IP LAB

FIRST COMPULSORY LICENSE ORDER

IMPACT ON THE PHARMACEUTICAL INDUSTRY

IP-PHARMA TEAM

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INTRODUCTION

The Controller General of Patents Design and Trademarks, Mr. P.H. Kurian, marked his last day in office with a landmark judgment granting the first ever compulsory license to an Indian generic company Natco Pharma to manufacture and sell a generic version of Bayer Corporation's patent protected anti-cancer drug 'Sorafenib Tosyalte', which is marketed as NEXAVAR by Bayer.[i] This judgment is expected to have a major impact on the Indian pharmaceutical industry.

COMPULSORY LICENSING

To appreciate the order, it is important to understand the provisions relating to CL. Compulsory Licensing (CL) is an involuntary contract between a willing licensee and an unwilling patentee imposed and enforced by the State.[ii]Upon grant of the CL, the grantee can manufacture and sell generic versions of a patented product for the remaining term of the patent, unless the CL is revoked earlier. The Controller determines the royalty payable by the grantee of the CL to the patentee.

Article 30[iii] and 31[iv]of the Agreement on "TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS" ("TRIPS") allows compulsory licensing and government use of a patent without the authorization of its owner, however this can only be done under a number of conditions aimed at protecting the legitimate interests of the right holder. Article 31 of TRIPs does not specify on what grounds a CL can be granted and leaves it open for member states to determine. Similarly, The Paris Convention of 1883 provides that each contracting State may take legislative measures for the grant of compulsory licenses.[v]Chapter XVI of the Indian Patent Act, 1970 ("Act") provides for detailed provisions for CL, when the application for the same is made by an intended licensee (person interested[vi]) and also in cases where government may *suomoto* issue a CL which is in consonance with Article 31 of TRIPs.

Under Section 84[vii] of Act, the Controller of Patents ("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:-

a) The reasonable requirements of the public with respect to the patented inventions have not been satisfied, or
b) The patented invention is not available to the public at reasonably affordable prices, or
c) The invention is not exploited commercially to the fullest extent within the territory of India.

Once an application has been filed, the Controller, needs to take into account the steps already taken by the patentee towards making full use of the patent and importantly, the capacity and ability of the applicant to work the invention to the advantage of the public and whether the applicant has made efforts to obtain a voluntary license from the patentee on reasonable terms and conditions.[viii]Once a CL is granted, after a period of expiry of two years from the date of grant of the CL, any interested person or the Central Government may apply to the Controller for revocation of the patent on the grounds that invention has not been worked in India or that the RRP has not been satisfied or that the patented invention is not available at a reasonably affordable price. (Section 85 (1)).

The CL provisions were part of the 1911 Indian Patents Act and thereafter were also incorporated in the 1970 Indian Patents Act. By 2002 amendment (effective May 20, 2003), the entire chapter of CL in the 1970 Act was replaced. In the present order, reliance on Paris Convention and TRIPS has been placed to

interpret certain provisions, as discussed later. It needs to be examined whether the interpretation as contemplated by the Controller, is in violation of the said conventions to which India is a signatory. The CL provisions as incorporated in the Act have not yet been challenged for being *ultra vires* of TRIPS or the Paris Convention.

The government of India has not yet invoked CL provisions nor has any private party litigated for the CL. This is the first time that the CL application has been prosecuted and CL provisions have been interpreted. This precedent setting judgment is creating significant ripples in the highly intellectual capital centric pharmaceutical industry. In this ipLab, we aim to provide detailed analysis of the order, the CL Chapter and international conventions.

THE DRUG

Sorafenib Tosyalte is a compound patented by Bayer Corporation, a renowned,Pittsburgh, USA based developer and manufacturer of innovative drugs ("Bayer"). It is marketed as NEXAVAR ("the Drug") and is used in the treatment of advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular carcinoma). The drug is life–extending drug and not a life-saving drug. It can increase the life of a kidney cancer patient by 4-5 years and that of a liver cancer patient by 6-8 months.

