2019 INSC 1391

[REPORTABLE]

IN THE SUPREME COURT OF INDIA
CIVIL APPELLATE JURISDICTION

CIVIL APPEAL NO. 9491 OF 2019
(Arising out of SLP(C) No.24727 of 2019)

M/s Genentech Inc. & Ors. Appellant(s)

Versus

Drug Controller General of India & Ors. Respondent(s)

J U D G M E N T

Hrishikesh Roy, J.

Leave granted.

2. This appeal has been preferred against the interim order dated 18.09.2019 passed by the Division Bench of High Court of Delhi in C.M. Application No. 22510/2016 in FAO (O.S) No.181/2016. Under the impugned order, the Division Bench allowed the application filed by respondent No.3-M/s Reliance Life Sciences Pvt. Ltd.[1]. The CS(OS) No.

[1] Defendant no.3 in O.S No.181/2016

3284/2015[2] before the High Court of Delhi was filed by appellant no.1-M/s Genentech Inc. together with appellant nos. 2 and 3 namely Roche Products (India) Pvt. Ltd. and F. Hoffmann-La Roche, AG[3] respectively.

3. Plaintiff no.1- M/s Genentech Inc. claimed themselves to be the innovators of the monoclonal antibody drug 'Trastuzumab' which is manufactured by the plaintiff no.3- F. Hoffmann-La Roche and is being marketed in India by plaintiff no.2- Roche Products (India) Pvt. Ltd. under the brand name HERCEPTIN, HERCLON and BICELTIS. The drug 'Trastuzumab' is approved globally for treatment of cancer. The suit before the Delhi High Court came to be filed seeking to *inter alia* restrain respondent No.3-M/s Reliance Life Sciences Pvt. Ltd. from launching, marketing or selling 'TrastuRel', the biosimilar version of the appellants drug 'Trastuzumab'. In the suit, the approval granted by respondent no.1-Drugs Controller General of India[4] to M/s. Reliance Life Sciences Pvt. Ltd. for the manufacture and marketing 'TrastuRel', was also challenged. The suit was filed at a stage when respondent no.3 was yet to introduce their drug in the market. The appellants had obtained patent for the drug 'Trastuzumab' but the same had lapsed on

[2] Reliance Suit

[3] Plaintiffs in O.S. No. 181/2016

[4] DCGI

3.5.2013 but they sought to restraint respondent no.3 from representing their product 'TrastuRel', as biosimilar to 'Trastuzumab'

4. According to the appellants, the biosimilar product in India to be launched by respondent no.3, has not been tested as a biosimilar drug in accordance with the law under the Drugs and Cosmetics Act, 1940[5] and other applicable norms and guidelines with the projection that the respondent no.3 has not undertaken requisite chemical trials and has not also generated adequate data to establish, *inter alia,* the safety, efficacy and immunogenicity of the drug-'TrastuRel', manufactured by respondent no.3.

5. Respondent no.3, however, contended that the appellants have no enforceable right in the drug 'Trastuzumab' as the patent right with respect to the drug, available with the appellants had lapsed in 2013. Therefore, any other intending manufacturer could rely upon the appellant's data relating to Phase I and Phase II trials, as available in public domain.

6. Prior to the Reliance suit filed against respondent no.3, the appellants had filed the suit being CS (OS) No. 355/2014 against F. Hoffmann-La Roche, AG, their associate Mylan Inc, seeking similar

[5] The Act

restraint against purported biosimilar version of the appellants drug, “Trastuzumab”. Biocon and Mylan were however already in the market by selling their products “Trastuzumab’ - ‘CANMab’ and ‘Trastuzumab’-‘HERTRAZ’ in the market.

