(2019) 09 DEL CK 0170

In the Delhi High Court

Case No : First Appeal From Order (OS) No. 181 Of 2016

Reliance Life Sciences Private Limited — APPELLANT

Vs

M/S Genentech Inc And Ors — RESPONDENT

Date of Decision : 18-09-2019

Acts Referred:

Drugs And Cosmetics Rules, 1945 — Rule 21(b), 96, 96(1)(A)(i), 122A, 122B, 122D, 122DA, 122DAC (b), 122DC, 122E
Code Of Civil Procedure, 1908 — Order 39 Rule 1, Order 39 Rule 2/li>

Citation : (2019) 10 AD(Delhi) 1 : (2019) 80 PTC 338

Hon'ble Judges : Vipin Sanghi, J;Rajnish Bhatnagar, J

Bench : Division Bench

Advocate : Chander M. Lall, Bitika Sharma, Kapil Midha, Namrita Kochhar, Luv Virmani, Nancy Roy, Darpan Wadhwa, Niti Dixit, N. Mahavir, Samiksha Godiyal, Muizz Drab, Aubert Sebastian, Aditi Mohan, Amit Mahajan, Arjun Dev

Final Decision : Allowed

Judgement

Vipin Sanghi, J

C.M. APPL. 6426/2017

Exemption allowed, subject to all just exceptions. The application stands disposed of.

C.M. APPL. 22510/2016

1. The aforesaid application has been preferred, by the appellant, seeking stay of the order of the Ld. Single Judge, dated 25.04.2016, passed in I.A. Nos. 23041/2015 & 25289/2015 in C.S.(OS) No. 3284/2015, whereby the Learned Single Judge permitted the appellant to launch; manufacture, market and advertise their drug TrastuRel without calling the same as biosimilar to the respondents/ plaintiffs drugs HERCEPTIN®, HERCLON? and BICELTIS®. The learned Single Judge has vide the aforesaid order dated 25.04.2016 imposed certain conditions against the appellant herein with regard to - ascribing

similarity of its drug TrastuRel with the respondents/ plaintiffs biological drug, use of data relating to safety, efficacy and manufacturing process of the respondents/ plaintiffs biological drug, and the manner of labeling on its package inserts and cartons in relation to the use of the respondents/ plaintiffs biological drug having International Non Proprietary name - Trastuzumab.

2. The aforesaid suit C.S. (OS) No. 3284/2015, has been filed by the respondents nos. 1-3 (Plaintiffs/ Roche), against the appellant (defendant no.3), respondent no. 4 (Drug Controller General of India) and respondent no. 5 (Secretary, Department of Biotechnology).

3. The respondent nos. 1-3 (Roche/ Plaintiffs) sought injunction against the appellant from launching, selling, marketing and/or distributing the appellant"s biosimilar drug "TrastuRel", in the domestic market as Trastuzumab, developed by the said respondents, for which they obtained Patent, which lapsed on 03.05.2013 for the indications, for which the respondents/ plaintiffs market their drugs under the brand names HERCEPTIN®, HERCLON? and BICELTIS®, and also sought restraint against the appellant from representing its said product as biosimilar to Trastuzumab and from relying on the data of the plaintiffs Trastuzumab, relating to manufacturing process, safety etc., on its package inserts and cartons.

4. The respondent nos.1-3 (Plaintiffs) also, inter alia, prayed for a decree of declaration that the approvals, with regard to clinical protocol trials and for manufacturing and marketing, granted by respondent nos. 4 to the appellants" biosimilar drug, be declared invalid on the ground that adequate tests were not conducted by the appellant, as per provisions prescribed under the Drugs and Cosmetics Act, 1940, as amended (the "D&C Act"), the Drugs and Cosmetics Rules, 1945, as amended (the "D&C Rules"), the Guidelines on Similar Biologies, 2012 (the "Biosimilar Guidelines").

5. The main contention of the plaintiff (respondent nos. 1-3) in the suit is that the appellant (defendant No.3) had not adequately tested its product "TrastuRel" for the indication - HER2+ metastatic breast cancer in accordance with the applicable laws aforementioned in India, for the purpose of obtaining the requisite approvals, and no tests were undertaken for the additional indications - HER2+ early breast cancer, and HER2+ metastatic gastric cancer.

6. The biological drug - having INN name "Trastuzumab" is an innovative drug of Respondent no. 1 - Genentech Inc., a corporation incorporated in the State of Delaware, USA, which is an affiliate of respondent no. 3 - F. Hoffmann-La Roche AG, a joint stock company incorporated under the laws of Switzerland, with its headquarters in Switzerland. It is also the registered proprietor of the trademark HERCEPTIN® worldwide (including India) and markets its biological drug "Trastuzumab" under the brand names HERCEPTIN®, HERCLON? and BICELTIS®.

