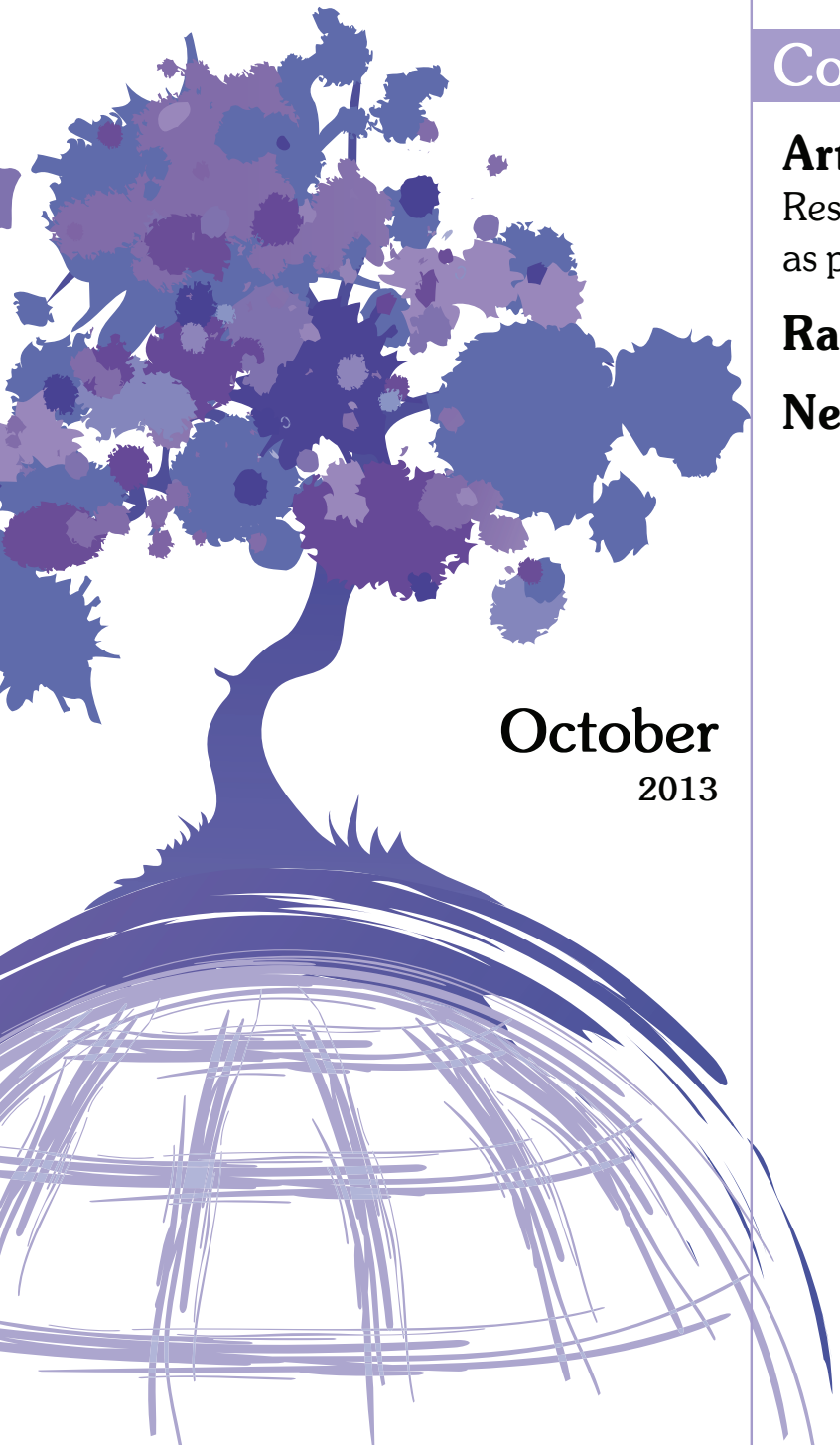
Lakshmikumaran & Sridharan ipr

IPR

amicus

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

October, 2013 / Issue–27



October
2013

Contents

Article

Research exemptions not deemed as patent infringement

By **Nidhi Verma**

Introduction

According to the Indian Patents Act, 1970 ('the Act'), a product patent gives an exclusive right to the patentee to prevent third parties, who do not have his consent, from making, using, offering for sale, selling, or importing the patented product into India till the product patent is valid. Further, a process patent gives the patentee an exclusive right to prevent such parties from using that process, and from using, offering for sale, selling or importing a product obtained directly by that process.

