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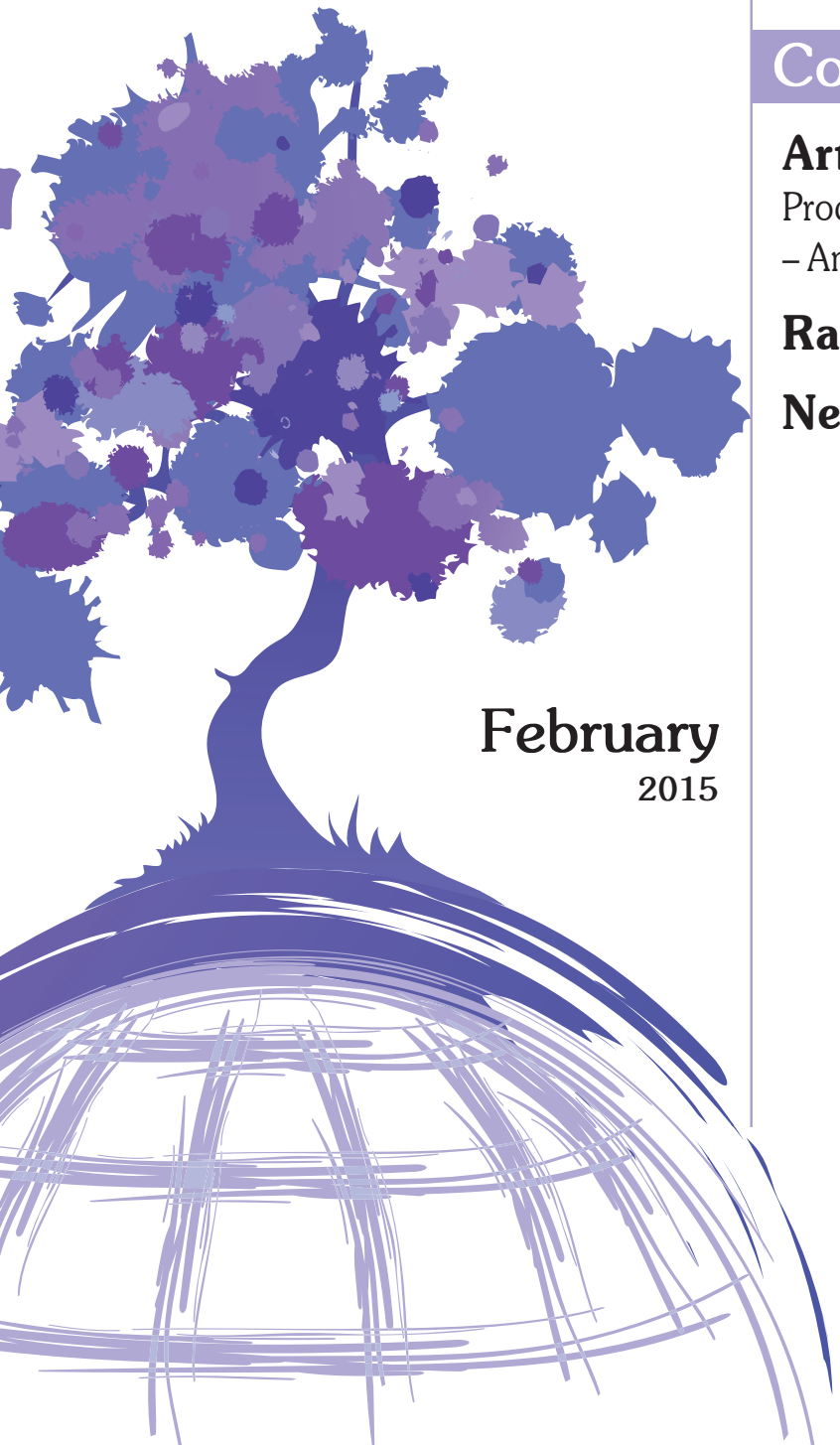

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Process patent litigation in pharma sector – An overview

By **Vindhya Srinivasamani**

Introduction

Since the inception of the Patents Act, 1970, Indian patent law has been a process patent regime in the field of pharmaceuticals. Based on the recommendations of a committee chaired by Judge Rajagopala Ayyangar in 1959, product patent protection in the pharmaceutical sector was abolished in order to ensure that medicines were available to the public at reasonable prices.