Bayer was granted a patent as well as regulatory approval for importing and marketing the Drug in India in the year 2008. It appears that Bayer does not hold a manufacturing approval in India, but has only a marketing and import license.

TIMELINE AND KEY FACTS

March 3, 2008	Bayer was granted patent No. 215758 for 'sorafenib'and for other compounds including sorafenib tosylate.
July 2011	Natco Pharma ("Natco") filed an application in July 2011 under section 84(1) of the Act for grant of CL in respect of sorafenib tosylate covered under patent No. 215758. In its application Natco proposed to sell the drug at a price of INR 8,800/- (about USD 175) for one month therapy as against Bayer's INR 2,80,428 (about USD 5,600) for one month therapy.
August 9, 2011	The Controller, upon noting that 3 years have elapsed since the grant of patent and Natco being person interested and being satisfied that a prima facie case existed, issued an order for publishing the CL application in the official journal.
October 2011	Bayer filed interlocutory petition seeking stay of proceedings on the ground that infringement suits and contempt petitions against Natco were pending in the Delhi High Court. These petitions were refused by the Controller.

Nov. 2011	Bayer filed writ petitions in the Hon'ble High Court of Bombay (which was rejected on the ground of jurisdiction) and thereafter Hon'ble High Court of Delhi challenging the order of the Controller dated August 9 2011 inter alia on the ground that the Controller did not conduct any enquiry or record any evidence before coming to a prima facie view and issuing notice to Bayer. Bayer however, withdrew the said petition with the liberty to raise the issue before the Controller.
Nov. 2011	Bayer filed its opposition to the compulsory license application. Each party filed their respective evidence.
Jan-Feb 2012	The parties were heard extensively.
March 9. 2012	Order of the Controller.
June 2012	On or before which Bayer may file an appeal from the order before the Intellectual Property Appellate Board ("**IPAB**") unless extension is granted by IPAB.

ISSUES

PRELIMINARY ISSUES

Bayer raised certain preliminary issues, which were not held in its favor:

Issue raised by Bayer	Controller's order & reasons
Natco has only raised ground mentioned in S. 84 (1) (a) of the Act and has failed to mention the grounds under S. 84(1) (b) and (c) of the Act.	This objection was dismissed as being hyper technical as all the grounds have been constructively raised by Natco.
Natco had not complied with the mandatory requirement under Section 84(6) (iv) of seeking a voluntary license from Bayer. Bayer contended that the tenor of the letter sent by Natco seeking voluntary license showed that it was sent merely to satisfy Sec 84 (6) (iv) and cannot be termed as an 'effort'.	This objection was dismissed as the Controller observed that Bayer had replied to Natco and had unequivocally refused to grant voluntary license. Hence Natco could not have made any more efforts. Thus and requirement of Section 86 (4) (iv) were satisfied.

Natco did not make out a prima facie case and the Controller ought not to have ordered the publication of the CL application in the Journal without giving Bayer an opportunity of being heard.

This objection was dismissed on the basis that as per Form 27 (statement of working of Patents) filed by Bayer at the Patent Office, Bayer had imported grossly inadequate quantities of NEXAVAR in the last 3 years – which was ample material that a *prima facie* case had been made out.

Natco had suppressed the fact that CIPLA Ltd – an Indian generic manufacturer ("Cipla") had been selling generic versions of the Drug and Bayer had instituted infringement proceeding against Cipla, which was pending.

This objection was dismissed as not being a material consideration for the purposes of CL proceedings.

SUBSTANTIVE ISSUES

While examining whether the grounds under Section 84 (1) are satisfied, the Controller examined the evidence submitted by both parties. Several questions of law and facts were raised and dealt with by the Controller. Various provisions in the CL ChapterXVI of the Act, provide guidance to the Controller as to which factors have to be taken into account while dealing with the CL application. One interesting aspect that was raised by Bayer was the infringing sales of the Drug by Cipla since early 2010. Bayer had filed a suit for infringement against Cipla in the Hon'ble High Court of Delhi but has not been granted interim injunction yet.