7. The High Court of Delhi passed respective orders on 5.12.2014,14.2.2014 and 28.02.2014 in the Biocon’s suit and permitted Biocon and Mylan to market their drugs subject to the conditions that they would not claim bio similarity with the appellants’ product HERCEPTIN, HERCLON and BICELTIS. However, in the Reliance suit, the learned Single Judge was of the *prima facie* view that the approval by the DCGI for the biosimilar drug of respondent no.3, was far more egregious than in the case of the drug marketed by Biocon. Accordingly, an interim order was passed on 2.11.2015 in the Reliance suit whereby respondent no.3 was restrained from launching and selling their product ‘TrastuRel’ in India, until the next date of hearing. In the Biocon and the Reliance suits, the appellants had claimed that the biosimilar version of the appellants ‘Trastuzumab’, were being launched without the required test and studies under the applicable laws requiring conducting of tests and obtaining of appropriate approval from the regulatory authority including the DCGI. The appellants’ injunction application was ordered

by the learned Single Judge on 25.04.2016. The Court recorded the *prima facie* finding that 'TrastuRel was approved by the DCGI under applicable law. The learned Single Judge observed that the approvals granted to 'TrastuRel' product are not on the basis of the adherence of the Guidelines 2012 and rules framed under the Drug Act. However, it was observed that the final finding in this respect is yet to be arrived after the suit is heard and completion of the trial. Accordingly, while permitting respondent no.3 to launch and market 'TrastuRel' on the basis of the approval from the DCGI, certain conditions were imposed by the learned Judge to safeguard public health and safety as also to protect the innovator of the biosimilar drug 'Trastuzumab'. The relevant stipulations of the learned Single Judge are noted as follows:

> "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 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 re-apply 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."

8. In a separate order, also dated 25.04.2016 in the Biocon suit, the learned Single Judge imposed similar conditions as those on respondent no.3.

9. Aggrieved by such restriction, Biocon and Mylan approached the Division Bench of the High Court. Likewise, the appellants filed appeal FAO (OS) No. 227 of 2016. Respondent no.3 filed appeal (FAO(OS) No. 181/2016) against the interim order dated 25.4.2016. The Division Bench noted that Biocon and Mylan has been in the market for almost two years and accordingly permitted them to continue to market 'CANMab' and 'HERTRAZ' without complying with the additional directions set forth in the order dated 28.06.2016.

10. In the appeals filed by respondent no.3 and in their challenge to the Single Judge order of 25.04.2016, the Division Bench had not granted any interim relief to respondent no.3 until the recent impugned order (18.9.2019); The respondent no.3 accordingly filed SLP(C) No.6203/2019 in this Court.

11. The earlier SLP(C) No.6203/2019 was disposed of by this Court on 8.3.2019 with a request to the High Court of Delhi to simultaneously take up the appeals preferred by the contesting parties at an early date and dispose of the same as expeditiously as possible preferably within four months. In case, the appeals are not heard and disposed of within the stipulated time frame, the High Court was requested to take up the interlocutory application(s) filed by both appellant and Respondent No. 3. The order passed by this Court on 8.3.2019 related to the FAO (OS) No.181/2016 and FAO (OS) No.227/2016.

12. The Division Bench of the High Court thereafter considered the FAO (OS) No.181/2016 and the C.M. Appln. No.22510/2016 filed by respondent no.3 against the interim order passed by the learned Single Judge on 25.04.2016 whereunder, respondent no.3 was permitted to launch and market their product 'TrastuRel' without projecting the same

as biosimilar to the appellants' drugs HERCEPTIN, HERCLON and BICELTIS. Under the impugned order dated 18.9.2019, the Division Bench allowed the application of respondent no. 3 and granted interim stay of the learned Single Judge order dated 25.04.2016 in terms of the orders dated 28.4.2016 and as clarified vide order dated 3.3.2017, in the FAO (OS) Nos.132/2016 and 133/2016, filed by Biocon and Mylan. The Court justified the interim order by observing that the regulatory authorities have granted their approval to the biosimilar drug of respondent no.3 and *prima facie* the said approval cannot be considered to be illegal. But it was not possible to determine at that stage, whether respondent no.3 has conducted the requisite trials as are prescribed for a bio similar drug. The Division Bench held that in the face of the expiry of the patent in favour of the plaintiff, their *locus standi* to file the suit was considered to be relevant issue to be determined and the possibility of the suit being filed with the objective of stifling competition was taken into account and accordingly relief was granted to respondent no.3 in marketing their product 'TrastuRel' on the same terms, as was granted to Biocon and Mylan.

