IP Hotline

August 20, 2014

BOMBAY HC UPHOLDS INDIA'S FIRST COMPULSORY LICENSE

- The Bombay HC in this case has upheld the order of the IPAB, which affirmed the order of the Controller of Patents to grant Compulsory License to NATCO for Bayer's Indian patent on Sorafenib Tosyalte (Nexavar).
- NATCO's application for Compulsory License of Patent was the first in India.
- This case is significant as it gives certain new interpretation to the conditions that needs to be met under the Indian Patents Act, 1970 for grant of Compulsory License.
- The Bombay HC held that in respect of medicine the adequate extent for meeting the demand of the drug has to be 100%.
- The Bombay HC held that dual pricing can be applied to meet the requirement of the public and not for making available the drug under reasonably affordable price.
- The Bombay HC held that the sale by the patent infringer can be taken into account to meet the reasonable requirement of the public only when the patentee has granted a defacto license i.e. has not filed a patent infringement suit against the infringer.

BACKGROUND

Bayer Corporation, USA ("**Bayer**") had developed Sorafenib Tosyalte (**"the Drug"**), marketed as Nexavar, and obtained a patent from US authorities (United States Patent Office) in 1999. The drug is a life extending drug which is used for treating patients suffering from advanced stages of kidney cancer (Renal Cell Carcinoma) and liver cancer (Hepatocellular Carcinoma).

Bayer was granted a patent for the Drug in India in March 2008. In December 6, 2010, Natco Pharma Ltd ("**Natco**") approached Bayer for grant of a voluntary licence. Bayer in a response dated December 27, 2010 rejected Natco's request for grant of voluntary license and requested Natco to approach within 14 days in case Natco had anything further to add. After the expiration of three years from the date of grant of the Indian patent to the Drug, Natco applied to the Controller General of Patents ("**Controller**") for a compulsory license under Section 84 (1) of the Patents Act 1970 ("**the Act**") proposing to manufacture and sell the drug at a price of Rs.8800/- per month of therapy. Bayer opposed this application on various grounds, however in March 2012, the Controller granted the first Compulsory License to Nacto to manufacture and sell the drug. A detailed analysis of Compulsory license provision under the Act and the analysis of Controller's order is available in our IP Lab **here**.

Thereafter, Bayer filed an appeal challenging the order of the Controller before the Intellectual Property Appellate Board ("**IPAB**"). The IPAB, in March 2013, dismissed the appeal and upheld the decision of the Controller. In the order IPAB raised the rate of royalty to be paid by Natco to Bayer from 6% to 7 %. A detailed analysis of the IPAB's order is given in our hotline **here**.

Bayer challenged IPAB's order before the High Court of Bombay **("HC")** by way of a writ petition**.** The HC examined the relevant provisions of the Act and upheld IPAB's Order.

ISSUES BEFORE THE HIGH COURT

a. Voluntary License

As per the Act, two conditions are required to be satisfied before an application for Compulsory Licence ("**CL**") is considered by the Controller.

- An application for CL can be made only after the expiry of three years from the date of grant of Patent.
- The applicant should make efforts to obtain a license ("**Voluntary License**") from the patentee on reasonable terms and conditions.

The first condition was satisfied. With regard to the condition of voluntary licence, Bayer argued that Natco did not make bonafide efforts to obtain a voluntary license as Natco failed to approach again after the communication dated December 27, 2010.

The HC was of the view that Bayer had clearly declined the request for license and no purpose would have been served by Bayer's vague statement in response that requested Natco to approach within 14 days in case Natco had anything further to add. The request made by Bayer only stated that Natco may revert in case they had anything to add to the application of voluntary license already made. The HC held that Natco has satisfied the second condition precedent to application for compulsory license.

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b. Reasonable Requirements of Public

Bayer contended that the **onus is on Natco** to establish that the reasonable requirement of the public has not been satisfied by Bayer. The HC accepted this position. Bayer contended that-

- Natco had failed to establish that the reasonable requirements of the public have not been satisfied;
- it was not possible to determine this without determining the number of patients requiring the Drug;
- the Drug is for treatment of persons in the final stages of the diseases and it is not required that every patient suffering from kidney cancer and liver cancer is required to consume the drug. The doctor has the option of adopting other measures rather than prescribing the drug.

