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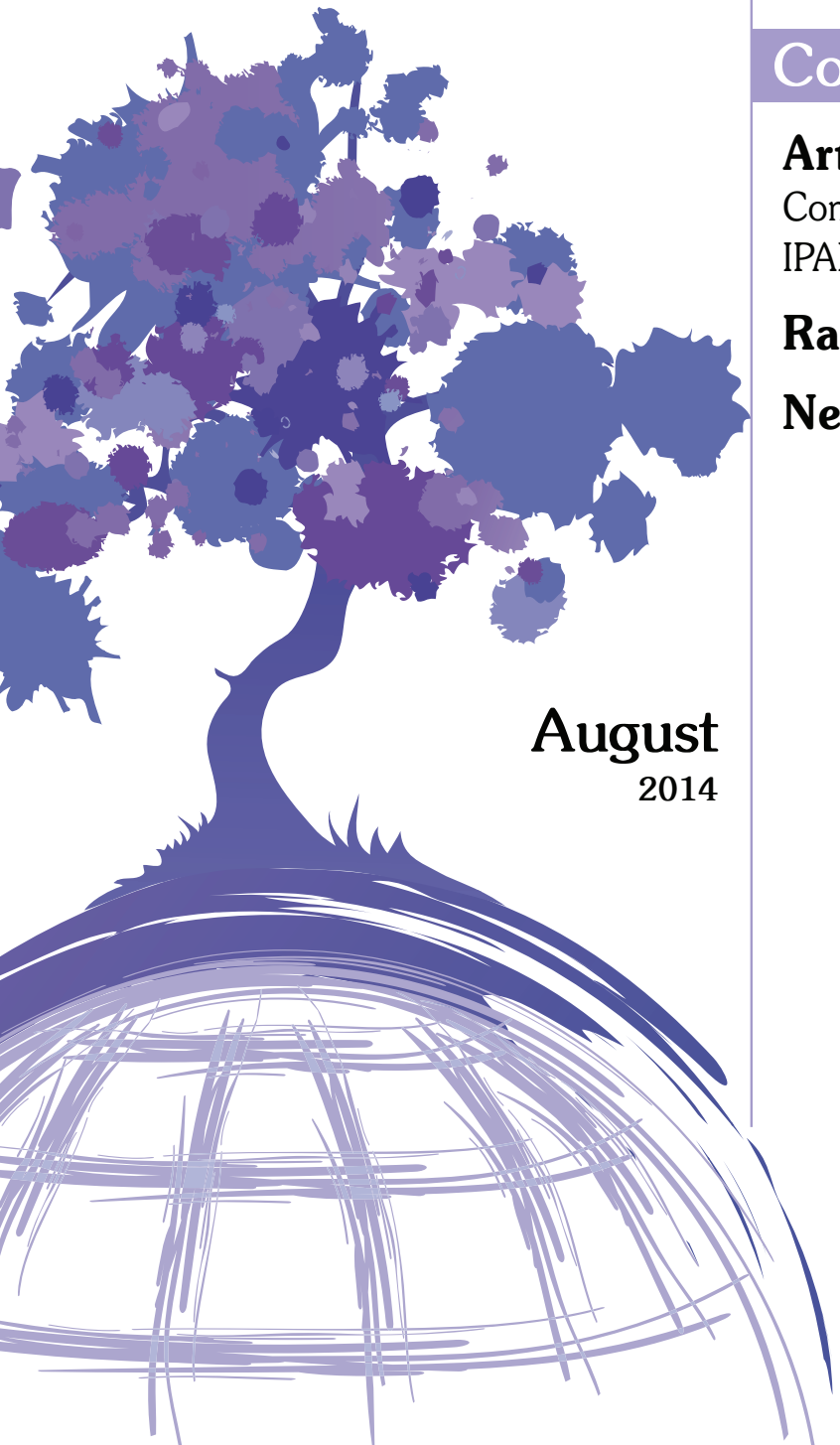
An e-newsletter from
Lakshmikumaran & Sridharan, New Delhi, India

August 2014 / Issue–37

Third Anniversary Issue



August
2014

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Compulsory license – High Court upholds IPAB Order

By **Vindhya S. Mani**

The Division Bench of the Bombay High Court by its recent order[1] dated 15th July, 2014 upheld the order of the Intellectual Property Appellate Board (IPAB)[2] dated 4th March, 2013 granting a compulsory license to Natco Pharmaceuticals (Natco) under Section 84 of the Patents Act, 1970 (the Act). The compulsory license was granted to Natco to manufacture and sell Bayer Corporation's (Bayer) patented anti-cancer drug, Sorafenib Tosylate sold under the brand name Nexavar. The IPAB and the Controller General (CG) had previously allowed the application filed by Natco for grant of compulsory license.