13.1 Assailing the impugned order of the Division Bench of the High Court, Mr. Shyam Divan, learned Senior Counsel appearing on behalf of

the appellants contends that the Division Bench failed to comply with the express directions contained in this Court's order dated 8.3.2019 in the SLP(C) No. 6203 of 2019 whereby this Court had expressly directed that the respective appeals and/or interim applications filed by the appellants and respondent No. 3 be heard analogously and disposed of. According to the appellants' counsel, the Division Bench however considered only the application of respondent No. 3 on merit, without simultaneously entertaining the appellants' application.

13.2. On the claim for parity for the drug 'TrastuRel', with the biosimilar drug produced and marketed by Biocon and Mylan, Mr. Divan submits that the DCGI itself did not consider the drug of respondent no. 3 to be entitled to be treated at par with the product of Biocon and Mylan. But this vital fact was ignored by the Division Bench in allowing parity of operation to Reliance, with Biocon and Mylan.

13.3 The appellants then project that the Reliance has been successful in participating in government tenders with their drug 'TrastuRel' and therefore, the conditions imposed by the learned Single Judge on 25.4.2016, should not have been interdicted without the final decision in the Reliance suit, pending before the Court instead the appeal filed by

appellant ought to have been considered, allowed and absolute injunction should have been granted.

13.4 According to Mr. Divan the issue of International Non-Proprietary Name (“INN”) goes to the very root of the dispute between the parties. He contends that Reliance is not entitled to use the INN, since their drug has been approved without undergoing the required testing, prescribed under the Act, the Rules and the 2012 Guidelines.

13.5 Referring to the consideration made by the learned Single Judge in the Reliance Suit in disallowing parity to the drug ‘TrastuRel’ manufactured by the respondent No. 3, the appellants’ counsel submits that the DCGI too had admitted that the Reliance did not conduct Phase-I and II of the mandatory three phase sequential clinical trials and that Reliance has misappropriated and reproduced the appellants’ data in their test dossiers and marketing material and therefore the possibility of jeopardising public safety was considered by the learned Single Judge in stipulating certain conditions to allow marketing of the drug ‘TrastuRel’, manufactured by Reliance. The learned Senior Counsel emphasizes that the direction issued to Reliance to add qualifier to the word ‘Trastuzumab’ was to avoid jeopardising the health and safety of

the patients and also to distinguish the Reliance's drug from that of the innovator.

14.1 On the other hand, Mr. Sajan Poovayya, learned Senior Counsel submits that the Division Bench while passing the impugned order had considered elaborate arguments advanced by the counsel representing the appellants and all their contentions were duly considered and therefore, there was adequate compliance with this Court's order dated 8.3.2019 in SLP(C) No. 6203 of 2019. According to the respondent no. 3, the Division Bench was conscious of this Court's order and therefore, dealt with the submissions of the appellants as can be seen from paragraphs 41 to 50 in the impugned order. The learned Senior Counsel would therefore argue that the impugned order of the Division Bench cannot be said to be in violation of the direction issued for analogous consideration of the appeals and interim applications, of the rival parties.

14.2 The learned Senior Counsel submits that the appellants' patent right on the product 'Trastuzumab' has lapsed in 2013 and therefore, in the Reliance's suit, the conditions imposed by the learned Single Judge on 25.4.2016 should not be allowed to continue to the prejudice of respondent No. 3.

14.3 Mr. Poovayya submits that respondent No. 3 has faced considerable difficulties in participating in tenders where the required product is described in its generic name ‘Trastuzumab’ and therefore, despite being identically placed with other Indian manufacturers like Biocon, Mylan, Zydus, the respondent No. 3 is unfairly restricted to market their bio similar drug.

14.4 Respondent No. 3 next contends that the condition imposed by the learned Single Judge on the packaging/labelling on the drug manufactured by the Reliance is contrary to Rule 96 of the Drugs and Cosmetic Rules, 1945 and accordingly, he argues that the Division Bench order which allows respondent No. 3 to manufacture and market their bio similar product with the labelling direction given in the Reliance’s suit, would not enable respondent No. 3 to conform to the statutory rules.

