(2015) 08 DEL CK 0108

In the Delhi High Court

Case No : I.A. No. 11225/2015 in CS (OS) No. 355 of 2014

Roche Products (India) Pvt. Ltd. and Others — APPELLANT

Vs

Drugs Controller General of India and Others — RESPONDENT

Date of Decision : 13-08-2015

Acts Referred:
Civil Procedure Code, 1908 (CPC) — Order 39 Rule 1, Order 39 Rule 2, Order 6 Rule 17

Citation : (2015) 9 AD 172 : (2015) 234 DLT 43 : (2015) 64 PTC 510

Hon'ble Judges : Manmohan Singh, J

Bench : Single Bench

Advocate : Rajiv Nayar, Sandeep Sethi, Senior Advs., Darpan Wadhwa, Niti Dixit, N. Mahabir, Samiksha Godiyal, Anugrah Robin Frey, Roshni Namboodiry and Tanmay Singh, for the Appellant; Sanjay Jain, ASG, Amit Mahajan, CGSC and Rishi Kant Singh, Advocates for the Resp

Judgement

Manmohan Singh, J.

I.A. No. 11225/2015 U/o Xxxix R.1 & 2 Cpc

1. The plaintiffs have filed the suit for injunction. The said suit was listed before Court along with the interim application on 5th February, 2014. After hearing, the summons in the suit were issued to the defendants for 28th February, 2014 and in the interim application, the defendants No. 2 to 4 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. By order dated 14th February, 2014, the earlier order passed by the Court on 5th February, 2014 was modified to the extent that if defendant No. 2 has already obtained the approval of Package Insert in question, then the defendant

No. 2 is entitled to use the same. However, it was clarified that the remaining interim order already passed would continue. The said order dated 5th February, 2014 was modified for the reason as the statement was made on behalf of defendant No. 2 that on 13th December, 2013 the defendant No. 2 also obtained the approval from the Drugs Controller General of India with regard to the Carton, Labels and Package Insert.

3. The interim applications for vacating the interim order and for rejection of the plaint were heard from time to time. For rejoinder arguments, the same are kept for 13th August, 2015.

4. During pendency of hearing, both parties have filed large numbers of applications, the details of which are mentioned in para 5 of my order dated 6th July, 2015. Out of many, few applications were disposed of in the said order.

5. The hearing of rejoinder arguments on behalf of the plaintiffs was stuck due to subsequent events in the matter when the plaintiffs filed the fresh application being I.A. No. 11224/2015 under Order VI Rule 17 CPC for amendment of the plaint as well as the fresh application being I.A. No. 11225/2015 under Order XXXIX Rules 1 & 2 CPC for passing the interim order.

6. As per order dated 6th July, 2015, the remaining applications were put up for hearing on 13th August, 2015. The operative part of para 45 of my order dated 6th July, 2015 reads as under:-

"45. With regard to interim application sought by the plaintiffs in view of subsequent events, admittedly the approval for additional indications, i.e. early breast cancer and metastatic gastric cancer for specimen of carton, labels and package insert is still sub-judice. Mr. Sanjay Jain, ASG has assured the Court that the request for approval would be considered as per rules and regulations and as per routine procedure and while considering the same, defendant No. 1 will also examine the orders passed by this Court. Under these circumstances, the directions are passed that in case defendant No. 2 gets approval from defendant No. 1 for specimen of the carton, labels and package insert for the proposed additional indications, copy of the same shall be filed along with an affidavit within one week from the date of approval. Under such situation, the defendant No. 2 shall also inform the Court as well as the other side two weeks in advance if after such approval they have any intention to launch the products for the additional indications, i.e. early breast cancer and metastatic gastric cancer. The prayer of the plaintiffs'' application would be considered at that stage."