THE REASONABLE REQUIREMENTS OF THE PUBLIC HAVE NOT BEEN SATISFIED

Natco urged that as per GLOBOCAN 2008[ix] there were 20,000 patients of liver cancer and 8,900 cases of kidney cancer in India. Assuming 80% of patients needed the Drug, approximately 23,000 patients required the treatment. According to the Form 27[x] filed by Bayer, they imported 0 units in 2008 and approximately 200 bottles in 2009 and 0 units in 2010. Hence, the reasonable demand was not being met. Bayer does not manufacture the Drug in India, but imports it. It is exorbitantly priced, usually out of stock and available only in pharmacies attached to few hospitals in metro cities. Bayer launched the product worldwide in 2006 and made thumping sales to the tune of 2,454 million dollars. Thus, the insignificant number of bottles imported in India showed Bayer's neglectful conduct. Cipla's infringing sales have no bearing as a civil suit is pending against them and any time they can be injuncted thereby stopping their manufacture and sale.

Bayer responded by demonstrating that actual number of patients of kidney and liver cancer requiring treatment is 8,842 and not 23,000. The Drug was being made available by Bayer to all cancer treatment centers in India. Exorbitant price has no link with reasonable requirement of the public. Sec 84 (7)[xi]of the Act lays down several deeming conditions as to what constitutes "reasonable requirement of the public has not been met". None of these deeming conditions have anything to do with price of the patented product. The availability of the Drug has been considerably increased due to sales by Cipla. Cipla was projected to sell about 4,686 boxes of the Drug in 2012.

The Controller decided against Bayer. Observations of the Controller:

- 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 a mere 2% of the 8,842 patients who according to Bayer's own estimate need the Drug. Bayer's conduct was not justifiable as it was already marketing the drug worldwide since 2006, it had all drug approvals in place as well as considerable field force.
- Sales of Cipla cannot be added to the Patentee's sales figures in view of Section 86 (6) (i) which requires the Controller to take into account measures already taken by the patentee and its licensee. 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.

NDA'S ANALYSIS

What is the "*Reasonable* requirement of public?** Section 84 (7) provides deeming provisions in relation to reasonable requirement of public (RRP). It provides for certain situations when it would be deemed that RRP is not satisfied. Apart from the demand of patented product not being met, it also contemplates situations where (i) export market for patented product is not developed, (ii) working of patented product on commercial scale in India is prevented / hindered by importation of such product. Thus RRP is intended to mean not only the demand for product but also development of the trade in India. We have discussed this aspect later in the Lab while discussing the "working requirement".

In the present matter, Natco relied only on one fact of market demandnot being met by Bayer's sales (Section 84 (7) (a) (ii)).

What is the requirement? Bayer did not challenge reliance by Natco on the GLOBOCAN 2008 data but relied on other factors such as percentage of patients having Stage IV (as opposed to Stages I to III) or advanced stage cancer to arrive at number of patients needing the Drug to be 8,842. The Controller concluded that the number of patients must he higher than 8,842. It appears that even if the Controller had proceeded on the number provided by Bayer, the admitted supply by Bayer was not sufficient to meet the demand. By its own showing, more than 8,000 patients need the Drug, whereas Bayer has imported 200 bottles in 2009 and 593 bottles in 2011. Dr. Milind Antani, head of our Pharma and Life Sciences says "according to oncologists, each patient needs from one tablet a day to three tablets a day. Each pack has 120 tablets. Hence Bayer's import of 593 bottles in 2011 could have met the needs of a minimum of 200 patients to a maximum of 2,400 patients."