14.5 Questioning the timing of the Reliance suit, Mr. Poovayya submits that the suit was filed by the appellants just when Reliance was ready to launch their product after obtaining all requisite approvals including manufacturing and marketing authorisation granted by the Subject Expert Committee (Oncology and Hematology) as also the approval granted by the DCGI for manufacturing ‘Trastuzumab’, under Form No.

46 and 46A of the Act. It was submitted that the package insert, the carton package were duly approved by the Subject Expert Committee, but on account of the interim order passed by the learned Single Judge on 25.4.2016, the respondent No. 3 had to revise their packaging and package insert to the extent that the INN name 'Trastuzumab' was to be qualified with the company's name.

15. The learned counsel appearing for Union of India makes no specific submissions in the appeal but only submitted that DCGI has granted the approval to respondent No. 3.

16. Before we consider the rival contentions, at the outset it is noted that the Reliance suit is now pending for final disposal in the High Court. In the detailed interim order recorded on 25.04.2016, the submissions of the learned ASG to the effect that the clinical trials of Phase I and Phase II for the drug manufactured by respondent no.3, are not registered with the DCGI but approvals were accorded on the basis of the justification given by respondent no.3 was noted by the court. Whether the injunction suit filed by the appellants is an abuse of the process of law and whether the approval was granted to the similar drug manufactured by respondent no.3, without following 2012 Guidelines was also borne in

mind. The possibility of the attempt by the defendants to pass off their drug as biosimilar product ‘Trastuzumab’, marketed by the appellants was thought out. After careful consideration of all those aspects including the projection from the DCGI, the learned Single Judge felt that the process of obtaining approval was flawed due to non-adherence to the statutory provisions of the Act and the Rules as also of the 2012 Guidelines. Then reflection was made on the protective conditions which can be imposed for allowing respondent no.3 to launch their product. Upon due assessment, the interim order dated 25.04.2016 was then passed.

17. As permitted by the interim order dated 25.4.2016, the respondent no.3 launched their bio similar product ‘TrastuRel’ and they have been in the market with their drug for the last about three and a half years. They have also participated in Government tenders and when certain doubts were raised on whether the drug ‘TrastuRel’ is biosimilar with ‘Trastuzumab’, the High Court had intervened in favour of respondent no.3, in separate proceeding. However, while the interim order passed by the learned Single Judge did not stop the marketing of the drug ‘TrastuRel’, the Division Bench even while adverting to the concern raised by the learned Single Judge on the issues, which are to be

determined when the suit is finally decided, allowed respondent no.3 the parity of operation with Biocon and Mylan. The Division Bench felt that respondent no.3 is on similar footing as Biocon and Mylan and therefore parity in marketing of their respective biosimilar product can be allowed.

18. In their challenge to the impugned order, the appellants have contended that in passing the impugned order, the Division Bench had failed to simultaneously consider and dispose of the pending appeals and the interim applications filed by the plaintiffs. We had earlier referred to the order passed by this Court on 8.3.2019 in SLP (C) No.6203/2019 which required the High Court to simultaneously take up the appeals and the interim applications filed by both sides. Although some of the contentions raised by the appellants counsel were taken into consideration, those submissions were examined by the Division Bench only in the context of the application filed by respondent no.3. On this aspect, the learned senior counsel for respondent no.3 submitted that non mentioning of the FAO and the IA of the appellants was an inadvertent omission. However such submission, in the face of the specific observation made by the Division Bench in paragraph 51 of the impugned order, cannot be accepted by us.

19. When the impugned order of the Division Bench is read in the context of the express direction of this Court, it is clearly discernible that the Division Bench had only considered the appeal and application filed by Reliance on merit that is FAO(OS) No. 227/2016 and C.M. Appl. No. 22510/2016; without entertaining the appellants' application. In fact the Bench itself clarified the position in paragraph 51 of the impugned order by stating the following:-

> "……. …….
>
> 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.
>
> …… …… …… …… …… …… ……."

