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ASCERTAINING THE LAW ON BIOSIMILARS IN INDIA

Medicinal drugs can either be synthesized chemically or synthesized within and using biological components. A drug which is similar to such biologically created medicine is called a biosimilar. The Delhi High Court has recently elucidated upon the law governing biosimilars in India in *Roche vs Drugs Controller General of India.*

The case in question pertains to the drug Trastuzumab, which was patented by Roche and marketed under the brands HERCEPTIN, HERCLON and BICELTIS. After the expiry of Roche's patent in 2013, the Defendants, Biocon, Mylan Inc & Mylan Pharmaceuticals Pvt Ltd., applied for and obtained marketing authorization for an alleged biosimilar of Trastuzumab, namely, bmab/CANmab.

PLAINTIFFS' ARGUMENTS:

Roche objected to the grant of said marketing approval on the ground that the Drugs Controller had overlooked the applicable 2012 Guidelines on Similar Biologies ("2012 Guidelines") and related formalities, granting such approval in a record span of 5 days. Therefore, the Defendants were misrepresenting their drug as a biosimilar of Trastuzumab wherein this was not the case, as they had obtained the marketing approval without fulfilling the necessary formalities and conditions. It was argued that the Defendant companies have thus compromised the safety of prospective patients and that they seek to pass off the Defendants' drugs as being of the same quality and class as HERCEPTIN.

The Plaintiffs also alleged that the package insert being distributed by the Defendants was a verbatim copy of the information on HERCEPTIN, without adequately disclaiming that the tests and other information pertained to HERCEPTIN and not the alleged biosimilar, further causing misrepresentation. The Defendants further had not mentioned any comparative tests or stated in the insert that their product is a biosimilar of Trastuzumab and not Trastuzumab itself.

DEFENDANTS' ARGUMENTS:

The Defendants, on the other hand, questioned the very jurisdiction of the Civil Court on the ground that the Drugs and Cosmetics Act, 1940 provides adequate remedy to appeal the Controller's decision under Rule 122. Accordingly, the nature of the reliefs sought by the Plaintiffs could not be granted by the civil court as this would amount to undermining the powers of the Controller.

The Defendants also argued that the 2012 Guidelines were not applicable to the present case being merely recommendatory in nature and further having been published only after the clinical trial protocol of the Defendants' drug had already been approved. The Defendants' drug had undergone a stringent approval process, spanning 5 years, which sufficiently established its similarity to Roche's HERCEPTIN and comparable efficacy and safety. It was on the basis of such similarity that the Drugs Controller had exercised his discretion under Rule 1(3), Schedule Y of the Drugs and Cosmetics Act, 1945 and dispensed away with the requirement of conducting certain clinical trials. The Defendants also questioned the basis of an action of passing off since the drug was marketed as the Defendants' version of HERCEPTIN.

Finally, the Defendants relied upon the WHO Guidelines on Evaluation of Similar Biotherapeutic Drugs, 2009 to state that the package insert of the biosimilar must contain information as similar as possible to the innovator drug data.

COURT'S RULING:

In a detailed judgment spanning 227 pages, the Court upheld Roche's claims and restrained the Defendant companies from marketing their drugs as a biosimilar of Roche's drug pending the disposal of the trial. The Court's findings are briefly summarized as follows:

i. Maintainability of the suit:

The Court observed that the Plaintiffs' concern was not mere grant of the approval by the Drugs Controller, but rather, the basis of such approval being that bmab was a biosimilar of HERCEPTIN and consequent injury to the public at large.

While the Drugs Controller could take action against companies that failed to conduct clinical trials under Rule 122DB, however, this does not address the grievance of the Plaintiffs, in as much as, the reference to bmab being a biosimilar of HERCEPTIN or use of the Plaintiffs' data would not be redressed. Even otherwise, a bar to jurisdiction must be explicit, which is not the case in the Drugs and Cosmetics Act.

ii. Regime of Biosimilar:

The Court rejected the Defendants' argument that the 2012 Guidelines were already encapsulated in the 2006 Mashelkar Committee Report which formed the basis of the process followed by the Defendants to seek approval.

