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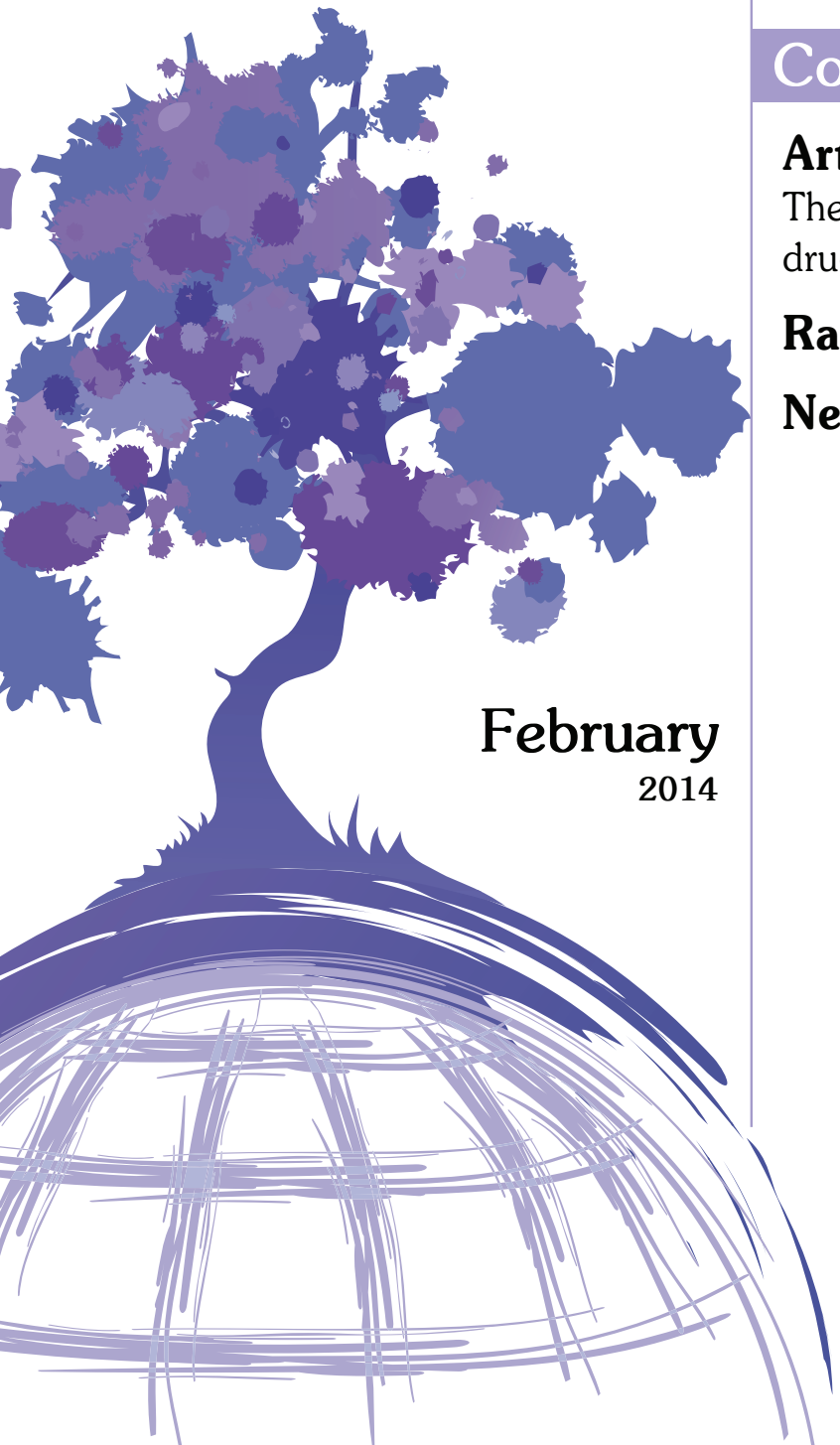

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Article

The shifting battlefield between innovator drugs and biosimilars in India

By **Divyendu Verma and Konpal Rae**

Recently, the Indian arm of Swiss pharma major F. Hoffman-La Roche Ltd. ("Roche") filed a suit[1] against Bangalore based Biocon Ltd. ("Biocon") and US based Mylan Inc. ("Mylan") in the Delhi High Court against the launch of a biosimilar version of Roche's innovator drug "Herceptin" in India. Roche also made the Drug Controller General of India (DCGI) a party to the suit for approving Biocon's and Mylan's drug as a biosimilar of Herceptin allegedly without following the required process for approval of biosimilars.