The HC noted that reasonable requirement of the public cannot be met on a mathematical basis and it can only be determined based on the evidences produced. The HC noted the Controller's observation of the figures provided in GLOBOCAN 2008 and the affidavit of Dr Manish Garg who was the Country Medical Director of Bayer at the relevant time. According to the affidavit an aggregate of 8842 patients suffering from kidney cancer and liver cancer would require the drug. However, Bayer had sold only 593 boxes of the drug which was sufficient only for 200 patients.

Bayer contented that the sales made by Cipla Limited ("**Cipla**"), who were producing the patented drug, infringing the rights of the patent holder should also be taken into account while considering the total quantum of the patented drug made available in India.

However, the HC was of the view that the quantity manufactured by Cipla could not be taken into account. This view was taken due to the pending patent infringement suit between Cipla and Bayer at the Delhi High Court and the possibility that the production by Cipla could be stopped any day if an Injunction order is passed. The HC held that Cipla's goods can be taken into account only when Bayer accepts the participation of Cipla and in essence grants a defacto license to Cipla.

The HC also noted the Controller's observation that even if the drug supplied by Cipla was added to Bayer's supply the aggregate will still not be sufficient to meet the reasonable requirement of the patients as, Cipla had supplied only 4686 packets of drug.

Further, the HC also held that Bayer did not consider Cipla' sale while filing Form 27.[1]

The HC also provided an interpretation to the words "adequate extent" given in Section 84(7). The HC was of the view that the aspect of adequate extent will vary depending on the type of patented product. The HC held that **in respect of medicine the adequate extent has to be 100%and the medicine should be made available to every patient. The rights given to a patentee cannot deprive any patient from satisfying their need for the medicine.**

c. Reasonably Affordable Price

Bayer argued that prior to determining whether the drug was available to the public at reasonably affordable price, it was important to first determine what can be construed as reasonable affordable price in relation to the drug. The HC was of the view that the Act does not bestow any investigative powers on the Controller. **The Controller can only ensure that patented article is available at reasonably affordable price based on the relative price offered by the patentee and the applicant.** The HC held that Bayer was not selling the drug at reasonably affordable price since Natco was offering the drug at Rs 8,800 per month of therapy as compared to Bayer's price of Rs 2,84,000 per month of therapy. This shows that the reasonably affordable price is that of Natco and not Bayer.

Bayer further argued that "reasonably affordable price" should not be seen from the perspective of the users alone but from the perspective of the inventor also. The inventor spends considerable expenditure in developing a drug, conducting its trials and launching it in the market. Many molecules developed incurring huge expenditure cannot be marketed at all. Cost incurred for research regarding such failed molecules also has to be recovered from those molecules which are finally launched for public use. Such cost factors have not been taken into account by the Controller while determining the reasonably affordable price. Bayer also submitted affidavits of Mr. Dintar, Head of Global Drugs Discovery Operations at Bayer before the Controller which stated that Bayer had invested about Rs 114 billion in the year 2010 towards research and development activities. In response Natco had filed an affidavit of Mr James Love stating that the amount spent on research by Bayer from 1994 to 2004 was recovered by Bayer one year.

The HC further noted that Bayer did not submit its own books of accounts to show the expenses incurred in development of the specific patented drug and the money already realized by sale of the patented drug worldwide. Bayer also refused to produce its Balance Sheet asked for by the Controller. The HC was of the view that, if the book of accounts and Balance Sheet were produced it could have aided in determining the reasonable price at which Bayer could have made the drug available to the public. Further, the HC also observed that that 50% of the cost had already been reimbursed by the US government since the drug had been classified as an orphan drug[2].

The next contention put forward by Bayer was that patients are from different economic strata with varying capacity for paying the cost of the drug. Bayer had already put in place a Patient Assistant Program ("PAP") under which needy patients as recommended by doctors were given free tablets for one full month if they bought medicines for three days' use.

The HC held that under the PAP programme patented drugs were being made available only to patients who are recommended by the doctor. Further, the patients who fall under PAP can avail the special price solely at Bayer's discretion. The special price is not available in ordinary course to every patient. Thus, this cannot be taken into consideration while determining "reasonably affordable price".