Whether Sales by Cipla should have been taken into account? From the facts is appears that Cipla's infringing activities started only in early 2010. Bayer has not provided any explanation as to why the patented product was not made available prior thereto. In any event patentee cannot rely on the sales made by infringer to show that reasonable requirement of the public has been satisfied. In the present case, Cipla is not even a licensee by acquiescence, as Bayer has instituted infringement suit against Cipla. We have examined this aspect later in the Lab with respect to the adjournment application filed by Bayer.

THE PATENTED INVENTION IS NOT AVAILABLE TO PUBLIC AT REASONABLE AFFORDABLE PRICE.

Natco argued that the price of the patented product is too high and unaffordable by the common man. The exorbitant pricing is an abuse of its monopolistic rights and amounts to unfair and anti-competitive practice. Natco also highlighted that Bayer had received tax credit since research on the Drug was under the US Orphan Drug Act[xii], thus lowering the net cost of investments to Bayer. Also, though the R&D outlay on the Drug was high, the total sales of the Drug in its first three years were to the tune of $ 1.2 billion.

Bayer's strongest argument was that innovative drugs cost significantly more than generics since the innovator's costs include R&D expenses which generics do not incur as they merely copy the drugs. The higher price includes the costs of failed projects which accounts for nearly 75% of total R & D cost as well as underwrites additional costs for future innovations. According to Bayer it takes an investment of more than €2 billion to bring a new medical entity (NME) to the market. Also, the price being charged by Bayer was comparable to other oncology drugs of innovation-based companies. Replacing innovative drugs with generics will in the long run damage patients as originators also provide for the education of doctors and pharmaco vigilance which generics do not. Only the patentee, being the innovator and having invested in the R&D can determine what would constitute a "reasonable affordable price" for the Drug. The term reasonable should be construed as to mean reasonable for both the patients and the patentee and a "reasonable" price has to factor in R & D costs and reasonable commercial gain. While Bayer placed strong reliance on its R & D costs being high, from the Controller's order it seems that it has not given any statement as to what was its outlay in the development of the Drug. It only gave a general statement that bringing a NME to the market usually costs €2 billion.

Bayer argued that "public" denotes different sections of public – rich class, middle class and poor class. A blanket CL which gives the patented product at the same price to all sections of the public is not reasonable, amounts to treating 'unequal as equal' and is discriminatory. A CL will lower the price of a patented product even for people who can pay – which cannot be the intention of the Legislature. One of the ways by which people afford medical treatment is medical insurance. "Affordability" should be determined by asking whether the patient can afford insurance cover or not.

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 "reasonably affordable price has to be construed **predominantly with reference to public**". The Controller observed that the sales by Bayer during last 4 years constitutes only fraction of the requirement of the public and came to the conclusion that lower sales have been due to high price of the patented product. Therefore, the Controller held that the Drug was not available to the public at a reasonably affordable price.

NDA'S ANALYSIS

What is "reasonably affordable price?" In the Act "reasonably affordable price" has not been defined nor are there any guidelines as to how it ought to be determined. While determining how much royalty is payable by the licensee to the patentee in relation to grant of the CL, the Controller is required to take into account expenditure incurred by patentee for making and developing invention, for obtaining patent

and for keeping it in force[xiii]. However, there is a co-relation between the price of the Drug determined by the Controller and royalty. We have examined this aspect later in the Lab. The Controller has observed that "reasonably affordable price has to be construed **predominantly with reference to public**", but has not delved into this aspect as based on the sales made by Bayer, he came to the conclusion that the drug was not available at "reasonably affordable price". While doing so, the Controller has considered that since the sales of Bayer were a small fraction of the actual demand, it was logical that people did not buy the Drug due to its exorbitant price. Hence, the Drug was not reasonably affordable to public. 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 reasonably affordable price.

The law on compulsory licensing requires a balance to be struck between the rights of the patentee as well the needs of the public at large.