Brief background of the orders of Controller General and IPAB

On refusal by Bayer to grant a voluntary license to manufacture and sell the drug Nexavar in India, Natco applied to the CG for grant of a compulsory license over the patented drug under Section 84(1) of the Act. On hearing both parties, the CG allowed Natco's application on the ground that the reasonable requirement of the public in India was not met and that the patented invention is not available to the public. With regard to the ground under Section 84(1)(c) of the Act, that the patented invention is not worked in the territory of India, the CG interpreted "worked in the territory of India " to mean "manufactured to a reasonable extent in India".

On appeal, the IPAB upheld the CG's order though it differed with the CG on the interpretation of the term "worked in the territory of India" under Section 84(1)(c) of the Act. It opined that the requirement of working of the patented drug in India does not necessarily mean that the drug ought to be manufactured in India. The requirement could also be fulfilled by importing the patented drug to India.

Issues before the Division Bench of the Bombay High Court

- Whether Bayer has satisfied the reasonable requirements of the public under Section 84(1)(b) of the Act?
- Whether the patented drug is available to the public at a reasonably affordable price?
- Whether the patented drug has been worked in the territory of India?
- Whether the terms and conditions for grant of compulsory license were proper under Section 90 of the Act?

Bombay High Court's reasoning and judgment - Reasonable requirement of the public

Burden of proof

Bayer argued that the initial burden to make out a prima facie case for grant of a compulsory license is on Natco and that Natco had failed to do so. The Bench observed that the initial burden is on the applicant who makes an application for compulsory license to show that a *prima facie* case is made out. Rejecting Bayer's argument the Bench observed that once the CG is satisfied of such a *prima facie* case, the patentee is

[1] Writ Petition No. 1323 of 2013
[2] Order No. 252 of 2013

required to establish with facts in its possession that the reasonable requirement of the public is satisfied.

Quantum of drug required by the public

The Bench observed that it was not possible to determine the reasonable requirement of the public without ascertaining the exact quantum of the patented drug required by the public and since this exercise cannot be carried out on a mathematical basis, it has to be determined based on the evidence provided by the parties. Before the previous forums, the parties relied upon the Globocan 2008 figures to determine the incidence of patients suffering from cancer in India. The Bench took into consideration Bayer's Country Medical Director's affidavit which clearly illustrated that the quantum of drugs sold was not in consonance with the quantum of patients requiring said drug.

Infringer's supply

In response to Bayer's contention that supplies by infringers of the patented drug is to be taken into account to determine the satisfaction of the reasonable requirement test, the Bench held that the obligation to meet the reasonable requirement of the public is on the patentee, either alone or through his licensees. The Bench agreed with the reasoning of the IPAB that in filing Form 27 under the Act on a yearly basis for showing working of the patent in India, Bayer had not included Cipla's sale of the patented drug.

Interpretation of "Adequate Extent"

The Bench also analyzed the interpretation of the term "adequate extent" under the deeming fiction in Section 84(7) of the Act, which states that the reasonable requirement of the public is not satisfied if the demand for the patented article is not met to an adequate extent. The Bench differentiated the test for 'adequate extent' with respect to medicines and luxury articles. With regard to medicines, the Bench held that the adequate extent test has to be 100%, i.e. to the fullest extent. The Bench, referring to the Doha Declaration 2001 held that "adequate extent" for medicines had to be interpreted as medicines to be made available to every patient and in the instant case, Bayer did not meet the requirements of all the patients.

Reasonably affordable price

Bayer contended that under Section 90(1)(iii) of the Act, there exists an obligation on the Controller to determine the reasonably affordable price of the patented drug. The Bench however held that the Act does not bestow any such powers of investigation on the authorities to determine the reasonable affordable price of the patented drug. The evidence led by parties would form the basis of determining reasonably affordable prices and it has to be determined on the basis of the relative price being offered by the patent holder and the applicant after hearing other interested parties opposing the application. While Bayer sold the drug at Rs. 2,84,000/- for a month's therapy, Natco was offering the same drug at Rs. 8,800/- for a month's therapy. Hence, the Bench held that Bayer did not sell the drug at a reasonably affordable price.

Adverse inference against Bayer

In response to the assertion, that the price of the patented drug should also cover the costs incurred in respect of research and development on failed drugs, the Bench held that under Section 90(1) of the Act, only the expenditure incurred for research and development on the

patented drug ought to be taken into account. Natco asserted that Bayer failed to produce audited accounts to establish the amount spent on research and development. Further, Nexavar is classified as an orphan drug[3] in the U.S.A and thus Bayer is entitled to be reimbursed either by tax credit or otherwise to an extent of 50% of its costs incurred on research and development of the patented drug. Bayer did not reveal the quantum of reimbursement received. The Bench upheld the order of the IPAB and the Controller that the patented drug was not made available to the public at a reasonably affordable price.

