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

\+ CS(COMM) 159/2024 with I.A. 4196/2024, I.A. 4198/2024, I.A. 5827/2024, I.A. 33509/2024 and I.A. 36101/2024

F- HOFFMANN -LA ROCHE AG & ANR. .....Plaintiffs

Through: Mr. Arvind Nigam and Mr. Sandeep Sethi, Sr. Advocates with Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Achyut Tewari, Mr. Aayush Maheshwari, Ms. Krisha Baweja and Mr. Sumer Seth, Advocates.

versus

ZYDUS LIFESCIENCES LIMITED, ...Defendant

Through: Mr. Dushyant Dave and Mr. Rajshekhar Rao, Sr. Advocates with Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms. Vrinda Pathak, Ms. Sandhya Kukreti, Mr. Rajnish Singh and Ms. S.L. Sojanya, Advocates.

CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

O R D E R

% 25.07.2025

1. The matter is listed on office noting.

2. The judgment in I.A. 5827/2024 was pronounced on 23rd July, 2025.

3. Inadvertently, the last page of the judgment records the date of the judgment as 22nd July, 2025 instead of 23rd July, 2025.

4. Accordingly, the date of the judgment would read as 23rd July, 2025, and not 22nd July, 2025.

5. The corrected judgment in terms of the above order be uploaded.

AMIT BANSAL, J

JULY 25, 2025
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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

[Corrected judgment as per order dated 25th July, 2025]

% ***Judgment Reserved on: 27.03.2025***
Judgment pronounced on: 23.07.2025

\+ **CS(COMM) 159/2024 with I.A. 4196/2024, I.A. 4198/2024, I.A. 5827/2024, I.A. 33509/2024 and I.A. 36101/2024**

F- HOFFMANN -LA ROCHE AG & ANR. .....Plaintiffs
Through: Mr. Arvind Nigam and Mr. Sandeep Sethi, Senior Advocates with Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Achyut Tewari, Mr. Aayush Maheshwari, Ms. Krisha Baweja and Mr. Sumer Seth, Advocates.

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CORAM:
HON'BLE MR. JUSTICE AMIT BANSAL

JUDGMENT

AMIT BANSAL, J.

I.A. 5827/2024 ***(seeking constitution of a confidentiality club)***

1. The present suit has been filed *inter alia* seeking relief of permanent injunction restraining infringement of the following two Indian patents (hereinafter collectively referred to as the '***suit patents***'):

a. Indian patent no. IN 268632 titled as '*PHARMACEUTICAL FORMULATION COMPRISING HER2 ANTIBODY*' (hereinafter '***IN'632***') is a product patent which relates to an aqueous pharmaceutical formulation comprising *Pertuzumab* and excipients such as sucrose, histidine acetate buffer, polysorbate such that the pH of the said formulation is between 5.5-6.5.

b. Indian patent no. IN 464646 titled as '*PERTUZUMAB VARIANTS AND EVALUATION THEREOF*' (hereinafter '***IN'646***') is a process patent which relates to the method for making a composition comprising *Pertuzumab* and one or more variants.

CASE SET UP IN THE PLAINT

2. The case set up by the plaintiffs in the plaint is as follows:

2.1 The plaintiff no.1, a Switzerland based company founded in 1896, is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. The plaintiff no.2, an American corporation founded in 1976, is the world's first biotechnology company, which was acquired by the plaintiff no.1 in March 2009 as its wholly owned independent subsidiary. The plaintiffs no.1 and 2 are hereinafter collectively referred to as the '***plaintiffs***'.

2.2 As of 2023, the Roche Group, of which the plaintiffs are a part, has a presence in over 100 countries. The Roche Group has invested significantly in the field of research and development and one of the major areas of focus and investment for the Group is treatment of cancer.

2.3 Human epidermal growth factor receptor (HER) are important mediators of cell growth, differentiation and survival and include four distinct members, *i.e.*, HER1, HER2, HER3 and HER4. The overexpression of HER2 gene is a primary cause for breast cancer tumours which is one of the most aggressive forms of cancer.

2.4 Both the suit patents pertain to *Pertuzumab*, which is a monoclonal antibody (MAb) biologic used to inhibit the dimerization of HER2 cells with other HER receptors, and thus inhibits tumour growth. *Pertuzumab* is a prescription medicine for treating patients with early-stage breast cancer and metastatic breast cancer and has been approved by regulatory authorities in several countries across the world.

