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

% ***Judgment Reserved on: 12.12.2024***
Judgment pronounced on: 18.02.2025

I.A. 5639/2022
In
\+ CS(COMM) 540/2016

F HOFFMANN-LA ROCHE LTD & OTHERS .....Plaintiffs

Through: Mr. Sandeep Sethi and Mr. Darpan Wadhwa, Senior Advocates with Mr. Vishal, Ms. Kritika Sachdeva and Mr. Vasu Singh, Advocates.

versus

DRUGS CONTROLLER GENERAL
OF INDIA & OTHERS .....Defendants

Through: Mr. Arnav Kumar, CGSC with Ms. Aayushi Sharma, Mr. Chtanya Kapoor and Mr. Tejas Kothari, Advocates for defendant no. 1/ DCGI. Mr. J. Sai Deepak, Senior Advocate with Ms. Bitika Sharma and Mr. Luv Virmani, Ms. Aadya Chawla and Mr. George Vithayathil, Advocates for defendant no. 3.

I.A. 2192/2022
In
\+ CS(COMM) 1119/2016

ROCHE PRODUCTS (INDIA) PRIVATE
LIMITED AND OTHERS .....Plaintiffs

Through: Mr. Sandeep Sethi and Mr. Darpan Wadhwa, Senior Advocates with Mr. Abhishek Tewari, Ms. Samiksha

Godiyal, Ms. Ishita Mathur, Mr. Utkarsh Trivedi and Mr. Raghav Makkar, Advocates.

versus

ZYDUS LIFESCIENCES LIMITED AND OTHERS .....Defendants

Through: Mr. Chander M. Lall, Senior Advocate with Ms. Bitika Sharma, Mr. Kapil Midha and Ms. Aadya Chawla, Advocates for defendant no. 1.

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

I.A. 5639/2022 in CS(COMM) 540/2016 *(under Order XI Rule 12 and 14 of CPC)*

I.A. 2912/2022 in CS(COMM) 1119/2016 *(under Order XI Rule 12 and 14 of CPC)*

1. By way of present judgment, I shall decide the above captioned applications filed on behalf of the plaintiffs under Order XI Rules 12 and 14 of the Code of Civil Procedure, 1908 (hereinafter the 'CPC') seeking disclosure and production of certain documents by the defendants in connected suits being CS(COMM) 540/2016 and CS(COMM) 1119/2016.

2. CS(COMM) 540/2016 (hereinafter the '***Hetero Suit***') has been filed by the plaintiffs seeking relief of permanent injunction restraining defendant no.3 (Hetero Drugs Limited; hereinafter '***Hetero***') from launching, selling, marketing and/or distributing any purported bio-similar version of the

plaintiffs' approved drug '*bevacizumab*', decree of declaration that the approval granted by the Drug Controller General of India (hereinafter the 'DCGI') to the Hetero's drug is invalid, along with other ancillary reliefs. The other suit, being CS(COMM)1119/2016 (hereinafter the '***Cadila Suit***'), has been filed by the plaintiffs seeking similar relief against defendant no.1 (Cadila Healthcare Limited; hereinafter '***Cadila***'), in respect of their drug '*trastuzumab*'.

3. The documents of which production is sought by the plaintiffs in the Hetero Suit are detailed in paragraph 11 of I.A. 5639/2022, and the documents of which production is sought by the plaintiffs in the Cadila Suit are detailed in paragraph 8 of I.A. 2912/2022.

4. Since both the aforesaid applications raise common issues, they are being decided by way of a common judgment.

BRIEF FACTS

5. The plaintiffs, a group of affiliate companies, are the innovators and developers of biological drugs used for cancer treatment. The plaintiffs are the innovators of the biological drug '*bevacizumab*', marketed under the brand name '*AVASTIN*', which is the subject matter of the Hetero Suit. Similarly, the plaintiffs are the innovators of the biological drug '*trastuzumab*', marketed under the brand names '*HERCEPTIN*', '*HERCLON*', and '*BICELTIS*', which is the subject matter of the Cadila suit.

6. In *Hetero Suit*, the plaintiff no.3 [Genentech Inc.], a company organised and existing under laws of USA, is the innovator of drug '*bevacizumab*', the plaintiff no.1 [F. Hoffmann-La Roche Ltd.], a company

organised and existing under laws of Switzerland, is its manufacturer, and the plaintiff no. 2 [Roche Products (India) Private Limited], an Indian Company, is responsible for its import and marketing in India.

6.1. Extensive clinical trials for '*bevacizumab*' began in 1997, and the drug was approved by the United States Food and Drug Administration (hereinafter the 'FDA') in 2004. It was launched in India in 2005 and had gained approvals in over 100 countries by 2016.

6.2. The defendant no.1, DCGI, granted approval to defendant no.3 [Hetero], to manufacture and market a bio-similar version of '*bevacizumab*' under the brand name '*HETERO*' on 13th May 2016 for anti-angiogenesis treatment of metastatic colorectal cancer.

6.3. On June 27, 2016, Hetero launched its alleged bio-similar variant of the plaintiffs' *'bevacizumab'* under the name of '*bevacizumab injection'* in the Indian market.

7. In *Cadila Suit*, the plaintiff no.3 [Genentech Inc] is the innovator of the drug '*trastuzumab'*, the plaintiff no.2 [F. Hoffmann-La Roche AG] is its manufacturer, and the plaintiff no.1 [Roche Products (India) Private Limited] handles its import and marketing in India.

7.1. Extensive clinical trials for the plaintiffs' drug '*trastuzumab'* commenced in 1992, and the drug received FDA approval in 1998. In India, the plaintiffs' drugs, 'HER2+ early breast cancer' and 'HER2+ metastatic gastric cancer' received approvals from the DCGI in 2006 and 2010, respectively.

7.2. The defendant no.2, DCGI, granted authorisation to the defendant no.1 [Cadila] to market a bio-similar version of '*trastuzumab*' under the

brand name '*VIVITRA*' on 28th October, 2015 for HER2+ metastatic breast cancer.

7.3. The plaintiffs' '*trastuzumab*' patent expired on 3rd May, 2013. In December 2015, Cadila launched its alleged bio-similar variant of the plaintiffs' '*trastuzumab*' in the Indian Market. Subsequently, the DCGI on 3rd March 2016 granted approval to Cadila to include indications 'HER2+ early breast cancer', HER2+ metastatic breast cancer' and 'HER2+ metastatic gastric cancer' on its package insert.

SUBMISSIONS ON BEHALF OF THE PLAINTIFFS

8. Mr. Sandeep Sethi and Mr. Darpan Wadhwa, learned senior counsel appearing on behalf of the plaintiffs have made the following submissions:

8.1. The defendants' drugs are being sold for the treatment of serious ailments such as metastatic colorectal cancer, metastatic gastric cancer, metastatic breast cancer and early breast cancer. Therefore, it is in the public interest and fair disclosure that all the trial and test data should be disclosed, particularly regarding the comparative safety and efficacy of the drugs.