Having said that, expenditure incurred by the patentee, may not as a rule be taken into account while determining "reasonably affordable price." Often taking into account the market dynamics, the pharmaceutical companies decide not to introduce patented products in India as they believe that the price which they seek, may not be afforded by the market. In such cases, it may not be prudent to take into account the expenditure incurred by the patentee to determine the "reasonable affordable price" as in the first place, the patentee was not even contemplating India as potential market. Hence, we believe that 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.

Interestingly, under the CL Chapter 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.

The Controller in his decision has not discussed the issue of insurance raised by Bayer. According to ASSOCHAM (2009), the medical insurance industry though pegged to be more than 5,000 crores INR covers only about 2% of the Indian population. Therefore in the Indian context an enquiry into whether medical insurance can cover the costs of the Drug may not be relevant.

PATENTED INVENTION NOT WORKED IN THE TERRITORY OF INDIA

This is by far the most contentious and controversial segment 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 of Section 84 (1) (c) does not mean that the patented product has to be locally manufactured. According to Bayer "working" of a patent means that there should be a supply of the patented product in the territory of India. Bayer also argued that it had centralized its manufacturing in Germany due to economies of scale and to maintain high quality.

The Controller relied on Paris Convention, TRIPS, the unamended Patents Act of 1970 and Sections 84 (7), 83 (b) and 90(2) to come to the conclusion that importation cannot amount to working of a patented product: "The term 'work the invention' does not include imports as a compulsory license holder has to necessarily work the patent by manufacturing the patented invention in India."

NDA'S ANALYSIS

Whether importation into India amounts to working of patent in India? It needs to be examined whether the bare reading of the CL Chapter, it is clear that "working in India" means manufacturing in India. If that conclusion is reached, then the next step would be to examine whether such provisions are in compliance of Paris Convention and TRIPS. The TRIPS challenge to the CL Chapter, if any, can be raised before the dispute resolution mechanism under the TRIPS[xiv] and not before local courts, as has been observed in the Novartis case[xv].

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

The provisions of Paris Convention and TRIPS: Even at the WTO level this issue is being debated and not yet settled. In the absence of Indian precedent and lack of clear guidance at the WTO level, the Controller has proceeded to interpret the provisions of the Act and Paris Convention and TRIPS. Article 27 (1)[xvi] of TRIPS requires nations not to discriminate between locally manufactured and imported products. On the other hand, Art 7 of TRIPs also 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 Article 7 and the developed countries getting Article 27. It is interesting to note that Brazil's IP law had a similar provision and the United States had filed a complaint in the WTO Dispute Settlement Body. This case was later settled and there was no decision on this point. Similarly, Art 5 (1) of the Paris Convention (which is also part of the TRIPS Agreement as per Art 2[xvii] of TRIPs Agreement) lays down that importation of patented articles shall not entail forfeiture of the patent. The Controller has held that Art 5 (1) lays down that importation will not lead to forfeiture, but Art 5 (1) does not exclude something less than forfeiture, the something less being CL. Hence, under Art 5 (1) of the Paris Convention, CL for importation of patented products is possible. From the reading of the Paris Convention, TRIPS and Sections 83, 84(7) (e) and 90 (2) of the Act, there still appears to be an ambiguity as to how to interpret "working" requirement. Section 83 is merely of a guiding nature and is not a substantive provision. Section 84 (7) lists down various situations that the Controller needs to take into account while determining whether RRP is satisfied (under Section 84(1)(a)). But the Controller has related this to the "working" provision. 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. By saying 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" appears an incorrect interpretation of the law. These provisions do not seem to clearly indicate that "local working" is a must.

Under the CL Chapter prior to 2002 amendment, 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 into this amendment, legislature seems to have to have interlinked RPP and "working" provisions, which has created confusion in the interpretation. Separately, as stated earlier, under Rule 131(1) and Form 27 indicates that "importation" may be considered as "working of the invention on a commercial scale in India". But again the Rule and the Form being delegated legislation cannot overstep the intention of the legislature depicted in the Act. Further, new CL Chapter is latter in point of time than Section 146 of the Act. This aspect also would have a bearing on the interpreting the legislative intent.