Herceptin is one of the brand names under which Roche markets the innovator drug Trastuzumab, which was created by the US firm Genentech and patented in various countries including India. Trastuzumab is used for the treatment of HER 2 positive breast cancer. The ownership of the patents and the brand names got transferred to Roche when it acquired Genentech. In a strategic move, Roche had let the patent for the innovator drug lapse in India by not paying the renewal fee for the 15th year in April 2013. Shortly after the lapse of the patent, the DCGI approved the biosimilar version developed jointly by Biocon and Mylan, who then planned to launch it in India under the brand names CANMAb and Hertraz respectively.

Two major issues were raised by Roche in the suit against defendants Biocon and Mylan. First, the defendants had not satisfied the requirements for obtaining marketing approval for a biosimilar drug in accordance with the Guidelines on Similar Biologics[2] (Guidelines) issued in 2012 by the Government of India and hence had indulged in misrepresentation of their drugs as biosimilars. Secondly, the defendants were seeking to pass off their products as being equivalent in quality and class to Herceptin by referring to their products as a biosimilar version of Herceptin or Trastuzumab.

Roche also sought an ex-parte interim order against the defendants to restrain them from indulging in any marketing activity related to their drugs, i.e. CANMAb and Hertraz, or any other biosimilar version of Trastuzumab, in the Indian market until the disposal of the suit. Further, Roche sought an injunction restraining the defendants from relying upon or otherwise referring to any brand name, including Herceptin, of the innovator drug or any data relating to Trastuzumab marketed under those brand names in any marketing material and from claiming any similarity with the innovator drug until the suit was disposed of. The learned Judge disposed of the interim applications earlier this month, while the suit itself is currently pending with the hearing scheduled to start in the end of this month.

1 CS(OS) No.355/2014

2 http://dbtbiosafety.nic.in/Files%5CCDSCO-DBTSimilarBiologicsfinal.pdf

Issue of approval of biosimilar drugs

Biosimilars are genetically engineered biological products that are highly similar and therapeutically equivalent, though not identical, to the innovator biological product. In order to tap the development and growth of the market for biosimilars in India, the Guidelines provide a thorough and comprehensive process for the development and evaluation of biosimilars. The Guidelines mandate various analytical studies to ensure comparability of the innovator biologic and the biosimilar. Based on the results of the analytical studies, the requirement for clinical trials for the biosimilar may be substantially reduced, but is not eliminated. Thus, under the Guidelines, some amount of clinical trial data is required for marketing approval of the biosimilar drug by the DCGI.

Roche contended that the defendants could not have established their drugs as biosimilar versions of Herceptin in accordance with the procedures laid down by the Guidelines in view of the long prescribed procedure dictated by the Guidelines and the short time period within which the approval was obtained.

While disposing the interim application, the learned Judge asked the defendant to disclose to the court about the nature of the approvals obtained for the biosimilar product in the next hearing. Further, the Judge opined that since the defendant is otherwise not entitled to introduce or launch the drug without the requisite approvals, no interim injunction was required to be passed on these grounds.

Issue relating to passing-off

Roche also argued that since the defendants have misrepresented their products by declaring them as biosimilar of Herceptin or Trastumzumab, such misrepresentations also affect the reputation and goodwill attached to the Roche's drug and are in the nature of passing off. Further, misrepresentations of the defendant's products could mislead the patients using Herceptin as anti-cancer drug about the efficacy and safety of the defendant's drugs.

The learned Judge found merit in this argument and opined that in case interim injunction is not granted, Roche would suffer prejudice and irreparable injury. Hence the learned Judge granted an interim injunction restraining the defendants from relying on any data relating to Roche's innovator drugs and also preventing the defendants from referring to or claiming any similarity to the innovator drugs.