7. Respondent no. 1 was granted a secondary formulation patent in relation to "Trastuzumab" by the Controller General of Patents, Designs and Trademarks of

India, which was deemed to be effective from May 3, 1999 and which lapsed on May 3, 2013. Respondent no.2 - Roche Products (India) Private Limited, a company incorporated under the Companies Act, 1956, as amended (the "Companies Act"), is an affiliate of respondent No. 3, and is the importer and marketer of innovator molecule "Trastuzumab" in India. The respondent nos.1-3"s (Plaintiffs/ Roche) biological drug "Trastuzumab", is used for the treatment of HER2+ metastatic breast cancer, HER2+ early breast cancer, and HER2+ metastatic gastric cancer (collectively, "Indications").

8. The Appellant"s biosimilar drug, on the other hand, is called "TrastuRel", which is stated to be biosimilar version of the respondent nos. 1-3 (Roche) "Trastuzumab". The appellant obtained approval for research, examination and analysis in relation to the said Biosimilar drug Trastuzumab in 2009. Subsequently on 18.11.2010, the Review Committee for Genetic Manipulation (RCGM) had granted the appellant the license to conduct pre-clinical toxicological studies and directed the appellant to approach respondent no. 4 (DCGI) for conduct of clinical trials on 28.07.2011. Thereafter, on 29th October, 2012, respondent no. 4 after being satisfied with the data so submitted, granted permission to the appellant herein to conduct Phase-III clinical trials. Finally, based on the data so generated from the trials, the permission to manufacture the bio similar drug was granted to the appellant on 2nd June, 2015. The grant of approval for manufacture was followed by the discussions and considerations of the data by the expert committees such as NDAC (New Drug Approval Committee)/ SEC(Subject Expert Committee),Technical Committee and Apex Committee.

9. The aforesaid suit by the respondent (Roche), was filed on account of an imminent threat and apprehension of the launch of the appellant"s purported biosimilar drug, "TrastuRel". The respondents (plaintiffs/ Roche) claim that they became aware of the appellant"s drug after making enquiries and search from the CTRI (Clinical Trial Registry of India) website and the available information gathered from the public domain.

10. The respondent nos. 1-3 (Roche) moved I.A. No. 23041/2015, under Order XXXIX Rule 1 and 2 of the Code of Civil Procedure, 1908 (C.P.C.) before the Ld. Single Judge, seeking grant of ad-interim injunction to restrain the Appellant from manufacturing and marketing their biosimilar drug as "Trastuzumab" on the ground of inadequate testing as prescribed under the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules 1945 as amended and the Guidelines on Similar Biologics, 2012. While on the other hand, the appellant moved I.A. No. 25289/2015 seeking leave to file documents in a sealed cover.

11. The suit was listed on 02.11.2015 along with I.A no. 23041/2015. A limited order restraining the appellant from launching its product was passed vide order dated 02.11.2015 by the Ld. Single Judge in the suit, which came to be challenged before a Division Bench of this Court in FAO (OS) 625/2015. This appeal was disposed of vide order dated 18.01.2016, by observing that since

arguments were heard and orders were reserved by the Ld. Single Judge in the aforementioned I.A.s on 13.01.2016, it would be futile to continue with the appeal. Thereafter, the impugned order came to be passed on 25.04.2016.

12. The case of the respondents (plaintiffs/ Roche) was that the appellant"s drug "TrastuRel" could not establish biosimilarity at each stage of product development and testing, specifically in product characterization, pre-clinical (i.e., animal) trials and clinical (i.e., human) trials, due to non testing of the same as mandated under the D&C Rules and the Biosimilar Guidelines. It was further contended that the defendant no. 3 (appellant herein) also failed to fulfill the safety criteria mandated under the aforesaid rules and guidelines, as adequate data to establish safety, efficacy and immunogenicity had not been generated. Thus, appellant"s could not claim their drug to be biosimilar for any of the indications.

13. Further, the respondents (plaintiffs/ Roche) claimed that the appellant"s could not claim their drug to be biosimilar, much less use the data and information relating to the sales and therapeutic benefits of the respondent's "Trastuzumab" (sold under the brand name HERCEPTIN®, HERCLON? and BICELITIS®), in their package insert and cartons, in relation to any of the indications, since the approval of carton and package insert was still pending, and usage of such would not only amount to infringement of the respondents (plaintiffs/ Roche) copyright in the package inserts, but also amount to misrepresentation, which may deceive medical doctors and the public at large, and that through such misrepresentations, the appellant would take unfair advantage of the reputation and goodwill enjoyed by the respondents (plaintiffs/ Roche), without having undertaken the appropriate tests under the D&C Act, the D&C Rules, the Biosimilar Guidelines and other applicable laws.

14. The respondent no.4 (DCGI), appeared as defendant no.1 in the suit and defended their actions. DCGI stated that all necessary tests to establish efficacy, safety and comparability were conducted by the appellant and the same came to be duly approved by the Committee of experts in the field of Oncology, after going through all relevant data submitted by the appellant with regard to its biosimilar drug "TrastuRel".

15. The respondent no. 4 (DCGI) further stated that the suit was not maintainable on account of the fact that the respondent/ plaintiffs in the suit (Roche) were a third party in the entire process of grant of permission to the appellant, and that in terms of Rule 122 DC under the D&C Rules, 1945 - an appeal could be preferred against any order passed by the respondent-DGCI. Thus the plaintiff/respondent (Roche) had not availed of the proper remedial course by filing the suit.

