GRANT OF COMPULSORY LICENSE FOR ANTI CANCER DRUG: ROAD TO CHEAPER DRUGS OR BLOW TO INNOVATION

Introduction

On March 9, 2012, the Indian Patent Office ended German Company Bayer's monopoly for its Nexavar drug and granted its first-ever compulsory license allowing Indian generic pharma company Natco Pharma Ltd. to make and sell the generic version of Nexavar (a kidney/liver cancer drug that goes by the generic name of Sorafenib Tosylate) at a much lower price in India.

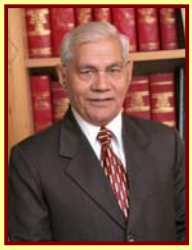
It is only the second time a nation has issued a compulsory license for a cancer drug after Thailand did same for four drugs between 2006 and 2008, also on affordability grounds. Thailand also issued licenses for HIV/AIDS and heart disease treatments.

This ground breaking ruling could be the first of many rulings in India, known as a global generics drug powerhouse.

Natco will pay Bayer a 6% royalty on net sales of the drug and sell the medicine for Rs. 8,800 (US$ 175) for a monthly dose (120 tablets) of the drug. That sum represents a 97% reduction on the Rs. 2.80 lakh (US$ 5,500) that Bayer charges in India for a monthly dose of the drug, which is used to extend the lives of patients suffering from advanced kidney and liver cancers. The license will be valid till such time the drug's patent is valid, i.e. 2020.

While TRIPS provided a minimum standard for protecting and enforcing patent rights, at the same time TRIPS also provides certain flexibility to national patent regime in the form of Art. 30 and 31 in line with the Paris Convention to enact provisions for compulsory licensing among other things. A provision of the Indian Patents Act allows for a compulsory license to be awarded after three years of the grant of the patent on drugs on various grounds.

This ruling of Indian Patent Office has major implications for global pharmaceuticals company seeking protection in India. These companies have expressed their apprehension on intellectual property protection in India. The one positive aspect of this ruling for global pharmaceutical companies is that it holds lesson for these companies on how to



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conduct business in India and make strategies to avoid such rulings for their product.

In order to understand the full import of landmark decision of Indian Patent Office in the Bayer case, it is important to know the concept of compulsory licensing in patents and the relevant provision in patent law.

Compulsory Licensing in Patents: its Rationale and Object

Compulsory licensing in patents refers to the practice by a government of authorising itself or third parties to use the subject matter of a patent without the authorisation of patent holder for reasons of public policy. Compulsory License (CL) under the Patent System is an involuntary contract between willing buyer and an unwilling seller imposed and enforced by the state. Compulsory licensing enables a government to licence to a company, government agency or other party the right to use the patent without titleholder's consent. A competent authority must grant a compulsory licence to a designated person who must compensate the titleholder through payment of reasonable remuneration. Although, it is generally associated with pharmaceuticals, it may in fact apply to patent in any field. It may also apply in case of copyright.

In case of patents the Compulsory license provides a safeguard against lack of use of a patented invention or "misuse of the patent holder's monopoly rights" in order to protect the public interest.

The compulsory license system is part of the WTO's agreement on intellectual property called the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement. It has existed since 1995 and was further clarified in 2001 through the Doha Declaration. Most countries have provision for compulsory license, except the US.

There are several possibilities of granting compulsory licences as interpreted from the TRIPS Agreement, 1994 (Art. 30 & 31) and Paris convention and as clarified in the Doha Declaration on Public Health (November, 2001). These several grounds for grant of compulsory licences are refusal to enter into deal with interested companies on reasonable commercial terms, situations of emergency or circumstances of extreme emergency (health or/and environmental crisis), governmental use, public interest, due to abuse of patent rights by the patentee(included in Section 84 of the Indian Patent Act. 1970), to use a patent which may not be exploited without infringing another patent (provided that the former patent covers an invention that involves an important technical advance of considerable economic significance over the latter patent).