8.2. The defendants cannot claim protection of the International Non-Proprietary Name (INN) as the defendants' drugs are not bio-similar to that of the plaintiffs' drugs. The approvals granted by the DCGI to the defendants are invalid as the said approvals have been obtained by suppressing and distorting material facts.

8.3. The defendants have deliberately and mischievously withheld enclosures relating to the regulatory dossier and the complete data submitted to DCGI for obtaining the requisite approval. Furthermore, the defendants have failed to produce before this Court the various correspondences,

including application forms and the results of tests purportedly conducted on the defendants' drugs at each stage.

8.4. The defendants have used the data of the plaintiffs' drugs without independently conducting the tests required under the applicable law and without complying with the provisions of the Drugs and Cosmetics Act, 1940 (hereinafter the 'Drugs Act'), the Drugs and Cosmetics Rules, 1945 (hereinafter the 'Drugs Rules') or Guidelines on Similar Biologics, 2012 (hereinafter the 'Bio-similar Guidelines').

8.5. The data pertaining to the development, testing, and approval of defendants' drugs are essential for the proper adjudication of the issues raised in the present suits and the defendants should be directed to submit the complete and comprehensive data regarding the development, testing, and approval of their drugs before this Court. Reliance is placed on the judgments of the Coordinate Bench of this Court in ***Genentech* v. *Drugs Controller General of India and Ors.***[1] and ***Roche India Pvt Ltd & Ors* v. *Drugs Controller General of India and Ors***[2], which involved similar issues concerning the approval of a bio-similar version of the plaintiffs' biological drug '*trastuzumab*', where the court allowed the discovery of documents in favour of the plaintiffs.

8.6. The documents have a material bearing on the issues at hand, and the defendants shall be directed to produce the documents to ensure complete and proper adjudication of the dispute.

8.7. For passing an order for discovery of documents, the plaintiffs are not required to make out a *prima facie* case on merits. The only test for allowing

[1] 2016 SCC OnLine Del 2572

an application for discovery is whether the documents relate to the matter in question. In this regard, reliance is placed on provisions of the CPC and judgment of ***M.L. Sethi* v. *R.P. Kapoor*[3], *M. Sivasamy v. Vestergaard Frandsen*[4]**.

8.8. Section 104A of the Patents Act, 1970 (hereinafter the 'Patents Act') is not applicable as the present suits are not for infringement of patents, which have already expired.

SUBMISSIONS ON BEHALF OF THE DEFENDANTS

9. Mr. C.M. Lall and Mr. J Sai Deepak, learned senior counsel appearing on behalf of the defendants have made the following submissions:

9.1. By way of these applications, the plaintiffs are seeking production of documents which are neither referred to nor mentioned in the plaint. The main case setup in the plaint(s) is that the defendants are passing off their drugs as those of the plaintiffs.

9.2. The privileged and confidential documents sought by the plaintiffs have no bearing on the issue involved in the present cases and the discovery and production request is merely an attempt to gain access to documents not in the public domain that may contain the sensitive proprietary information of the defendants. Since the plaintiffs are the competitors of the defendants, the applications have been filed to commercially exploit the said proprietary information of the defendants and use the same to the detriment of the defendants. The applications have been filed by the plaintiffs for the purpose of a roving and fishing enquiry.

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[2] 2016 SCC OnLine Del 2358
[3] (1972) 2 SCC 427
[4]2009 SCC OnLine Del 2310

9.3. In terms of Section 104A of the Patents Act, a *prima facie* case has to be established by the plaintiffs before the defendants can be asked to disclose the documents.

9.4. The defendants' drugs were deemed to be bio-similar by the DCGI in accordance with the due process provided under the Bio-similar Guidelines.

9.5. The plaintiffs' patent has already expired and is now an International Non-proprietary Name (hereinafter 'INN'). Hence, the plaintiffs cannot claim a monopoly over the same.

9.6. The reliance placed on the judgement in ***Genentech* v. *Drugs Controller General of India and Ors.***[5] is misplaced as in the said judgment, the plaintiffs were able to make a *prima facie* case in their favour as the testing conducted by the DCGI itself was faulty.

9.7. Furthermore, the reliance placed on the judgment of ***Roche India* v. *Drugs Controller General of India and Ors***[6] is misplaced, as the said judgment has been stayed by the Division Bench of this Court, and therefore, no discovery has been ordered in the said case.

ANALYSIS AND FINDINGS

10. I have heard counsel for the parties and examined the material on record.

MATTER IN CONTROVERSY IN THE SUITS

11. On behalf of the defendants, it is contended that the main focus of the plaint in the present suits is with regard to a passing off action, that the defendants are passing off their drugs as those of the plaintiffs.

[5] 2016 SCC OnLine Del 2572
[6] 2016 SCC OnLine Del 2358

12. On the other hand, the plaintiffs contend that the crux of the plaints in the present suits is with regard to the fact that the defendants have wrongfully obtained approvals for their drugs from DCGI by claiming that their products are bio-similar to those of the plaintiffs.

13. To appreciate the rival submissions, it may be useful to refer to the plaints in the two suits. After discussing the regulatory framework under the Drugs Act, Drugs Rules and Bio-similar Guidelines, including the regime for testing and approval of a new drug, the plaintiffs have averred that the approvals granted to the defendants' drugs were not in accordance with the aforesaid regulatory regime. It has also been averred that the studies conducted by the defendants are not adequate to establish the bio-similarity between the defendants' drugs and the plaintiffs' drugs. It is the plaintiffs' case that the defendants have not established bio-similarity with the plaintiffs' drugs on the basis of independent tests which were required to be conducted by the defendants to show bio-similarity.

14. Paragraphs 35 and 36 of the plaint in the Hetero suit summing up the aforesaid submissions of the plaintiffs are set out below:

> "*35. In the light of the above discussion, it is evident that the approval given by Defendant No. 1 in respect of the Defendant's CTR on 28 April 2015 and the clinical trials purportedly conducted pursuant to the Defendant's CTR by Defendant No. 3 are in violation of the Drugs Act, and other applicable laws.*
>
> *36. The Defendant No. 3 has failed to establish the bio-similarity between the Defendant's drug and the Plaintiffs' bevacizumab on the basis of the Clinical Trials, purportedly conducted pursuant to the Defendant's CTR. Accordingly, the marketing authorization should not have been granted on the basis of the Defendant's CTR and its approval by the Defendant No. 1 is in violation of the Drugs Act, the Drugs Rules and the Bio-similar Guidelines and should to be declared invalid by this Hon'ble Court.*"

15. Similarly, paragraph 37 of the plaint in the Cadila suit, which sums up the aforesaid submissions of the plaintiffs, is set out below:-