7. On 6th August, 2015, it was informed by both the sides that the defendants filed appeals against the order dated 6th July, 2015 being FAO (OS) Nos. 425/2015 & 427/2015 and the same came up for hearing before the Division Bench of this Court on 4th August, 2015. The copy of the order was not produced by either of the parties. Mr. Sandeep Sethi, learned Senior counsel appearing on behalf of the plaintiffs had pressed for the prayer made in I.A. No. 11225/2015. Therefore, the plaintiffs filed the application being I.A. No. 15985/2015 for early

hearing as the plaintiffs apprehended that the defendants No. 2 to 4 may launch the drug for two additional indications, i.e. Early Breast Cancer and Metastatic Gastric Cancer for Trastuzumab (hereinafter referred as "Two Additional Indications"), approval of which was granted to defendant No. 2 by defendant No. 1 by letter dated 17th March, 2015 and another approval for the Carton, Labels and Package Insert on 28th July, 2015. Photocopy of the same was also filed in the Registry along with the affidavit of Mr. Vasu Raghavan, Director - Legal of defendant No. 2, dated 5th August, 2015. But defendant No. 2 did not file the specimen/actual Package Insert along with the affidavit. It was shown to the Court at the time of hearing of fresh interim application.

8. In the interim application, it is stated by the plaintiffs that during the course of the hearing of the interim application, the defendants have applied for approval of two additional indications and the apprehension of the plaintiffs is that the defendants may launch the drug for the said two additional indications, if granted, would be contrary to the various provisions of the Drugs Act as well as the Guidelines issued by the Government in the year 2012. Therefore, interim order is sought against the defendants.

9. The application was opposed by the defendants on various grounds. It is stated by the defendants that as far as the approval of the said two additional indications is concerned, the same was granted on 17th March, 2015 as per due procedure under the Act. The defendants for the purpose of approval for extrapolation are not required to conduct any additional pre-clinical or clinical trials, since the approval is only for additional indications for which the plaintiffs'' Trastuzumab has already been approved and the requirements of defendant No. 1 have been duly met.

10. As per the Guidelines on Similar Biologics issued by Central Drugs Standard Control Organization (CDSCO), the defendant No. 2 has met all the conditions for extrapolation, i.e. safety and efficacy data from the Metastatic Breast Cancer indication (for which Phase 3 clinical studies were conducted) to other clinical two additional indications.

11. It is denied by defendant No. 2 that defendants No. 2 to 4 do not appear to have conducted clinical trials on Bmab-200 for the additional indications and that no data is available with defendant No. 2 to be filed with defendant No. 1. It is stated that the defendant No. 2 is not required to conduct any additional pre-clinical or clinical trials for extrapolation or submit fresh clinical data and the same has been justified to the satisfaction of defendant No. 1.

12. It is alleged by the defendants that drug for additional indications is a ''follow-on-drug'' and has been granted approval after establishing bio-similarity in quality, safety and efficacy to the reference drug. Thereafter, upon fulfilment of conditions laid down for extrapolation to other indications for which the reference drug is already approved, the defendant No. 2 has been approved for extrapolation to other indications without having to perform any additional

clinical studies for each indication. The defendant No. 2 has been granted approval for additional indications after obtaining the requisite approvals from the Expert Bodies/defendant No. 1 which has followed an extensive approval process in strict compliance of law and the plaintiffs ought not to be permitted to act as a ''super Regulator''.

13. In reply, it is stated that the approval for the additional two indications, viz. EBC and MGC does not make the Biocons drug (CANMAb) a ''new drug''. The plaintiffs'' HERCEPTIN is an already approved drug for all three indications in India. By way of the present application filed on 5th August, 2015, the plaintiffs seek to challenge the approval for additional indications. The defendant No. 2 proposes to launch its drug CANMAb in the market for the additional two indications (MGC and EBC) by 10th August, 2015. There is no change in the composition of the drug in any manner whatsoever and only the contents of Package Insert would be changed. Approvals for additional indications implies that earlier CANMAb was approved for only one indication i.e. Metastatic Breast Cancer ("MBC") and now it is approved and can be prescribed for other two indications i.e. MGC and EBC, the approval of which has already been granted in March, 2015.

14. Mrs. Pratibha M. Singh, learned Senior counsel appearing on behalf of defendant No. 2 has informed the Court that till the earlier interim applications which are being heard by this Court are decided on merit, the defendant No. 2 shall abide the undertaking given to Court on 14th February, 2014 i.e. the defendant No. 2 shall not use the plaintiffs'' trade mark HERCEPTIN, HERCLON and BICELTIS in any press release or public announcement for its product. Secondly, the defendants if allowed to manufacture and market the other indications, they shall not change the composition/contents of the drug for which earlier approval was granted nor the defendants shall change the Carton, Labels in any manner except the Package Insert, the approval of which is granted on 28th July, 2015 received by the defendant No. 2 on 30th July, 2015 for the purposes of two other indications, the same were approved by defendant No. 1 by letter dated 17th March, 2015.

