

## Roche Products (India) Pvt. Ltd. and Others Vs Drugs Controller General of India and Others

**Court:** Delhi High Court

**Date of Decision:** Feb. 14, 2014

**Acts Referred:** Civil Procedure Code, 1908 (CPC) â€” Order 39 Rule 1, Order 39 Rule 2, Order 39 Rule 4, Order 43 Rule 43, 151

Delhi High Court Act, 1966 â€” Section 10

**Citation:** (2014) 4 AD 99 : (2014) 58 PTC 420 : (2014) 58 PTC 165

**Hon'ble Judges:** Manmohan Singh, J

**Bench:** Single Bench

**Advocate:** Neeraj Kishan Kaul, Mr. Rajiv Nayar, Sr. Advs., Mr. Darpan Wadhwa and Ms. Juhi Singh, Advocate for the Appellant; Harish Salve, Ms. Prathiba M. Singh, Sr. Advs., Mr. Vijay Sondhi, Mr. Astush Prasad, Mr. Manu Yadav, Mr. Mayank Grover and Mr. Sohan Kumar, Advocates for D-2, Dr. A.M. Singhvi, Mr. Prag Tripathi, Sr. Advs., Ms. Gytri Rai, Ms. Nirupum Lodha, Mr. Ankhush Mahajan, Mr. Udit Sood and Ms. Akanksha Singh, Advocates for D-3 and 4, Ms. Niti Dixit, Mr. Mahabir Neetiah, Ms. Shivani Singhal, Mr. Dhruv Agarwal and Ms. Samiksha Godiyal, Advocate for the Respondent

### Judgement

Manmohan Singh, J.

I.A. No. 2988/2014 & I.A. No. 2990/2014

1. The plaintiffs in the above said matter filed the suit for injunction against the four defendants. Along with the suit, the plaintiffs also filed an

application under Order XXXIX Rule 1 & 2 C.P.C., being I.A. No. 2371/2014. Summons and notice were issued to the defendants, returnable

on 28th February, 2014. Various prayers were made in the interim application. However, after hearing, limited interim order was passed against

the defendants No. 2 to 4 and they were restrained from relying upon or otherwise referring to HERCEPTIN., HERCLONTM or BICELTIS or

any data relating to Trastuzumab marketed as HERCEPTIN., HERCLONTM 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., HERCLONTM or BICELTIS.

2. It appears that the said order was challenged by the defendants No. 2 to 4 by filing two appeals under Order XLIII read with Section 151

C.P.C. and Section 10 of Delhi High Court Act, 1966, being FAO (OS) 91/2014 and FAO (OS) 92/2014, which were listed before the Hon'ble

Division Bench. In the said appeals, the following order was passed:

After hearing the learned counsel for the parties on both sides, we feel that these appeals be treated as applications under Order XXXIX Rule 4

C.P.C. on behalf of the appellant and they be re-numbered as such.

The matters be listed before the learned Single Judge today itself at 2:15 pm.

3. In view of the direction issued by the Court, Registry has numbered the appeals which are to be treated as applications under Order XXXIX

Rule 4 C.P.C. The next date in the matter is fixed for 28th February, 2014.

4. Mr. Harish Salve and Ms. Prathiba M. Singh, learned Senior counsel appearing on behalf of the defendant No. 2, and Dr. Singhvi, learned

Senior counsel appearing on behalf of the defendants No. 3 & 4 after small hearing are agreeable that without prejudice to contest the matter on

merit, till the next date of hearing, the defendants No. 2 to 4 shall not use the trade marks HERCEPTIN., HERCLONTM or BICELTIS. in any

press releases or public announcements for the defendants' drugs, i.e., CANMAb and HERTRAZ. But with respect to the remaining part of the

order, they are pressing for modification/vacation of the order dated 5th February, 2014 in view of hardship of their clients as they have now

introduced the drug in question in the market.