Compulsory Licensing In India

India has one of the widest provisions on the compulsory licensing. Chapter XVI of the Indian Patents Act deals with compulsory licenses. Section 84 of the Indian Patent Act provides for compulsory licensing in the domestic arena while section 92A looks at exporting of drugs. Section 92A, elucidates that compulsory license for export of patented pharmaceutical products can be granted in certain exceptional circumstances. This provision was incorporated as a result of 30th August 2003 Declaration. These sections can be summarised as follows:-

A) Section 84 — To prevent the abuse of patent as a monopoly and to make way for commercial exploitation of invention by an interested person.

B) Sections 92 (1) and 92 (3)—Circumstances of national emergency or extreme urgency and public health crises.

C) Section 92 A—For exports of pharmaceutical products to foreign countries with public health problems.

Background of the Present Case

In this case the patentee, Bayer AG first applied for a patent in the USPTO on January 13, 1999 and subsequently filed a PCT International Application on PCT/US00/000648 in January 12, 2000. The patentee entered the national phase in India on July 5, 2001. After examination under the provision of the Patents Act, 1970, a patent was granted on March 3, 2008 with Patent No. 215758.

In the meanwhile, the patentee developed the drug and lanunched it in 2005 under the trade name Nexavir for treatment of Renal cell Carcinoma-RCC (kidney cancer) and subsequently got additional approval for treatment of Hepatocellular Carcinoma-HCC (liver cancer) in 2007. The Patentee received the regulatory approval for importing and marketing drug in India and launched it in India in the year 2008.

The Applicant for the compulsory licensing in this case Natco Pharma Ltd. is a leading Indian generic drug manufacturer. The Applicant has developed the process to manufacture this drug and received a license for manufacture the drug in bulk and for marketing it in the form of tablets in April 2011.

It is pertinent to mention here that the drug Sorafenib tosylate with brand name Nexavir is not a life-saving drug, but a life extending drug.

The present case is the first of its kind in the history of Patents Act, 1970, wherein the provisions of Section 84 have been invoked by the Applicant herein for seeking the grant of Compulsory License. As such, there is no precedent to guide the tribunal.

In order to appreciate the order, one must begin with Section 84 of the Indian Patents Act, which reads as below:-

Under this Section, any person interested can make an application for a grant of compulsory license for a patent after three years from the date of the grant of that patent, on any of the following grounds:

(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 a reasonably affordable price.

(c) The patented invention is not worked in the territory of India.

As long as the reasonable expectations of the public to the patented medication have not been satisfied or the medication is not fairly priced, any person interested may apply to the Controller for a compulsory license three years after the grant of a patent. The Indian government has been given considerable leeway in issuing compulsory licenses under this provision based on the desired policy objective. If, for example, the objective would be to lower prices, the government is free to make the sale of patented inventions on unreasonable terms grounds for compulsory license.

The Controller found that all the 3 criteria above were satisfied in this case, namely:

1. that since Bayer supplied the drug to only 2% of the patient population, the reasonable requirements of the public with respect to the patented drug (Nexavar) were not met.

2. that Bayers pricing of the drug (2.8 lakhs(US$ 5,500)) for a months' supply of the drug) was excessive and did not constitute a "reasonably affordable" price.

3. that Bayer did not sufficiently "work" the patent in India.

Each of these grounds are explained below:

1. Issue of Reasonable Requirements of the Public Not Being Met:-

Based on Bayers' own admission, the Patentee has made available the drug only to a little above 2% of the total number of kidney and liver cancer patients. Sale figure of the drug in India is abysmally low as compared to global figure which shows the patentee has failed to satisfy reasonable demand of public at a reasonable price. In the aforementioned circumstances, the Patentee's conduct of not making drug available as per the requirement of public in India during four years, since the grant of patent is not at all justifiable. Accordingly, the Controller held that the reasonable requirements of the public with respect to the patented invention have not been satisfied in this case and consequently a compulsory license be issued to the Applicant under section 84 of the Act.