Different aspects to the unfolding battle

As we know, Roche's patented drug Herceptin has been in controversy since its inception. The patent was granted in India as patent number IN205534 on 5th April, 2007. While there were reports that Roche's patent was being considered for a compulsory license under Section 92 of the Patents Act, 1970 (Act), in a surprising development, Roche decided not to pursue Herceptin's patent in India and chose to let the patent lapse in 2013 by not paying the renewal fee for the remaining term of the patent, which could have been otherwise enforced till 2019. However, when Roche had decided to let their patent lapse by not paying renewal fee, there were no biosimilars of Herceptin on the horizon, the demand for Herceptin in India was building and Roche was also confident about the commercial success of Herceptin in India.

As the patent has lapsed, Roche cannot initiate action against Biocon and Mylan for patent infringement. Further, while Sections 60 and 61 of the Act provide for restoration of a lapsed patent, it could be difficult for Roche to establish that the failure to pay the renewal fee was unintentional and that there is no undue delay in making the restoration application given the media attention that the lapse of the Herceptin patent has been receiving. Moreover, Section 62 provides safeguards to those who undertake actions to avail of the patented invention between the time the patent ceased to have effect and the date of publication of application of restoration.

Thus, it appears that Roche has now shifted the battleground from patents to regulatory approvals and the available common law remedies against passing-off. Indian courts have rich jurisprudence in dealing with passing-off issues. However, it remains to be seen how the Indian courts would deal with passing-off in case the defendants establish their drugs as biosimilars of the innovator drug. As it appears now, the onus is on Biocon and Mylan to prove that they have followed the Guidelines and have not indulged in misrepresentation of their products as being biosimilars. It will also be interesting to note what obligations will be placed on the DCGI by the court for granting marketing approvals to biosimilars. The Indian courts have earlier held that there can be no linkage between regulatory approvals provided by the DCGI for marketing of drugs and patent infringement. However, in this case, the question is whether the required procedure for obtaining the regulatory approval for biosimilars was properly followed. It is possible that the courts will require the Guidelines to be strictly implemented given the repercussions it could otherwise have on public health.

[The authors are, respectively, Senior Associate and Joint Director, IPR Practice, Lakshmikumaran & Sridharan, New Delhi]

Ratio Decidendi

Copyright extends only to manner of expression of idea, not idea per se

Protection under Trademark Act or Copyright Act cannot extend to techniques, processes or sequences and hence pranic healing and performance of the *asanas*, postures, communicating the same to public will not constitute infringement. At issue, was the conduct of courses, sale of materials (books and CDs) and teaching of techniques of modern pranic healing claimed to be the intellectual property of the plaintiffs. The Delhi High Court denied grant of permanent injunction reasoning that even if new *asanas* had been evolved, novel processes were in the realm of patents and in any case copyright in a book could not extend to art described in the book. Copyright may extend to manner of description but not performance. Also, the *asanas* were not eligible for protection as dramatic works since though they could be performed (akin to choreography), there was no fixation or certainty of performance.

On the claim of joint ownership by one of the defendants, the court held that the test was

whether the contribution by the said co-author approximated to penmanship with labour and skill expended towards creativity and in the instant case compilation, transcribing and editing work carried out by the defendant satisfied this test. [*Institute of Inner Studies* v. *Charlotte Anderson*, Delhi High Court Order dated 10-1-2014]

No absolute bar on registration of common words

Emphasising on acquired distinctiveness and use as trademark in trade dress, product catalogues etc, the Bombay High Court granted relief to the plaintiff in respect of the registered trademark MARINE PLUS for adhesives. It reasoned that the word per se was not descriptive of the goods and the word formed a prominent feature of the trademark as a whole and this composite mark was entitled to protection. The defendant sought to register JIVANJOR MARINE Plus as a label mark and contended that the presence of house mark FEVICOL in the plaintiff mark and JIVANJOR in its mark was sufficient to distinguish between the goods. The court opined that house mark by itself could not distinguish between the goods. [*Pidilite Industries Ltd* v. *Jubilant Agri & Consumer Products Ltd*, Bombay High Court Order dated 13-1-2014]

Use of keywords when amounts to commercial communication

Examining damage to origin function, the advertisement function and the investment function of trademark when the word /mark 'lush' is used in the site of the online retailer (defendant) though the trademarked products are not sold , the High Court (UK – Chancery Division – Intellectual Property) upheld the claim of infringement.