16. Respondent no. 4 (DCGI) further stated that under the D&C Act or Rules, no specific mention of generic or biosimilar drugs is to be found. However, Form 44 in entry (2)(b) of the D&C Rules, prescribe for obtainment of obtainment of

approval or permission by the DGCI, for manufacture of already approved new drugs. Accordingly, the DGCI could grant permission to manufacture drugs already approved.

17. Respondent no. 4 (DCGI) further stated that a manufacturer seeking to manufacture a similar drug could rely upon the data of the innovator drug as available in the public domain, after establishing its safety and efficacy as required under schedule Y of the D&C Rules, titled "REQUIREMENTS AND GUIDELINES FOR PERMISSION TO IMPORT AND/OR MANUFACTURE OF NEW DRUGS FOR SALE OR TO UNDERTAKE

CLINICAL TRIALS'.

18. It was further stated by the respondent no. 4, that when an applicant applies for approval of such a drug in India - which has already been approved outside the country, no specific requirement was mandated in the Rules for the conduct of Phase I or Phase II clinical trial, as apparent on a reading of Appendix IA, titled "DATA REQUIRED TO BE SUBMITTED BY AN APPLICANT FOR GRANT OF PERMISSION TO IMPORT AND/ OR MANUFACTURE A NEW DRUG ALREADY APPROVED IN THE COUNTRY', under Schedule Y of the D&C Rules. The rationale behind it being that the usefulness, efficacy and side effects etc. of the drug - of which the biosimilar drug is produced, are already known.

19. It was further pointed out by the respondent no. 4 (DGCI) that under Appendix IA, which is a specific appendix incorporated for such category of drugs under Schedule Y of the D&C Rules, no necessity is mandated for conducting any trial, if the drug to be manufactured is already approved in the country as defined in Rule 122E - 'New Drug', of the Drugs & Cosmetics Rules, while the requirements and guidelines for permission to Import and /or Manufacture of new drugs for sale, or to undertake clinical trials are specified in Rule 122A, 122B, 122D and Schedule-Y of the Rules. Further the respondent (DGCI) stated that the need for Phase III trials could be waived off, as was done in many cases, as per the provisions of Rule 122(B)(3), which provides that with regard to new drugs already approved by the licensing authority, results of local clinical trials may not be necessary, if the drug is of such a nature that the licensing authority may, in public interest, decide to grant such permission on the basis of data available from other countries.

20. DGCI further stated that under the provisions of Schedule Y (1)(3), for the drugs indicated in life threatening / serious diseases or the diseases of special relevance to the Indian health scenario, the toxicological and clinical data requirement may be abbreviated, deferred or omitted as deemed appropriate by the Licensing Authority as mentioned under Rule 21(b).

21. Further, the DGCI stated that the appellant"s application for manufacture of its drug was in conformity with the statutory requirements as contained in the relevant Rules read with schedule Y of the D&C Rules. Consequently, the application of M/s. Reliance (appellant) was considered and permission to

manufacture and market the drug Trastuzumab injection 150 mg/vial and 440 mg/vial Trastuzumab Bulk was granted on 2nd June, 2015, based on the data and the report of the study submitted, which was conducted in 20 sites across India and after the recommendations for the same were made by the SEC in its meeting held on 7th May, 2015, as per the provisions of Drugs and Cosmetics Rules.

22. The appellant, in defence to the suit had pleaded, firstly, that the respondent"s (plaintiffs/ Roche) patent with regard to its Drug "Trastuzumab" had lapsed in the year 2013. Thus, in view of the same the respondents (plaintiffs/ Roche) had no enforceable right to restrain the appellant from relying on the data of the respondent"s (plaintiffs/ Roche) drug for manufacturing and marketing its biosimilar drug, or question the approvals granted by the respondent no.4 to the appellants biosimilar drug "TrastuRel".

23. Secondly, the appellants also contended that the said suit was not maintainable as, essentially, the suit was but a challenge by the respondents (plaintiffs/ Roche), to the approvals granted by the respondent no. 4 to the appellants drug, and that any grievance in that regard could be raised only by way of filing an appeal under Rule 122DC of the D&C Rules, 1945. Further, all requisite tests, studies and trial were duly undertaken and conducted since 2009, and that the approval with regard to the appellants drug "TrastuRel" was granted after following the regular procedure by various authorities such as the Institutional Bio Safety Committee (IBSC), the Review Committee on Genetic Manipulation (RCGM), The Subject Expert Committee (SEC), and other authorized bodies.

24. Lastly, it was contended that respondent no. 4 was vested with the discretionary power to either abbreviate or omit, conduct of Phase I and II clinical trials under schedule Y and to allow the appellant to rely upon the available clinical trials of the respondents"/ plaintiff"s (Roche) data, which had fallen in the public domain after expiry of its patent rights, and also since the concept of data exclusivity was not recognized in Indian jurisprudence, the respondents could not seek to restrict the appellant from relying on the data of the reference drug (Trastuzumab).