In order to make its drug more accessible to the general public, Bayer argued that it must be given some more time to work the patent. Bayer offered to amend its existing patient assistance programme (where a patient would have to buy 1 months drug supply at the regular price (Rs 2.8 lakhs(US$ 5,500)) and would get it free for the remaining 3 months) such that a patient would only have to pay Rs 30,000 (US$ 600) per month for the drug. In this way, it hoped to match Cipla's pricing and thereby thwart a compulsory licensing order.

However, the Controller found that this proposed philanthropy, while noteworthy did not enable Bayer to escape the issuance of a compulsory license on the ground that such steps amount to work the invention on a commercial scale to an adequate extent.

2. Issue of Excessive Pricing:

The Controller of Patents found that the price of the drug was not "reasonably affordable" to the public:

The Controller observed that during the last four years, the sales of the drug by the Patentee at a price of about Rs 2.8 lakhs (US$ 5,500) (for a therapy of one month) constitute a fraction of the requirement of the public. It stands to common logic that a patented article like the drug in this case was not bought by the public due to only one reason, i.e. its price was not reasonably affordable to them.

The Controller further countered Bayer's argument that "reasonably affordable" price had to be construed with reference to the public and the patentee (in other words, the patentee's R&D costs must be considered):

The Controller held that reasonably affordable price has to be construed predominantly with reference to the public.

The order also criticized Bayer for adopting a "two faced" stand before the tribunal. There was a double standard in the argument of the Bayer. The Bayer took one position before the tribunal and exactly opposite position before the High Court of Delhi where it is prosecuting infringement proceedings against the Cipla. Bayer argued that since Cipla sells cheaper generic versions in the market (at Rs 30,000(US$ 600) per monthly dose of Sorefanib), there was no need for a compulsory license. The Bayer has challenged Cipla's right to sell the generic version in the market through a patent infringement law suit, and was now relying on this alleged illegality to ward off a compulsory licensing order.

The Controller observed that the Patentee appears to be indulging in two-facedness by adopting one stand before this tribunal and another stance before the Hon'ble High Court of Delhi, in order to defend the indefensible. M/s Cipla is an alleged infringer, as per the patentee's own submissions, and accordingly cannot discharge the obligations of Patentee under the Act. The Patentee appears to have treated M/s Cipla, in this case, as if they are their licensee.

3. Non Working of the Patent:

The Controller of Patents found that mere importation of Bayer's drug into India did not amount to "working" and held that “worked in the territory of India" means manufactured to a reasonable extent in India.

The Controller observed that if the patentee’s argument of the of importation of Bayer's drug into India amount to "working" is accepted then it would render Section 84(1)(c) of the Act redundant.

This part of the decision is likely to generate a lot of controversy, as almost 90% of all pharmaceutical patents are only imported into India.

The Controller of Patents convincingly argues that the Indian patents act endorses a "local" working provision and that such a provision is compatible with TRIPS and the Paris Convention.

The Controller of Patents cited Section 83 of the Indian Patents Act, 1970 which makes clear that patents are not granted only for the purpose of “importation” of the patented product. In fact, the Act uses the terms "working" and "importation" quite distinctly throughout the Act, making it evident that "working" as used in the Act cannot include "importation".

The Controller of Patents also cited Paris Convention which clearly states that “importation” would not amount to working of a patent, and that if a patent is not worked, this could be treated as an “abuse”. Further, TRIPS is premised on the promise of technology transfer to developing countries. And a local working provision is geared towards encouraging such technology transfer. By forcing patentees to “work” their patents in India, the regime encourages local use/transfer of the said technology.

Issue of Royalty Rates

In this regard Controller of Patents had very less material to rely upon. After discussing the not so complete figures submitted by the patentee, he endorsed the UNDP proposal for 6% royalty rate in cases of good therapeutic value. The Controller of Patents observed that the present case that

anything lesser than 6% would not be just and reasonable given the facts and circumstances of this case.