2.5 The bibliographic details of the suit patents are set out below:

a. Suit Patent IN'632

Title	**PHARMACEUTICAL FORMULATION COMPRISING HER2 ANTIBODY**
Patentee	Plaintiff No. 2
Application No.	1730/DELNP/2007
Patent No.	268632
Priority Date	20.10.2004
National Phase entry-filing date in India	05.03.2007
Date of Publication u/s 11 A	24.08.2007
PCT International Application Number	PCT/US2005/037471

PCT International Filing date (Date of patent)	19.10.2005
FER Issue Date	26.08.2010
FER Response Date	18.05.2011
Date of Grant	09.09.2015
Date of expiry	19.10.2025

b. Suit Patent IN’646

Title	**PERTUZUMAB VARIANTS AND EVALUATION THEREOF**
Patentee	Plaintiff No. 1
Application No.	6979/CHENP/2015
Patent No.	464646
Priority Date	16.04.2013
PCT International Filing date (Date of patent)	15.04.2014
PCT International Application Number	PCT/US2014/034200
National Phase entry-filing date in India	12.11.2015
Date of Publication u/s l1A	01.07.2016
FER Issue Date	30.12.2019
FER Response Date	30.06.2020
Pre-grant opposition date	12.10.2020

Pre-grant order date finding the application in order for grant	31.10.2023
Date of Grant	01.11.2023
Date of expiry	15.04.2034

2.6. IN'632 has 4 claims which are set out in paragraph no.28 of the plaint. IN'646 has 8 claims which are set out in paragraph no.15 of the plaint.

2.7. The inventiveness of IN'646 resides in the method of making a composition having *Pertuzumab* and its variant(s) comprising unpaired cysteine variants, low-molecular-weight-species (LMWS), high-molecular weight-species (HMWS), afucoslated variant, *Pertuzumab* Peak 1, and *Pertuzumab* Peak 2 and quantifying the said variants within the range disclosed and claimed in IN'646.

2.8. The plaintiffs' product *Pertuzumab*, which is sold under the brand name Perjeta, is covered within the scope of the claims of the suit patents. Perjeta (*Pertuzumab*) Concentrate for Solution for Infusion 420 mg/ 14 ml vials have been granted approval on 8th June 2012 by the US FDA and on 29th December 2014 in India. The import and sale of the plaintiffs' product Perjeta amounts to working of both the suit patents in India.

2.9. The suit patents, granted after examination, are currently valid and subsisting. Patents corresponding to the suit patents have also been granted in several other countries.

2.10. During the term of the suit patents, the plaintiffs, being the rightful owners/ exclusive licensees, have the exclusive right under Section 48 of the Patents Act, 1970 (hereinafter '***Act***'/ '***Patents Act***') to prevent unauthorized

third-parties from making, using, offering for sale, selling or importing any product which fall within the scope of the claims of either of the suit patents.

2.11. The defendant is an Indian pharmaceutical company and is engaged in the manufacturing and sale of drugs, active pharmaceutical ingredients, etc.

2.12. The plaintiffs, in February 2024, came across the recommendations of the Subject Expert Committee (hereinafter '***SEC***') (Oncology) of the Central Drugs Standard Control Organization (hereinafter '***CDSCO***'), which were made in the SEC meetings held on 23rd January 2024 and 24th January 2024. As per the information available from the aforesaid SEC meetings, the defendant filed an application for grant of permission to manufacture a new drug formulation for sale and distribution of *Pertuzumab* as per the New Drugs and Clinical Trials Rules, 2019. The SEC recommended for grant of permission to manufacture and market *Pertuzumab* 30 mg/ ml concentrate solution for infusion (420 mg/ 14 ml single-dose vial) to the defendant.

2.13. Previously, in January 2023, the defendant had procured 480 vials of the original innovator biologic reference product *Pertuzumab* (Perjeta) from the plaintiff no.1's affiliate. Thereafter, the plaintiff no.1's affiliate representatives came across a document uploaded on the website of Clinical Trial Registry of India (hereinafter '***CTRI***') which detailed that the defendant was undertaking clinical trials for a similar biologic/ biosimilar of the plaintiffs' *Pertuzumab* for its product under the nomenclature ZRC-3277. In the said document, the defendant had mentioned the plaintiffs' product *Pertuzumab* (Perjeta®, Genentech Inc.) as the reference product.

2.14. Upon further verification, the plaintiffs also came across the defendant's application dated 9th September 2021 filed with the CDSCO seeking permission to conduct clinical trials for its aforesaid similar biologic

ZRC-3277 under the provisions of the New Drugs and Clinical Trial Rules, 2019 with the reference drug being *Pertuzumab* (Perjeta®, Genentech Inc.), which is covered within the scope of the claims of the suit patents.

2.15. The defendant has also filed applications for registering its patents relating to formulations of *Pertuzumab* including patent applications no. WO/2020/084503 (international filing date – 23rd October 2019) and WO/2021/079337 (international filing date – 23rd October 2020), which are currently pending.

