FY17 – the net profit (of Natco) rose three-fold to Rs. 486 crore on YoY basis, and in FY18 it further jumped 43 percent to Rs. 695 crore against a Rs. 2,242-crore revenue. EBITDA margins stood at 33.5 percent and 43.2 percent in the last two years respectively — the highest among the peers [16].

15. The local industries which produce counterfeit goods employee thousands of workers and therefore reduce unemployment [17].

16. In order to advance in science and technology, third world countries need maximum access to intellectual property of advanced nations [17]. Compulsory licensing or Bolar Exemption are some of the few techniques which might assist.

17. The proponents of compulsory licensing argue that compulsory licensing does not discourage research and development because the costs incurred on research are recovered from sales of the patented products in the advanced states of the world having stringent patent protection [17]

18. If the government prefers to issue Compulsory license, it will enable technology transfer (which is less costly as compared to Research and Development) [18]

19. Compulsory licensing can be seen as an effective remedy in such cases where the public interest is involved to a large extent and anti-competitive practices of companies have damaged the interest of consumers as well as competitors in legal sense [21].

THE BAD

1. The company Bayer (patent owner) didn't get a "second chance" to make the product commercially available themselves. In the end, they only obtained a certain percentage of royalty. In this case, Bayer obtained only 7% of royalty from net sales by Natco [3]. This could have been disheartening, particularly for the inventors of the product.

2. It is difficult to determine the exact quantum of patented drug required by public. Authorities rely on Globocan 2008 figures to track the number of patients suffering from cancer in India. The number of incidence (according to Bayer) might be incorrect and might cause financial losses if compulsory license is granted on basis of such incorrect/non-reliable figures.

   According to figures, there were 4004 RCC patients and 4838 HCC patients, total 8842 patients. Bayer only sold 593 boxes and around 200 patients received the drug in 2011. On the other hand, the goods supplied by infringer (Cipla) were not considered because they could stop any day and "defacto license" was not provided to them by Bayer. Thus, concluding that public demand was not satisfied.

3. The compulsory license was taken negatively by many overseas companies because the reasonable price of patented drug was not arrived at by taking into account the research and development cost of patented drug and failed drug but arrived at by taking into account the lowest price (Rs. 8,800). Bayer invested Rs. 114 Billion in Research and Development activity and considered their patented product priced reasonably (Rs. 2,80,000 which is uniform throughout the world, subject to factors like exchange rate, tax etc.).

4. The share price of company whose patented drug is produced by a generic company under the pretext of compulsory license declined. The share price of Bayer decreased

from 804.75 (07/03/2012) to 802.30 (09/03/2012) when compulsory license was granted to Natco on 08/03/2012.

5. If the compulsory license precedent were followed widely, not just in India but elsewhere, it would simply undermine the purpose and function of patent protection. Simply taking away Intellectual property in an attempt to make medical care affordable is not viable precedent in a market economy [7]. The absence of business congenial legal climate may discourage patent owning firms to start any new ventures in a country that makes use of compulsory licensing provisions [17].

6. Natco obtaining the compulsory license sends negative signals to some, especially to overseas companies. It introduces all kinds of uncertainties into the minds of innovative pharma multinationals. They will be very apprehensive that the indiscriminate use of compulsory licensing can potentially damage their business in India. For the multinationals, this will make a dent in their innovation returns.

7. Indigenous ability to produce innovative drugs for neglected diseases (like kala-azar, malaria and tuberculosis) will therefore largely be unaffected by the issue of compulsory licenses.

   Product based patent systems were encouraged in developing countries in the hope that it would trigger innovation in drugs for countering neglected diseases. However, domestic companies still lack the required technical competence or the financial muscle to develop a drug from start to finish. As a result, a number of Indian companies have entered into collaborative deals with MNEs (who try to evade compulsory license by collaboration). Thus, while there has been an increase in R&D expenditure, it has mainly been used to develop drugs for treating diseases that are more prevalent in the developed world.

8. India's intellectual property regime has been perceived as not robust, and this may affect India's global image as an investment hub especially with regard to its research-intensive sectors [8]. Compulsory licenses may raise safety concerns; the consumers of counterfeit products are at risk because the inferior quality unapproved generics may contain many dangerous impurities [17].

9. If generic producers are prohibited from manufacturing and selling low-cost drugs, a large number of patients in poor countries will remain without access to affordable essential medicines.