Implications of the Decisions For the Domestic And Foreign Pharmaceutical Industries: Good For The Public But Bad For Innovation In India.

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 Global Pharma Companies, which spend substantial amounts on R&D before they find a new drug.

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.

Global pharmaceutical manufacturers are likely to be worried as a result given that the wording in the Indian Patent Act 1970 that had been amended from 'reasonably priced' to reasonably affordable priced' has come into play now.

Global Pharma Companies argue that the compulsory licenses should only be granted in case of a public health crisis. Compulsory licences should be used only in exceptional circumstances, such as in times of a national health crisis. They further opine that 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.

The new wording is seen as a lower threshold for compulsory licenses, which can be issued under world trade rules by nations that deem major life-saving drugs to be too costly. The license allows them to authorise the local manufacturer or importation of much cheaper, generic versions.

The Bayer case has serious implication for Global Pharma Companies seeking patent protection in India and could act as a disincentive for many of them.

The many generic companies have not acclimatized themselves to product patent regime introduced by way of amendment in 2005 in the Indian Patent regime. The research and development in the pharmaceutical is costly and time consuming. The Indian generic companies do not have adequate capacity to carry out research. There is a need of caution here that the instrument of compulsory license which has it avowed object of the protecting the public interest and more particularly the poor in a developing country should not be turned into an instrument of circumventing product patent regime in pharmaceutical which India introduced by way of the Patent (Amendment) Act, 2005 in India to make Indian Patent Act, 1970 TRIPS compliant. If this were to happen, then this will be a big blow to introduction of innovative drugs in India.

Natco Pharma which has been granted compulsory license in this case is involved in many other compulsory license applications, pre and post grant opposition proceedings, and a few infringement proceedings. Natco has the distinction of having made first application for compulsory licensing in India under Secton 92A of Indian Patent Act,1970 which provides for compulsory licensing in India for export of patented pharmaceutical in certain exceptional circumstances.

It is recently reported that Natco is eyeing compulsory licensing for many more drugs manufactured by the Global Pharma Companies. Natco Pharma Ltd. for its acitivity of seeking compulsory license is increasingly being perceived as compulsive seeker of compulsory licenses.

Lessons for the other Pharmaceuticals from this decision:

Global drugmakers see emerging markets such as India is key growth opportunities, but remain concerned over intellectual property protection. The HIV-related medicines were likely to be the most at risk by compulsory license in the future.

India has one of the world's fastest-growing rates of HIV and heart disease is also the country's biggest killer. Widespread poverty in Asia's third-largest economy, however, makes many non-generic drugs unaffordable for millions.

At present, Pfizer and GlaxoSmithkline sell a modern HIV/AIDS drug known as Selzentry through their joint venture firm ViiV Healthcare. The treatment costs more than Rs. 60,000 ($1,200) for one month's dosage in India.

Bayer's Nexavar cancer drug cancer cost around $ 5,500 a month in India, making it "not available to the public at a reasonably affordable price", the patent office ruled.

About 40 percent of Indians live below the poverty line, government data show.

Economist and intellectual property expert James Love said, "The Bayer price of Rs 34,11, 898 per year ($69,000) is more than 41 times the projected average per capita income for India in 2012, shattering any measure of affordability. Bayer tried to justify its high price by making claims of high R&D costs, but refused to provide any details of its actual outlays on the research for Sorafenib, a cancer drug that was partly subsidized by the US Orphan Drug tax credit, and jointly developed with Onyx Pharmaceuticals. Bayer has made billions from Sorafenib, and made little effort to sell the product in India where its price is far beyond the means of all but a few persons."

This decision was in fact invited by the Bayer AG by selling drug in India at the exorbitant price making it out of reach of most Indian patient and not making or working sufficiently in India.