Any violation of these rights by third parties who do not have patent holder's consent will amount to infringement of the patent. However, the Act provides for certain actions by third parties which will not be considered as infringing the rights of any patentee.

What acts do not constitute infringement? - Bolar Exemption

Amongst these exceptions are activities which are required for purposes of regulatory approval. This exception is provided in Section 107A (a) of the Act.

> "107A. For the purposes of this Act,—
>
> (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product;
>
> shall not be considered as an infringement of patent rights."

The exemptions from infringement as provided by Section 107A (a) are informally known as Bolar Provisions or Bolar Exemption. The aforementioned provision is similar to 35 U.S.C. § 271(e)(1) which also exempts such activities from being considered as infringing acts. In the US, the Bolar Exemption provides an exemption from patent infringement to companies that are involved in research, trials or testing of patented inventions to seek marketing approvals. The US provision was an outcome of the US Court of Appeals for Federal Circuit in *Roche Products Inc.* v. *Bolar Pharmaceutical Co. Inc.*, 733 F.2d 858 (Fed. Cir. 04/23/1984) from and hence the reference 'Bolar Exemption'.

Patent linkage is a system where the drug controller of a country can refuse to grant marketing approval for a generic drug if a patent for that drug is already in existence. The patent linkage system originated in the US under the Drug Price Competition and Patent Restoration Act of 1984, commonly known as the Hatch-Waxman Act. Many developing countries, such as China, Chile, Singapore, Morocco, Bahrain, Oman, and South Korea have adopted the patent linkage system. Although, an exemption from patent infringement is provided in the US to companies that are involved in research, trials or testing of patented drugs, the companies may not get marketing approval for generic drugs until patents for those drugs expire.

In India, intention of Section 107A (a) is to ensure that a generic version of a patented drug is ready, with the necessary regulatory approval, for launch in the market, immediately after

© 2013 Lakshmikumaran & Sridharan, India
All rights reserved

expiry of the patent or invalidation rather than going through the lengthy process of getting the necessary regulatory approval only after expiry of the patent. Thus, generic companies need not wait till expiry of the patent to develop generic versions of the patented drug and hence can introduce the generic versions in the market immediately after the expiry of the patent. Consumers may benefit from this early launch since the generic versions are typically more economically priced compared to their patented counterparts.

Although, often more applied to drugs and pharmaceutical products, it should be noted that the invention, referred to in Section 107A, refers to any invention and is not limited to drugs and related inventions. Consequently, the exemption as recited in the foregoing section would be equally applicable for other fields of invention that require similar regulatory approvals.

Recent developments relating to Bolar exemption

In India, availability of essential medicines at affordable price has led to fierce competition among pharmaceutical companies. As a result, it can be seen that large pharmaceutical companies often take their competitors to court or try using other measures to protect their patent rights.

In March 2008, Bayer Corporation (Bayer) was granted a product patent for Sorafenib Tosylate, a drug used for treatment of kidney and liver cancer. Bayer marketed this drug as Nexavar in India and hence under Section 48 of the Act, Bayer got an exclusive right to prevent third parties, who did not have its consent, from the act of making, using, offering for sale, selling, or importing Sorafenib Tosylate into India till the patent is in force.

Bayer contended that Cipla which had filed an application with the Drug Controller General of India (DCGI) for marketing approval of generic version 'soranib' would become liable for infringement. To support their contention, Bayer relied on Section 2 of the Drugs and Cosmetics Act (DCA), 1940, and Section 48 of the Act. Relying on Section 2, Bayer pointed out that the DCA requires that its provisions are to be considered in addition to and not in derogation of "*any law for the time being in force*". Bayer argued that Section 48 of the Act would be a "*law for the time being in force*", as provided by Section 2 of the DCA. Bayer had submitted that a combined reading of Section 2 of the DCA and Section 48 of the Act imposes a legal obligation on the drug regulatory authority to ensure that his decision on the grant of the marketing approval should not derogate from any other law for the time the patent is in force and if it does so, it would be liable for patent infringement.

