On 9th March, 2012, the Controller General of Patents Design and Trademarks of India, Mr. P.H. Kurian, marked his last day in office with a landmark judgment granting the first ever compulsory license to an Indian generic pharmaceutical company Natco Pharma to manufacture and sell a generic version of Bayer Corporation's patent protected anti-cancer drug 'Sorafenib Tosyalte' (NEXAVAR). This watershed development is likely to alter the complexion of the pharmaceutical industry in India. This judgment brings to the fore many contentious issues such as whether "local manufacturing" of a patented invention is mandatory in India, what drug price is 'reasonable' under the current patent regime.

Aditi Jha, Associate
Milind Antani, Head, Pharma and Life Sciences Practice
Gowree Gokhale, Head, Technology, Media and Entertainment law practice
Nishith Desai and Associates (NDA), India

The grant of compulsory license (CL) to Natco Pharma in relation to Bayer Corporation ("Bayer")'s patented anti-cancer drug Sorafenib Tosyalte' sold under trademark NEXAVAR ("Drug') is expected to have a major impact on the strategies devised by both generic and innovative companies. Since this is the first time that the CL has been granted in India, several issues arise in relation to the interpretation adopted by the Controller of Patents (Controller). Grant of CL is contemplated under the international conventions as well, viz. Paris Convention of 1883 and agreement for the Trade Related aspects of Intellectual Property Rights (TRIPS) (Article 31).

What is CL

CL is an involuntary contract between a willing licensee and an unwilling patentee imposed and enforced by law. Up on grant of the CL, the licensee can manufacture the patented product for the remaining term of the patent, unless the CL is revoked earlier. The CL may be granted by the government suo moto in situations of national emergency, extreme urgency or may be granted on an application of any person interested. The Controller determines the royalty payable by the grantee of the CL to the patentee.

The Controller may grant a CL at any time after three years of the grant of a patent on any one or all of the following grounds on application of the person interested:-

1) The reasonable requirements of the public with respect to the patented inventions have not been satisfied, or

2) The patented invention is not available to the public at reasonably affordable prices, or

3) The invention is not exploited commercially to the fullest extent within the territory of India.

In the Order, Natco raised all the above grounds against Bayer and the Controller upheld Natco's contention on all the three grounds.

Ground 1: Reasonable requirements of public not satisfied

Natco urged that

(i) As per GLOBOCAN 2008[1] there were approximately 23,000 patients of kidney and liver cancer (for which Drug is used) requiring treatment in India,

(ii) Form 27[2] filed by Bayer, denotes that 200 bottles were imported during 2008-2010

(iii) The Drug was exorbitantly priced, out of stock and had limited availability in India

(iv) Bayer launched the product worldwide in 2006 and made sales of approximately US$ 2,454 million internationally

(v) The insignificant number of bottles imported in India showed Bayer's neglectful conduct.

Bayer responded by demonstrating that actual number of patients requiring treatment is 8,842 and that exorbitant price has no link with reasonable requirement of the public. Bayer argued that the availability of the Drug has been considerably increased due to the infringing sales by another Indian generic company Cipla Ltd ("Cipla") who was projected to sell about 4,686 boxes of the Drug in 2012.

The Controller in deciding against Bayer held that:

• The number of patients needing the Drug will be much higher than 8,842.

• As per Bayer's own numbers they have been able to supply the Drug to not more than 200 patients which is just 2 per cent of the 8,842 patients.

• Sales of Cipla cannot be added to the Patentee's sales figures as Cipla can be injuncted anytime and thus "an uncertain supply by an alleged infringer cannot be considered."

The Controller did not deal with the issue whether expensive price of the Drug has any connection with it being reasonably unavailable to the public.

Bayer did not challenge the reliance by Natco on the GLOBOCAN 2008 data. Bayer urged that the Drug is only required by patients having Stage IV (as opposed to Stages I to III). Hence the number of patients requiring the Drug was 8,842. Even if the Controller had proceeded on the number provided by Bayer, the admitted supply was not sufficient to meet the demand. By its own showing, more than 8,000 patients needed the Drug, whereas it had imported 200 bottles in 2009 and 593 bottles in 2011. Cipla's sales started only in 2010. Bayer had no explanation as to why it did not manufacture/import the Drug between 2008 and 2010. In any event, the Controller was right in holding that Bayer cannot take advantage of sales by Cipla.

Ground 2: The patented invention is not available to public at "reasonable affordable price" (RAP)

Natco argued that the price of the patented product is too high and that at INR 2,80,428 per month supply , the exorbitant pricing is an abuse of its monopolistic rights.