It was only in 2005, in order to comply with the obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) that India permitted patent rights to pharmaceutical products. Thus, the law as it stands today under the Patents Act, 1970 (the Act) expressly states that an invention under the Act means a new product or process involving an inventive step and capable of industrial application. Although much of the patent litigation till date in the field of pharmaceutical has arisen out of product patent infringement, a recent judgment by the High Court of Delhi in *Glenmark Pharmaceuticals Ltd. & Anr.* v. *Symed Labs Limited* [FAO (OS) No. 60 of 2015, dated 5th Feb., 2015] has brought back the spotlight on process patent infringement in the pharmaceutical sector. In this case, the Division Bench of the Delhi High Court set aside the order of the Single Judge of the Delhi High Court granting an interim injunction in favour of the patentee plaintiff, Symed.

Relevant statutory provisions

It is important to note that rights of a process patentee differ from that of a product patentee. Section 48 of the Act demarcates the right of patentees and states that with respect to a process patent, a patentee has the exclusive right not only to prevent third parties from the act of using the patented process without consent but also to prevent them from using, offering for sale, selling or importing the product obtained directly by the patented process in India. This is in contrast to the rights of a product patentee, whereby a product patent confers upon the patentee the right to prevent third parties from making, using, offering for sale, selling or importing the patented product in India.

Specifically with regard to process patent infringement, Section 104A of the Act is relevant. This provision states that in the case of a suit for infringement of a process patent, if the patentee is able to prove that the product manufactured by the patented process is identical to the product manufactured by the defendant, then the burden of proof in the infringement suit shifts to the defendant to establish that the process used to manufacture its product is different from that of the patented process.

Major cases on process patent litigation in the pharma sector

Teva v. Natco

One of the first major process patent infringement litigation was initiated by Teva Pharmaceuticals Industries Ltd. (Teva) against Natco Pharma Ltd. (Natco) in 2007. Teva filed

a suit [CS (OS) 1708 of 2007; the First Suit] for permanent injunction before the Delhi High Court against Natco to restrain them from infringing Patent No.190759 for an invention titled "*a method for manufacturing Co-polymer I fraction*". The patented process is used in the manufacture of the drug glatiramer acetate that is useful in the treatment of multiple sclerosis. Natco on the other hand contended that the process employed by them for producing glatiramer acetate was entirely different from the process patented by Teva. Further, Natco also filed a counterclaim for revocation of Teva's patent. However, by order dated 20th August, 2014, the Single Judge of the Delhi High Court dismissed the First Suit and the counterclaim filed by Natco on the ground that both the parties failed to lead evidence to support the averments made in the plaint or in the counterclaim.

While the First Suit and the counter claim were pending trial before the Delhi High Court, Teva filed another suit against Natco in 2012 [CS (OS) 3193 of 2012 - the Second Suit] for a *quia timet* permanent injunction to restrain Natco and its agents from infringing Teva's patent no. 190759. After a series of appeals before the Division Bench of the Delhi High Court and subsequently the Supreme Court, the Bench restored the matter to the Single Judge of the Delhi High Court who has *vide* order dated 16th January, 2015 reserved judgment in the Second Suit.

BMS v. Mylan

Bristol-Myers Squibb (BMS) filed a suit for infringement (O.S No. 670 of 2014) before a trial court in Hyderabad against Mylan Laboratories Ltd. (Mylan) to prevent them for infringing its processes patented in India by virtue of Patent Nos. 206217 and 210496. The patents in suit were directed to *a stereo-selective process for preparing substituted oxobutanes* and a *process for preparing alpha-chloroketones,* respectively. Both the above mentioned processes are used in the manufacture of Atazanavir, an antiretroviral drug for the treatment of AIDS. Specifically BMS sought to prevent Mylan from manufacturing Atazanavir using the patented process and exporting the same to Venezuela.

Mylan contended that its manufacture of Atazanavir Sulphate Capsules does not fall within the purview of the patented processes of BMS. Further, Mylan also asserted that the suit patents are immaterial and irrelevant to Mylan's export of Atazanavir Sulphate product to Venezuela in compliance with the contractual obligations undertaken with International Bodies i.e., Pan American Health Organization (PAHO) / World Health Organization (WHO). The trial court by order dated 26th Sept., 2014 denied BMS an interim injunction for having failed to establish a *prima facie* case of infringement of its process patents. On appeal the Andhra Pradesh High Court [AP High Court *vide* order dated 5th Dec., 2014 *(Bristol-Myers Squibb Holdings Ireland* v. *Mylan Laboratories Limited* - 2015(1)ALT4)] upheld the order of the trial court denying an interim injunction in favour of BMS.