Importance of PAP Schemes

Bayer argued that schemes such as Patient Assistance Program (PAP) whereby if a patient buys three dosages (12 tablets) of Nexavar, the remaining tablets (108 tablets) for the month are given free of cost, suggests that the patented drug was available to the public at a reasonably affordable price. Natco responded that the special price under PAP was only given to particular patients on the recommendation of the doctor and at the discretion of Bayer. The Bench held that under Section 84(1)(b) of the Act, the patented drug should be available to any member of the public at a reasonably affordable price and not an exceptional price like PAP.

Worked in the territory of India

Bayer argued that in light of Article 27 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) there can be no discrimination in respect of a patented product whether legally manufactured or imported and the patented drug Nexavar has been worked in India. In Form 27 wherein the patent holder has to provide details under two heads, namely, manufacture in India and imported from other countries and thus working the patent product in the territory of India does not exclusively mean manufacture of the patented product in India.

The Bench referring to Section 83 of the Act held that some efforts to manufacture in India should be made by the patent holder. Referring to Form 27, the Bench agreed with the interpretation by the IPAB that whether a patent has been worked in the territory of India, has to be determined on a case-to-case basis. When a patent holder is faced with an application for compulsory license, it is for the patent holder to show that the patented invention is worked in the territory of India by manufacture or import. The Bench also clarified that manufacture in all cases may not be necessary to establish working in India. However, the patent holder would have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India.

Terms and conditions for grant of compulsory license

Bayer argued that the grant of compulsory license to Natco was done contrary to the terms mentioned under Section 90 of the Act. Section 90 of the Act states amongst other terms that the Controller has to ensure that the royalty and other remuneration paid to the patent holder should reasonably cover the expenses incurred by the patent holder in making or developing

[3] Section 316.3(b)(10) & (11) of the US Orphan Drug Act (21 CFR Part 316)

"(10) Orphan drug means a drug intended for use in a rare disease or condition as defined in section 526 of the act.
(11) Orphan-drug designation means FDA's act of granting a request for designation under section 526 of the act."

the patented invention. The CG fixed the royalty rate to be paid by Natco to Bayer at 6% of the net sales made by Natco, on the basis of the United Nations Development Programme Report which recommends that the normal rate of royalty should be at 4% of the net sale. The IPAB however, increased the royalty rate to 7% of the net sales. The Bench held that the terms of the compulsory license were not contrary to Section 90 of the Act since Bayer did not adduce any evidence to show in what manner the royalty rate of 7% of the net sales was inadequate or on the cost incurred to develop Nexavar.

Conclusion

After 2005, Chapter XVI of the Patents Act, 1970 which deals with compulsory license, has been invoked very few times. Nexavar is the only case which has been examined at three different levels, i.e. by the Controller General, the IPAB and the High Court. In the above-mentioned decision of the Bench of the Bombay High Court, the Court elaborated and clarified the provisions pertaining to compulsory licenses. It also emphasized that the proceedings under Section 84 of the Act are in public interest and that public interest is fundamental in deciding a matter of compulsory license with respect to medicines or drugs. This decision has thus paved the way for more applications of compulsory licenses for medicines.

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Ratio Decidendi

Trademark – Assignment not registered before dissolution of assignee-company deemed as removed

Assignment of trademark should be registered within a reasonable period and if the trademark is not so registered before dissolution of the assignor company, the mark is deemed to have been removed or rectified from the Registry of Trademarks. Holding thus, while allowing the rectification application in respect of mark US PRO, the Intellectual Property Appellate Board, placing reliance of various precedents, also held that assignment deeds which are not registered as required under Section 45 of the Trademarks Act, 1999 cannot be used as evidence. It was noted that principles applicable in infringement proceedings are also applicable in proceedings relating to rectification.