5. Mr. Neeraj Kishan Kaul and Mr. Rajiv Nayar, learned Senior counsel appearing on behalf of the plaintiffs, state that time be granted to the

plaintiffs to file reply to the applications. They have no objection if the applications filed by defendant No. 2 and defendants No. 3 & 4 for

modification be considered on the next date i.e. 28th February, 2014.

6. As pressed by the defendants, both parties have made their detailed arguments with regard to the interim order passed by this Court. It is not

necessary to discuss the said arguments at this stage, as the next date in the matter is fixed for 28th February, 2014 and I am also of the view that it

is not proper to decide the applications without replies of the plaintiffs. The submissions have been noted by the Court and the same would be

considered when the applications are decided.

7. At present, in view of as is stressed by the defendants No. 2 to 4 as to whether the specimen of package insert, which is being used by the

defendants No. 2 to 4 produced in Court are entitled to use while marketing the drug in the country.

8. Contention of the Defendants No. 2 to 4 is that the said package insert is duly approved by the Drug Authority. Thus, unless the main approval

or the approval package insert is revoked/cancelled, the defendants No. 2 to 4 are entitled to use the same in their packaging while marketing the

drug in question.

9. On the other hand, Mr. Kaul and Mr. Nayar have made various submissions with regard to the package insert who argued that the package

insert for marketing drug is reproduction of the package insert of the plaintiff. It is also argued that defendant No. 2 has made various

misrepresentations and given the details in the said package insert which are contrary to the main approval to market the drug by defendant No. 1.

According to the plaintiffs, there is no approval with regard to the package insert used by the defendant No. 2 while marketing its drug in the

country as being inserted by defendant No. 2 in the packaging while launching the drug. The submissions of the plaintiffs is that for the package

insert produced in Court, the defendant No. 2 had not received the approval; it was merely they have submitted the carton, packaging and insert

before the Drug Authority in December, 2013 but approval is not granted. Thus, a case of passing off is made out.

10. They state that in case the approval is not granted with regard to the package insert, then the defendant No. 2 is not entitled to use the package

insert in question and even otherwise, the said package insert is a slavish copy of the package insert of the plaintiffs.

11. Mr. Nayar has referred to page 935 of the appeal paper book which contains the copy of the Permission/Approval for manufacture of New

Drug formulation issued by the defendant No. 1 on 23rd October, 2013 with regard to the new drug Trastuzumab. He also referred to item No. 8

of the Conditions for Grant of Approval/Permission which stipulates that ""Specimen of the carton, labels, package insert that will be adopted for

marketing the drug in the country shall be got approved from the Licensing Authority before the drugs is marketed.

12. Mr. Nayar has also referred the letter dated 13th December, 2013 issued by defendant No. 2 which is available at page No. 948 and reads as

under:

This has reference to File No. 4-207/Biocon/13-BD dated 23.10.2013, we here by submit copy of SmPC, label, carton and package insert.

13. He submits that the label, carton and package insert were submitted by the defendant No. 2 to the Drugs Controller General (India) only on

13th December, 2013. However, no document has been placed by the defendant No. 2 to show that the said package insert has been approved

by the Drugs Controller General (India).

14. Arguments are advanced by defendants No. 2 to 4 irrespective of the fact that even otherwise insert being used by the defendants is not

protect able in law by the plaintiffs. The defendants have infringed the rights of the plaintiffs in any manner.

15. At present, there are two versions of the parties which are contrary to each other. The defendant No. 1 is present who has or has not granted

the approval of purchase insert. No opportunity has been granted to the plaintiffs to file replies to these applications. Thus, in case the defendant

No. 2 has already obtained the approval of package insert in question, then it is entitled to use the same till the next date of hearing, in other case,

the remaining part of the interim order for which the defendants sought modification shall continue.

16. Under these circumstances, without deciding anything on merit with regard to the arguments addressed by both the parties, the plaintiffs are

granted ten days" time to file the reply to the appeals which are to be treated as applications under Order XXXIX Rule 4 C.P.C. as this Court

feels that final order in this regard would be passed when the exact picture comes into light. List on 28th February, 2014, the date already fixed.