The AP High Court interpreted Section

104A of the Act and held that in a suit for infringement of a process, if the patentee proves that the product of the defendant is *identical* to the product obtained by the patented process, then the burden of proving that the process used by the defendant in obtaining his product is different from the patented process lies on the defendant. The AP High Court also held that in the context of Section 104A of the Act, the word 'identical' means the same and not similar.

On the question as to whether BMS was successful in establishing a *prima facie* case of infringement so as to warrant an interim injunction in its favour, the High Court observed that the suit patents neither claim the drug Atazanavir nor any process for the preparation of Atazanavir but were essentially directed to the process of producing intermediates used in the manufacture of Atazanavir. Further, the Court also observed that BMS did not assert that Mylan was producing the intermediates claimed in the suit patent, namely, choloroketones or oxobutanes. Thus, in the light of failure by BMS to satisfy the threshold under Section 104A of the Act, the High Court held that BMS failed to produce evidence to show that the process used by Mylan is the same as that of the process covered under the suit patent.

Symed v. Glenmark

Arguments Advanced

On April 12, 2013, Symed filed a suit before the Delhi High Court [C.S. (OS) No. 678 of 2013] seeking an injunction restraining Glenmark Pharmaceuticals Limited and Glenmark Generics Limited from infringing Symed's process patents in their manufacture of Linezolid. Linezolid is useful in the treatment of serious infections caused by Gram-positive bacteria that are resistant to several other antibiotics[1].

Symed asserted that its patent nos. 213062 ('062 Patent) and 213063 ('063 Patent) are directed to a more economical, safe and commercially viable process of manufacturing Linezolid as compared to the processes known in the art. Based on the fact that the patented processes were directed towards the production of linezolid by producing novel intermediates such as, N - [3 – Chloro – 2 - (R) - hydroxprophy1] – 3 – fluoro – 4 –morpholinyl - anlaniline" (CHFA claimed in Claims 18 and 19 of the '063 Patent) and "N – 3 [Phthalimido – 2 - (R) - hydroxprophyl] – 3 – fluoro – 4 (morpholinyl) aniline" (PHPFMA claimed in Claims 23, 24 and 25 of the '062 Patent); Symed argued that the presence of any of these intermediate compounds in the final product (Linezolid) would be indicative of the fact that the product has been manufactured by the patented process. It was further argued that on testing samples of the Linezolid (marketed under the brand name 'Lizolid') manufactured by Glenmark both before and after filing the instant suit, presence of intermediates PHPFMA, CHFA and Zodiac-4 were detected (Zodiac-4 is obtained by carbonylating CHFA) and thus, Glenmark was infringing Symed's patents.

[1] Source: Wikipedia

Glenmark, on the other hand, besides challenging the jurisdiction of the Court to entertain the instant suit also filed a counterclaim challenging the validity of the suit patents on the ground of lack of novelty. Further, Glenmark asserted that the pre-suit lab reports did not indicate the presence of CHFA, whereas, the post-suit reports showed the presence of CHFA. Therefore, Glenmark assailed the veracity of Symed's averments as to the presence of the intermediates in the final product. Glenmark also stressed that the presence of the intermediates Zodiac-4 and PHPFMA in the final product prepared by Glenmark i.e. Linezolid API (Active Pharmaceutical Ingredient) was not indicative of infringement as said intermediate compounds could also be found in the final product produced by processes of manufacture of Linezolid already known in the art.

Order of the Single Judge of the Delhi High Court

On hearing the above arguments raised by the parties, the Single Judge *vide* order[2] dated 19th Jan., 2015 granted an interim injunction in favour of Symed, thereby restraining Glenmark from manufacturing Linezolid in a manner so as to result in infringement of the suit patents.

With regard to the pertinent issue raised by Glenmark as to the lack of detection of the intermediate CHFA in the pre-suit reports and the sudden detection of the same in the post-suit reports, the Single Judge dismissed the argument observing that this was possibly due to the fact that the samples were not tested for CHFA and further, upheld Symed's argument that presence of CHFA, PHPFMA and Zodiac-4 is a strong indicator of the fact that Glenmark employed Symed's patented process to manufacture Linezolid API. The Single Judge in coming to such a finding also considered the fact that the test reports relied upon by Symed were from both Symed's own facility and independent laboratories.

In light of the above, the Single Judge held that Symed satisfied all the tests for grant of an interim injunction, namely establishing a *prima facie* case, that the balance of convenience is in favour of Symed and that irreparable loss and injury will be caused if the interim injunction is not granted.

