* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% *Order delivered on: February 05, 2014*

\+ **CS(OS) No.355/2014**

ROCHE PRODUCTS (INDIA) PVT LTD & ORS ..... Plaintiffs

Through Mr.Mukul Rohatgi, Sr. Adv. and Mr.Neeraj Kishan Kaul, Sr. Adv. with Mr.Darpan Wadhwa, Ms.Juhi Singh, Ms.Niti Dixit, Ms.Shivani Singhal, Mr.Dhruv Agarwal, Ms.Samiksha & Ms.Roshni Namboodiry, Advs.

versus

DRUGS CONTROLLER GENERAL OF INDIA AND ORS ..... Defendants

Through None

CORAM:
HON'BLE MR. JUSTICE MANMOHAN SINGH

MANMOHAN SINGH, J. (ORAL)

I.A. No.2373/2014 (exemption)

Exemption allowed, subject to just exceptions.

The application is disposed of.

I.A. No.2372/2014 (u/s 80(2) CPC)

The abovementioned application has been filed by the plaintiffs under Section 80(2) read with Section 151 CPC seeking exemption from serving the notice to defendant No.1 as required under the law.

Issue notice to the defendants, returnable on 28th February, 2014.

In the meanwhile, the exemption is granted to the plaintiffs to file the present suit and interim application without the issuance of notice under Section 80(2) CPC, at this stage.

CS(OS) No.355/2014

The present suit has been filed by the plaintiffs for injunction against defendants No.2 to 4.

Let the plaint be registered as a suit.

Issue summons to the defendants through all modes, on filing of process fee and Regd. A.D. Covers within a week, returnable on 28th February, 2014.

I.A. No.2371/2014 (u/o XXXIX R.1 & 2 CPC)

1. Issue notice to the defendants, for the date fixed.

2. Learned Senior counsel appearing on behalf of the plaintiffs is pressing for an *ex parte* ad-interim order, restraining the defendants No.2 to 4 from launching, introducing, selling, marketing and/or distributing the defendants' drugs, i.e. CANMAb and HERTRAZ or any other biosimilar version of Trastuzumab, in the Indian market until the disposal of the present suit, and also sought an injunction restraining the said defendants from relying upon or otherwise referring to HERCEPTIN®, HERCLON™ or BICELTIS® or any data relating to Trastuzumab marketed as HERCEPTIN®, HERCLON™ or BICELTIS® including data relating to its manufacturing process, safety, efficacy and sales, in any press releases, public announcements, promotional or other material for the defendants' drugs, i.e. CANMAb and HERTRAZ and from claiming any similarity with HERCEPTIN®, HERCLON™ or BICELTIS®.

3. Brief facts of the matter are that the plaintiffs are globally engaged in the business of healthcare in the fields of pharmaceuticals and diagnostics. Plaintiff No.1 is the importer and marketer of innovator molecule 'Trastuzumab' in India, plaintiff No.2 is the manufacturer of innovator molecule 'Trastuzumab' and plaintiff No.3 is the innovator of the biological

drug 'Trastuzumab'. Trastuzumab is a biological drug used primarily for the treatment of HER 2 positive breast cancer. In India, Trastuzumab is sold under the brand names HERCEPTIN®, HERCLON™ and BICELTIS®. It is stated that Trastuzumab has become the accepted biological treatment for HER 2 positive breast cancer on a worldwide basis and enjoys a global reputation.

4. Defendant No.1 is the Drug Controller General of India, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of India. Defendants No.2 and 3 are co-developers of a purported biosimilar version of Trastuzumab under the brand name CANMAb. Defendant No.4 is a subsidiary of Defendant No.3 and it is stated that pursuant to the co-development agreement between defendants No.2 and 3, defendant No.4 launched a purported biosimilar version of Trastuzuman in India under the brand name HERTRAZ.

5. It is the case of the plaintiffs that the defendants' drugs are being misrepresented as "Trastuzumab", "biosimilar Trastuzumab" and a "biosimilar version of HERCEPTIN®" without following the due process in accordance with the Guidelines on Similar Biologics for the purpose of obtaining appropriate approvals.

6. It is stated that the plaintiffs obtained approval for the import and marketing of innovator Trastuzumab in India in the year 2002 which was granted by defendant No.1 under Rule 122A of the Drugs and Cosmetics Rules, 1945, as amended.

7. It is further stated that the defendants No.2 and 3 have stated in their press statements that they have entered into an exclusive strategic collaboration for the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds for

the global marketplace. Defendant No.2's press release specifically stated that CANMAb will become available in India in the first week of February 2014 and further, defendant No.3's press release refers to the imminent launch of HERTRAZ.

8. It is stated that pursuant to the notification No.F.No.12-01/09-DC-(Pt-32) issued by defendant No.1 (effective from June 15, 2009), registration of all phases of a clinical trial with the Clinical Trials Registry-India (CTRI) is mandatory prior to the initiation of any such clinical trial. However, there is no publicly available record of registration of Phase I and Phase II clinical trials by defendants No.2 or 3 for the purported biosimilar Transtuzumab.