The HC further held that the concept of dual pricing would be sufficient to comply with reasonable requirement of the public and not under reasonably affordable price. The HC took this view after placing reliance on Section 84(7) of the Act which provides for factors for satisfying the reasonable requirement of the public. Section 84(7)(a)(ii) necessitates that the patented article be available to an adequate extent or on reasonable terms. The HC held that the term "reasonable terms" refers to cases where the medicine is made available to economically backward patient through adoption of special prices.

d. Not Worked in the Territory of India

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June 04, 2025

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This has been the most important point in dispute. While the Controller was of the view that the patented product will be considered to be worked in India **only if** the patentee **manufactures the patented product in India** within reasonable time, the IPAB held that this issue should be considered on a case to case basis and the same approach cannot be adopted for all patented products and import of a patented product can also be considered as working the patent in the territory of India.

Bayer drew attention to Article 27 of the TRIPS which provides that there would be no discrimination in respect of patented product whether legally manufactured or imported. The same view is also apparent from Form 27 prescribed under the Act and the Patent Rules. Patentee has to file a statement in Form 27 with the Controller regarding the working of the patent in India. In the aforesaid form the patentee while giving details of working of patented drug in India, has to make declaration of working in India of the patented product under two classifications namely manufacture in India and imported from other countries.

The HC observed that working a patented invention in the territory of India has to be considered by reading Section 83 of the Act which provides for legislative guidelines to predict the meaning of the words "worked in the territory of India". The HC focussed on the following provision of Section 83:

(b) the patent is not granted to enable the Patentee to enjoy a monopoly for the importation of the patented article;

(c) the technological knowledge must be transferred and disseminated to the mutual advantage of producers and users of technological knowledge;

(f) the patent right should not be abused by the patentee by indulging in activities that unreasonably restrain trade or adversely affect the international transfer of technology.

Reading the above guidelines, the HC was of the view that the patentee is required to make some efforts to manufacture the patented product within the territory of India and user of the technological knowledge included patients who consumed the patented drug. Having said that the HC agreed with the view of IPAB that the matter should be considered on case to case basis and manufacture in India is not the sole method of working a patent in India. A patent can be worked in India by importing the patented article in adequate quantity and supplying it. However, working by import can be accepted only after the patentee provides satisfying reasons for not manufacturing the patented product in India.

CONCLUSION

The observations of the HC are summarised below:

Reasonable requirement of the public:

- This cannot be calculated on a mathematical basis and it can only be determined based on the evidences produced by both parties.
- The aspect of "adequate extent" for meeting the demand of the patented article will vary depending on the type of patented product. In respect of medicine the adequate extent has to be 100% of the requirement. The patented drug should be made available to every patient.
- The concept of dual pricing will help in satisfying reasonable requirement of the public and not for making available the drug under reasonably affordable price.

Reasonably affordable price*:*

- The Act does not bestow any investigative powers on the Controller. The Controller can only ensure that patented article is available at reasonably affordable price based on the relative price offered by the patentee and the applicant.
- The investment made by the patentee in developing the patented drug can be taken into account while determining whether the patented drug is available at reasonably affordable price, based on the evidence adduced by the patentee.

Use by the infringer*:* The sale by the patent infringer can be taken into account to meet the reasonable requirement of the public only when the patentee has granted a defacto license i.e. has not filed a patent infringement suit against the infringer.

Use by importation*:* A patent can be worked in India by importing the patented article in adequate quantity and supplying it. However, working by import can be accepted only after the patentee provides satisfactory reasons for not manufacturing the patented product in India.

The above observations will have a bearing on subsequent applications for CL.