Order of the Division Bench of the Delhi High Court

Aggrieved by the order of the Single Judge of the Delhi High Court, Glenmark approached the Division Bench of the Delhi High Court in appeal on the following two grounds:

- that prior commercial use of the product before filing of the process patents, would not entitle Symed to an injunction, subsequently.
- that the Single Judge failed to adhere to the statutory mandate under the proviso to Section 104A(1)(b) of the Act that the initial burden of proof rests on the patentee to show that the product manufactured by the other party is identical to the product manufactured by the patented process.

Essentially, it was asserted that the Linezolid API manufactured by Glenmark was not identical to the Linezolid API manufactured by

[2] *Symed Labs v. Glenmark Pharmaceuticals and Anr.* – CS (OS) No. 678 of 2013, Delhi High Court

the patented process because the intermediates or markers in the Linezolid manufactured by Glenmark were different from the Linezolid manufactured by the patented process. It was argued that merely because a product is known as Linezolid API, it does not mean that the same is identical to the product manufactured by the patentee directly through patented processes.

The Division Bench of the Delhi High Court observed that in a case of process patent infringement, it was incumbent upon the Single Judge to ascertain whether the requirements under Section 104A of the Act were fulfilled. Specifically, it was observed that the Single Judge ought to ascertain as to whether the Linezolid API manufactured by Symed was identical to that manufactured by Glenmark.

Further, the Bench upheld the argument made by Glenmark that while the '062 Patent results in Linezolid API with two intermediates or markers, namely CHFA and Zodiac-4 and the '063 Patent results in CHFA and PHPFMA; the Linezolid API manufactured by Glenmark consists of three intermediates namely, Zodiaz-4, CHFA and PHPFMA. Thus, the Division Bench held that this clearly indicated that Glenmark was manufacturing Linezolid API by a different process.

In light of the above, the Division Bench vacated the interim injunction granted by the Single Judge and directed Glenmark to maintain accounts and file the same in Court along with a copy to Symed. The next date of hearing in the instant case is 6th April, 2015.

Conclusion

In the case of process patents in the field of pharmaceuticals, where the processes are mostly directed towards the manufacture of a drug, proving infringement of such a process patent poses a significant challenge. The primary reason for this difficulty in proving that a process has been infringed is that there is no way to conclusively determine the process used by the defendant. This is because the patentee will never be able to legally enter the premises of the defendant to ascertain the actual process of manufacture of the final product.

The above difficulty is probably the reason Article 34 was included in the TRIPS Agreement. In light of the obligations under TRIPS, India enacted Section 104A of the Act which essentially reproduces Article 34 of TRIPS, whereby it is the defendant who is to establish that they did not employ the patented process, provided the product manufactured by them is identical to the product manufactured by the patented process.

It is to be noted that the *Symed* v. *Glenmark* case is the first process patent case in India that actually demonstrates the difficulties and uncertainties that arise in establishing that the products are identical. While markers and intermediates many be one way of establishing the identical nature of two APIs there is no legal basis to say that it is the only way. It will be interesting to see if courts continue to employ intermediates as the criteria or if parties are able to convince the courts of other parameters to ascertain the identical or distinguishing features between APIs, as the case may be.

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Ratio Decidendi

Suit against disparaging advertisement Trade Marks Act applicable

If a plaintiff intends to file a suit alleging infringement of the registered trade mark of his product, no Court inferior to a District Judge can entertain the said suit. The Calcutta High Court set aside the order of the Civil Judge agreeing with the appellant that the suit having been filed by proprietor of the trademark who alleged that the advertisement by the appellant was disparaging, provisions of the Trade Marks Act would apply. The respondent argued that the suit was filed in exercise of its right under the law of tort which is the common law right and lack of jurisdiction under Trade Marks Act could not be a ground to set aside the order of injunction. [*Reckitt Benckiser Healthcare India Limited* v. *Emami Limited,* FMAT No. 1408/2014, Judgment dated 29-1-2015, Calcutta High Court]

Infringement suit - Power of attorney holder when cannot depose for the principal

Emphasing on proper procedure, the Calcutta High Court dismissed the suit for infringement holding that the power of attorney granted in Japan was not proved to be valid in India and the witness produced by the plaintiff did not have the power to depose on his behalf. The defendant - alleged infringer contended successfully that the suit had not been properly instituted since the plaintiff's advocate who verified the plaint was not the principal officer or director and was not being duly authorised by any Board resolution. Further the evidence of the sole witness produced by the plaintiff was found inadmissible in as much as the document granting power of attorney was notorised in Japan but was not valid since no notification was obtained under Section 14 of the Indian Notaries Act, 1952. The High Court also held that power of attorney holder cannot depose for a principal in respect of matters in which only the principal can have personal knowledge and in respect of which the principal is liable to be cross-examined. [*Sony Kabushiki Kaisha* v. *Sony Trade Links (India) P. Ltd.*, Judgment dated 14-1-2015, Calcutta High Court]