9. "Biosimilars" are biological products that are similar to the innovator biopharmaceutical product. In view of the structural and manufacturing complexities involved in the production of the biopharmaceuticals, a biosimilar product can only be *similar* to the innovator biopharmaceutical product; it cannot be a generic *equivalent* of the innovator biopharmaceutical product. In view of the development and growth of the market for biosimilars in India and the international standards for approval of such products, the Guidelines on Similar Biologics were issued in 2012 which lay down specific standard for development and evaluation of similar biosimilar biologics. The said guidelines seek to ensure comparability of safety, efficacy and quality between the innovator biologic and the biosimilar, prior to the approval of such biosimilar.

10. After the issuance of the Guidelines on Similar Biologics, which provide for a detailed and structured process for comparison of similar biologic with the reference biologic, all the applications for manufacturing and marketing authorization of similar biologics in India are required to be evaluated on the basis of the standards set forth on the Guidelines and only

products which have been approved under the said Guidelines should be allowed to be represented as biosimilar products.

11. It is the case of the plaintiffs that defendant No.2's protocol and design study for testing for Bmab-200 was filed with and approved by defendant No.1 prior to the said Guidelines becoming effective. As per the annual report for the year 2012 of the defendant No.2, in June 2012, much before the said Guideline became effective, the defendant No.2 was already conducting Phase III clinical trials in relation to Bmab-200(which the last stage of tests to be conducted on a new drug prior to the grant of marketing authorization).

12. In view of the same, it has been submitted that the approval granted to the defendant No.2 cannot be said to have satisfied the requirements for a biosimilar drug under the said Guidelines and the defendants' drugs cannot be considered biosimilar products.

13. It is the case of the plaintiffs that since, as claimed by defendants No.2 to 4, Bmab is developed for the treatment of HER 2 positive metastic breast cancer, it completes directly with the plaintiffs' biological drug HERCEPTIN® which is used for the treatment for HER 2 positive breast cancer throughout the world. It is stated that the defendants' No. 2 to 4 ought to be restrained from introducing the defendants' drugs in the Indian market as a biosimilar product until appropriate tests and studies as prescribed under the said Guidelines have been conducted and appropriate approvals have been obtained. Defendants No.2 to 4 ought to be further restrained from using the plaintiff's trademark HERCEPTIN®, and the reputation and goodwill attached to it, for their commercial benefit.

14. Mr.Mukul Rohatgi, learned Senior counsel appearing on behalf of the plaintiffs has referred the list of Recombinant DNA based Drugs approved in

the country (Form-46) from January, 2010 to 31st October, 2013 wherein entry No.53 depicts the name of Biocon Limited who has obtained the approval of BULK-242/2013 on 23rd October, 2013 in respect of molecule TRASTUZUMAB-BULK. However, his submission is that it is doubtful that the said approval has not been obtained under the Guidelines on Similar Biologics prepared by Central Drug Standard Control Organization and the Department of Biotechnology laying down the regulatory pathway for similar biologic claiming to be similar to an already authorized reference biologic. According to him, such approval on similar biologics could not have been granted in such a short period in view of the long prescribed procedure.

15. Mr.Rohatgi has also fairly conceded that in case the approvals are granted under the law and the said Guidelines referred by him, then under those circumstances, he would be taking the necessary steps for cancellation of the said approval and the interim orders are not to be passed.

16. At this stage, it appears to me that apparently, the detail of some approvals has been mentioned in the list of recombinant DNA based Drugs approved in the country from January, 2010 to 31st October, 2013 by defendant No.2 as entry No.53 available in the document filed by the plaintiff. No doubt, it is imperative and necessary for defendant No.2 to disclose to the Court about the nature of the approvals of biosimilar product obtained by it on the next date.

17. In view of the above said situation, I am of the view that at this stage, no specific orders of interim injunction are required to be passed, for the reason that defendant No.2 is otherwise not entitled to introduce or launch the drug without the requisite approvals.

18. As regards the second prayer made by Mr.Rohatgi, it is stated in the plaint that the defendants No.2 to 4 have misrepresented the nature of the defendants' drugs as a "biosimilar Trastuzumab", a "Trastuzumab" and a "biosimilar version of HERCEPTIN®". Such misrepresentations are in the nature of passing off since they seek to pass off the defendants' drugs as being of the same quality and class as HERCEPTIN®. Such misrepresentations are likely to deceive the patients using Trastuzumab regarding the efficacy and safety of the defendants' drugs. Defendants No.2 to 4, through such misrepresentations, will take unfair advantage of the reputation and goodwill enjoyed by plaintiff No.3's brand HERCEPTIN®, for innovative and original product Transtuzumab, in the Indian market.

19. I find force in the submission of Mr.Rohatgi in this regard. In case, the interim order is not passed in this regard, the plaintiffs would suffer prejudice and irreparable injury. Thus, defendants No.2 to 4, till the next date of hearing, are restrained from relying upon or otherwise referring to HERCEPTIN®, HERCLON™ or BICELTIS® or any data relating to Trastuzumab marketed as HERCEPTIN®, HERCLON™ or BICELTIS® including data relating to its manufacturing process, safety, efficacy and sales, in any press releases, public announcements, promotional or other material for the defendants' drugs, i.e. CANMAb and HERTRAZ and from claiming any similarity with HERCEPTIN®, HERCLON™ or BICELTIS®.

20. Compliance of Order XXXIX Rule 3 CPC be made within one week.

21. Dasti.

(MANMOHAN SINGH)
JUDGE

FEBRUARY 05, 2014