25. The aforesaid interim applications (I.A.) came to be decided vide impugned order dated 25th April 2016, vide which the Ld. Single Judge allowed the I.A. No. 23041/2015 of the respondent 1-3, while disallowing the I.A. no. 25289/2015 moved by the appellant for placing additional documents in a sealed cover. The relevant extract of the decision dated 25.04.2016 reads as under:

"262. I am of the view that the approvals granted to TrastuRel product are not on the basis of the adherence of the Guidelines of 2012 and rules framed under the Drug Act. The final finding in this respect is yet to be arrived after the present suit is heard upon completion of the trial. Pending the final outcome of the suit, there is a need to arrive at interim measure by working out certain terms

between the parties by passing the following directions:

a) The defendant No.3 may launch to manufacture, market and advertise their product under the name TrastuRel on the basis of the approvals already granted to defendant No.3 without calling their product as "bio similar" and/ or "bio similar to HERCEPTIN, HERCLON, BICELTIS" or in any way ascribing any bio-similarity with that of the plaintiffs products HERCEPTIN, HERCLON, BICELTIS in any press releases, public announcements, promotional or other in printed form and from relying upon or referring the plaintiffs' names.

b) The defendant No.3 may also manufacture and market the drug by qualifying the INN name Trastuzumab but not to use the said name stand alone on the carton or package insert as a brand name. The defendant No.3 can use the INN name as Reliance Trastuzumab or TrastuRel wherever applicable to describe the composition of molecule on the product as well as in its insert and not in a prominent manner. The said expression shall be used at the bottom part of the carton and should be in small size letters than the brand name TrastuRel.

c) In view of prima facie findings that the use of the data by the defendant No.3 in the product insert without undergoing the entire process of the trials is misleading, the defendant No.3 is also restrained from using the data relating to manufacturing process, safety, efficacy and tests conducted for the safety of the drugs as complained of by the plaintiffs till the time the final decision on the issue of the bio similarity is made in the present suit.

d) In the event, the defendant No.3 intends to claim bio similar as a description of its product or part of its promotional campaign or otherwise in any other form, the defendant No.3, if so advised, can reapply the said license before the relevant authorities including defendant No.1 and in which case, the defendant No.1, the authorities and committees framed therein shall decide the said approval application in accordance with the Rules and Guidelines of 2012 and also the observations made by this court in the present order. The defendant No.3 shall also be entitled to use the data of the plaintiffs for the comparison purposes before the Regulatory Authority. In the alternative, the defendant No.3 may await the outcome of the present suit and can continue with the present arrangement as an interim measure.

e) This interim measure is made only in view of the peculiar facts in the present case only wherein the defendant No.3 is already in possession of approvals granted rightly or wrongly validity of which is questioned in this suit. In future application for approval(s) of biosimilar shall be decided by the defendant No.1 and authorities and committees while considering the guidelines of 2012 and also the findings arrived at in the present order by this Court as well as strictly as per the provisions of the Act and Rules.

263. The findings made herein above are all tentative in nature and shall have no bearing when the main suit would be decided after trial on merits."

26. On the same day, the learned Single Judge also passed interim orders in CS(OS) 355/2014 preferred by the same plaintiff against, inter alia, (defendant No.2) BIOCON Ltd. and MYLAN INC. (defendant No.4) on similar grounds, who had already launched their Biosimilar Drug, as Trastuzamab. The learned Single Judge passed the following interim order in CS(OS) 355/2014:

"334. I am of the view that the approvals granted to CANMAb and Hertraz (used by Mylan) product are not on the basis of the adherence of the Guidelines of 2012 and rules framed under the Drug Act. The final finding in this respect is yet to be arrived after the present suit is heard upon completion of the trial. Pending the final outcome of the suit, there is a need to arrive at interim measure by working out certain terms between the parties by passing the following directions:

a) The defendants No.2 to 4 may continue to manufacture, market and advertise their product under the name CANMAb or Bmab-200 or Hertraz on the basis of the approvals already granted to defendant No.2 without calling their product as "bio similar" and/ or "bio similar to HERCEPTIN, HERCLON, BICELTIS" or in any way ascribing any bio-similarity with that of the plaintiffs products HERCEPTIN, HERCLON, BICELTIS in any press releases, public announcements, promotional or other in printed form and from relying upon or referring the plaintiffs' names.

b) The defendants No.2 to 4 may also manufacture and market the drug by qualifying the INN name Trastuzumab but not to use the said name stand alone on the carton or package insert as a brand name. The defendants No.2 to 4 can use the INN name as Biocon's Trastuzumab or Mylan's Trastuzumab wherever applicable to describe the composition of molecule on the product as well as in its insert and not in a prominent manner. The said expression shall be used at the bottom part of the carton and should be in small size letters than their respective brand names.

c) In view of prima facie findings that the use of the data by the defendants No.2 to 4 in the product insert without undergoing the entire process of the trials is misleading, the defendants No.2 to 4 are also restrained from using the data relating to manufacturing process, safety, efficacy and tests conducted for the safety of the drugs as complained of by the plaintiffs till the time the final decision on the issue of the bio similarity is made in the present suit.