> "*37. In view of the above, (i) the RCGM approvals for preclinical trials for the Defendant's Drug; (ii) the approval of the Defendant's CTR by Defendant No. 2 on March 10, 2014; (ill) the clinical trials purportedly conducted by Defendant No.1 pursuant to the Defendant's CTR; (iv) the SEC Recommendation; (v) the Package Insert Recommendation; (vi) the Manufacturing Authorisation; (vii) the manufacturing and marketing authorisation received from the State FDA; and (viii) the NOC for Additional Indications are in violation of the Drugs Act, the Drugs Rules and the Biosimilar Guidelines. Defendant No. 1 has failed to establish bio similarity between the Defendant's Drug and the Plaintiffs' Trastuzumab on the basis of the clinical trials purportedly conducted pursuant to the Defendant's CTR. Consequently, the launch and marketing of the Defendant's Drug for all three indications i.e. HER2+ metastatic breast cancer, HER2+ early breast cancer and HER2+ metastatic gastric cancer) is in violation of the Drugs Act, the Drugs Rules and the Biosimilar Guidelines and deserves to be restrained by this Hon'ble Court.*"

16. Based on the aforesaid averments, the plaintiffs have sought a decree of declaration to the effect that the defendants' drugs in both suits are not bio-similar to the plaintiffs' drugs, and the approvals granted by the DCGI are not in accordance with the law. The relevant prayers in the two suits are set out below:

16.1. In the Hetero suit:

> "*(a) a decree of declaration that the Defendant's drug, a purported biosimilar version of the Plaintiffs' bevacizumab, has not been tested as a bio-similar product under applicable laws;*
>
> *(b) a decree of declaration that Defendant No. 3's CTR Registration Number CTR/2015/05/005757 dated 08 May 2015, which was last modified on 04 August 2015, is invalid and is not in accordance with applicable laws;*

(c) a decree of declaration that the approval granted on 28 April 2015 by Defendant No. 1 to Defendant No. 3's Clinical Trial Protocol for the Defendant's drug is invalid and is not in accordance with applicable laws;

(d) a decree of declaration against Defendant No.1 that the marketing authorization, if any, granted by Defendant No.1 in respect of Defendant's drug is invalid and against the provisions of the applicable laws and guidelines;

(e) a permanent injunction restraining Defendant No. 3 from launching, introducing, selling, marketing and/or distributing the Defendant's drug, or any other bio-similar version of Plaintiffs' bevacizumab, in the Indian market, until the appropriate tests and studies prescribed under the applicable laws have been conducted and appropriate approvals have been obtained.

(f) a permanent injunction restraining Defendant No. 3 from representing the Defendant's drug as a bio-similar of the Plaintiffs' bevacizumab or from claiming similarity and/or comparability with Plaintiffs' bevacizumab until biosimilarity between the Defendant's drug and the Plaintiffs' bevacizumab is established for each of the indications pursuant to appropriate tests under the Bio-similar Guidelines and other applicable laws;"

16.2. In the Cadila suit:

"*(i) a decree of declaration that the Defendant's Drug has not been tested as, and is not, a biosimilar product under applicable law;*

(ii) a decree of declaration that the RCGM approval of the preclinical protocol of the Defendant's Drug dated March 30, 2012, the RCGM approval of the preclinical test results of the Defendant's Drug dated September 18, 2012, Defendant No. 1's CTRI registration bearing CTRI Number CTRI/2014/05/004605 and Defendant No. 2's approval dated March 10, 2014 in relation to the clinical trial protocol for the Defendant's Drug are invalid and are not in accordance with applicable law.

xxx *xxx* *xxx*

(viii)an injunction restraining Defendants No. 1 from representing the Defendant's Drug as a biosimilar version of the Plaintiffs' Trastuzumab or of HERCEPTIN®, HERCLON^{TM} or BICELTIS® or from claiming similarity and/or comparability with 'Trastuzumab' or with HERCEPTIN®, HERCLON^{TM} or BICELTIS® until biosimilarity between the Defendant's Drug and the Plaintiffs' Trastuzumab is established pursuant to appropriate tests under the Drugs Act, the Drugs Rules and Biosimilar Guidelines;"

17. The defendants, in their respective written statements, have denied the aforesaid averments made in the plaints and claimed that the approvals granted by the DCGI to their drugs were in accordance with the law. The defendants contend that their drugs met the required bio-similar standards and underwent appropriate testing as mandated under the Bio-similar Guidelines and other applicable laws.

18. Upon a careful perusal of the pleadings in the two suits, there is no doubt that the main controversy in the two suits is with regard to:-

(i) the validity of clinical trials conducted by Cadila and Hetero, along with the fact that whether the defendants' drugs are bio-similar to the plaintiffs' drugs;

(ii) the approvals granted by the DCGI as being non-compliant with the applicable laws and procedure.

19. The aforesaid conclusion is also fortified by the observations made in the judgment passed by the predecessor bench in the present suits on 11th September 2023[7]. In the aforesaid judgment, the issue arising in the present suits has been noted, i.e., the plaintiffs have questioned the validity of clinical trials conducted by Cadila and Hetero and the approvals granted by

[7] ***F Hoffmann-LA Roche Ltd.*** **v.** ***Drugs Controller General of India*** [2023 SCC OnLine Del 5615]

the regulator as being non-compliant with the applicable laws and procedure. [Ref. paragraphs 81-83]

SCOPE OF INTERROGATORIES AND DISCOVERY OF DOCUMENTS

20. It is a settled position of law that the purpose of interrogatories and discovery of documents is to reduce the trial duration and minimise the litigation costs. The only issue to be considered by the Court while adjudicating an application for interrogatories or discovery of documents is whether the answer to such an application would have a bearing on the determination of the dispute between the parties.

21. A reference may be made to the provisions of Order XI Rules 12 and 14 of the CPC, which read as under:

> "***12. Application for discovery of documents***—*Any party may, without filing any affidavit, apply to the Court for an order directing any other party to any suit to make discovery on oaths, of the documents which are or have been in his possession or power,* ***relating to any matter in question therein****. On the hearing of such application the Court may either refuse or adjourn the same, if satisfied that such discovery is not necessary, or not necessary at that stage of the suit, or make such order, either generally or limited to certain classes of documents, as may, in its discretion be thought fit: Provided that discovery shall not be ordered when and so far as the Court shall be of opinion that it is not necessary either for disposing fairly of the suit or for saving costs.*
>
> *xxx xxx xxx*
>
> ***14. Production of documents****.—It shall be lawful for the Court, at any time during the pendency of any suit, to order the production by any party thereto, upon oath, of such of the documents in his possession or power,* ***relating to any matter in question*** *in such suit, as the Court shall think right; and the Court may deal with such documents, when produced, in such manner as shall appear just."*

22. A reading of the aforesaid provisions would show that the process of discovery and production of documents under Order XI Rules 12 and 14 of the CPC involves two distinct steps: application for discovery of documents, followed by their production if they relate to the matter in question.