15. Dr. Abhishek Manu Singhvi, learned Senior counsel, who is also appearing for defendant No. 2, has pointed out para 15 and argues that it was stated by the plaintiffs themselves that in case the approvals are granted under the law and the said Guidelines referred by him, then under those circumstances, they would be taking the necessary steps for cancellation of the said approval and the interim orders are not to be passed.

16. Mr. Singhvi has also referred the written statement filed by the defendant No. 1, i.e. DCGI in which it was stated that defendant No. 2 has been validly granted approvals as the defendant No. 2''s application for manufacture of its drug was in conformance with the statutory requirements as contained in the relevant Rules read with Schedule-Y. There was no deviation from the statutory requirements or that there was any undue haste in dealing with the defendant No. 2''s application

for manufacture of its drug and the defendant No. 1 after considering all relevant aspects, including the opinion of NDAC, granted permission to defendant No. 2 to manufacture Trastuzumab on Form-46 to market Trastuzumab in bulk and its formulation were granted to M/s. Biocon, Bangalore in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

17. On behalf of the plaintiffs, arguments were addressed by Mr. Rajiv Nayar and Mr. Sandeep Sethi, learned Senior counsel. The first contention is that the approval and launch of Canmab for additional indications is in violation of the interim orders. Admittedly defendant No. 2 does not have any independent data for seeking the approval for additional indications. The orders dated 5th February, 2014 and 14th February, 2014 were referred and submit that the defendant No. 2 to 4 were restrained from relying upon data relating to the plaintiffs'' Trastuzumab and from claiming similarity with the plaintiffs'' Trastuzumab, in any manner, including for obtaining approvals from defendant No. 1. The approval and proposed launch for additional indications violates this injunction since such approval was admittedly granted by relying and using the data of plaintiffs'' Herceptin, Herclon and Trastuzumab and proposed to be used on the new Package Insert.

18. The second submission of Mr. Nayar, learned Senior counsel is that no meeting of the Subject Expert Committee was held on 24th February, 2015. The approval for the additional indications was granted by defendant No. 1 to defendant No. 2 pursuant to a letter dated 17th March, 2015. Such approval for additional indications was allegedly granted on the basis of the Subject Expert Committee recommendations dated 24th February, 2015. However, the minutes of the meeting of the Subject Expert Committee claimed to be held on 24th February, 2015 are not available on the website of the Central Drugs Standard Control Organization and no such meeting was held on 24th February, 2015.

19. Mr. Nayar, learned Senior counsel has also referred copy of the acknowledgment, copy of submitted application for protocol amendment, Protocol No.BM200-CT3-001-11, Version 2.02 dated 4th July, 2012 for Bmab-200 (Trastuzumab) (Diary No. 29033, dated 19th July, 2012) and copy of CTRI registration of Bmab 200 Phase III CT:CTRI/2011/08/001958 dated 23rd August, 2011 which are available at page 912-913 where the available details about the public title of study as well as scientific title of study are mentioned. The same reads as under:

20. It is argued by him that when defendant No. 2 himself has filed the application with regard to scientific study pertaining to one indication, i.e. Metastatic Breast Cancer, the same study of other two additional indications cannot be used as the purpose and nature of the ailment of cancer drug are wholly different. Defendant No. 2 ought to have filed a separate/new application in the prescribed manner. It is submitted by Mr. Nayar that in order to take the advantage of pending interim application and without disclosing the fact,

defendant No. 2 has adopted the short route which is not permissible in Drugs Act and Rules.

21. Mr. Sandeep Sethi, learned Senior counsel for the plaintiffs has relied upon the reply filed by defendant No. 2 wherein it was admitted that Bmab-200 has not been tested for the treatment of the additional indications as it is not required as phase III test were conducted for all three indications which includes two additional indications. The plaintiffs'' contention is that such testing is mandatory under applicable law and in the absence of such tests, the launch of Bmab- 200 for the additional indications is illegal and against public health and safety.

