COMPULSORY LICENSE:
Compromise or Necessity

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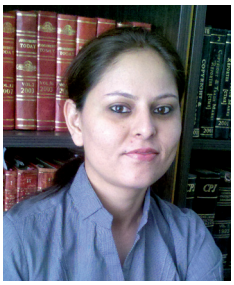

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We have affirmed our commitment to the protection of intellectual property rights. But, the global economy, the global community, cannot afford the complete privatization of research, of knowledge generation, especially in fields like medicine. We need to evolve mechanisms that protect intellectual property and, at the same time, address the needs of the poor," stated Dr. Manmohan Singh in his remark at the Tenth Fortune Global Forum.

The provision of compulsory license (CL) provided in the Indian Patent Act, in fact, serves to strike balance between these two disparate objectives—rewarding patentees for their invention and making them available to third parties in case of need. It is an intervention mechanism that enables the government to balance the rights of the patent holder with its obligations to ensure working of patents, availability of the products at a reasonable price, promotion and dissemination of technological invention and protection of public health and nutrition.

Though after the Doha Declaration on the TRIPS agreement and Public Health, about 52 countries have issued CLs (including Brazil, Thailand, Malaysia, South Africa and Ecuador)[1], India granted its first CL recently in March 2012 to Hyderabad based **Natco Pharma Ltd.** for producing generic version of **Bayer Corporations's** patented medicine **Nexavar,** used in the treatment of liver and kidney cancer. The article discusses the international debate stirred by the said judgment and the broader ramifications on the Indian and global patent system as well as the apprehensions of the innovating companies.

Natco vs. Bayer for Nexavar

Last year in July, Natco Pharma had filed application for CL in respect of Nexavar stating that the German company's drug was unaffordable for the average Indian. It had also claimed to sell the copycat version of the drug for just INR 8,800 for a month's course. Interestingly the price is about 3 % of what is charged by the multinational giant for the same course. Natco had earlier approached Bayer with a request for a voluntary license to manufacture and sell the drug, which did not materialize. It is worth noting here when the application for CL is considered by the Controller, he also takes into account as to whether the applicant has made efforts to obtain voluntary license from the patentee and if the same has been rejected by the innovator company. The Patent Office held that the conditions specified in the Patent Act, i.e., reasonable requirements of the public, availability to

[1] Department of Industrial Policy and Promotion: Discussion paper on Compulsory License, August 24, 2010

Grant of CLs will not only help patients but also spur competition by increasing domestic manufacturing capacity and know how in newer lines of drugs. However unrestricted awarding of CLs could be a major setback to drug discovery and development programmes both in India and abroad

public at a reasonable affordable price and working of the invention in India, have not been met and hence granted the CL. It was settled that 6% of the net sales of the drug would be paid to Bayer by Natco as royalty.

Pharmaceutical Sector in India and Significance of the Case

With third rank in terms of volume of production and fourteenth in terms of value, the Indian pharmaceutical sector is recognized as a leading global player in the international market. Despite this, India itself has a large unmet domestic demand for critical medicines. The prevalence of cancer is estimated to be about 205 million people, with about 8,00,000 new infections every year and 5,50,000 deaths occurring each year due to cancer[2]. The Parliamentary Standing Committee on Health and Family Welfare had also raised issues about the availability and accessibility of drugs to the poor in the country in its forty-fifth report on *"Issues Relating to the Availability of Generic, Generic Branded and Branded Medicines..."* In light of the above facts and also in the wake of takeovers of Indian pharmaceutical companies by multinationals the grant of compulsory license assumes significant importance.

The table below delineates five of the major pharma takeovers in India: (please refer the table below.)

Since most of the above companies are export oriented, their acquisition would further alienate them from the domestic market thereby reducing the local availability of products manufactured by them which may further affect the drug prices. The CLs thus could possibly be used to promote competition. The CL on Nexavar is not only expected to help cancer patients, it is also is a step towards building domestic manufacturing capacity and knowhow in a new range of drugs.

Analysis of the Case

For Indian domestic companies the Controller's decision would set precedence of the legal and administrative procedure adopted and would define modalities of operation of the provision for CL provided in the Patent Act. At the same time, it would open the gate for them to market copycat drugs under CL; the MNCs however would be at the receiving end as it would break their monopoly.