'Lush' was used as an adword. The person using the internet would find among others, links to the site of the defendant and on clicking the same would enter the website of the defendant. Though the products were not sold by the online retailer, competing products were on display. The fact there was no overt message that the particular brand/trademarked product of Lush was not available and a shopper could not ascertain the same 'without difficulty' convinced the court to hold against the defendant. Thus, it was not a case of ordinary keyword advertising.

On investment function, the claimant submitted that it had made a commercial decision not to sell goods through the defendant's site. Since the defendant was a large online retailer, the consumer would expect goods of the claimant also to be sold by it and use of its mark by the defendant damaged its reputation.

One of the arguments put forth by the defendant as regards presence of the mark 'Lush' in its website which was connected to goods of third parties whose goods were sold through its website was that it was only to enable navigation and the site was used merely as online market place. However, the court was of the opinion that since the defendant designed and operated the website so as to maximise sales such display was part of its own commercial communication.

The defendant also used certain internal software which after analysing the behaviour of previous consumers (users) suggested options to the user which would lead them to competing products. For instance, when the user misspelt the

word as 'lsuh' the option would show competing products or those with lush mark on them. The court ruled that such use of a trademark as a generic indicator of a class of goods damaged the origin function as well as advertising and investment functions. [*Lush Limited* v. *Amazon Co UK & another* - [2014] EWHC 181 (Ch)]

Communication to public must be to 'new public'

Providing clickable links which lead the user to copyrighted material otherwise available to public is not unauthorised communication. Answering a reference from Svea Court of Appeal (Sweden), the CJEU has ruled that in order to be 'communication to the public' as per Article 3(1) of Directive 2001/29, it must be also be directed at new public. In the instant case, the defendants placed links to certain articles by journalists which were available in *Göteborgs-Posten* newspaper. The copyright holders sought compensation for this unauthorised use of protected work. The CJEU reasoned that since the works were available in the newspaper site without any restriction, the initial communication had been meant to be available to the public at large and would include those who accessed the works through the site of the defendant. Hence, it could not be said that when subsequently it was made accessible by providing clickable links, there was any infringement. The CJEU also opined that member states must refrain from wider protection than provided under the Directive. [*Nils Svensson & Ors.* v. *Retriever Sverige AB*, Case C466/12 dated 13-2-2014]

News Nuggets

Seizing essence of IP protection

Time and again the question of when and how Customs can aid in enforcement of IP rights has come before the courts. It was the CJEU's turn, answering a reference by the Danish court, to interpret Council Regulation (EC) No 1383/2003 of 22 July 2003, on measures to be taken against goods suspected of infringing IPR. The intended recipient of the goods - a Danish national had bought a Rolex watch through a Chinese online retailer. Customs authorities detained the watch which was later proved to be a counterfeit and sought consent of the recipient to destroy the watch. The recipient pleaded that the watch had been bought legally, from a EU non-member state where IP protection did not apply. Some of other points on which clarity was sought were whether a purchase for personal use without breaking any IP laws in Denmark could be acted upon by the Customs authorities. The CJEU ruled that though there was no offer of sale targeting EU members, where IP rights were affected, the customs regulation would protect the IP holders. EC 1383/2003 was repealed with effect from 1-1-2014 and stronger regulation (EU) No 608/2013 was adopted extending

the regulations to illegal parallel trade and small consignments among others.

To have a bean to grind

What was brewed or is brewing is uncertain. Is adding the word 'dumb' and imitating the interior design, colour, store layout - parody? Perhaps. Atleast one American comedy star thought so, set up and ran 'Dumb Starbucks' store for four days before it was shut down by the department of health. Parody has received 'fair' share of attention in recent times with UK attempting to bring in exemption for parody. However, whether a trademark can be used in this way is an open question. Use of a fake Louis Vuitton bag in a movie has been subject of a suit for infringement though it was not held to be infringement.