The defendants have admittedly pursued applications for approval of Bmab-200 for the additional indications during the pendency of the suit, while deliberately not disclosing these facts before this Court and delaying a determination of the present proceedings (the plaintiffs have argued the matter for 11 hearings while the defendants have taken 24 hearings until now and defendant No. 1 has sought four adjournments in this matter since the date of the application for approval for additional indications).

22. It is submitted on behalf of the plaintiffs that the defendants No. 2 to 4 themselves claim that they are presently conducting clinical trials globally for early breast cancer and gastric cancer. Therefore, data relating to metastatic breast cancer cannot be extrapolated for early breast cancer and metastatic gastric cancer outside India. If such trials are required to be conducted outside India for regulatory approvals, a similar standard should be applied by the defendants for obtaining and granting approvals in India.

23. It is stated by the plaintiffs that the defendants No. 2 to 4 were required to conduct detailed pre-clinical and clinical trials for the approval of Bmab-200 for any new indication under the Drugs and Cosmetics Act, 1940 as amended (the "Drugs Act"), the Drugs and Cosmetics Rules, 1945, as amended (the "Drugs Rules") and the Guidelines on Similar Biologics, 2012 (the "Bio-similar Guidelines"). Under the Drugs Rules, in case of an application for approval for import and/or manufacture of a "new drug", the party is required to conduct detailed pre-clinical and clinical trials. Under Rule 122E(b) of the Drugs Rules, a drug already approved by the DCGI, which is now proposed to be marketed for a new indication, is a "new drug" for the purposes of the Drugs Rules and under the Drugs Rules (Rule 122B) and the Bio-similar Guidelines (paragraph 11), an application for marketing permission has to be filed in Form 44 of the Drugs Rules. In terms of Clause D of Form 44 of the Drugs Rules, in case of an application for approval for a new indication, the party should provide therapeutic justification for the new claim and the data generated on safety or quality parameters. Defendant No. 2 in para 14 has admitted that they have not provided therapeutic justification or data on safety or quality parameters for the additional indications. The defendants have admitted during hearing that they have even not filed Form 44 while seeking marketing approval for additional

indications.

24. The plaintiffs submit that approval for additional indications could not have been granted on the basis of data relating to HER 2+ metastatic breast cancer for the reasons that defendant No. 2 has admittedly tested Bmab-200 only for HER2+ metastatic breast cancer which is an incurable stage of cancer. In many cases, early breast cancer is curable, Bmab-200 has never been tested to ascertain if it can cure cancer. Therefore, Bmab-200 should not have been approved for the additional indications. Patients suffering from HER2+ metastatic breast cancer are immunosuppressed patients whereas in early breast cancer, the patients are not immunosuppressed. According to paragraph 10.7 of the WHO Guidelines, immunogenicity data in immunosuppressed patients (metastatic breast cancer) would not allow extrapolation to an indication in which patients are not immunosuppressed (early breast cancer).

Extrapolation of the clinical data relating to one therapeutic indication to another is not automatic. It must be therapeutically justified with safety and quality data. The use of package insert on first approval is unauthorised as there was no written approval granted by the defendant No. 1 filed by defendant Nos. 2 to 4.

25. It is submitted on behalf of the plaintiffs that the limited reliance on existing test data for approval of a bio-similar drug for a new indication contemplated in para 8.5 of the Bio-similar Guidelines relates to "safety and efficacy data of a particular clinical indication". Safety and efficacy tests are conducted as part of Phase III clinical trials and there is no exemption from conducting pre-clinical and Phase I and Phase II clinical trials for approval for a new indication in case of purported bio-similar drugs. In any event, reliance on existing data is permitted only where bio-similarity for one indication. The plaintiffs have already challenged the approval of HER2+ metastatic breast cancer which is the subject matter in the present suit.

26. It is argued by Mr. Nayar that the Package Insert for the additional indications proposed to be used by defendants No. 2 to 4 is in violation of the interim orders dated 5th February, 2014 and 14th February, 2014 as indicated in the first paragraph of the new Package Insert, almost all the data included in the new Package Insert is data relating to the plaintiffs'' Trastuzumab. The new Package Insert is substantially different from the earlier Package Insert. Further, "the references" included at the end of the new Package Insert are to give a direct and indirect impression of association with the plaintiffs. Defendants No. 2 to 4 have used HERCEPTIN, Roche, HERCLON, Genentech and the plaintiffs'' website. The new Package Insert cannot include the section on "references" in view of the interim orders dated 5th February, 2014 and 14th February, 2014. All the articles are of plaintiffs'' Herceptin.