d) In the event, the defendant No.2 intends to claim bio similar as a description of its product or part of its promotional campaign or otherwise in any other form, the defendant No.2, if so advised, can reapply the said license before the relevant authorities including defendant no. 1 and in which case, the defendant No.1, the authorities and committees framed therein shall decide the said approval application in accordance with the Rules and Guidelines of 2012 and also the observations made by this court in the present order. In the alternative, the defendant No.2 may await the outcome of the present suit and can continue with the present arrangement as an interim measure.

e) This interim measure is made only in view of the peculiar facts in the present

case wherein the defendant No.2 is already in possession of approvals granted rightly or wrongly validity of which is questioned in this suit. All the decisions made by the defendant No.1 and authorities and committees made therein in connection with future approvals shall take into consideration the guidelines of 2012 and also the findings arrived at in the present order by this court." (emphasis supplied)

27. Aggrieved by the said order, FAO (OS) 132/2016 and FAO (OS) 133/2016 were preferred by Biocon and Mylan Inc., respectively. The impugned order dated 25.04.2016 rendered in the aforesaid suit CS(OS) 355/2014 was effectively stayed vide order dated 28.04.2016 in the appeals. The Division Bench directed:

"Meanwhile, the position, as obtained on 24.4.2016 (i.e. prior to the issuance of the impugned judgment dated 25.4.2016), shall continue to operate till the next date of hearing.

The matter shall be taken up for hearing on 10.05.2016. (emphasis supplied)"

28. The stay granted to the appellants BIOCON Ltd. and MYLAN, INC. in the aforesaid appeals was further clarified vide order dated 03.03.2017, and the court had vide the same order granted liberty to the appellants to manufacture "Trastuzumab" under the names of "CANMAb" and "HERTRAZ", and use the approved package inserts marked as "A" by the DCGI, for all the three indications of early breast cancer, metastatic breast cancer, and metastatic gastric cancer. The relevant extract from the said order dated 03.03.2017 reads as follows:

"In two of the remaining appeals, i.e., FAO(OS) Nos. 132/2016 and 133/2016, this court had already passed an order, while issuing notice in these appeals, that in the meanwhile, the position as obtaining on 24.04.2016 (i.e., prior to the issuance of the impugned judgment dated 25.04.2016), shall continue to operate till the next date of hearing. To be clear, this meant that the directions given in the impugned judgment dated 25.04.2016 would not operate till the next date of hearing.

However, prior directions had been given with regard to the use of the insert in the packaging for the product of Biocon (CANMAb) and Mylan (HERTRAZ) in respect of the second and third indications.

It is an admitted position that at this interim stage there is no restraint on the production or sale of Trastuzumab by Biocon or Mylan which are to be marketed as CANMAb and HERTRAZ. It is also an admitted position that there is no restraint vis-à-vis the first indication (Metastatic Breast Cancer) even insofar as the insert is concerned." (emphasis supplied)

29. After the passing of the impugned order dated 25.04.2016, the appellant launched its Biosimilar Drug TrastuRel on 10.05.2016.

30. Aggrieved by the aforesaid order passed in CS(OS) 3284/2015, the appellant

has preferred the present appeal.

31. In the present appeal, notice was issued on 03.06.2016; and matter was further adjourned on different dates. Finally, vide order dated 03.12.2018, the Division Bench had fixed the hearing for 13th, 14th and 15th February, 2019.

32. When the matter came up on 13.02.2019, this Court had directed the appeal and the other connected appeals i.e. FAO(OS) 132/2016 preferred by BIOCON Ltd., FAO(OS) 133/2016 preferred by MYLAN INC. and FAO(OS) 226/2016 and FAO(OS) 227/2016 preferred by the plaintiffs to be listed for 16.09.2019. Aggrieved by the same, the appellant filed a Special Leave Petition before the Supreme Court for early disposal of the matter. The Supreme Court, vide order dated 08.03.2019, requested this court to expeditiously dispose of the appeal, and, if not the appeal, the interlocutory applications, preferred by both parties, within four months. Vide order dated 11.04.2019 of this court, the matter was pre-poned for hearing to 08.07.2019, and the order on the aforesaid application was reserved on 16.07.2019 for stay of the judgement dated 25.04.2016 during pendency of the appeal.

33. The Respondents Nos.1 to 3/ plaintiffs (Roche) contest the said stay application, and have filed their reply. Essentially, the same pleas are raised by them, as raised in their plaint.

34. Mr. Lall, learned senior counsel for the appellant submits that the appellant is aggrieved by the conditions set out in the order dated 25.04.2016 passed by the Ld. Single Judge, and the imposition of the aforesaid conditions is unjustified.

35. Mr. Lall, firstly, submits that since 2009 - after obtaining permission to conduct studies, tests and trials for the biosimilar drug "TrastuRel", it has obtained all requisite approvals with respect to its product from the appropriate authorities. He submits that on the date of impugned order, the appellant was ready to launch its product in the market on the basis of the approvals granted, but due to the unreasonable conditions set by the learned single judge the launch was delayed.