As India joins Thailand as only the second country to grant a compulsory license for a cancer drug, proponents of the CL believe that the recent judgment would ultimately lead to lowering of exorbitantly-priced life-saving cancer and HIV drugs. It would also compel the MNCs to reconsider the pricing of patented drugs, not only in India but also in other developing countries. Reportedly, Roche has announced its decision to sell cheaper variants of breast and blood cancer

The table below delineates five of the major pharma takeovers in India[3]

Year	Indian Company taken over	Foreign Company which took over	Country of Origin	Take over amount US$ million
May 2010	Piramal Health Care	Abbot Laboratories	US	3720
Dec 2009	Orchid Chemicals	Hospira	US	400
July 2008	Shanta Biotech	Sanofi Aventis	France	783
June 2008	Ranbaxy Laboratories	Daiichi Sankyo	Japan	4600
April 2008	Dabur Pharma	Fresenius Kabi	Singapore	219

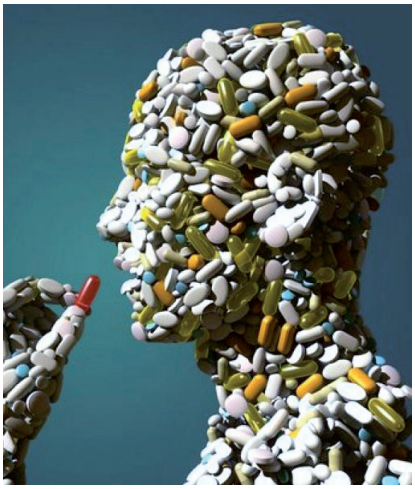
[2] Dinshaw KA, Shastri SS, Patil SS, Cancer Control Program in India: Challenges for the Millennium, Health Administrator Vol XVII, Number 1: 10-13 pgs. (2001)

[3]Department of Industrial Policy and Promotion: Discussion paper on Compulsory License, August 24, 2010

It is pertinent to point out that as the fast developing Indian economy integrates and carves its niche internationally, the Patent Office's decision may have implications beyond the pharmaceutical sector.

Brand name	MNC	MRP (INR)	Disease
Herceptin Injection 50 ML	Roche	1.35L	Anti-cancer
Erbitux 700 Mg Injection 50 ML	Merck	87,920	Anti-cancer
Erbitux 700 Mg Injection 50 ML	Bristol Myers	66,430	Anti-cancer
Actemra 400 Mg Injection 1	Roche	40,545	Anti-cancer
Zenapax 25 Mg Injection 5 ML	Roche	28,875	Anti-cancer
Eraxis 100 MG Injection 1	Pfizer	9,107	Anti-infectives
Granocyte 34 Injection	Sanofi-Aventis	5,720	Anti-cancer
Victoza 6Mg Injection 3 ML	Abbott	4,315	Anti-diabetic

Estimated cost of life saving drugs produced by leading MNCs in India[4]



drugs in the Indian market soon. At the same time, in order to circumvent CLs, the patent holders may contemplate collaboration with local manufacturing companies in India. This would not only bring down manufacturing cost but the technology transfer would also help the local industries.

It is pertinent to point out that as the fast developing Indian economy integrates and carves its niche internationally, the Patent Office's decision may have implications beyond the pharmaceutical sector. It is already being criticized by innovating R&D companies as well as industrial lobbies such as Organization of Pharmaceutical Producers of India. Bayer, in its arguments before the Patent Office, had defended the higher price of the patented drug stating that although innovation-based products may cost a price over generics, this price pays for the pipeline (i.e. the future innovation) and competition not to mention the failed projects, which is about 75% of the total R & D cost. It has been argued that any CL will not help unless issues such as healthcare infrastructure, disease diagnosis and medical insurance are tackled as even the generic version of Nexavar (priced at INR 8,800) would be beyond the reach of poor Indians suffering from diseases like cancer.

Keeping in view the cost incurred and time spent on the research and development of any new drug (almost 15 years and $800 million to $2 billion), rampant granting of CL may become a major setback in research and development. Last year Cipla had applied for a "voluntary license" for Merck's anti-HIV drug *Isentress* and Natco Pharma had sought a similar voluntary license from Pfizer to make and sell "copies" of the US Company's HIV medicine in India. Both the companies have cited similar reasons—that the drugs were exorbitantly priced and were inaccessible to Indian patients. This clearly is the first step in the grant of CL as, if denied voluntary license, both the firms would have the option of applying for CL with the Controller General of Patents. Generic companies may exploit the process as a mean to generate revenue, thus restrictions on granting CL as a commercialized affair and resorting to it with the sole aim of procuring drugs at a cheaper rate need to be imposed. Thus grant of CL without addressing key issues would be a major setback for the drug discovery and development programmes in India and abroad. It may prove to be a deterrent factor for innovators and MNCs that are contemplating investment in intellectual property in India. This may be quite ironical for a country that has declared the current decade as the "Decade of Innovation".

Disclaimer:

The article intends to provide general information only and should not be taken as legal advice or opinion related to specific situations. Every possible effort has been made to ensure accuracy of the information contained in the article but the author cannot be held responsible for any misrepresentation or inaccuracy.

[4] MUKHERJEE, Rupali, 2012, Road to Cheaper Drugs, Times of India, March, 24