ANALYSIS

Importantly this case demonstrates that out rightly rejecting an application for a voluntary license of a patent by the patentee might not be the most prudent way of addressing a potential compulsory licensing application by the same voluntary licensing applicant. It should be kept in mind that the Act does envisage under Section 84 (6) of the Act that the Controller needs to look into the below factors

- *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;*
- *the ability of the applicant to work the invention to the public advantage;*
- *the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;*
- *as to whether the applicant has made efforts to obtain a licence 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,*

A patentee while responding to a request for a voluntary license to put forward queries to the applicant in relation to the applicant's ability to manufacture the patented drug to the advantage of the public, the capital capacity of the applicant to undertake the process of manufacturing of the patented drug etc. In case the voluntary licensing applicant responds to the queries it would be clear that the voluntary license applicant is a serious applicant and based on the response a call could be taken by the patentee, whether further negotiations can be carried put on terms and conditions to grant a voluntary license from the patentee. In case the voluntary license applicant fails to respond it proves that the applicant has not made any credible attempt to obtain the voluntary license.

Another important outcome of this order is while reaffirming the position of the IPAB, the HC held that in case a patented product is not manufactured in India but is wholly imported, it cannot be said that the patented product is 'not worked in India'. Though the court observed manufacturing in India is not necessary, but the burden is on the patentee to show the reasons behind the inability to manufacture the product in India. The reason may also include delay in obtaining regulatory permission for manufacturing the patented product in India. However, "not worked in India" will be determined on a case to case basis and the court has not provided any specific guidelines. It would be advisable to consider manufacturing on loan license basis in India, in case the Patentee does not have manufacturing facilities in India.

Another important takeaway from the order can be the application of dual pricing to meet the reasonable requirement of the public. Thus different prices for the same product can be offered to meet the requirement of patients who are from different economic strata with varying capacity for paying the cost of the drug. However, practically this may be difficult to achieve.

The HC has not dealt in detail regarding what can be construed as reasonably affordable price. The HC just observed that if the book of accounts and Balance Sheet were produced to determine the expenses and reimbursement it could have aided in determining the reasonable price at which Bayer could have made the drug available to the public. However, this could create a problem since the price considered reasonable to the patentee might not considered as reasonable to the authorities even after looking at the book of accounts. This is still a question entirely based on facts that needs to be resolved.

The decision has also opened a plethora of questions. First question is in relation to the grant of *de facto* license to the infringer by the patent. According to the decision the *de facto* license will be considered to be given when the patentee has not filed a patent infringement suit against the infringer. This leads to the question, whether the patentee should sue or not sue the infringers? If the patentee sues, the product manufactured by the infringers will not be taken into consideration for the purpose of meeting the reasonable requirement of the public. If the patentee does not sue, it will be considered that the patentee has given a *de facto* license to the infringer to manufacture the patented product. Even if the patentee sues, there is no certainty that an interim injunction will be granted. This leads to a precarious situation, where there is no injunction and the infringing sales affect the business plan of the patentee.

Further, the HC has held that in relation to the interpretation of *"adequate extent"* for medicines the adequate extent has to be 100% and the medicine should be made available to every patient.. What is an "*adequate extent"* should ideally be decided on a case to case basis. The number of patients in need of the drug will vary from case to case. Various factors such as :

- The alternative drugs or therapies available for the treatment of the disease,
- The possibility that the doctor would not prescribe the patented drug,
- The graveness of the disease intended to be treated using the patented drugs.

will have to be considered before arriving on the number of patients that need the patented drug. Both the applicant for the compulsory license and the patentee will have to lead evidence i.e. data on this point and based on the evidence produced by the parties the Controller will have to analyse the data to determine the number of patients that need the patented drug. This process will get complicated as there will be substantial contention between the parties on the methodology and the factors to be considered in determining the number of patients needing the patented drug.

Further, Section 84 (7) (iii) does not give such a strict interpretation, that is the reason why it states an *"adequate extent"* and not *"full extent"*.

This order may raise serious concerns to patent holders, especially of drugs. Striking a balance between the rights of the patent holder and the users of the patented product is always difficult and it is all the more difficult in the case of drugs wherein a humanitarian approach takes precedence over commercial approach. However it may be too early to come to such conclusion since this is the first ever compulsory license and also considering various facts specific to the case.

– Ankita Mathew, Ajay Chandru & Gowree Gokhale
You can direct your queries or comments to the authors

[1] Form 27 is required to be filed by the Patentee providing information related the extent of use of the patented invention and reasons if any for non-use. For more details on Form 27 filings please refer to our Hotline at this link.

[2] An orphan drug refers to a drug which is intended to treat or prevent a rare disease.