27. After hearing both the sides, the order in the fresh interim application was reserved. Defendant No. 1 was directed to file the specimen copy of the Package Insert, which is approved by it by letter dated 28th July, 2015, for comparison

purposes by 10th August, 2015. The file was deposited in the Registry on 12th August, 2015. In the meanwhile, it was also directed that till the order is pronounced, defendants No. 2 to 4 shall not launch the product pertaining to the additional two indications.

28. On 11th August, 2015, the matter was mentioned by learned counsel for the plaintiffs after lunch in the presence of all the counsels for the defendants informing that the order dated 6th August, 2015 was challenged by the defendants No. 2 to 4 before the Division Bench who had passed some interim direction. However, the copy of the same was not produced by either of the parties.

29. Having considered the rival submissions of the parties, it is apparent that most of the arguments addressed by the parties in the present application are repetitive in nature and are on merit, which have already been addressed in the pending interim applications where they are at the stage of rejoinder arguments.

30. The present application has been filed after the plaintiffs came to know that defendant No. 2 either has obtained or trying to obtain the approval for two additional indications. The argument of the plaintiffs is that the approval of two additional indications is contrary to the provisions of Guidelines on Similar Biologics issued in 2012 and various provisions of the Drugs Act. As far as the Package Insert is concerned, they submit that the said approval granted on 28th July, 2015 is in violation of the orders dated 5th February, 2014 and 14th February, 2014.

It is to be decided that till the points raised by the parties are decided on merit in the pending applications where the arguments were made for number of times, whether the defendant No. 2 is entitled to launch the drug of two additional indications as well as the Package Insert and whether the Package Insert, which contains the data of the plaintiffs and references, can be used by defendant No. 2 or the said approval has been obtained in breach of the orders dated 5th February, 2014 and 14th February, 2014.

31. It is evident that the approval sought by defendant No. 2 on 10th November, 2014 for two additional indications was granted on 17th March, 2015. Similarly, the application for approval of Carton, Labels and Package Insert for additional indications was made on 21st May, 2015 and the approval was granted by defendant No. 1 on 28th July, 2015.

32. In between the period of 10th November, 2014 to 17th March, 2015, the arguments in the pending applications were being addressed by defendant No. 2 and defendant No. 1, i.e. on 12th November, 2014, 13th November, 2014, 18th November, 2014, 19th November, 2014 by defendant No. 2 and on 1st December, 2014, 18th December, 2014, 15th January, 2015, 9th February, 2015, 11th February, 2015 by defendant No. 1 and on 4th March, 2015, 12th March, 2015 and 13th March, 2015 again by defendant No. 2 who addressed additional arguments after the submissions of defendant No. 1. None of the defendants has

informed the Court that defendant No. 2 has applied for approval of two additional indications before defendant No. 1 despite of discussions of two said indications many times during the hearing of the applications. The suit was originally filed against defendants No. 2 to 4 on the basis of the indication i.e. Metastatic Breast Cancer (hereinafter referred to as the "first indication") which was launched by the defendants No. 2 to 4 after filing of the suit. Defendant No. 2 was fully aware that the said issue of remaining two additional indications are also being discussed. If an application filed by the plaintiffs for injunction is read, it appears that even the plaintiffs were not fully aware about the details and nature of approval applied in November, 2014 and granted in March, 2015. It was only first time disclosed to the Court on 25th May, 2015 when the plaintiffs'' fresh applications for amendment of plaint and for injunction as prayed in the application were listed. The defendants have not chosen to provide the said vital information to the Court. After obtaining the approval of two additional indications, now their argument is that as the approval is granted, the Court cannot interfere and has to pass interim order as earlier after obtaining the approvals, the Court had allowed to launch the drug by modifying the order, therefore, by applying the similar principle the prayer be rejected and the defendant Nos. 2 to 4 be allowed to launch the drug for two additional indications. It is necessary to mention here that when the arguments were being addressed on behalf of the defendant No. 1 on many dates, it was noticed by the Court that the Authorized Representative(s) were present almost on all dates before Court.

33. Learned Senior counsel appearing on behalf of defendant No. 2 submits that it is not a material fact or a vital information which should have been shared with the Court or to the plaintiffs.