Cipla counter-argued stating that mere grant of marketing approval, would not amount to patent infringement. Cipla insisted that the patent infringement needs to be established in a Court of Law in accordance with the provisions of the Act. Cipla further argued that the role of DCGI is only to approve or disapprove the drug for marketing based on assessment of the drug for which the marketing approval was sought and not to decide if the drug for which the marketing approval was sought was infringing any patented product.

Cipla argued that its actions would be covered under Section 107A . Clause (a) of Section 107A of the Act clearly exempts any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably *related to the development and submission of information*

© 2013 Lakshmikumaran & Sridharan, India
All rights reserved

required under any law for the time being in force, such as the DCA, that regulates the manufacture, construction, use, sale or import of any product, from patent infringement. It would be illogical to argue that regulatory approval from DCGI amounts to an infringement because then clause (a) of the Section 107A would be rendered redundant. In addition, Cipla contended that there is no concept of patent linkage in India, and accused Bayer for trying to introduce a new system in India, i.e., the patent linkage, which is only possible by bringing legislative amendments.

Issues before the court

- Whether DCGI can grant marketing approvals under DCA to generic versions of patented drugs
- Whether the grant of such marketing approvals to generic versions of a patented drug is in derogation of the Act
- Is there a patent linkage in terms of the Patents Act and the DCA?

In February 2010, the Delhi High Court dismissed Bayer's appeal to introduce the patent linkage system in India by concluding that the DCA and the Act have different objectives and serve different purposes. The Court also confirmed that there is no patent linkage system in India and DCGI can grant marketing approvals under DCA to generic versions of patented drugs without derogation of the Act. Therefore, grant of such approvals would not be considered as falling within the scope of Section 48 of the Act.

After the Delhi High Court dismissed Bayer's appeal, Bayer filed an appeal against the decision to the Supreme Court of India. The Supreme Court too dismissed Bayer's appeal against the Delhi High Court's decision on its plea for patent linkage. Further, the Supreme Court pointed out that if Bayer's plea for patent linkage is accepted, it would have undermined public health safeguards contained in India's patent legislation.

[The author is an Associate, IPR Practice, Lakshmikumaran & Sridharan, New Delhi]

Ratio Decidendi

International application - Filing date

Examining the questions on International filing date and permission from the Indian patent authorities under Section 39 of Patents Act, 1970, the Delhi High Court held that an international application must necessarily be accompanied by a request under Section 39 of Patents Act unless such a permission has already been obtained or an application for a patent for the same invention had been made in India not less than six weeks before the international application is made. The petitioners had submitted the application on 14-9-2012 along with request for permission in Form 25 and the written permission under Section 39 was issued on 27-9-2012. The Delhi High court held that the application could be treated as international application dated 27-9-2012. The petitioners had contended that the international application received by the Indian patent office under PCT scheme is an application made in India. The Court held that as per the PCT scheme, the Indian patent office receives it and after giving a filing date, transmits it to the International Bureau and Searching authority. Hence, the processing is done outside India and Section 39 is necessarily

© 2013 Lakshmikumaran & Sridharan, India
All rights reserved

attracted. [*Puneet Kaushik and Anr* v. *UOI,* Delhi High Court, Order dated 23-9-2013]

Trademarks – Laudatory mark and foreign exchange earnings

Claim for removal of mark 'Bemisal' used for rice was rejected by the India's Intellectual Property Appellate Board (IPAB) observing that the respondent was valuable foreign exchange earner for the country. The Board noted that the respondent has massive sales – aggregating over Rs. 69 crore in domestic market and in addition also has exports under the impugned mark. It was held that the mark had acquired secondary significance and hence balance of convenience is in allowing the mark to continue to remain on the register. IPAB, in this regard noted that the old theory that some trademarks are incapable of distinguishing the goods/services and can never serve as a badge of origin has now been relaxed under the current provisions and that it is the market place that determines what is a good trademark. Interestingly, the Board in this order observed that the mark is highly laudatory and should never have been registered in the first place. [*P.K. Overseas Pvt. Ltd.* v. *KRBL Ltd.* – IPAB Order dated 12-7-2013 in ORA/161/2011/TM/DEL].