Well, after perusing the above deliberations, readers will wonder, finally does the Act require "local working" or not ! The answer at this stage is not clear. One would need to await the decision of the IPAB. The matter may be litigated up to the Supreme Court of India, which may provide clear guidance, taking into account the international conventions and the ability of India to insist on having "local working" requirement provision. On practical side, most companies these days, including Indian companies (almost all mobile, telephone, watch, battery manufacturers) have outsourced their manufacturing to centralized locations to ensure economies of scale, low costs, and better harmonization. The Controller's order means that every patent holder will now have to sufficiently manufacture in India, else he will be facing the prospect of having a compulsory license issued against him. 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.

Another interesting aspect is, under CL Chapter, definition of the term "patented invention" includes any article made by a patented process. In relation to the process, if the process is not carried out in India then it would not amount to working in India. If, however, it is held that "importation" amounts to "working in India", it may then mean in relation to process patents, importation of articles manufactured by use of patented processes, would be working of processes within India?

Request for adjournment. Section 86[xviii] of the Act allows for a CL proceeding to be adjourned for a year to give the innovator /patentee the first right option to work the patent. Bayer's main contention was that Cipla's presence in the market prevented Bayer from fully working the patent. The Controller held that Cipla launched its product in early 2010 and Bayer has two years to modify its pricing strategy to enable Bayer to commercially work the patent. The Controller held that the time which has elapsed since the grant of the patent was not insufficient for Bayer and Bayer did not show any prompt action to work the patent in the territory of India to an adequate extent.

The Act provides for minimum 3 years for the patentee from the date of grant of patent to work the patent. So Bayer had until March 2011. In the year 2008 Bayer did not have any sales, but in the year 2009, they had commenced importation of the Drug. In early 2010, Cipla's infringing sales commenced. The Delhi High Court did not grant interim injunction against Cipla.

It may not have made business sense for Bayer to import more of the Drug when the demand for the Drug was being met by Cipla's low cost infringing product, because of which the market for Bayer's Drug was significantly reduced. The Controller, in view of these facts, should have exercised its power under Section 86 to adjourn the hearing of CL application.

Computation of Royalty payable to Bayer. In the present matter, the Controller has also ordered that Natco should make the drug available at INR 8,880 for a packet of 120 tablets, required for one months' treatment (this was based on Natco's undertaking). Since the royalty earned by patentee would be % of net sales, in absolute terms, the amount of royalty received by patentee may not be

commensurate with the expenditure incurred by the patentee. The Controller determined that Natco should pay 6% of net sales as royalty to Bayer. In doing so, it relied on UNDP guideline that recommends rate of 4% and adjusted upwards as much as 2% for products of particular therapeutic value. The Japan Patent Office guidelines on royalties to be paid for non-voluntary use of patents specify a range of 2% to 4 % which can be adjusted by 2 % upwards or downwards. The Canadian government in 2005 has fixed royalty rates of 0.02 % to 4 % for compulsory license of pharmaceuticals. Looking at these ranges, it seems the price at which Natco is required to supply the Drug is Rs. 8,880 per packet and therefore, in absolute terms the total quantum of royalty received by Bayer will be low.

ORDER

The Controller granted a non-exclusive and non-assignable CL to Natco solely for the purpose of making, using, offering to sell and selling the Drug for the purpose of treating Renal Cell Carcinoma and Hepato Cellular Carcinoma in humans within the territory of India. The Drug will have to be manufactured by Natco in its own manufacturing facility only and cannot be outsourced.

APPEAL

As stated earlier, Bayer has the option to file an appeal to the IPAB against the order. It appears that Bayer has not prayed for the stay of the order of the Controller and unless, it applies to the IPAB and is able to obtain stay immediately, Natco will be able to start the manufacture and sale of the Drug in India.