36. He further submits that launching of its biosimilar product with the required modifications as imposed vide order dated 25.04.2016, caused the appellant to face practical difficulties when applying for government tenders as, under the conditions imposed by the Ld. Single Judge, the appellant was compelled to use the name "Reliance Trastuzumab" or "TrastuRel", which is not acceptable in government tenders/forms. As per the tender conditions, the manufacturer is obliged to indicate the generic name/ International Non-proprietary Name (INN) - "Trastuzumab", without the name of the company such as "Reliance", before it. He submits that such a condition of inserting a qualifier - "Reliance" before the INN, is contrary not only to trademark law and international practice, but also Rule 96 of the Drug Rules (amended).

The said rule is extracted hereunder:

"96. Manner of Labelling.-

(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:-

(i) The name of the drug:

(A)For this purpose, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be.--" (emphasis supplied)

37. Thus, Mr. Lall submits that the conditions imposed by the Ld. Single Judge, are in contravention of Rule 96 of the Drugs and Cosmetics Rules, 1945 as amended. He submits that as per sub-rule (1) clause (i) (A) of Rule 96, the proper name of the drug "Trastuzumab" is to be printed or written in a more conspicuous manner than the brand name/ trade name "Reliance", and that the trade name "Reliance" is to be shown immediately after, or below the proper drug name. Thus the conditions imposed by the Learned Single Judge vide the impugned order dated 25.04.2016, is but erroneous and in contravention of the Rule.

38. Mr. Lall, further submits that the appellant is entitled to parity in the matter of interim relief granted to the other manufacturers of the same biosimilar drug, viz. BIOCON Ltd. and MYLAN, INC. who are defendants in similar suit, C.S. (O.S.) 355/2014. Near identical restrictions were imposed by the ld. Single Judge on Biocon Limited and Mylan Inc. (defendants 2 and 4 therein) for their biosimilar product for "Trastuzumab" vide order dated 25.04.2016. The said decision was effectively stayed in F.A.O.(O.S.) 132/2016 and F.A.O. (O.S.) 133/2016, preferred by the said defendants/ appellants, Biocon Limited and Mylan, Inc., respectively, vide orders dated 28.04.2016. Further the said order was clarified vide order dated 03.03.2017, as taken note of hereinabove.

39. Mr. Lall further submits that the appellant, like the other two manufacturers of biosimilar Trastuzumab viz. Biocon Limited and Mylan, Inc., had extrapolated data from the tests conducted by respondent (Roche), for the 1st indication (Metastatic breast Cancer), for obtaining approvals as specified under the Biosimilar Guidelines, 2012. He submits that the appellant"s drug "TrastuRel" has been in the market for the last three years as on date, while the other two appellants/ defendants Biocon and Mylan have had their product for the last five years. Thus, the appellant should not be deprived of similar relief. The only reason that the Division Bench did not pass a similar order in the appeal of the appellant - as passed by the Division Bench in the appeals of Biocon and Mylan,

was that the appellant had not launched its biosimilar drug by the time the interim stay applications in those other connected appeals by Biocon Limited and Mylan Inc., were heard and decided.

40. Learned counsel for Respondent No. 4 - DCGI, has put in appearance and supports the aforesaid submission of Mr. Lall with regard to the mandate of Rule 96 (as amended), and submits that the aforesaid Rule 96 of the D&C Rule (amended) is a condition which is applicable not only to future approvals, but also with regard to past approvals.

41. On the other hand, Mr. Darpan Wadhwa, learned senior counsel for respondent nos. 1-3 (Roche), firstly submits that the interim relief sought by the appellant is mainly premised on the ground that it is facing difficulty in obtaining government tenders due to the conditions imposed by the order of the Ld. Single Judge. He submits that this is not true, since the appellant has been allowed to participate in government tenders, despite the conditions imposed by the learned Single Judge. He submits that there is no such predicament being faced by the appellant in obtaining tenders, and has tendered a chart disclosing the tenders awarded to the appellant by various state governments for their purported biosimilar drug "TrastuRel" for the years 2016 - 2019.

42. Mr Wadhwa, further submits that the appellant had violated the D&C Rules, as it had launched its drug on 10.05.2016, without the prior approval of the respondent no. 4 - DGCI, which is apparent from the appellant"s letter dated 12.05.2016, seeking approval for the revised package insert, and that the final approval of which has also not been placed on record in the present appeals by the appellant. He submits that under Schedule Y paragraph 1 (1) (vi) of the D&C Rules, changes in the package insert can be effected only after such changes are approved by the Licensing Authority. Paragraph 8 of form 46 of the D&C Rules, prescribes as under:

"(8) 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 drug is marketed"

43. Mr Wadhwa further submits that under the Biosimilar Guidelines, a similar biologic/ biological drug "must have established comparability with the reference drug" and the same can only be proved when the same is tested at each stage of product development and testing with the innovator drug as mandated under the Drugs Act and Rules. Thus, the appellant was rightly restrained vide the impugned order.