34. I do not agree with the learned counsel whether these are material facts or not, it is for the Court to consider. When the subject matter is being discussed and argued in Court, it was the duty of the defendants to disclose the vital information.

35. The submission of defendant No. 2 does not hold good particularly when the two additional indications are linked with the subject matter of the suits, the same was also discussed during relevant dates of hearing between November, 2014 and March, 2015. The outcome of the decision of the pending applications would have bearing in the matter. In case it would go into the root of the matter, the said information is definitely to be disclosed to the Court.

36. It is settled law that the litigant, who approaches the Court, is bound to produce all documents executed by him which are relevant to the litigation. If he withholds a vital document in order to gain advantage on the other side then he would be guilty of playing fraud on the Court as well as on the opposite party. If the party who approaches the Court with unclean hands is not entitled to justice.

37. In the unamended plaint, the plaintiffs have sought the injunction against the

defendants restraining defendants No. 2 to 4 from launching, introducing, selling, marketing, distributing or representing the defendants'' drugs, i.e. CANMAb and HERTRAZ or any other biosimilar version of Trastuzumab in the Indian market until appropriate tests and studies as prescribed under the Guidelines on Similar Biologics have been conducted and appropriate approvals have been obtained.

38. As regards the claim of data exclusively, it is the case of the plaintiffs that defendant No. 2 has a limited right to rely upon publicity available data in order to conduct comparability studies for the purpose of seeking the approval of biosimilar product from the office of defendant No. 1, however, it is alleged by the plaintiffs that defendant No. 2 is not entitled to reproduce the data in any document released to the public, i.e. the Doctors and patients, in order to avoid confusion and to harm the patients, as defendant No. 2 has failed to conduct the trial as per the Guidelines. The plaintiffs are pressing the interim orders against the defendants restraining them from reproduction of the identical data as used by the plaintiffs.

39. The defendant No. 2 has claimed that it has used the data for comparison purposes for which the plaintiffs did not claim of data exclusively in that regard and the approval of two additional indications has been granted.

40. It is alleged by defendant No. 2 that the indications as sought to be approved by the defendant No. 2 are not beyond the already approved indications for which the plaintiffs'' drug/reference drug has already been approved. This practice is also internationally accepted. It is further submitted that the defendant No. 2 had vide letter dated 10th October, 2013 issued to the defendant No. 1 had along with submitting the Phase-III clinical trial reports claimed for all the three indications i.e. MBC, EBC and MGC and an approval was granted on 23rd October, 2013 for MBC to the defendant No. 2 after establishing Biosimilarity to the drug of the plaintiffs. The extrapolation of indications is thus simply a case of administrative confirmation by the defendant No. 1 whereby the defendant No. 2 is permitted to manufacture and sell its biosimilar Trastuzumab for EBC and MGC indication.

41. It is also stated that the approval as granted to the defendant No. 2''s drug cannot be considered as an approval for a ''New Drug'' as for the purpose of categorizing as a ''New Drug'' under the applicable Drugs Rules, as already approved drug has to show further ''new indications''. In this context, it is pertinent to note Rule 122E(b) of the Drug Rules :

"A drug already approved by the licensing authority mentioned in rule 21 for certain claims, which is now proposed to be marketed with modified or new claims, namely, indications, dosage, dosage form (including sustained release dosage form) and route of administration."

42. It is further submitted that ''drug'' in the above provision refers to ''Trastuzumab'' which has been already approved for certain claimsi.e. MBC, EBC and MGC and is not proposed to be marketed with modified or new claims/

indications. It is further submitted that for the purposes of the defendant No. 2''s drug, the above provision is not applicable as the defendant No. 2'' s Trastuzumab has been granted an approval for ''additional indications'' by way of extrapolation which indications have already been approved for the reference drug. Since the defendant No. 2 has not sought an approval for any new indication beyond MBC, EBC and MGC, the defendant No. 2'' s drug is a ''follow on drug'' and does not qualify as a ''New Drug'' under Section 122 E(b) of the Drug Rules, 1945. Furthermore, approval for additional indications leads to no change in the ingredients of the drug and thus the drug does not become a ''New Drug''.

It is also contended by the defendants that as per Explanation (ii) to Rule 122E of the Drug Rules, 1945, a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval. Since Trastuzumab was approved in the year 2000, the defendant No. 2''s Trastuzumab ceases to be a new drug.