It was opined that the 2012 Guidelines had been authored keeping in mind the greater stringency of standards applicable to biosimilars and aimed at filling the gaps in the Drugs and Cosmetics Act, being complementary, not contradictory to the Act. Therefore, notwithstanding that the 2012 Guidelines were non-statutory in nature, post their publication, all applications for manufacturing and marketing authorization of similar biologics in India had to be assessed on the basis of the set standards in the Guidelines.

It also dismissed the Defendant's argument that the clinical trial protocol for bmab had been approved prior to the 2012 Guidelines being published, stating that the Drugs Controller ought to have insisted that the companies amend their protocol and conform to the 2012 Guidelines.

Importantly, the Court held that the exemptions to local clinical trials and abbreviation of the approval process under Section 122B can only be applicable only if such drug is sought to be manufactured in India, which has already obtained approval elsewhere in the world. In the present case, the Defendants had not stated that bmab had obtained such prior approval. A biosimilar is not the same drug as the innovator drug and therefore, all phases of trials had to be conducted by the Defendants in the absence of prior approval. Further, reliance on the Plaintiffs' data was misconceived as a biosimilar is a new drug and not a replica of the innovator drug.

iii. Use of INN Trastuzumab and Package Insert Data:

The Court upheld Roche's claims that the package insert, being a verbatim copy, misrepresented several aspects of the bmab drug, including conducting Phase I and II trials, test subjects of such trials, the racial composition of the testing pool etc. The WHO Guidelines state that the package information of biosimilars should be as similar as possible but that does not imply stating facts that do not exist or are different in the case of the biosimilar.

iv. Data Exclusivity

Use of data relating to Trastuzumab available in the public domain cannot be extended to test dossiers and/or marketing material in the absence of all clinical trials.

CONCLUSION:

Based on the aforesaid, the Court restrained the Defendants from marketing their product as a biosimilar or a biosimilar of the Plaintiff's HERCEPTIN or use the data thereof. The Defendants were also directed to re-apply for a license to manufacture a biosimilar, in accordance with the 2012 Guidelines and the findings arrived at by the court, if they wish to claim their product as a biosimilar.

The decision of the Single Judge does emphasize the need and necessity for greater standards of care when granting approvals to drugs claiming to be biosimilars. The Court has taken due notice of the unique position of biosimilars as opposed to generic drugs. The decision is also to be noted as it contemplates that an innovator's goodwill and reputation may be injured by association to inferior drugs, long after the patent rights expire.

Presently, the decision of the Single Judge has been challenged in appeal to the Division Bench, which has instructed parties to maintain *status quo* as on the date preceding the judgment. The IP fraternity will be closely watching this appeal in order to have some much needed lucidity on India's position on biosimilars.

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DELHI HIGH COURT CLARIFIES CCI'S JURISDICTION IN SEPS CASES

The Delhi High Court on 30.03.2016 delivered a landmark judgment in *Ericsson v. Competition Commission of India, W.P. Nos. 464/2014 & 1006/2014* providing some clarity on the jurisdiction of the Competition Commission of India (CCI) in cases involving Standard Essential Patents (SEPs).

SEP Holders are obligated to license their patents to third parties at Fair Reasonable And Non Discriminatory (FRAND) terms, leading to an apparent conflict between patent law and competition law. The issue therefore, is which statutory authority can take cognizance when a SEP holder is accused of abusing its dominance by charging excessive royalty rates, in exercise of its patent rights.

Ericsson is the owner of 8 patents pertaining to EDGE, AMR, 2G & 3G technologies which have been designated SEPs by the European Telecommunication Standard Institute ('ETSI'). Intex and Micromax are Indian Companies engaged in the manufacture of devices that deploy 2G and 3G technology. On becoming aware of the sale of such devices, Ericsson contacted Micromax and Intex and attempted to negotiate a license with both companies individually. However, the negotiations failed, which led to Ericsson filing suits before the Delhi High Court for infringement, and Intex and Micromax filing separate complaints against Ericsson before the CCI, alleging abuse of dominant position. The CCI passed orders under Section 26(1) of the Competition Act directing investigation into both complaints. Ericsson challenged these orders in the present petitions.