44. Mr. Wadhwa submits that under paragraph 7.2 and 7.3 of the Biosimilar Guidelines, a mandatory comparative pre clinical trial is to be conducted, which comprises of: (a) animal toxicology, (b) animal pharmacology and (c) study of immune responses in animals. Further this is also mandated under Rule 122 B and also under paragraph 1(1) (ii) and (iii) of Schedule Y of the D&C Rules. Learned senior counsel submits that only animal toxicology studies were

conducted for the indication of Metastatic Breast Cancer, while animal pharmacology studies were not conducted as per Rules by the appellant. Further, the animals on which the appellant had conducted the preclinical studies, were of a different species as compared to the respondents "Trastuzumab", thus, in contravention of the biosimilar guidelines as animal trials for a purported biosimilar must be conducted on the same species as conducted by the innovator drug.

45. Learned senior counsel further submits that despite the mandatory condition, for which no exemption can be granted, under Rule 122 DA read with paragraph 1(1)(iv)(a), 1(1)(iv)(c) and 2(6) to 2(8) of Schedule Y of the D&C Rules, requiring conduct of all three clinical trials in a sequential manner, i.e. Phases I, II and III, for a "new drug" as defined under Rule 122 E of the D&C Rules, the appellants have not conducted Phases I and II trials. Further, as mandated under Rule 122 DA read with paragraph 2(8) of Schedule Y of the D&C Rules safety, efficacy and immunogenicity studies were required to be conducted by the appellant, but the appellant has failed to conduct any of these studies.

46. Mr. Wadhwa further submits that the approval for conduct of Phase III clinical trials by the DGCI on 29.10.2012, was wrongly granted by the DGCI, which is apparent from the fact that the DGCI had suo moto sought justification from the appellants, as to why Phase I and II trials were not conducted. Further as mandated under Rule 122 DAC (b) of the D&C Rules, prior approval had to be sought by the appellant from all Ethics committees for conduct of Phase III trials, but in the present case, such approval was granted - that too by certain committees, only after the initiation of the clinical trials on 16.05.2013.

47. Mr. Wadhwa further submits that the appellant was granted no waiver by the DGCI from conducting Phases I and II of the clinical trials and no waiver was sought by the appellant. Learned senior counsel submits that, on this aspect, the Ld. Single Judge has prima facie held that the approvals granted were in contravention of the aforesaid D&C Act and D&C Rules, due to the fact that Phase I and II clinical trials, in relation to the appellant"s alleged biosimilar Drug "TrastuRel", have not been got conducted for the additional indications of metastatic early breast cancer, and metastatic gastric cancer, while only one phase of clinical trial was conducted for the indication of metastatic breast cancer.

48. Learned senior counsel further submits that the Phase III human clinical trials conducted by the appellant were also inadequate, as only a preliminary evaluation of efficacy was carried out by the appellant, which is grossly insufficient. Further, the sample size of 105 patients, out of which only 84 patients were tested, and only 53 completed the evaluation phase of the study, was not in accordance with the paragraph 8.3 of the Biosimilar Guidelines and paragraph 1 (iv) (c) of Schedule Y of the D&C Rules which provides that the sample sizes should have a statistical rationale. Further, as per the Good Clinical Practices Guidelines (GCP Guidelines), which requires that for new drugs discovered in India and not marketed in any other country, Phase III trials should

be obtained on atleast 500 patients.

49. Mr. Wadhwa also points out that a biosimilar drug - though is permitted to use the INN, same cannot be for drugs not adequately tested. For such usage, there is no inherent right to freely copy and rely on the data of the innovators drug. It also contended that the condition 'b' set in paragraph 262 of the impugned order, was not erroneous, as the WHO (World Health Organization) in its guidelines and resolutions finalized in 2015, has approved addition of biological qualifiers so as to differentiate the innovator and the biosimilar drug, the practice of which is being followed by the US FDA, which has concluded that an INN would be followed by a proprietary placeholder, like in the case of "filgrastim-sndz". The INN being "filgrastim", while the suffix qualifier/ placeholder being "sndz" (Sandoz).

50. Learned senior counsel for the respondents/ Plaintiffs lastly contends that granting the interim relief to the appellants would disturb the status quo that has operated for the last three years.

51. We have heard learned counsels and considered their respective submissions. The submissions made on behalf of the parties are being examined in the context of the appellant"s application for stay of the impugned order.

52. It is firstly noted that in the suit filed against Biocon and Mylan Inc., in CS (OS) 355/2014, by Roche/ Plaintiff, identical allegation about the alleged non-compliance of the Statutory Rules by the Defendants Biocon and Mylan have been made, prior to their launching their respective Biosimilar Drugs, of which the respondent/ Plaintiff is the innovator viz. Trastuzumab. Allegations of the said manufacturers not conducting the requisite trials have been made, like in the present suit against the appellant. The approvals granted to Biocon and Mylan by the respondent Authorities have been challenged, as in the present suit. The stand taken by the Defendants in that suit - including the statutory authorities, is also similar. Pertinently, the DCGI has defended its grant of permissions/ approvals to Biocon and Mylan, as it has defended its decision to grant approval to the appellant Reliance for its Biosimilar Drug TrastuRel. Near identical conditions were imposed by the Ld. Single Judge vide order dated 25.04.2016 on the defendants 2 and 4 (Biocon and Mylan Inc.) therein, as set out hereinabove.