43. Therefore as far as the additional indications of the drug in question are concerned, without expressing any opinion at this stage, I am not inclined to pass the interim order to launch the drug by the defendant Nos. 2 to 4 as per approval granted on 17th March, 2015 mainly on the reason that earlier till the disposal of injunction application on the basis of approval of first indication the defendants were allowed to do so. The objections of the plaintiffs on merit would be decided at the time of passing the orders in the earlier interim applications. But at the same time, I must mention that the defendants have not disclosed the vital fact to the Court and the approval dated 17th March, 2015 was obtained by the defendant No. 2 in hidden manner and the said act is not appreciated by the Court.

44. With regard to approval of Carton, Labels and Package Insert, the application was filed on 21st May, 2015 and the same was granted on 28th July, 2015. On 29th May, 2015, it was orally argued by defendant No. 1 to the Court that the approval of Carton, Labels and Package Insert would be considered as per Rules, Regulations and after going through the pleadings and the documents. Earlier to that date, it was not informed by any defendants till 25th May, 2015 that the approval of Carton, Labels and Package Insert is pending. The defendants have filed various pleadings by way of applications and replies etc. but there was no whisper about the applying and granting of approval of two additional indications granted in March, 2015 or filing of application for approval of Carton, Labels and Package Insert.

45. Admittedly, there is continuous injunction against defendant No. 2 to the following effect:-

"...Thus, defendants No. 2 to 4, till the next date of hearing, are 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?."

46. The said order was only modified in the order dated 14th February, 2014 to a limited extent. In para 16 of the said order, the order dated 5th February, 2014 was modified only to the extent that:-

"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."

47. The said order of modification was pertaining to first indication as well as the insert on the basis which the suit was filed. It is apparent that despite of continuation of remaining order, the defendant No. 2 has filed the application for two additional indications. In case both the orders are read in a meaningful manner, it is clear that there are continuing interim orders against the defendants pertaining to the references of the plaintiffs as well as about the public announcement, promotional and other material for the defendants'' drug. However, despite of interim orders defendant No. 2 has mentioned and reproduced the date of the plaintiffs for public announcement as well as references given in the Package Insert before the defendant No. 1. The defendants No. 2 to 4 were allowed by order dated 14th February, 2014 to use the Package Insert granted for first indication as obtained in the said approval on 9th December, 2013. The same was different and other than the proposed materials of two additional indications as mentioned in the package insert.

48. Learned counsel for defendant No. 2 has admitted that the said earlier insert does not mention any references about the plaintiffs. Such approval however is denied by the plaintiffs who stated that the insert used by the defendant No. 2 to 4 is without approval as only information was given by the defendant No. 2 in the office of defendant No. 1, who acknowledged the letter of December, 2013.

49. When the continuous interim order was confronted to defendant No. 2, the reaction was that without prejudice it would be deleted despite of no interim order operating against the defendants. The said explanation given by the defendants is an afterthought. When the matter was mentioned on 11th August, 2015, the counsel for the defendant No. 2 has handed over the copy of the letter dated 7th August, 2015 addressed to the defendant No. 1 informing about the deletion of references part.

50. The extracts of copy of the request dated 7th August, 2015 filed by defendant No. 2 with defendant No. 1 reads as under:-

"We have fully complied with the approval dated 28.03.2015 and 28.07.2015. Keeping in view the litigation pending and without prejudice to the contention of

the parties, we have voluntarily made cosmetic changes in the Package Insert of our drug CANMAb i.e. under the Section ''References'', at Serial No. 1, the word "Herceptin" is replaced with the word "Trastuzumab (reference product) " and the sentence "United Kingdom: Roche Registration Ltd: 2014" is deleted and at Serial No. 3, the word "Herclon" is replaced with the word "Trastuzumab (reference product) " and the sentence "New Zealand: Roche Products (New Zealand"; 2014" is deleted and Serial No. 14, stands deleted."

51. Counsel has also produced the changed version of the references mentioned in the Package Insert which was approved by letter dated 28th July, 2015. Both the earlier as well as the changed versions are reproduced here as under:-

"a) EARLIER ONE

1. Herceptin [summary of product characteristics]. United Kingdom: Roche Registration Limited; 2014. Available at: http://www.ema.europa.eu/docs/ en_GB/ document_library/EPAR_-Product_Information/human/ 000278/ WC500074922.pdf. Link accessed on 17/April/2015.