CONCLUSION

This order marks a watershed in the development of jurisprudence of compulsory licensing, not only in India, but also in the international legal framework. There has not been significant interpretation of Arts. 7,8, 30, 31 of the TRIPs agreement, nor how it interplays with Art 27 (1) of TRIPs and Art 5 of the Paris Convention. This decision will not only impact the pharmaceutical industry but also be applicable to all industries. It remains to be seen how concepts such as “reasonable requirement of public” and “reasonably affordable by public” will be interpreted when dealing with non pharmaceutical products.

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

A more pragmatic approach to CL on a case by case basis is the approach taken by countries such as Brazil. Instead of private generic companies obtaining CLs, the government studies which diseases need intervention from the State and uses the CL only as a bargaining tool to get the innovator companies to come to the negotiating table. Brazil has been successful in getting various US and European innovator companies to reduce drug prices by even upto 40%. 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 at large, the innovator retains its exclusivity and the public gets access to medicine at a reasonable

price. Several substitute drugs may be available in the market for the patented drug, hence as such the public need may get satisfied with other available drugs. In fact, prior to the 2002 Amendment, the Patent Act provided for license of rights by way of which only the government could issue CLs as opposed to any interested party applying for a CL.

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 has promulgated The Drug Price Control Order ("DPC Order") which fixes the ceiling price of some active pharmaceuticals and formulations. The authority set up under the legislation is the National Pharmaceutical Pricing Authority ("NPPA"),which is responsible for the collection of data and the study of the pricing structure of active pharmaceuticals and formulations. Upon the recommendation of the NPPA, the Ministry of Chemicals and Fertilizers fixes the ceiling prices of active pharmaceuticals and formulations and issues notifications on drugs. The DPC Order 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 a lot of takeaways for innovator companies, especially pharmaceutical companies. One, is the importance of Form 27. Due care and diligence needs to be undertaken while filing the Form 27 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 an adjournment under Section 86. Pharmaceutical companies should take care to 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, then grant of a CL in relation to such drug does not have an economic impact on the patentee, in fact, patentee may get certain royalty from India. Innovator companies need to rethink their strategy especially if they plan to only sell and not manufacture for initial period.

What remains to be seen in relation to present matter, is whether oncologists 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 "reasonably affordable price" means and whether "worked" in the territory of India excludes importation, thereby necessitating that every patent holder needs to locally manufacture patented products in India. This battle is far from over. The interpretation of "working" of a patent to mean "local working" (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.

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[i] Full text of the judgment is available at: http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (Last accessed: 21 March 2012)

[ii] Compulsory License dates back to as early as the 1830s. Provisions for Compulsory License can be found in the patent laws of most countries – both developed and developing. It is part of the Paris Convention of 1883 and has also been sanctioned in Art 31 of TRIPS which addresses uses "of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government."

[iii]Exceptions to Rights Conferred Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

[iv]Other Use Without Authorization of the Right Holder

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, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

[v] Art 5 (A) (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

[vi] Section 2 (t) "person interested" includes a person engaged in, or in promoting , research in the same field as that to which the invention relates;

[vii]"(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, namely:— (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 worked in the territory of India."

[viii] Section 84 (6) In considering the application filed under this section, the Controller shall take into account, -

(i) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) The ability of the applicant to work the invention to the public advantage;

(iii) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

(iv) As to whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee, But shall not be required to take into account matters subsequent to the making of the application.

[Explanation.- For the purpose of clause (iv) "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months.]

[ix] A publication by GLOBOCAN project of the World Health Organization.

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

[xi](7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a license or licences on reasonable terms,-

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licences under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by-

(i) the patentee or persons claiming under him; or

(ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceedings for infringement.

[xii]In the US, research conducted by companies on diseases which have fewer than 200000 patients are entitled to tax credit. Bayer had received 50% orphan drug tax credit.

[xiii]Section 90 (1) (i) of the Act.

[xiv]Under the WTO mechanism, a dispute can be brought by a member state against another member state and the Dispute Settlement Body (DSB) decides the dispute as per the Dispute Settlement Understanding (DSU).