The table[1] herein below provide an overview of the market of the patented drug vis-à-vis total pharmaceutical market, and exorbitant prices of the drugs manufactured by the Global Pharma majors:

BITTER SWEET PILL

Patent status of new drugs marketed in India, 1995-2010

	No	**Sales 2010** (Rs crore)	**Sales 2010**(%)	**MNC share 2010**
New Drugs	**180**	**4,727**	**9.1**	**10.9**
Patented post 1995	**51**	**600**	**1.2**	**25.2**
Patented pre 1995	**67**	**2,173**	**4.2**	**5.5**
Patent expired	**62**	**1,953**	**3.8**	**12.6**
Total Pharmaceutical market		**52, 052**	**100**	**19.1**

OUT OF REACH ***in Rs**

Brand Name	**MNC**	**MRP***	**Disease**
Herceptin Injection 50 ML	Roche	**1.35L**	Anti-cancer
Erbitux 700 Mg Injection 50 ML	Merck	**87,920**	Anti-cancer

[1] The Times of India, March 24, 2012, p. 24.

Ixempra 45 Mg Injection 1	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 6 Mg Injection 3 ML	Abbott	**4,315**	Anti diabetic

The decision holds valuable lesson for Global pharmaceutical Companies in terms of framing strategies to avoid such ruling for their drug. The Global Pharma Companies should not seek to set exorbitant prices of their product so as to make these drugs out of reach of a large section of the public. Innovator drug companies must engage in more significant differential pricing schemes and introduce drugs at much cheaper prices in countries with a significant number of extremely poor patients such as India.

Applicability of the Provisions of Compulsory License to Fields of Technology Other Than Pharmaceuticals

It may be noted that even though the present case is related to the pharmaceutical substance, it should be noted that provision of compulsory licensing under Section 84 of the Indian Patents Act, 1970 is applicable to all fields of technology. Thus, the Compulsory license can be granted under Section 84 in all fields of technology if the grounds and conditions mentioned under the Section 84 are satisfied.

Non-Working of a Patent in India Does Not Necessarily Mean Grant of the Compulsory License

It may also be noted that non-working of a patent alone does not mean automatic grant of a compulsory license. For the grant of a compulsory license, an application for the grant of compulsory license has to be made in the prescribed format. Although, it is a separate ground for the grant of compulsory license, but the Controller of Patents is guided by a number of factors before deciding an application for the compulsory license. The Controller of Patents takes holistic view in deciding application for the grant of the compulsory license rather than taking narrow view of the matter.

CONCLUSION

The jurisprudential basis of the compulsory licensing in patents is balancing of the public and private interest. The proper balance between the right of the patent holder and affordability and accessibility of the drugs to the common people in developing and underdeveloped countries is a biggest challenge for the patent regime. The provision of compulsory licensing may be used as an instrument to provide life saving drugs to millions of people in the third world countries suffering from killer diseases HIV/AIDS, malaria, tuberculosis, lung cancer, heart disease, etc. The Bayer case might become a trend-setter, wherein generic players can make copies of patented products. In many ways, it sets the tone for future cases and will encourage many other generics to resort to this route.

While global companies might not like this, generic companies will benefit alongwith common people.

This order may also act as a guide for other countries, particularly developing countries to adopt similar provisions and issue similar orders. One hopes and expects that it prompts innovator drug companies to engage in more significant differential pricing schemes and introduce drugs at much cheaper prices in countries with a significant number of extremely poor patients such as India.

The Bayer case underscores the still fractious relationship between global pharmaceutical firms and India. Companies such as Pfizer, GlaxoSmithkline and Novartis are eyeing India and other emerging markets, notably China, as a growth opportunity but worry about intellectual property protection in a country that is also a leading source of cheap copycat medicines. Global Pharma Companies has dubbed the move that will stifle innovation. But that would be ignoring the point that it is perfectly legal, and is in fact provided for in the patents regime to balance public interest and corporate profits.

Bayer AG has expressed its disappointment over the ruling Indian Patent Office and evaluating its option of challenging the ruling of the granting compulsory license to Indian company Natco Pharma.

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