23. In the leading judgment on the subject, in ***M.L. Sethi* v. *R.P. Kapoor***[8], the Hon'ble Supreme Court, while dealing with the aspect of discovery of documents, has held that the discovery of documents shall be ordered if the documents throw light on the matter in controversy. The relevant extract is set out below:

> *"9. Nor do we think that the High Court was right in holding that the documents ordered to be discovered were not relevant to the inquiry.* ***The documents sought to be discovered need not be admissible in evidence in the enquiry or proceedings. It is sufficient if the documents would be relevant for the purpose of throwing light on the matter in controversy. Every document which will throw any light on the case is a document relating to a matter in dispute in the proceedings, though it might not be admissible in evidence. In other words, a document might be inadmissible in evidence yet it may contain information which may either directly or indirectly enable the party seeking discovery either to advance his case or damage the adversary's case or which may lead to a trial of enquiry which may have either of these two consequences.*** *The word "document" in this context includes anything that is written or printed, no matter what the material may be upon which the writing or printing is inserted or imprinted. We think that the documents of which the discovery was sought, would throw light on the means of the respondent to pay court-fee and hence relevant."*
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> [Emphasis is mine]

[8] (1972) 2 SCC 427

24. The judgment of ***M.L. Sethi*** (supra) was followed by a Division Bench of this Court in ***M. Sivasamy* v. *Vestergaard Frandsen A/S*[9],** wherein the Court elucidated the features of Order XI Rules 12 and 14 of CPC. The court observed that the documents for which discovery and production is sought must be in power and possession of the opposite party and must be relevant for the adjudication of the suit. The relevant extract is reproduced below:

> *"7. A reference to the aforesaid provisions show that the first step is the discovery of documents and after discovery of documents there is a second step, and this is again a material step, which is of production of documents. However, the two steps are necessarily distinct and separate in as much as ordinarily there is no production till the affidavit is filed in the Court discovering the documents in the appropriate form as prescribed in the CPC. Of course, when the particulars of documents are known, a party can straightaway invoke Order 11 Rule 14 because the particular documents are known to be in the power and possession of the opposite party.* ***A reading of the aforesaid provisions of Order 11 Rules 12 and 14 bring out certain salient features as under:***
>
> ***(i) The documents sought to be discovered and produced have to be relevant to the matter in controversy viz. matters in question.***
>
> ***(ii) The documents have to be in the possession and power of the person against whom discovery and production is sought.***
>
> ***(iii) Discovery and production of the documents which are sought for are necessary at that stage of the suit;***
>
> ***(iv) The discovery and production is necessary for fairly disposing of the suit or for saving costs.***
>
> ***(v) The discovery and production may be general or limited to certain classes of documents as the Court in its discretion deems fit and the production will only be ordered if the Court considers it just.****"*

[9] 2009 SCC OnLine Del 2310

[Emphasis is mine]

25. The amendments carried out in the Code of Civil Procedure, 1908, pursuant to the enactment of the Commercial Courts Act, 2015 have laid great emphasis on disclosure by means of interrogatories and discovery of documents. In respect of commercial suits, a separate Order XI dealing with disclosure, discovery, interrogatories and inspection of documents has been enacted. The primary objective of Order XI of the CPC, as applicable to the Commercial Courts Act, 2015, is to assist the parties in clarifying and narrowing down the issues in dispute before the trial begins.

26. A reference may be made to **Order XI Rule 5** of CPC, as applicable to Commercial Suits. The relevant extract is reproduced below:

> "***5. Production of documents.***—*(1) Any party to a proceeding may seek or the Court may order, at any time during the pendency of any suit, production by any party or person, of such documents in the possession or power of such party or person,* ***relating to any matter in question in such suit****.*
>
> *(2) Notice to produce such document shall be issued in the Form provided in Form No. 7 in Appendix C to the Code of Civil Procedure, 1908 (5 of 1908).*
>
> *(3) Any party or person to whom such notice to produce is issued shall be given not less than seven days and not more than fifteen days to produce such document or to answer to their inability to produce such document.*
>
> *(4) The Court may draw an adverse inference against a party refusing to produce such document after issuance of a notice to produce and where sufficient reasons for such non–production are not given and order costs.*"

[Emphasis is mine]

27. In fact, there is an obligation cast on the defendant to file all documents in its power and possession along with the written statement or

the counterclaim and to give reasons whenever a stand to the contrary is taken. In this regard, a reference may also be made to **Order XI Rule 1(7)** of the CPC as applicable to Commercial Suits.

> "*(7) The defendant shall file a list of all documents and photocopies of all documents, in its power, possession, control or custody, pertaining to the suit, along with the written statement or with its counterclaim if any, including—*
>
> *(a) the documents referred to and relied on by the defendant in the written statement;*
>
> *(b)* ***the documents relating to any matter in question in the proceeding in the power, possession, control or custody of the defendant, irrespective of whether the same is in support of or adverse to the defendant's defence****;*
>
> *(c) nothing in this Rule shall apply to documents produced by the defendants and relevant only—*
>
> *(i) for the cross-examination of the plaintiff's witnesses,*
> *(ii) in answer to any case set up by the plaintiff subsequent to the filing of the plaint, or*
> *(iii) handed over to a witness merely to refresh his memory."*
>
> [Emphasis is mine]

28. Now, a reference may also be made to the Delhi High Court Intellectual Property Rights Division Rules, 2022 ('hereinafter IPD Rules'), enacted on 24th February 2022. The objective of the IPD Rules is to provide practice and procedural directions for the effective adjudication of original and appellate intellectual property cases. Rule 17 of the IPD Rules provides that the procedure relating to discovery and disclosure of documents, including by way of interrogatories, shall be governed by the Code of Civil Procedure, 1908, as amended by the Commercial Courts Act, 2015.

29. The issue of disclosure by way of interrogatories and production of documents in the context of a patent infringement suit came up before a Coordinate Bench of this Court in ***Koninklijke Philips N.V.* v. *VIVO Mobile***

Communication Co. Ltd. & Ors[10]**.** The court held that an application for discovery of documents should be allowed if it sheds light on the subject matter of the suit and provides answers that would assist in the fair disposal of the case.

30. In ***Largan Precision Co Ltd* v. *Motorola Mobility India Pvt Ltd & Ors***[11]**,** I had an occasion to deal with the aspect of discovery of documents in a patent infringement suit. In the said case, the defendants raised similar defences as raised by the defendants herein, i.e., the plaintiffs are indulging in roving and fishing inquiry to obtain confidential business information. Even though the said case was a patent infringement suit, I had observed that a party is obligated to disclose all information and documents within its power and possession that are relevant for the adjudication of the suit. A party cannot claim the right to withhold information or refuse to file documents which may go against its interest in the suit proceedings. It was also held that a liberal view must be taken while deciding an application for discovery of documents, especially in commercial cases. The relevant extract is reproduced below:

> *"19. From the discussion above, it is clear that Courts should adopt a liberal approach in allowing request for interrogatories as well as production of documents, especially in commercial cases. The only factor the Court has to consider is whether the disclosure/ document sought by the party would have a bearing on the determination of the dispute between the parties. The issue of whether the said disclosure/ document would be against the interest of a party in the suit is wholly irrelevant."*

[10] 2022 SCC OnLine Del 53
[11] 2024 SCC OnLine Del 8663

31. The aforesaid principles would be squarely applicable in the present case as well. The relevant consideration while adjudicating an application for discovery and production is that the documents must be relevant to the issues in controversy, within the power and possession of the opposite party, necessary at the relevant stage of the suit, and essential for the fair disposal of the suit or for saving costs.