Bayer's arguments were as follows:

(i) Innovative drugs cost more than generics since the innovator's costs include R & D expenses which generics do not incur.

(ii) The higher price includes the costs of failed projects which accounts for nearly 75 per cent of total R&D cost and underwrites additional costs for future innovations.

(iii) Replacing innovative drugs with generics will damage patients as originators also provide for the education of doctors and pharmacovigilance which generics do not.

(iv) The term 'reasonable' should be construed as to mean reasonable for both the patients and the patentee. Bayer argued that "public" denotes different sections of public. A blanket CL which gives the patented product at the same price to all sections of the public is not reasonable.

The Controller in his decision agreed with Bayer that "public" includes different sections of the public, but also observed, that Bayer was free to have offered differential pricing to different classes, but chose not to. The Controller partially disagreed with Bayer that in determining reasonableness, both the Patentee and the public need to be factored in, but observed that "RAP has to be construed predominantly with reference to public", but has not delved into this aspect.

In the Act, RAP has not been defined nor are there any guidelines as to how it ought to be determined. In his analysis, the Controller has not discussed:

1) what would have been a reasonably affordable price,

2) how to arrive at the conclusion of whether a price is reasonable or not, or

3) what costs of the Patentee ought to be considered while arriving at what is a RAP.

Often pharmaceutical companies decide not to introduce patented products in India as they believe that the price which they seek will not be afforded by the market. Innovator companies have no intention of making the patented product available in India. Therefore, the expenditure incurred by the patentee, may not as a rule be taken into account while determining RAP. The interest of the patentee may be taken into account only if the Controller determines that patentee indeed intends to make the drug available in India.

> "Under the Essential Commodities Act, 1955, the government of India has promulgated The Drug Price Control Order ("DPCO") which fixes the ceiling price of certain active pharmaceutical ingredients and formulations."

1 A publication by GLOBOCAN, a project of the World Health Organization.

2. A statement of working of patents required to be mandatorily filed by all patentees with the Indian Patent Office.

Interestingly, under the CL Chapter of the Act, prior to 2002 amendment, the expression used was "reasonable price" and in the current CL Chapter the expression used is "reasonably affordable price". Thus, the element of "affordability" has been specifically brought in. The English Oxford Dictionary defines "affordable" as "inexpensive; reasonably priced". Hence, one would wonder whether the intention of the legislature indeed was to take only public interest into account.

Ground 3: Patented invention not worked in the territory of India

This is the most contentious section of the order. Natco urged that since the Drug is being imported, it is not being 'commercially worked' in India.

Bayer argued that the 'working requirement' does not mean that the patented product has to be locally manufactured. According to Bayer, "working" of a patent meant that there should be a supply of the patented product in the territory of India. Bayer argued that it had centralised its manufacturing in Germany due to economies of scale and to maintain high quality.

The Controller came to the conclusion that mere importation cannot amount to 'working' of a patented product for the purposes of the Act.

The CL Chapter of the Act does not define "working of the patent". But interestingly, Form 27 that all patentees are required to file to inform the patent office about the 'extent to which the patented invention is worked on commercial scale in India' requires the patentee to provide information about manufacturing in India and importation into India. Section 48 which relates to the rights of the patentee, specifically recognises the exclusive right of the patentee to import patented product into India.

Even at the WTO level this issue has not been settled. Article 27(1) of TRIPS requires nations not to discriminate between locally manufactured and imported products. On the other hand, Art 7 of TRIPs states that intellectual property rights should lead to transfer of technology and dissemination of information. It is not clear, how the two provisions will be read together. In fact, the existence of both these provisions highlights the difficult negotiations that marked the signing of the TRIPs agreement with the developing bloc getting Art.7 and the developed countries getting Art.27. Brazil's IP law had a similar provision requiring local manufacture of a patented product. USA had filed a complaint in the WTO Dispute Settlement Body. This case was later settled. Similarly, Art 5(1) of Paris Convention lays down that importation of patented articles shall not entail forfeiture of the patent.

From a reading of the Paris Convention, TRIPS and the Act, there still appears to be an ambiguity as to how to interpret the "working" requirement. The Controller relied on Section 83 of the Act which states that "regard must be had that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article." Sec 83 is merely of a guiding nature and is not a substantive provision. The controller relied on Section 90 (2) of the Act which states that a grantee of a CL cannot import the patented product into India. The Controller stated that "if the licensee cannot import the product into India, for working the invention… Then it implies that importing cannot amount to working for a license". Section 90(2) is a fetter on the grantee of a compulsory license. It ensures that the ambit of the compulsory license remains the territory of India, and does not adversely affect other markets of the patentee. The Controller's view seems to be an incorrect interpretation of the law.