53. Though the said appeals preferred by BIOCON Ltd. and MYLAN Inc. are pending before this Court and are scheduled for hearing on 11.02.2020, along with other connected matters, the stay granted in their favour has not been disturbed ever since, and has continued to operate. Thus, we do not see any reason as to why similar relief should not be granted to the appellants (Reliance) herein, until then. The appellant Reliance is similarly placed - if not identically placed, as Biocon and Mylan. The appellant is entitled to parity in the matter of treatment qua the interim relief. This aspect was also noticed by the Learned Single Judge in its order dated 25.04.2016, wherein it had observed as under:

"16. It is a matter of fact that most of the issues involved in the present case are

similar with the facts in the suit, being CS(OS) No.355/2014, wherein the injunctions applications and other applications were heard at earlier point of time. Thus, I consider appropriate to decide the pending applications in both the matters together.

17. Both parties have made their respective submissions on the basis of pleadings and documents produced. They have also filed the written submissions. The submissions of both parties on legal issues, reliance of decisions same as in earlier suit, being CS(OS) No.355/2014." (emphasis supplied)

54. Further, this court had found, while passing the order dated 28.07.2016, that the present appeal is identical to the appeal preferred by BIOCON Ltd. i.e, FAO (OS) 132/2016. The order dated 28.07.2016 in the current appeal no. FAO (OS) 181/2016, reads as under:

"This appeal raises virtually identical issues as raised in FAO(OS) 132/2016, which is listed before the Bench comprising of Badar Durrez Ahmed and Sanjeev Sachdeva, JJ. That matter is listed before the said Bench on 29.07.2016.

Accordingly, this appeal be listed along with that appeal, subject to orders to Hon'ble the Chief Justice and be listed before the said Bench tomorrow."

55. Pertinently, the respondent/ Plaintiff had not contested this position, and has not been able to point out any material difference in the case of the appellant, to warrant a harsher interim arrangement when compared to the cases of Biocon and Mylan. Thus, denying parity to the appellant with the connected matters - wherein interim relief was granted vide order dated 28.04.2016, and clarified on 03.03.2017 would be unjustified.

56. Further, on a perusal of Rule 96 of the D&C Rules (amended), we find that the condition 'b' set in the impugned order in CS (OS) 3284/2015, prima facie, is in contravention of the same. The said Rule prescribes the manner of labeling of drugs as set in clause (i) (A) of sub rule (1) of the same, which categorically prescribes that "the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be.--". Learned counsel for Respondent no. 4 (DCGI) also states that placing of a qualifier before an INN could not have been mandated, as the same would be contrary to the aforesaid Rule. Thus, we cannot accept the submission of Mr. Wadhwa, who has relied on the WHO guidelines of 2015, and the practice followed in the United States, as the said Rule is statutory and binding on all concerned.

57. Since the respondent authorities have granted their approval to the

appellants Biosimilar Drug, prima facie, it cannot be said that the said approval is illegal. Pertinently, the learned Single Judge did not completely injunct the appellant from manufacturing or marketing their Biosimilar Drug. If the learned Single Judge would have been convinced and if he had found that the approval granted to the appellant by the DCGI was bad, he would have completely injucted the appellant - which is not the case. The learned Single Judge has himself observed that at this stage it cannot be determined whether the appellant has conducted the requisite trials as are prescribed for a Bio Similar Drug. Thus, the approval granted by the competent authority i.e. DCGI could not be injuncted as an interim measure, as that would tantamount to virtually decreeing the suit. The locus standi of the respondent/ Plaintiff in filing the suit is also an issue, which would need determination in the suit. Pertinently, the Patent granted in favour of the Plaintiff has expired. The submission of the appellant that the suit is actuated by malice -with the object of stifling competition, needs serious consideration. There is no purpose to be achieved in creating unnecessary and meaningless obstacles in the conduct of its business by the appellant. Even according to the respondent/ plaintiff, the appellant is manufacturing and marketing its biosimilar drug for over three years. Thus, we find the objection of the respondent/ plaintiff to grant of similar interim relief to the appellant, as is operating in the appeals of Biocon and Mylan, to be completely unjustified.

58. The submissions of Mr. Wadhwa in opposition to this application revolve around the merits of the case which, as aforesaid, even the learned Single Judge has not yet determined. In any event, examination of those submissions would have to await the final hearing of the present and the connected appeals.

59. In view of the aforesaid, we allow the application of the appellant and grant interim stay of the impugned order dated 25.04.2016, passed in CS (OS) 3284/2015, in terms of the orders dated 28.04.2016 and as classified vide order dated 03.03.2017 in FAO(OS) 132/2016 and FAO(OS) 133/2016.

60. The application stands disposed of in the above terms.

C.M. APPL. 6363/2017

This is an application moved by the appellant to seek early hearing of C.M. No. 22510/2016. Since we have heard the said application, the said relief does not survive. The other two reliefs sought in the application would be considered at the appropriate stage and do not call for consideration at this stage.

The application stands disposed of.

FAO (OS) 181/2016

List on 11.02.2020.