Patents registered in the name of inventor-Managing Director, whether breach of fiduciary duty

In a suit for derivative action by the plaintiff who alleged that valuable intellectual property asset of the company had been improperly registered in name of the inventor, the Bombay High Court considered the argument as to whether registering of patents in the name of the inventor who was the Managing Director of company amounted to breach of fiduciary duty. The High Court held against the defendant's reasoning that the inventions were not made in the course of employment and no proof was shown that Indian statute that recognizes that employee patents belong to the employer. On facts, there was no agreement between the Managing Director and the company that he

was required to do research or invent. [*Darius Rutton Kavasmaneck* v. *Gharda Chemicals Ltd.*, Suit No. 2931/2011, Judgment dated 12-12-2014, Bombay High Court]

View of public relevant to assess descriptiveness

The CJEU held that for the purpose of assessing the descriptive character of the mark applied for, the stated or real purpose of the goods at issue is not conclusive, since account must be taken solely of the point of view of the relevant public. The dispute revolved around refusal of registration of mark GLISTEN for cleaning preparations for dish washing. The applicant argued that the word meaning to shine was not the actual effect of the product on the goods and the product was meant to cleanse and disinfect. However the Court agreed with the analysis of the OHIM that GLSITEN would bring to the mind of the customer the idea of shine which could mean cleanliness and was descriptive of the product. The argument that the mark had been registered in the US and hence it could be said that it had distinctiveness was also rejected. The Court held that only the relevant EU rules should be used to decide registrability of the mark. [*IOIP Holdings LLC* v. *OHIM*, Case T-648/13, Judgement of General Court dated 10-2-2015]

News Nuggets

USA and Japan join the Hague System on industrial designs

On February 15, 2015, the United States of America and Japan joined the Hague System for the International Registration of Industrial Designs which is a World Intellectual Property Organization (WIPO)-administered registry, introduced on January 9, 2015. With the accession of these two major economies of the world, the membership of the Hague System has increased to 64 contracting parties. With the increased use of Madrid filings around the world through acceding to the Madrid Protocol, now through the Hague system, designers can easily protect and promote their industrial designs in all the Hague member countries. The Hague System offers a cost-effective, efficient means of registration of industrial designs in a large number of countries, providing design owners broad geographical protection of their designs in a streamlined manner.

To file an international application for protection of an industrial design under the Hague Agreement, an applicant must be either a national of a Contracting Party or a member State of an inter-governmental organization which is a Contracting Party, such as the European Union or the African Intellectual Property Organization or have a domicile in the territory of a Contracting Party or have a real and effective industrial or commercial establishment in the territory of a Contracting Party.

An interesting point under the Hague system is that an international application

does not require any prior national application or registration. Therefore, an industrial design can be protected for the first time at the international level through the Hague Agreement. Through a single application filed with the International Bureau of WIPO, a design can be registered in the 64 countries and inter-governmental organizations that are members of the Hague Agreement. The international registration is valid for an initial period of five years and may be renewed. An international application under the Hague system may include up to 100 different designs. All designs must, however, belong to the same class of the International Classification of Industrial Designs (the Locarno Classification). International registrations are published weekly in the International Designs Bulletin on the WIPO web site.

US set to debate Innovation Act again

The 'Innovation Act' Bill (HR 9) to amend the patent statute of US was introduced in the Congress on 5-2-2015. The bill (HR 3309) introduced earlier was not successful and this is the next attempt to find a way to deal with the problem of non-practising entities or 'patent trolls' as they are called. A patent troll describes an entity which owns patents but does not work them and uses litigation as a tool to enhance it's revenue from owning the patent. One of the problems which the bill tries to remedy is aggressive enforcement targeting end-use customers and retailers. The bill requires a claimant to provide details about the infringement alleged as far as possible in the initial complaint itself, a description of the principal business if any of the claimant, awarding of reasonable fees and expenses unless the Court is satisfied that the alleged infringement was reasonably justified in law and fact. It also provides for a customer suit exception by granting stay when the customer agrees to be bound by the decision as to the manufacturer who is also involved in the dispute. Opinion is divided on whether the bill will help protect start-ups and small players who may not have the resources to fight infringement claims and whether the bill will promote innovation.