Prior to the 2002 amendment of the Act, there existed only two grounds for the grant of CL (i) RRP not being satisfied; (ii) the patented invention not being available at a reasonable price. The "non-working" aspect has been brought in only by 2002 amendment. While bringing in this amendment, the legislature seems to have to have interlinked RRP and "working" provisions, which has created confusion in its interpretation.

After perusing the above deliberations, one wonders, does the Act require "local working" or not! The answer at this stage is not clear. We need to await the decision in appeal. The matter may be litigated up to the Supreme Court, which may eventually provide guidance.

On a practical note, most companies, including Indian companies have outsourced their manufacturing to ensure economies of scale. The Controller's order means that every patent holder will now have to sufficiently manufacture in India, else it will be facing the prospect of having a CL issued against it. If we look at the economics of international trade, by requiring local manufactures against availing the advantages of economies of scale will no doubt adversely impact the Indian consumer.

The Controller granted a non-exclusive, non-assignable CL to Natco to make the Drug available at INR 8,880 for a packet of 120 tablets. Natco has to pay a 6 per cent royalty to Bayer. Since the royalty earned by patentee would be a Per cenage of net sales, in absolute terms, the amount of royalty received by Bayer may not be commensurate with the expenditure incurred by it.

Conclusion

This order marks a watershed in the development of jurisprudence of CL. There has not been significant interpretation of Articles 7, 30, 31 of the TRIPs agreement, nor how it interplays with Article 27(1) of TRIPs and Article 5 of the Paris Convention.

For the pharmaceutical industry, patents occupy a significant place. Drugs, due to high R&D costs, a significantly high level of failed research and ease of successful copying, depend highly on patent protection. Hence, measures that reduce this protection, such as CL, are viewed as harmful for the innovator companies.

A more pragmatic approach to CL is the approach taken by Brazil. Instead of private generic companies obtaining CLs, the government studies which diseases need intervention from the State

and uses the CL as a bargaining tool to get the innovator companies to come to the negotiating table. Brazil has been successful in getting various innovator companies to reduce drug prices by up to 40 per cent. The advantage of this approach is that a calculated decision is arrived at as to which diseases and medicines are really required to be made available to the public while at the same time, the innovator retains its exclusivity and the public gets access to medicine at a reasonable price.

A significant issue to be considered is whether price control of drugs can only be achieved through CL. Under the Essential Commodities Act, 1955, the government of India has promulgated The Drug Price Control Order ("DPCO") which fixes the ceiling price of certain active pharmaceutical ingredients and formulations. The DPCO provides the government an effective mechanism to regulate drug prices thereby increasing access to medicines without interfering with patent rights of innovators.

This case offers takeaways for innovator companies, especially pharmaceutical companies. First is the importance of Form 27. Due care and diligence needs to be undertaken while filing the Form and not treat it as a mere mechanical exercise.

The second takeaway relates to the working requirement. If Bayer had been able to show a readiness and willingness to manufacture the Drug, they may have been able to get some concessions. Pharmaceutical companies should be able to demonstrate intention and willingness to make the patented product available in India. Of course, if the patentee does not view India as a market for its product on the assumption that the market will not be able to 'afford' its drug and then grant of a CL may not have any economic impact on the patentee.

What remains to be seen is whether oncologists and other treating doctors will consider only the reduced prices of generic versions of the Drug while prescribing it to advanced stage liver / renal cancer patients. While Natco will sell the Drug at INR 8,800, it still has the task of convincing doctors about the quality and efficacy of its product.

The IPAB or the Supreme Court will need to determine what RAP and RRP means. This battle is far from over. The interpretation of "working" of a patent to mean 'local manufacture' within India is highly contentious. It is likely that this issue will be agitated right up to the Supreme Court in India as well as at the WTO. ■

AUTHOR BIO

Aditi Jha has presented her research findings on legal issues in life-form patenting, assisted reproductive technologies to national symposia and her research forms part of a book on IP law in India. She won national legal writing contest on the subject of freedom of speech & expression on the internet and she has regularly written on legal and non-legal issues.

Milind Antani's practice areas include Pharmaceutical, Life Sciences, Healthcare, Intellectual Property and Medical Devices. Antani is also the member of FICCI, National Pharmaceutical Committee, FICCI-Gujarat Healthcare committee and the Committee of Telemedicine Society of India.

Gowree Gokhale's specialisation includes Litigation and Dispute Resolution, Franchising, Pharma and Life Sciences laws, Commercial laws, HR laws and Intellectual Property. Gokhale is a Solicitor and a registered Patent & Trade Mark attorney. She is also a visiting faculty at Institute of Intellectual Property Law Studies at Mumbai.