ERICSSON'S ARGUMENTS:

Ericsson's main arguments centered on the assertion that the Patents Act being a special enactment prevails over The Competition Act. The Patents Act contains several provisions to adequately redress the grievances of any party to use a patent on reasonable terms, thereby eliminating the need for any interference by the CCI. Ericsson also argued that a patent or its licensing is not 'goods' or 'services' and thus would not fall within the purview of The Competition Act. Lastly, it submitted that it had already filed a suit before the High Court wherein a preliminary determination of royalty rate had already been made thereby excluding the jurisdiction of the CCI to entertain any proceedings in respect of same issues.

CCI'S ARGUMENTS:

The Respondents in turn argued that the CCI's powers are in addition to all other laws and therefore the CCI is not precluded by any other law from ensuring compliance with Sections 3 & 4 of the Competition Act. It argued that The Patents Act and The Competition Act can be interpreted harmoniously. The Competition Act empowers the CCI to take any inputs from the Controller of Patents and then formulate its opinion, and *vice versa*, thereby eliminating any conflict between the authorities. The CCI further contended that the definition of 'enterprise' was wide enough to include Ericsson, who controlled the technology for production of goods and services and therefore would fall within the definition of enterprise;

COURT'S FINDINGS:

The Court after comprehensively examining all arguments came to the conclusion that there is indeed no irreconcilable inconsistency between The Patents Act and The Competition Act. The Court noted that the remedies provided under Section 27 of The Competition Act are materially different from the remedies under Section 84, Patents Act, for instance, the former being remedies *in rem* while the latter are limited to the person seeking a compulsory

license. The remedies are also not mutually exclusive and thus, exercising one does not take away the right of a licensee to approach the other forum.

The Court took note of Sections 21 & 21, which allow the CCI to either invite or another authority to partake in the CCI's decision-making process, and thus concluded that the intention of the parliament was clearly not to abrogate any provision of either law but to have orders pertaining to both statutes be passed with the consensus of their respective authorities.

The Court thereafter determined that patents are 'goods' under Indian jurisprudence and therefore come within the purview of The Competition Act.

Most importantly, the Court considered several US and EU cases, including the *Orange Book Standard* of Germany and the ECJ case of *ZTE v. Huawei* and held that an SEP holder may abuse of its dominant position in certain circumstances by seeking injunctive reliefs, given their naturally advantageous position. The Court also stated that instituting suits or other threats to a licensee, in order to coerce the licensee into accepting non-FRAND terms, would amount to an abuse of dominance. The Court held that in the present cases, the conduct of Ericsson could lead to a finding of abuse of dominance, justifying the jurisdiction of the CCI.

One of the most significant findings of the Court was that a potential licensee cannot be precluded from challenging the validity of the patents in question. Readers may note that in its infringement suit against Intex, Ericsson had successfully argued that Intex was estopped from challenging the validity of the suit patents as it had based its complaint before the CCI on the premise that Ericsson' s patents were SEPs. The Court rejected such an argument, stating that the expression "willing licensee" does not imply that a potential licensee is willing to accept a license for invalid patents or it has to waive his rights to challenge the patents in question.

The judgment of the Court is extremely important in evincing jurisprudence regarding SEPs in India. It is heartening to note that the Court's decision is in line with the judgments of EU and US and attempts to balance the bargaining power of licensees against the rights of SEP holders, as well as the power of the CCI in such cases.

However, the judgment does not clarify the manner of determining royalty or which judicial authority is empowered to do so. One can only wait for further judgments in the connected civil suits to look for answers. It is also to be noted that an appeal against the judgment has been admitted by the Division Bench as on 19.04.2016.

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LAW ON TERRITORIAL JURISDICTION IN IP SUITS ELABORATED FURTHER

A Division Bench of the Delhi High Court has imported the interpretation given by Supreme Court to Section 20 of the CPC in the judgment of *Patel Roadways,* to Section 134 of The Trade Marks Act and Section 62 of The Copyright Act.