10. Almost 90 per cent of all patent-protected pharmaceutical products are imported. "Therefore, under the terms of compulsory license, all these drugs are now susceptible to compulsory license order in India". This decision serves as a warning that when drug companies are price-gouging and limiting the availability, there are major consequences [9].Threat of non-voluntary licensing may be helpful in negotiating a reasonable price of the necessary drug acceptable to both the patent owner and the government [17]

11. The decision of a government to grant compulsory licenses may lead to the loss of foreign direct investment (FDI). In order to protect their products from compulsory licensing, the pharmaceutical companies may find a different venue for their clinical trials. Therefore, a country may lose a potential source of economic growth by issuance of compulsory licenses. [17]

12. As a result of weak intellectual property regime, a country becomes less competitive, and brain drain is an obvious result. It becomes nearly impossible for such countries to retain their human capital; the talented scientists and researchers leave the country in search of better opportunities elsewhere in the world [17]

13. Court rejected Lee Pharma's application for compulsory license for saxagliptin. Due to rejection, Lee pharma was unable to manufacture the drug of Rs. 27/ saxagliptin 2.5 mg tablet and Rs. 29/ saxagliptin 5mg tablet. It also couldn't manufacture combination of saxagliptin and metformin at Rs. 30/tablet for 5/500mg strength and Rs. 31.50/tablet for 5/1000 mg strength against the price of Rs.41-45 imported by AstraZeneca. According to Lee pharma, one million people were prescribed Saxagliptin in one year, then the requisite number of tablets per year would be 365,000,000 but the total number of tablets imported for a year was only 823,855 which is about 0.23% of the total number of tablets for a year. Claiming that there existed 99% shortage of Saxagliptin in the Indian market. Later, Lee Pharma's cost and availability claims were obscured given that patients can already obtain an Indian-manufactured generic

version of a similar drug, sitagliptin for slightly less than what Lee Pharma says it would sell saxagliptin for.

14. Court rejected BDR Pharma's application for compulsory license for Dasatinib. Due to rejection, it was unable to manufacture a month's drug at Rs. 8,100 against the price of Rs. 1 lakh imported by Bristol Myers Squibb. Annual incidence of Chronic Myeloid Leukemia (CML) in India was originally reported to be 2,200 per 100,000 people and they are unable to afford it. Later, Indian patent office rejected compulsory license application because it did not follow the procedures for obtaining a voluntary license [12].

15. If Bolar Exemption is provided instead of compulsory license, then patentee's interest may be prejudiced because the patentee may not have a patent in the country of export which would leave the patentee completely remedy-less. The patentee will have to undertake a global surveillance, tracking the products exported to establish what purpose they are being used for and then enforce their patents (if any) in multiple countries. This will give importer a free reign to export patented products (and get profitable market venture) without fear of prosecution [14].

16. If interim injunction is granted towards the export of a drug (Regorafenib) under Bolar Exemption, the impugned order will not account for the balance of convenience and the prejudice that would be caused to the exporter (Natco) would be separate. If annual sale of drug by patentee (Bayer) in Indian market is Rs. 25 crores, Natco was prepared to deposit in the court Rs. 5 crores without prejudice to its rights and contentions towards the plausible losses that might be suffered by Bayer [15].

THE NEUTRAL

1. Even though companies like Lee pharma and BDR pharma could not obtain compulsory license for costly cancer drug, other companies like Alembic and Natco were able to obtain "Bolar Exemption". The Bolar exemption provides an exception from patent infringement to the generic manufacturers from using patented drugs for research and development, for the sole purpose of submission of information for regulatory approvals of generic versions of patented products before the concerned patents expire [11].

2. Bolar exemption-

a) encourage generic 'competition' in the pharmaceutical industry by streamlining the process of regulatory approval for generics,

b) stimulate investment in pharmaceutical research and development by restoring to the patent owner a part of the patent term consumed by regulatory delay, and

c) facilitate immediate competition in the market place upon patent expiration by securing for the generic industry an exemption from infringement activities relating to FDA submissions.

3. With Bolar exemption, Natco exported Nexavar API, sorafenib to Chinese company M/s Hisun Pharmaceutical Co. Ltd

4. With Bolar exemption, Alembic exported Xarelto API, Rivaroxaban to Brazil and Middle East companies

5. Instead of Compulsory license, some companies might also obtain "Marketing License". Natco Pharma has started selling copies of global pharma major Bristol Myers Squibb's (BMS) cancer drug Dasatinib, sold under the brand name of Sprycel at Rs. 9,000 for a month, as compared to Rs. 1 lakh charged by BMS, in the Indian market, after it got a marketing license from the Uttarakhand government to sell a generic version of the drug [13]. Through this license, Chronic Myeloid Leukemia patients could afford their treatment and increase their life expectancy.

6. The crux of the compulsory license debate between the pharmaceutical industry of the developed world and the governments of the developing world is the very idea of such licenses in patent law. The innovator pharmaceutical industry and their governments view compulsory licenses solely through the prism of competition law or scenarios of national emergencies. The developing world views them in the context of human rights, where every patient is entitled to life-saving medicine [19].

7. To have success in price negotiations with multinationals, in order to have the option of using compulsory license option credibly, developing countries must strengthen their bargaining powers broadly. Further, compulsory licensing should be the last rather than first option to debate about [20].

8. Countries should use other flexibilities in TRIPS, such as research exemption and parallel imports [20].

9. There is an urgent need to facilitate the issuance of CL to export vital drugs to the least developed countries. Institutional changes in this direction would not only benefit the least developed countries, but all countries that do not have enough manufacturing capacity for a given drug. India has implemented a special compulsory license regime for the manufacture and export of patented medicines to countries with insufficient or no manufacturing capacity to address public health needs. However, those countries also need to amend their local IPR regulation in order to take full benefit from the Indian regime [20].

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