JUDGMENTS/ORDERS PASSED IN SIMILAR SUITS FILED BY THE PLAINTIFFS

32. Suits similar to the present suits were filed by the plaintiffs against other drug manufacturing companies, details of which are given below: -

(i) **CS(OS) 355/2014** titled as ***Roche (India)* v. *Drugs Controller General of India and Ors***., where the contesting defendants were defendant no.2/Biocon Limited, defendant no.3/ Mylan Inc and defendant no.4/Mylan Pharmaceuticals Pvt. Ltd. [hereinafter the '**Biocon case**']

(ii) **CS(OS) 3284/2015** titled as ***Genentech* v. *Drugs Controller General of India and Ors.***, where the contesting defendant was defendant no.3/ Reliance Life Sciences (P) Ltd. [hereinafter the '**Reliance case**']

33. In the Biocon case, the plaintiffs filed a similar application for the discovery of documents against the defendant no.2/ Biocon. While resisting the said application, the defence taken on behalf of Biocon was that the discovery sought by the plaintiffs was in respect of sensitive and proprietary information, and its disclosure would be damaging to Biocon. Yet another defence taken was that the plaintiffs cannot be permitted to assume the role

of a licensing authority and usurp the role of the statutory authority, i.e. DCGI.

34. Relying upon the judgment of the Supreme Court in ***M.L. Sethi*** (supra), the Coordinate Bench of this Court, *vide* judgment dated 25th April 2016[12], allowed the discovery application in the Biocon case. The relevant observations of the Court in the Biocon case are set out below:-

> **"***130. The defendant No.2 in the present case has not only refused to discover or produce the documents but also opposed the request to inspect the file submitted by the defendant No.1. The approvals which have been granted to defendant No.2 are on the basis of certain documents produced before the Regulatory Authority who may or may not rightly or wrongly granted the approvals.* ***The defendant No.2 now cannot claim the confidentiality in nature on the grounds that the access to the said documents would damage the case of the defendant No.1 particularly in view of the fact that the approvals of bio-similar product were obtained on the basis of the plaintiffs' product and their data has been used.***
>
> *xxx* *xxx* *xxx*
>
> *132. It is a matter of fact that the defendant No.2 is claiming that the approvals have been granted as per Act and approval and all the requisite clinical trials have been conducted. It is also stressed by the defendant No.2 that after approvals they are entitled to refer its drug as biosimilar to the drug of the plaintiffs and they can declare to all hospitals, doctors and the entire world that their product is biosimilar and can compare both drugs.* ***In view of such circumstances, the party has a right to know that under what circumstances the approvals were granted to the defendant No.2 of their bio-similar product or not. The plaintiffs are the aggrieved party. One fails to understand that once the approval is granted why now the data used by defendant No.2 before defendant No.1 cannot be examined by the plaintiffs. Though record has been submitted by the defendant No.1, this Court is not an expert for comparing characterisation of two***

[12] ***Roche India Pvt Ltd & Ors v. Drugs Controller General of India and Ors,*** [2016 SCC OnLine Del 2358]

drugs of the parties. Further the aggrieved party is entitled to know the nature of the clinical trials conducted by the party who intends to use the biosimilar drug of the innovator.

133. I have gone through the submissions made by the defendants while resisting the application for discovery of documents filed by the plaintiffs. ***It appears that the plaintiffs are seeking discovery of the documents so as to prove their case clinically and to provide the infirmities in the defendant's approval process of the drug.*** *The defendant's position while resisting the injunction application has always been that the drug of the plaintiffs is already approved in India and thus data of the plaintiffs and its approval process can come in aid of the defendant while seeking its approval of the drug BMAB 200 based on referenced biologic.*

134. If this position taken by the defendant No.2 qua the data and approval of the plaintiffs' drug by calling it a publically [sic: publicly] available documents, it is beyond comprehension as to how the defendant No.2 after submitting the documents with defendant No.1 can call their documents as confidential in nature. The defendants' stand is surprising when they go on state that the plaintiffs cannot also inspect the documents from the office of the defendant No.1 as it is hotly contested matter. Off course [sic: Of course], there is an attempt to withhold the documents from the plaintiffs who are the aggrieved parties whose product is referenced against by the defendant No.2 who cannot withheld the documents which would only reveal whether the requisite and crucial trials have been conducted by the defendant No.2 or not. There is no force in the submission of the defendant No.2 that since the original record is submitted by the defendant No.1, the Court may examine the same. As a matter of fact, the plaintiffs' assistance on this issue is required in order to find out the truth.

135. Under such circumstances, I do not find any impediment in allowing the application seeking discovery of the documents in as much as the moment the approval has been allowed, the document submitted before the defendant No. 1 can be examined by the plaintiffs being aggrieved party."

[Emphasis is mine]

35. In light of the aforesaid observations, the Court permitted the plaintiffs to examine the documents filed on behalf of the defendants and to address the concerns of confidentiality expressed by the defendants, the Court constituted a confidentiality club comprising two lawyers and an expert each, from the side of the plaintiffs and the defendants.

36. In the same judgment, the Court expressed its *prima facie* opinion that Biocon has not obtained the approvals as per the existing protocols in respect of bio-similar drugs, and the approvals were contrary to Bio-similar Guidelines. Accordingly, pending the final decision in the suit, the Court permitted Biocon and Mylan to continue to manufacture, market and advertise their products based on the approvals already granted, without calling their products as bio-similar to plaintiffs' products 'HERCEPTIN', 'HERCLON', 'BICELTIS'. Along with this, certain other conditions and the riders were also imposed on the defendants.

37. Similar interim directions were also passed in the Reliance case[13], and the discovery application filed on behalf of the plaintiffs was also allowed.

38. Both Biocon andP Mylan approached the Division Bench by way of appeals, FAO(OS) No. 132/2016 and FAO(OS) No 133/2016, challenging the judgment passed by the Single Bench on 25th April 2016. In FAO(OS) 132/2016, Division Bench passed the following order on 28th April 2016:

> *"Meanwhile, the position, as obtaining 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."*

39. Subsequently, vide order dated 3rd March, 2017, the Division Bench, after noting that Biocon and Mylan had been in the market for almost two

years, permitted Biocon and Mylan to sell the drug '*trastuzumab'* under their brand names, subject to their maintaining accounts.

40. The plaintiffs challenged the aforesaid order before the Supreme Court by way of special leave to appeal being (SLP (C) No. 15532-15537/2017), however, the same was later dismissed as withdrawn.