In this case, namely, *Ultra Home Construction v. Purushottam Chaubey*, the plaint had been rejected by a Single Judge, placing reliance on the 2015 Supreme Court judgment of *Sanjay*

Dalia, since the Plaintiff operated a hotel at Deogarh (Jharkhand) and the Defendant had launched a residential project under the impugned trade mark in the same city. The Single Judge held that the principle laid down in *Sanjay Dalia* precluded the Plaintiff from filing the suit in Delhi and obliged it to go to Deogarh.

The Division Bench dismissed the appeal and upheld the Single Judge's findings on the law. Relying on the dictum of the Supreme Court in *Sanjay Dalia* that "*if the plaintiff is residing or carrying on business, etc. at a place where the cause of action, wholly or in part, has also arisen, he has to file a suit at that place …*", the Division Bench ruled that in a case where the Plaintiff has principal office at one place but cause of action has arisen at a place where its subordinate office is also located, the Plaintiff would be deemed to carry on business at the place of its subordinate office and not at the place of the principal office.

The *Ultra Homes* judgment has summarized the various situations and the corresponding jurisdiction in case of Section 134(2) TM Act and Section 62(2) Copyright Act in the following manner:

Place of Plaintiff's office	Place of Plaintiff's subordinate/ branch office	Place where cause of action arose	Place where Plaintiff can sue under Sec. 134(2) TM Act and Sec. 62(2) Copyright Act
A	--	C	**A**
A	B	A	**A**
A	B	B	**B**
A	B	C	**A**

The Special Leave Petition against the judgment passed by the Division Bench in *Ultra Homes* has been dismissed by the Supreme Court. Hence, the *Ultra Homes* judgment is as of now, the decisive authority on the subject.

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PATENT AMENDMENT RULES, 2016 NOTIFIED

The Indian Government has, on 16.05.2016, brought into effect the Patent Amendment Rules, 2016. The Rules provide for several welcome changes to the practice and procedure of patent filing, including provision and forms for expedited examination of patent application (Rule 24C & Form 18-A), withdrawal of request for examination, withdrawal of application for patent (Form 29) as well as an innovative miscellaneous Form 30, to be used when no other remedy is prescribed.

The Rules also attempt to encourage innovation, by granting several advantages and benefits to new companies focused on innovation, which it defines as 'Startups'. Readers may be aware that prior to this amendment, India recognized 3 types of applicants, i.e., natural persons, 'small entity' and 'other than small entity'. Rule 2(fb) states that a Startup is an entity where - 5 years have not lapsed from the date of its incorporation or registration; the turnover for any of the financial years, out of the 5 years has not exceeded 25 crores and the startup is working towards innovation, development, deployment or commercialization of new products, processes or services driven by technology or intellectual property.

A Startup is allowed, particularly, expedited examination under Rule 24C. Under this Rule, the Examiner is required to complete his report within 2 months of the receipt of application. Further, the Controller is required to dispose off the report received by the examiner within one month from its receipt. Rule 24C is also applicable to those applications which have indicated India as the International Preliminary Examining Authority. The government fee charged for start-ups will also be equivalent to that charged for natural persons. However, it is to be noted that should a Startup transfer its patent application to any other person or entity, it would have to pay the balance fee, thereby ensuring that the provisions are not misused for purely commercial gains.

The Rules also mandate submission of a clean copy and a marked copy, in the event of an amendment to the specification of an invention. Another noteworthy change is that Applicants may delete a claim at the National Phase Filing Stage, which was not possible earlier as such applications had to be 'as it is'.

Another interesting and welcome change is that hearings can now be held *via* video conferencing. However, written submissions, as well as other documents, need to be submitted within 15 days of such hearing. Moreover, in a bid to reduce the time taken for grant of patent, the new Rules have reduced the time to respond to objections to Examination Report from a period of one year to six months.

Patent applicants will also now be able to obtain certified copies on an expedited basis- within one week from the date of request, as per Rule 133(2).

These are just *prima facie* observations on the Rules, since the same were notified only 4 days ago. One will have to wait to see how the Rules are translated into action by the Indian Patent Office.

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