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Case report: Biocon's breast cancer biosimilar gets green light

In a recent decision in India, biopharma company Biocon and its partner Mylan were allowed to continue marketing a biosimilar breast cancer drug, as Vikrant Rana and Sanjeeta Das of SS Rana report.

The Division Bench of the Delhi High Court, in its order dated April 28, 2016, has allowed Indian biopharmaceutical company Biocon and its partner Mylan Pharmaceuticals to continue marketing their breast cancer drug trastuzumab until the next court hearing, on July 21, 2016. Mr Justice Badar Durrez Ahmed and Mr Justice Sanjeev Sachdeva delivered the ruling in the case of *Biocon Limited v Roche Products (India) Private Limited & Ors.*

The case at hand is an appeal filed by Biocon against an earlier order, dated April 25, 2016, of the Delhi High Court's single judge Mr Justice Manmohan Singh in *Roche Products (India) Private Limited & Ors v Drug Controller General of India & Ors.*

Trastuzumab is a monoclonal antibody used primarily for the treatment of HER2-positive breast cancer. It has been assigned international nonproprietary name (INN) status by the World Health Organization (the INN is an official generic and nonproprietary name given to a pharmaceutical drug or active ingredient in order to provide a unique standard name for the active ingredient and avoid prescribing errors).

The order dated April 25, 2016 was likely to have sweeping ramifications on the biomedicine industry as it imposed some restrictions on the sale and marketing of biosimilar drugs. The order was stayed by the Division Bench of the Delhi High Court on April 28, 2016 and subsequently on May 10, 2016 the appeal was further adjourned until July 21, 2016 with continued operation of the stay. Let us take a closer look at the events leading up to the present appeal.

Roche's case

Genentech is a biotechnology corporation and has been a subsidiary of Roche since 2009. The companies developed the drug trastuzumab in 1990, and after being granted approval by the Drugs Controller General of India (DCGI) in 2002, Roche started importing and marketing the drug in India under the brand names Herceptin, Herclon and Biceltis. Additionally, Genentech obtained a formulation patent for trastuzumab effective from May 3, 1993, and it lapsed on March 3, 2013. Biocon and Mylan have been allegedly selling a biosimilar version of trastuzumab under the brand names Canmab and Hertraz respectively.

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Aggrieved by the act of the DCGI in granting the approval of the biosimilar drug and by the conduct of Biocon and Mylan in selling the drug, Roche filed the earlier suit before the Single Bench of the Delhi High Court. As the single judge noted in paragraph 21 of the judgment, it was necessary to answer five main questions:

1. Does Roche have any right of action in the present case? If yes, is the suit expressly or implicitly barred in law in view of the provisions of the Drugs and Cosmetics Rules, 1945?
2. If the suit is maintainable, is the court within its powers to embark on the approvals granted by the DCGI in relation to the drugs in case it impinges the civil rights of Roche?
3. What is the impact of the "Guidelines on Similar Biologics" (the biosimilar guidelines) formulated in 2012 by the DCGI and the government of India, and would these guidelines have any bearing in relation to the grant of the marketing and manufacturing approvals by the DCGI, especially grants after the creation of the said guidelines?
4. Would the approval granted by the DCGI to Biocon by omitting the requirements of the clinical trials phases I and II have any bearing on the already granted approvals in the case of the similar biologics product, and did Biocon conduct all the clinical trials of the drug as required under the strict provisions of the Drugs and Cosmetics Act, 1940 and 1945 rules, and the biosimilar guidelines of 2012?
5. Can the common law remedy be pursued by Roche for misrepresentation and false information allegedly made by Biocon and Mylan in view of peculiar circumstances of the present case?

The primary grievance of Roche was the fact that Biocon and Mylan circumvented the approval process laid down in the 2012 biosimilar guidelines for selling the biosimilar version of the drug, and the impugned act on their part results in putting the health of cancer patients at risk. Since Biocon and Mylan got the approval in eight days, it inevitably calls into question the entire evaluation process.

Second, Roche contended that by using the testing and sales material of Herceptin in its own packaging and promotional material, Biocon was trying to take undue advantage of the considerable reputation that Roche's Herceptin has attained in the Indian drugs market.

Last, on the issue of maintainability of the suit, Roche argued that the Delhi High Court did possess the jurisdiction to adjudicate the dispute in light of the fact that the defendants' actions impinged the plaintiffs' civil rights for which the plaintiffs could not approach any other forum except the High Court.

Judge's rulings

The single judge came to the conclusion that:

- The suit was maintainable in the High Court as, according to the guidelines, there is scope for judicial intervention when the procedure followed during the grant was inimical to the prescribed procedure and contrary to public purpose;
- The court further elaborated on the legality of the approval by drawing attention to paragraph 1(1)(iv)(a) of Schedule Y to the 1945 rules, which makes it clear that all the associated phases of the clinical trials have to be mandatorily conducted, so by inference, it was erroneous on the part of the DCGI to grant the approval;
- Regarding the use of the INN, the court held that in order to use the INN for the said drug all requisite clinical trials and fulfilment of all protocols under the act, rules and guidelines are required. If the same is not met, the INN can be used only by indicating some mark of distinction to avoid any possibility of deception;
- On the issue of false representations made on the package of the product, the court held that it was legally unacceptable for Biocon to make such misleading assertions and while it is permissible to use the appropriate data of the innovator drug, the same could not be wrongly used in such a way as to make it appear that the biosimilar drug possessed every attribute of the innovator drug; and
- On the issue of data exclusivity, the single judge remarked in paragraph 303 that: “After having considered the arguments of the parties, I am of the opinion that unless the government of India frames a policy to declare as to whether after expiry of a patent, the data in the public domain can be used as pathways or not, the regulatory authority can neither disclose nor rely upon the first applicant’s data at the time of granting marketing approval to the subsequent applicants.”

After the single judge’s ruling in the earlier case, Roche reportedly stated that it is not particularly against biosimilars, but will continue challenging companies that do not follow the Indian biosimilar framework. It further applauded the ruling of the single judge, stating that: “The ruling sends a strong, positive signal that the development, manufacture and approval of biosimilars in India must be subject to rigorous clinical and regulatory standards as per the applicable law.”

The judgment of Singh inevitably tries to find a middle ground between the problem of a lack of affordable lifesaving medication and strict adherence to the regulatory approval process. It will be interesting to follow the final decision of the Division Bench with regard to the way in which it tries to find a harmonious construction between the two opposing perspectives.

Additionally, the court’s observation that there is an impending need for a law relating to data exclusivity in India is a welcome move as the need was already felt by industry insiders for a long time. In the meantime, the much awaited 2016 “Proposed Guidelines for Similar Biologics”, which are expected to include a new post-market study on phase IV tests of biosimilar drugs, have yet to be officially announced.

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