41. *Reliance* also filed an appeal being FAO(OS) No. 181/2016 against the judgment passed by the Single Bench, and while no relief was granted initially, the Division Bench later stayed the Single Judge's judgment *vide* order dated 18th September, 2019, noting that the Reliance is entitled to parity with Biocon and Mylan in its treatment *qua* interim relief.

42. The plaintiffs challenged the order dated 18th September 2019 passed by the Division Bench in the Reliance case before the Supreme Court. The Supreme Court set aside the order passed by the Division Bench and allowed the appeal filed by the plaintiffs[14]. The Supreme Court upheld the judgment passed by the Single Judge on 25th April 2016. The relevant paragraphs of the judgment are set out below:-

> ***"25. The appellants' suit before the Delhi High Court is not a trade mark action nor is it 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.***
>
> *xxx* *xxx* *xxx*
>
> *29.In view of the aforesaid, the impugned order is set aside and appeal is allowed.* ***The interim direction given by the learned Single***

[13] ***Genentech* v. *Drugs Controller General of India and Ors.*** [2016 SCC OnLine Del 2572]
[14] ***Genentech Inc. and Others* v. *Drugs Controller General of India and Others*** [(2020) 13 SCC 371]

> ***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."*
>
> [Emphasis is mine]

43. After the judgment of the Supreme Court, acting on the judgment passed by the Single Bench in the Reliance case on 25th April, 2016[15], another Single Bench, vide order dated 12th February, 2020, permitted two Advocates and an expert from the plaintiffs' side to inspect the documents filed by the defendants in a sealed cover.

44. Immediately thereafter, an application (I.A. 2790/2020) was filed by Reliance wherein it was stated that the documents ordered to be inspected contained confidential information and test data generated by Reliance for the purposes of Drug Authority, and grave prejudice would be caused to Reliance if access of the same is provided to an internal person of the plaintiffs under the garb of being an expert. The said application was dismissed by the Coordinate Bench *vide* order dated 2nd March 2020.

[15] ibid14

45. Therefore, the judgment dated 25th April 2016[16] passed by the Coordinate Bench in the Reliance case relating to the discovery of documents has attained finality.

RELEVANT PROCEEDINGS IN THE PRESENT SUIT

46. In the present suits, both Cadila and Hetero had also preferred applications under Order VII Rule 11 of the CPC seeking rejection of the plaints on the grounds that the plaints failed to disclose any cause of action against them. The grounds for rejection of the plaints were as follows:-

i. Failure of the plaintiffs to avail remedy of appeal under Rule 122 DC of the Drug Rules.

ii. Lack of jurisdiction of a Civil Court to entertain a challenge to the decision of a regulatory authority acting within the provisions of the Drugs Act.

47. The Predecessor Bench, vide judgment dated 11th September, 2023[17], dismissed the applications preferred by the defendants. While rejecting the aforesaid applications, the Coordinate Bench relied on the afore-noted litigation history in the Reliance case[18] and Biocon case[19]. The Bench noted that the defences taken by Reliance and Biocon are similar to the defences taken by Cadila and Hetero in the present suits. Therefore, the judgment dated 25th April 2016[20], as upheld by the Supreme Court[21], would be applicable in the present suits as well.

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[16] ibid 13
[17] ibid 7
[18] ibid 13
[19] ibid 12
[20] ibid 13
[21] ibid 14

48. Pertinently, the judgment dated 11th September 2023 passed by the Predecessor Bench in the present suits was also taken in appeal, which was dismissed as not maintainable.

OTHER SUBMISSIONS OF THE DEFENDANTS

49. On behalf of the defendants, it is submitted that the impugned judgment dated 25th April 2016 in the Biocon case has been stayed by the Division Bench, and the said stay is still continuing. It is further submitted that in light of the stay order passed by the Division Bench, no discovery has been granted to the plaintiffs in this case.

50. In my view, the aforesaid orders passed by the Division Bench do not stay the directions passed by the Single Bench with regard to the discovery of documents. The order passed by the Division Bench was solely concerned with the interim directions and conditions imposed by the Single Judge, and there is nothing in the Division Bench's order to suggest otherwise. In any event, in the *Reliance* case, the Supreme Court has upheld the judgment of the Single Judge dated 25th April 2016[22].

51. Therefore, the judgment of the Single Bench dated 25th April, 2016, insofar as it dealt with the issue of discovery of documents, has attained finality. I am in respectful agreement with the findings in the aforesaid judgment. Once Cadila and Hetero have sought approval from the regulatory authorities based on data filed by them claiming bio-similarity vis-à-vis the plaintiffs' products, Cadila and Hetero cannot claim confidentiality in respect of the said documents. Given that the approval has already been granted to Cadila and Hetero, I see no reasonable ground to restrict the

[22] ibid 14

plaintiffs from examining the data submitted by Cadila and Hetero before DCGI as part of the approval process. Since the approvals were obtained on the basis of the plaintiffs' product and the plaintiffs' data, the plaintiffs have the right to inspect the data and examine the basis on which the said approvals were granted.

52. As noted above, the present suits have been filed by the plaintiffs on the ground that Cadila and Hetero have wrongfully claimed bio-similarity with the products of the plaintiffs, and the approval granted in their favour is unlawful. The aforesaid contention of the plaintiffs has been denied by the defendants. Therefore, the data filed on behalf of Cadila and Hetero before the regulatory authority, i.e., DCGI, in support of its claim for bio-similarity with plaintiffs' products has a material bearing on the issues at hand and relevant for the adjudication of the present suits. Resultantly, the plaintiffs have the right to seek discovery of the aforesaid documents in order to substantiate their allegation that approvals have been granted to the defendants wrongfully by DCGI and the fact that the defendants have wrongfully claimed their drugs to be bio-similar to those of the plaintiffs.

53. The present case is squarely covered by the aforesaid judgment of the Coordinate Bench, which has been upheld by the Supreme Court[23].

54. Mr. Lall and Mr. Sai Deepak, Senior Counsel appearing on behalf of the defendants, sought to distinguish the present cases from the Reliance case on the ground that in the Reliance case[24], there was a *prima facie* finding of faulty testing, which is not there in the present cases.

[23] ibid 14
[24] ibid 13

55. I have already held above that there is no requirement to make out a *prima facie* case for allowing an application for the discovery of documents. The discovery has to be ordered by the Court only on the basis of whether the documents are relevant for the purposes of adjudication of the suit. Therefore, I do not find any merit in the aforesaid submission made on behalf of the defendants to distinguish the judgment in the Reliance case from the present case.

56. Another submission by the defendants was that the current application for the discovery of documents cannot be allowed unless the plaintiffs have fulfilled the requirement contained in Section 104A of the Patents Act. As the language of Section 104A of the Patents Act itself suggests, the section comes into play only in respect of the process patent infringement suits. In the present suits, the patents had already expired and hence, have not been asserted in the suits. Therefore, Section 104A of the Patents Act has no relevance for the purposes of the present suit.