The Board in this regard also observed that merely because there is no prescribed period of limitation, the assignee cannot sleep over the matter. It upheld the contention that adoption of the said trademark under Class 25 by the respondents was dishonest. Further, noting various infirmities in the assignment documents, including the fact that the deed was executed on 11-3-2008 on non-judicial stamp paper purchased from the State of Uttar Pradesh on 4-7-2014; absence of attestation of any witness or notary; absence of name of the person signing the deed, etc., the IPAB held that the so-called assignment deeds were not on the basis of established procedure of law and hence were not validly executed. [*Montfort Services SDN BHD.* v. *USA PRO Limited* - Order No. 104 of 2014, dated 10-7-2014, IPAB]

Green dot inside a square symbolizing vegetarian food cannot be copyrighted

Allahabad High Court has quashed the order granting injunction restraining the defendants-appellants from using the "green dot" on the label of the packaging of its product "Zincovit Syrup". The court in this regard held that green dot inside a square outlined by green colour is a symbol for which copyright cannot be claimed by anybody as the symbol is prescribed by a statute, namely Food Safety and Standards Act, 2006 read with Prevention of Food Adulteration Act, 1954 (PFA). Contention that this symbol was the artistic work of the plaintiff-respondent, was found to be patently erroneous. The court noted that there was no evidence that the plaintiff was using the symbol prior to its enforcement under the PFA.

On the question of prior use of the trademark "Zincovit", the court rejected the plea of prior use by the plaintiff noting that if they were the owner and prior user of the mark, they would not have agreed to manufacture the product and the label in their factory for the defendants-appellant. It was also noted that there was no indication that while applying for registration under Copyright Act vide his application dated 29-12-2009, the plaintiff had attached a certificate from the Registrar of Trademarks that no identical or deceptively similar trademark has been registered under the Trademarks Act, more so when the artistic work of the plaintiff, registered on 29-3-2011, was found not only to be deceptively similar, but more or less identical to the artistic work of the defendants, which was registered on 22-10-1997. [*Apex Laboratories Pvt. Ltd.* v. *K. Prasad Reddy* - First appeal from order No. 487 of 2014, decided on 11-7-2014, Allahabad High Court]

Trademarks – Use of family name by family members

The Supreme Court of India has quashed the order granting interim relief inasmuch as it restrained one party from using their surname for running business identical to the business of another. Taking into consideration Section 35 of the Trademarks Act, 1999, the court held that there was no *prima facie* case in favour of the plaintiff and hence, the defendants should not be restrained from doing their business. It was also noted that both plaintiff and defendants were related to each other, being family members in the same business of jewellery. Hoardings of their respective shops were also found to be not similar to each other by the court in this regard. The defendants were doing business in the name and style of "Neena and Ravi Rakyan", whereas the plaintiff firm was also dealing in jewellery and doing the business in the name and style of "Rakyan's Fine Jewellery". [*Precious Jewels* v. *Varun Gems* - Civil Appeal No. 7191 of 2014, decided on 4-8-2014, Supreme Court of India]

News Nuggets

Pharma patent applications – IPO issues draft examination guidelines

The Indian Patent Office released the 'Revised Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals' on 12th August, 2014. Comments and suggestions can be sent before 2nd September, 2014. The draft guidelines discuss the approach to

determine 'invention', 'inventive step' and 'industrial application' besides Section 3 on non-patentable inventions and sufficiency of disclosure and support of claims.

Illustrative examples are provided at various points to better explain the conclusions drawn. The guidelines state that combination or composition claims should be dealt under novelty also since a combination may already be in public domain and cite the example of a corneal healing aid comprising Vitamin A and a sterile buffer administered to the eye which may be found in a prior art disclosing the use of the eye-drops to rewet contact lenses, wherein said eye-drops comprise of Vitamin A, the sterile buffer and other excipients. For product by process claims, the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process.

The guidelines for examination of biotechnology applications and guidelines for processing of patent applications relating to traditional knowledge and biological material released earlier are to be incorporated appropriately while processing patent applications.

When a generic and geographically descriptive term combine to give distinctiveness

The Trademark Trial and Appeal Board (TTAB) found the mark 'BOATS DIRECT USA' to be inherently distinctive without requiring proof of acquired distinctiveness. Directing a reversal of the refusal to register, the TTAB opined that the mark is not highly descriptive, generic or highly suggestive and laudatory. The trademark examining attorney had held that the mark was geographically descriptive of the applicant's services.

The TTAB re-examined the evidence - third party registrations and definitions of the word 'direct'. It decided that there was no evidence that the word 'direct' described a feature of the dealership in boats. Though USA is generally understood to be United States of America and is geographically descriptive, the mark did not consist of a geographically descriptive term combined with a highly descriptive, generic, or highly suggestive and laudatory term making it primarily geographically descriptive.

Interestingly in an earlier decision, the Board had found 'VENEZIA-MILANO' to be geographically descriptive. The mark was in respect of women's clothing which were made in China. The Board opined that there was a reasonable goods/place association and consumers were likely to mistake the origin of goods and adding a label 'made in China' did not detract from the geographically deceptive mis-descriptiveness of the mark.