[xv] The Madras High Court had held that the challenge to Section 3 (d) of the Indian Patent Act being non-compliant with TRIPS was not maintainable since the proper authority to settle this matter was the WTO dispute settlement panel.

[xvi] Patents shall be available and patent rights enjoyable without discrimination… whether products are imported or locally produced.

[xvii]**Article 2**Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

[xviii] **Section 86. Power of Controller to adjourn applications for compulsory licenses, etc., in certain cases.-**(1) Where an application under section 84 or section 85, as the case may be, is made on the grounds that the patented invention has not been worked in the territory of India or on the ground mentioned in clause (d) of sub-section (7) of section 84 and the Controller is satisfied that the time which has elapsed since the sealing of the patent has for any reason been insufficient to enable the invention to be worked on a commercial scale to an adequate extent or to enable the invention to be so worked to the fullest extent that is reasonably practicable, he may, by order, adjourn the further hearing of the application for such period not exceeding twelve month in the aggregate as appears to him to be sufficient for the invention to be so worked:

Provided that in any case where the patentee establishes that the reason why a patented invention could not be worked as aforesaid before the date of the application was due to any State or Central Act or any rule or regulation made thereunder or any order of the Government imposed otherwise than by way of a condition for the working of the invention in the territory of India or for the disposal of the patented articles or of the articles made by the process or by the use of the patented plant, machinery, or apparatus, then, the period of adjournment ordered under this sub-section hall be reckoned from the date on which the period during which the working of the invention was prevented by such Act, rule or regulation or order of Government as computed from the date of the application, expires.

(2) No adjournment under sub-section (1) shall be ordered unless the Controller is satisfied that the patentee has taken with promptitude adequate or reasonable steps to start the working of the invention in the territory of India on a commercial scale and to an adequate extent.

RESEARCH @ NISHITH DESAI ASSOCIATES

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Our dedication to research has been instrumental in creating thought leadership in various areas of law and public policy. Through research, we develop intellectual capital and leverage it actively for both our clients and the development of our associates. We use research to discover new thinking, approaches, skills and reflections on jurisprudence, and ultimately deliver superior value to our clients. Over time, we have embedded a culture and built processes of learning through research that give us a robust edge in providing best quality advices and services to our clients, to our fraternity and to the community at large.

Every member of the firm is required to participate in research activities. The seeds of research are typically sown in hour-long continuing education sessions conducted every day as the first thing in the morning. Free interactions in these sessions help associates identify new legal, regulatory, technological and business trends that require intellectual investigation from the legal and tax perspectives. Then, one or few associates take up an emerging trend or issue under the guidance of seniors and put it through our "Anticipate-Prepare-Deliver" research model.

As the first step, they would conduct a capsule research, which involves a quick analysis of readily available secondary data. Often such basic research provides valuable insights and creates broader understanding of the issue for the involved associates, who in turn would disseminate it to other associates through tacit and explicit knowledge exchange processes. For us, knowledge sharing is as important an attribute as knowledge acquisition.

When the issue requires further investigation, we develop an extensive research paper. Often we collect our own primary data when we feel the issue demands going deep to the root or when we find gaps in secondary data. In some cases, we have even taken up multi-year research projects to investigate every aspect of the topic and build unparallel mastery. Our TMT practice, IP practice, pharma/lifescience/healthcare practice and energy sector practice have emerged from such projects. Research in essence graduates to *Knowledge*, and finally to *Intellectual Property*.

Over the years, we have produced some outstanding research papers, articles, webinars and talks. Almost on daily basis, we analyze and offer our perspective on latest legal developments through our regular "*Hotlines*", which go out to our clients and fraternity. These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *Lab Reports* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research articles and disseminate them through our website. Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with much needed comparative research for rule making. Our discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged. Although we invest heavily in terms of time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear your suggestions on our research reports. Please feel free to contact us at

research@nishithdesai.com