2. WHO Collaborating Centre for Drug Statistics Methodology. ACT/DDD Index. Available from http://www.whocc.no/atc_ddd_index/?code''L01XC03. Link accessed on 23/December/2015.

3. Herclon [data sheet]. New Zealand: Roche Products (New Zealand) Limited; 2014. Available at: http://www.medsafe.govt.nz/Profs/Datasheet/h/Hercloninf. pdf. Link accessed on 17/April/2015."

"b) PROPOSED AMENDED REFERENCES

1. Trastuzumab (Reference product) [summary of product characteristics]. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/ EPAR_-Product Information/human/000278/ WC500074922.pdf. Link accessed on 17/ April/2015.

2. WHO Collaborating Centre for Drug Statistics Methodology. ACT/DDD Index. Available from http://www.whocc.no/atc_ddd_index/?code''L01XC03. Link accessed on 23/December/2015.

3. Trastuzumab (Reference product) [data sheet]. Available at: http:// www.medsafe.govt.nz/Profs/Datasheet/ h/Hercloninf.pdf. Link accessed on 17/ April/2015."

52. It is also settled law that the subsequent developments that have an impact on the rights and obligations of the parties can be taken into consideration by the Court while granting the relief prayed for.

53. There is no force in the submission of defendant No. 2 that there was no injunction against the defendants to use data in the public announcement and references. If that is so, then why defendant Nos. 2 to 4 agreed to delete the references part about the plaintiffs in the fresh application before defendant No.

1 for modification of Package Insert.

54. Prima facie it shows that the expression ''without prejudice'' by defendant No. 2 in its letter dated 7th August, 2015 written to defendant No. 1 is afterthought, as defendants were aware that the approval of Package Insert might be in breach of orders dated 5th February, 2014 and 14th February, 2014. It is mandatory for a party who approaches to the Court in order to seek relief, it is presumed that the party should come with clean hands, no litigant can derive benefit from the Court in other way. If such attempt is made such party would not be entitled to any indulgence from the Court as the truth and fairness is an integral part of the justice delivery system.

55. It is evident that defendant No. 2 who has applied for approval of Carton, Labels and Package Insert on 21st May, 2015 was fully aware about the interim order. The application for amendment of insert was filed by the defendant No. 2 on 7th August, 2015 after the arguments the order was reserved. Defendant No. 1 after receiving the said application has taken the same on record on 11th August, 2015. The file pertaining to it was deposited in the Registry on 12th August, 2015.

56. Therefore, for the reasons stated it is clear that the approval of Carton, Labels and Package Insert was granted contrary to the interim order. Once the Court finds that the order has not been complied by the party whose hands are unclean, no benefit of equity goes in favour of that party. The conduct of defendant No. 2 in obtaining the approval of carton, labels and purchase of insert was in improper way and contrary to the interim order already operating.

57. Pertaining to approval already granted in March, 2015 for launch of two additional indications, as already mentioned, the same be launched and the Court is not inclined to pass interim order at this stage, however, the objections of the plaintiffs and submissions of the defendants would be considered and decided on merit in the pending interim applications.

58. With regard to the name Trastuzumab is concerned, as earlier it was allowed by this Court vide order dated 14th February, 2014, the contention of the plaintiffs would be considered at the time of passing of the order in the interim applications where both parties have already addressed their arguments. Counsel for the defendants has already made the statement on behalf of the defendant No. 2 to 4 not to amend the Carton/Label of the two additional indications. Therefore, at present no interim order is passed.

59. In respect of approval of Package Insert, the same has been obtained by defendant No. 2 contrary to the interim orders passed, thus, the reproduction of data for information to public, i.e. Doctors and patients cannot be allowed. The interim order is being passed in this respect till the disposal of pending interim applications.

60. It is clarified that defendant No. 2 would, however, during the period would

be entitled to use different data in the Package Insert which shall not be contrary to the interim orders already granted against the defendants after obtaining the approval.

61. The application is disposed of accordingly. The findings and any observation made in this order shall have no bearing when the pending interim applications are decided on merit. The same would be decided without any influence of my present order.