57. In view of the discussion above, I am of the view that the documents in respect of which discovery is sought by the plaintiffs are materially relevant for effectually and expeditiously adjudicating the case. Further, the production of the documents would reduce the time to adjudicate the present suit as well as the costs incurred by the parties in the trial. This approach would be consistent with the objectives and intent of the Commercial Courts Act, 2015 and the IPD Rules, as discussed above. Therefore, I am unable to accept the submissions of the defendants that the aforesaid discovery of documents is in the nature of roving and fishing enquiry to obtain sensitive and confidential information.

58. In light of the above, the present applications seeking discovery of the documents are allowed.

59. Consequently, Hetero and Cadila are directed to file the documents mentioned in paragraph 11 of I.A. 5639/2022 in CS(COMM) 540/2016 and paragraph 8 of I.A. 2912/2022 in CS(COMM) 1119/2016, respectively [annexed as Annexure A and Annexure B, respectively to this judgment] in a sealed cover within four weeks from today.

60. Taking into account the confidentiality of the data, I direct the formation of confidential clubs, in both Hetero suit and Cadila Suit, comprising of the following members:

(i) Two advocates and an expert from the plaintiffs' side

(ii) Two advocates from the defendants' side.

61. The necessary affidavits in terms of Annexure F Chapter VII Rule 17 of the Delhi High Court (Original Side) Rules, 2018, be filed by the aforesaid members of the confidentiality club within two (2) weeks. The members of the confidentiality club shall be bound by the protocol prescribed in the aforesaid Rules.

62. The documents filed by Cadila and Hetero in a sealed cover shall be provided to the members of the confidentiality club.

63. The mode of sharing the aforementioned documents/ information shall be agreed upon among the parties after the said documents have been filed.

64. The applications stand disposed of.

65. Needless to state that the observations made herein are only for the purpose of deciding the present applications and shall have no bearing on the final outcome of the suit.

CS(COMM) 540/2016

CS(COMM) 1119/2016

66. List before the Joint Registrar on 24th March, 2025, for further proceedings.

AMIT BANSAL
(JUDGE)

FEBRUARY 18, 2025
ds

ANNEXURE A

DISCOVERY OF DOCUMENTS SOUGHT IN CS(COMM) 540/2016

In CS(COMM) 540/2016, the plaintiffs seek discovery and production of all the regulatory dossier, including the following documents:

(a) All documents (including enclosures) relating to Defendant No.3's application to the Review Committee on Genetic Manipulation (the "RCGM") to develop cell lines in relation to the Defendant's Drug.

(b) All documents (including enclosures) relating to the RCGM's approval to Defendant No. 3 's application to develop cell lines in relation to the Defendant's Drug.

(c) All documents (including enclosures) relating to the Product Characterization data (chemical and pharmaceutical information) of the Defendant's Drug.

(d) All documents (including enclosures) relating to Defendant No.3's application to the DCGI seeking NOC to manufacture the Defendant's Drug for test, analysis and examination purposes.

(e) All documents (including enclosures) relating to the DCGI's NOC to obtain manufacturing license in Form-29 for the manufacture of Bevacizumab for the purpose of examination, test and analysis.

(f) All documents (including enclosures) relating Defendant No.3's application to the State Food and Drug Administration ("State FDA") seeking NOC to manufacture its drug for test, analysis and examination purposes and any approval granted in this regard.

(g) All documents (including enclosures) relating to the Form-29 licenses for purposes of examination, test and analysis.

(h) All documents (including enclosures) relating to the product characterisation studies conducted by Defendant No.3 in relation to the Defendant's Drug.

(i) All documents (including enclosures) relating to Report given by Defendant No. 1 permitting the conduct of the clinical trials for the Defendant's drug.

(j) All documents (including enclosures like the application letter, pre-clinical study protocol, Form C3, draft study plans, etc.) relating to Defendant No. 3's correspondence(s) with the RCGM seeking permission to conduct pre-clinical studies on the Defendant's Drug.

(k) All documents (including enclosures) relating to amendments, if any, suggested by the RCGM to the pre-clinical study protocol for the Defendant's Drug.

(l) All documents (including enclosures like Form CS, the study reports etc.) relating to Defendant No. 3's application to the RCGM seeking (i) approval of its pre-clinical study data; and (ii) permission to conduct all phases of clinical trials in relation to the Defendant's Drug.

(m) All documents (including enclosures) relating to the RCGM's correspondence(s) approving the pre-clinical study data generated by Defendant No. 3 for the Defendant's Drug.

(n) All documents (including enclosures like the clinical trial protocol and the results of previous tests) relating to Defendant No.3's application to the DCGI seeking (i) approval of its clinical trial protocol; and (ii) permission to conduct clinical trials for the Defendant's Drug. This should include all further correspondence between Defendant No. 3 and the DCGI regarding the phases of clinical trials proposed to be conducted by Defendant No. 3 for the Defendant's Drug.

(o) All documents/correspondence (including enclosures) relating to modifications suggested by the DCGI with respect to the clinical trial protocol for the Defendant's Drug and responses submitted by Defendant No.3.

(p) All documents (including enclosures) relating to the DCGI's approvals relating to Defendant No.3's clinical trial protocol for the Defendant's Drug.

(q) All documents (including enclosures) relating to the review and approval of the clinical trial protocol by the Subject Expert Committee (SEC), the Technical Committee (TC), the Apex Committee (AC) and the Ethics Committees.

(r) All documents (including enclosures) relating to the submission of complete data of Phase I, II and III clinical trials for the Defendant's Drug by Defendant No. 3 to DCGI along with the Clinical Trial Report.

(s) All documents (including Form 44 and its enclosures) relating to Defendant No. 1 's manufacturing and marketing authorisation for the Defendant's Drug, including its application filed before DCGI.

(t) All documents (including enclosures) relating to DCGI's recommendation to the State FDA for the grant of manufacturing license to Defendant No.3.

(u) All documents (including enclosures) relating to the review and approval of the clinical trial data and application for manufacturing and marketing authorisation for the Defendant's Drug by the Subject Expert Committee, the Technical Committee and the Apex Committee.

(v) All documents (including Form 28D and its enclosures) relating to Defendant No.3's application to the State FDA for manufacturing and marketing authorisation for the Defendant's Drug.

(w) All documents (including enclosures) relating to the DCGI's authorisation for the Defendant's Drug.

(x) All documents (including enclosures) relating to the approval of the State FDA for the Defendant's Drug.

(y) All documents (including enclosures) relating to Defendant No.3's application to the DCGI seeking no-objection to use the Defendant's Drug for additional indications.

(z) All documents (including enclosures) relating to the SEC's review and approval of Defendant No. 3's package insert for the Defendant's Drug.

(aa) All documents (including enclosures) relating to the Defendant No. 3 's application to the DCGI for approval of the package insert of the Defendant's Drug for one indication.

(bb) All documents (including enclosures) relating to the DCGI's approval Defendant No. 3 's package insert of the Defendant's Drug for additional indications.