Designs of components are not aesthetic designs

Supreme Court of Appeal of South Africa has held that designs for certain components of particular models of BMW motor vehicles – bonnet, grille, headlight assembly, and front fender, cannot be registered as aesthetic designs. The Court in this regard rejected the contention that because the designs of vehicles qualify as aesthetic designs, albeit they might incorporate functional features, it follows that the components that go to make up that design are also aesthetic designs. It was held that designs of individual components must be judged for the qualities of the individual components, independently of the design of the built-up vehicle as the articles embodying the designs are not selected by customers for their appeal to the eye and that most customers will not even see the component before it is fitted to the vehicle, nor make any selection at all. The Court further clarified that they were not concerned with components that are interchangeable between vehicles where designs are capable of being registered as aesthetic. [*Bayerische Motoren Werke Aktiengesellschaft* v. *Grandmark International (Pty) Ltd.* – Supreme Court of Appeal of South Africa, Judgment delivered on 18-9-2013].

News Nuggets

WIPO releases draft of revised Lisbon Agreement

The WIPO Working Group on the Development of the Lisbon System (Appellations of Origin) recently released the draft of the revised Lisbon Agreement on Appellations Of Origin And Geographical Indications. The draft seeks to provide for revising current legal framework, ensuring that the Lisbon system also applies in respect of geographical indications and possibility of accession by intergovernmental organizations. The provisions relating to applications "Concerning a Good Originating in a Trans-border Geographical Area" are

© 2013 Lakshmikumaran & Sridharan, India
All rights reserved

particularly interesting in light of disputes over the Austro-Hungarian sausages and so on. The provisions also talk about freedom to grant more extensive protection as envisaged in the Act and protection to prior registered trademarks, use of personal name in business, shield against becoming a generic term, phasing out of prior use as a generic term, etc.

US District Court rules on infringement while reformatting television signals

Enabling streaming is not distribution of content, it is 'performing'. In yet another case which saw the fencing match between statute and technology, denying preliminary injunction, the District Court of Massachusetts agreed with the defendant that it was transmitting private performances rather than public performance of a work. At issue in *Hearst Stations Inc.* v. *Aereo Inc.* was the alleged infringement of the appellant's copyright in program content. The defendant intercepting the former's television signals and converted its programs into a different format for retransmitting over the internet without paying any fee. It argued that there was no infringement and it had merely provided the technology (antennas) to enable consumers to make private copies of freely accessible over-the-air television broadcasts.

The appellant contended that since unintended audience received the same content though not the same transmission, there was infringement of its right to publicly perform the content and the defendant had transmitted the content to the public, without permission. Further by enabling consumers to create copies of the program, the appellant's right to reproduce the content had been infringed. Though the court observed that the defendant's service might infringe the appellant's rights, it held that volitional conduct and harm are important factors and in this case it was the consumer who chose to make a copy and the company which supplied the technology cannot be liable. The Court was also not convinced that irreparable harm of 'full magnitude' would be caused to the appellant though it agreed that the threat of harm was real.

As seen in the judgement itself, different courts in the US have expressed divergent views on such making available of content/programme almost simultaneously. In a judgement delivered in May, the District court of Columbia held that even when each consumer received the content though individual antennas to view it over mobiles or computers, there was infringement. It was of the opinion that even if the terms of the statute were ambiguous, legislative history supported the interpretation that transmitting a performance of the work to the public by the means of a device or process was prohibited.

Disclaimer: *IPR Amicus* is meant for informational purpose only and does not purport to be advice or opinion, legal or otherwise, whatsoever. The information provided is not intended to create an attorney-client relationship and not for advertising or soliciting. Lakshmikumaran & Sridharan does not intend to advertise its services or solicit work through this newsletter. Lakshmikumaran & Sridharan or its associates are not responsible for any error or omission in this newsletter or for any action taken based on its contents. The views expressed in the article(s) in this newsletter are personal views of the author(s). Unsolicited mails or information sent to Lakshmikumaran & Sridharan will not be treated as confidential and do not create attorney-client relationship with Lakshmikumaran & Sridharan. This issue covers news and developments till 16th October, 2013. To unsubscribe, e-mail Knowledge Management Team at newsletteripr@lakshmisri.com
www.lakshmisri.com http://cn.lakshmisri.com

© 2013 Lakshmikumaran & Sridharan, India
All rights reserved