20. The fact that the Division Bench was singularly concerned with taking up the Reliance's interim application is further established from the separate order passed on 16.7.2019 in FAO (OS) No. 132, 133, 226, 227 and 268 of 2016 which directs the applications (including the appeal and the application of the plaintiffs) to be listed on 11.2.2020. By way of a separate order, of the same date i.e. 16.7.2019, the Division Bench reserved orders on Reliance's application. Therefore, it is difficult for us to accept as has been suggested by the learned Senior Counsel for the

respondent no.3 that the segregation of the application of one party by the Division Bench, could be an inadvertent error.

21. In the above context, the Division Bench even without considering the appellants' interim application through their observations in paragraph 57, had clearly shut out any scope for the appellants' application to be heard and in effect, ordered on the application.

22. In the interim order passed by the learned Single Judge on 25.4.2016, the conditions imposed on Reliance's product by the DCGI were taken into account. The said interim order was operating without causing much hindrance and respondent No. 3 was successful in participation in government tenders and supplies, with their drug. Therefore, the contrary submission made by the learned Senior Counsel for respondent no.3 is found to be incorrect.

23. As regards the contention made by Mr. Poorvayya that the condition imposed by the learned Single Judge on the packaging/labelling is contrary to the statutory prescriptions, it must be borne in mind that the arrangement ordered by the learned Single Judge has been in operation since 25.04.2016. Therefore without a final decision on the suit on the basis of relevant evidence, the continuing

arrangement in our opinion should not have been disturbed, on this count.

24. The appellants' suit before the Delhi High Court is not a trade mark action nor it is an attempt to enforce the appellants' patent, which admittedly expired in 2013. The suit is an action for extended passing off and to prevent the respondent from using the appellants' data and improper reference to its drug 'Trastuzumab'. Therefore, the expiry of the appellants' patent right on the drug 'Trastuzumab' may not have any direct bearing on the contention raised in the Reliance suit.

25. As regards the submission on the timing of the suit and the other contentions raised on the approval secured from the Subject Expert Committee, these are matters which should appropriately be dealt with when the suit is finally decided. Those need not be factored in at this stage, in support of the impugned interim order.

26. Reverting back to the impugned order, the Division Bench had not only considered the contention raised by the appellants in paragraphs 41 to 50 but then rejected those, in paragraphs 52 to 60 of the same order. In such circumstances, directing the Division Bench to now consider the appellant's appeal FAO No. 227/2016 and CM No. 26902 of 2016 would in our view be nothing but an empty formality, more particularly in the

present appeal when this Court taking note of the order passed by the learned Single Judge imposing conditions and the same being in operation from 25.4.2016 has approved the same to be an appropriate interlocutory order considering the nature of the suit where all other issues are to be considered.

27. Because of the foregoing, and more particularly because the Division Bench did not keep in view the order of this Court dated 8.3.2019 to ensure analogous consideration of the interim applications of both sides in terms of this Court's earlier direction and having regard to the fact that the position prevailing since last three and a half years (pursuant to the learned Single Judge's order dated 25.4.2016) have been upset without considering the issue of balance of convenience, we are persuaded to hold that the Division Bench was in error. Without analogous consideration of the appellant's applications, the Court should not have unsettled the prevailing situation for the last three and half years, without final conclusion of the Reliance suit.

28. In view of the aforesaid, the impugned order is set aside and appeal is allowed. The interim direction given by the learned Single Judge on 25.4.2016 is accordingly made operational. At the same time, as the Reliance's suit is pending since 2016, the High Court is requested

to dispose of the CS (OS) No. 3284/2015 expeditiously and preferably within 12 months of receipt of this order. In the meantime, to avoid prejudice to respondent No. 3, whenever government procurement is proposed for the drug by its generic name 'Trastuzumab', the Reliance should be allowed to participate with their biosimilar product, without any impediment. It is made clear that the views expressed here is only for the purpose of this appeal and should have no bearing in the proceeding pending in the High Court.

29. With the above order, the appeal stands allowed without any order on cost.

……J.
[R.BANUMATHI]

……J.
[A.S.BOPANNA]

……J.
[HRISHIKESH ROY]

NEW DELHI
DECEMBER 17, 2019