(cc) All documents prepared by Defendant No. 3 for marketing of the drug the Defendant's Drug. This includes any information authorised by Defendant No.3 to be provided or shared by its medical representatives/ agents/ suppliers with hospitals, state medical corporations, doctors, practitioners, patients, and consumers.

(dd) All documents (including enclosures) relating to phase IV clinical trial data for the Defendant's Drug submitted by Defendant No. 3 to the DCGI and any response received from the DCGI.

(ee) All documents (including enclosures) relating to the renewal of manufacturing and marketing licenses for the Defendant's Drug.

(ff) Updated statement of account in relation to the sale of the Defendant's Drug maintained by Defendant No.3 since the launch of the drug in 2016 until date.

(gg) Any other document (including enclosures) relating to the development, testing and approval of the Defendant's Drug.

(hh) All documents which are in the power and possession of Defendant No. 3 leading to approval and manufacturing of the Defendant's Drug.

ANNEXURE B

DISCOVERY OF DOCUMENTS SOUGHT IN CS(COMM) 1119/2016

In CS(COMM) 1119/2016, the plaintiffs seek discovery and production of all the regulatory dossier, including following documents:

a. All documents (including enclosures) relating to Defendant No.1's application to the Review Committee on Genetic Manipulation (the "RCGM") to develop cell lines in relation to Vivitra.

b. All documents (including enclosures) relating to the RCGM's letter dated September 20, 2010 taking note of Defendant No. 1's application to develop cell lines in relation to Vivitra.

c. All documents (including enclosures) relating to Defendant No.1's application to the DCGI seeking NOC to manufacture Vivitra for test, analysis and examination purposes.

d. All documents (including enclosures) relating to the DCGI's NOC dated April 4, 2012 to obtain manufacturing license in Form-29 for the manufacture of Trastuzumab for the purpose of examination, test and analysis.

e. All documents (including enclosures) relating Defendant No.1 's application to the State Food and Drug Administration ("State FDA") seeking NOC to manufacture its drug for test, analysis and examination purposes and any approval granted in this regard.

f. All documents (including enclosures) relating to the Form-29 licenses dated April 11, 2012, April 17, 2013, December 21, 2013 and April 25, 2014 for purposes of examination, test and analysis.

g. All documents (including enclosures) relating to the product characterisation studies conducted by Defendant No. 1 in relation to Vivitra.

h. All documents (including enclosures like the application letter, pre-clinical study protocol, Form C3, draft study plans, etc.) relating to Defendant No. 1's letter dated February 6, 2012 to the RCGM seeking permission to conduct pre-clinical studies on Vivitra.

i. All documents (including enclosures) relating to amendments, if any, suggested by the RCGM to the pre-clinical study protocol for Vivitra. This should include all correspondence between Defendant No. 1 and the RCGM in this regard.

j. All documents (including enclosures like Form C5, the study reports etc.) relating to Defendant No. 1 's application to the RCGM seeking (i) approval of its pre-clinical study data; and (ii) permission to conduct all phases of clinical trials in relation to Vivitra.

k. All documents (including enclosures) relating to the RCGM's letter dated September 18, 2012 approving the pre-clinical study data generated by Defendant No.1 for Vivitra.

l. All documents (including enclosures like the clinical trial protocol and the results of previous tests) relating to Defendant No.1 's application to the DCGI dated October 15, 2012 seeking (i) approval of its clinical trial protocol; and (ii) permission to conduct clinical trials for Vivitra.

m. All documents (including enclosures) relating to Defendant No.1's response to DCGI's letter dated January 23, 2013. This should include all further correspondence between Defendant No. 1 and the DCGI regarding the phases of clinical trials proposed to be conducted by Defendant No. 1 for Vivitra.

n. All documents/correspondence (including enclosures) relating to modifications suggested by the DCGI with respect to the clinical trial protocol for Vivitra and responses submitted by Defendant No.1.

o. All documents (including enclosures) relating to the DCGI's letter dated March 10, 2014 approving Defendant No.1's clinical trial protocol for Vivitra.

p. All documents (including enclosures) relating to the review and approval of the clinical trial protocol by the Subject Expert Committee on November 27, 2013, the Technical Committee on January 15 and 16, 2014, the Apex Committee on January 24, 2014 and the Ethics Committees.

q. All documents (including enclosures) relating to the submission of phase III clinical trial data for Vivitra by Defendant No. 1 to the DCGI.

r. All documents (including Form 44 and its enclosures) relating to Defendant No. 1's application for manufacturing and marketing authorisation for Vivitra to the DCGI.

s. All documents (including enclosures) relating to DCGI's recommendation to the State FDA dated November 27, 2015 for grant of manufacturing license to Defendant No. 1.

t. All documents (including enclosures) relating to the review and approval of the clinical trial data and application for manufacturing and marketing authorisation for Vivitra by the Subject Expert Committee, the Technical Committee and the Apex Committee.

u. All documents (including Form 28D and its enclosures) relating to Defendant No.1 's application to the State FDA for manufacturing and marketing authorisation for Vivitra.

v. All documents (including enclosures) relating to the DCGI's authorisation dated October 28, 2015 for Vivitra.

w. All documents (including enclosures) relating to the approval of the State FDA dated November 30, 2015 for Vivitra.

x. All documents (including enclosures) relating to Defendant No.1's application to the DCGI seeking no objection to use Vivitra for two additional indications, namely, HER2+ early breast cancer and HER2+ metastatic gastric cancer.

y. All documents (including enclosures) relating to the NOC granted by the DCGI on January 21, 2016.

z. All documents (including enclosures) relating to the SEC's review and approval of Defendant No.1's package insert for Vivitra dated October 27, 2015.

aa. All documents (including enclosures) relating to the Defendant No. l's application dated December 7, 2015 to the DCGI for approval of the package insert of Vivitra for one indication.

bb. All documents (including enclosures) relating to the DCGI's approval dated December 22, 2015 of Defendant No. 1's package insert of Vivitra for one indication.

cc. All documents (including enclosures) relating to the Defendant No. l's application dated February 10, 2015 to the DCGI for approval of the package insert of Vivitra for additional indications.

dd. All documents (including enclosures) relating to the DCGI's approval dated March 3, 2016 of Defendant No. 1's package insert of Vivitra for additional indications.

ee. All documents prepared by Defendant No. 1 for marketing of the drug Vivitra. This includes any information authorised by Defendant No. 1 to be provided or shared by its medical representatives/agents/ suppliers with hospitals, state medical corporations, doctors, practitioners, patients and consumers.

ff. All documents (including enclosures) relating to phase IV clinical trial data for Vivitra submitted by Defendant No. 1 to the DCGI and any response received from the DCGI.

gg. All documents (including enclosures) relating to the renewal of manufacturing and marketing licenses for Vivitra.

hh. Updated statement of account in relation to the sale of the drug Vivitra maintained by Defendant No. 1 since the launch of the drug in 2015 until date.