2.16. In view of the aforesaid SEC recommendation dated 24th January 2024, there is an imminent threat that the defendant is attempting to manufacture, launch and otherwise deal in *Pertuzumab* 30 mg/ ml concentrate solution for infusion (420 mg/ 14 ml single-dose vial) during the term of the suit patents without the plaintiffs' authorization.

2.17. As the defendant had claimed its product to be a similar biologic of the plaintiffs' product covered by the suit patents, the present suit has been filed as a *quia timet action* in view of the apprehension that the defendant would launch its product.

CASE SET UP IN THE WRITTEN STATEMENT

3. The broad defences taken up by the defendant in the written statement are as follows:

3.1. None of the suit patents covers the active ingredient *Pertuzumab per se* and the same is evident from the titles of the suit patents. In fact, there cannot be a patent for *Pertuzumab per se* in India because *Pertuzumab* was admittedly first disclosed on 4th January 2001 in WO/2001/00245 (international filing date 23rd June 2000) for which no corresponding patent was filed in India.

3.2. The active ingredient *Pertuzumab* and the process of making it are *publici juris* and several publications since 1986 have been cited to substantiate the same (*refer paragraph 11 of the written statement*). Notably, the product claim for *Pertuzumab* was deleted by the plaintiffs by way of an amendment in the course of prosecuting IN'632, which amounts to a clear acknowledgement by the plaintiffs that *Pertuzumab* and its variants were known.

3.3. There is no explanation provided by the plaintiffs about the grounds to allege that the formulation/ process employed by the defendant is covered within the scope of the suit patents. The plaintiffs are only attempting to show its similarity to *Pertuzumab*, which is already in the public domain.

3.4. As per the claim mapping of IN'632 with claim 1 of the defendant's patent application, the defendant's formulation is entirely different from the formulation claimed by the plaintiffs.

3.5. With regards IN'646, the following defences have been taken:

a. The plaintiffs have not satisfied the conditions to invoke Section 104A of the Act in the present case.

b. The plaintiffs' claim is solely on the basis of the defendant's application filed with the CDSCO for obtaining approval of its similar biologic.

c. IN'646 is liable to be invalidated on account of various grounds under Section 64 of the Act.

d. The process adopted by the defendant does not infringe the plaintiffs' process patent IN'646.

RELEVANT PROCEEDINGS IN THE SUIT

4. Summons in the present suit and notice in I.A. 4196/2024, the application for interim injunction, were issued, and accepted on behalf of the

defendant on 23rd February 2024. On the same day, after noting the contentions of the parties, the Court passed a detailed order. Some of the relevant extracts from the said order for the purposes of adjudicating the present application are set out below:

> *"19. This lawsuit concerns allegations of patent infringement, specifically targeting the 'formulation' and 'process' associated with an innovator 'Reference Biologic Product'. The Plaintiffs contend that their Suit Patents are on the verge of being infringed upon by a competing entity (the Defendant) through development of a 'Similar Biologic product'. Thus, this case delves into the complexities inherent in the intersection of biotechnological innovation and intellectual property law.* ***At issue is the precise determination of whether the Similar Biologic's development encroaches upon the intellectual proprietary rights encapsulated within the patents of its Reference counterpart.*** *Thus, the Court is called upon to not only navigate the intricacies of patent law, but also scientific principles that are foundational for the biologic and its biosimilar contender.*
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> *** *** ***
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> *25. Thus, in view of the aforenoted responses by Dr. Singhvi, and given the fact that the reference biologic is protected under the Suit Patent IN'632 and the Defendant's similar biologic is encapsulated by Claim 1 in their patent application No. 2021079337, we must begin with the process of claim mapping. The Court will have to discern whether the formulation disclosed in Claim 1 of patent application No. 2021079337 is a variant of Pertuzumab, different from the Plaintiffs' formulation patent which is also "pharmaceutical formulation comprising Pertuzumab". However, the absence of such claim mapping substantially restricts the Court from fully assessing the infringement allegations.* ***In the Court's opinion, the Plaintiffs ought to have carried out this claim mapping, as this procedural step is essential not only for clarifying the contours of the controversy but also for enabling the Court to make an informed decision on the matter.*** *Accordingly, they must now do so expeditiously and present the same to the Court. The Defendant is also permitted to do the claim mapping, in case they so desire.*
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> *** *** ***
>
> *28.* ***Given the above-discussed contest of similar and reference biologics in this case, the Court, drawing upon the aforementioned provision, deems it appropriate for the Defendant to reveal the process employed by them to develop the formulation for which drug approval/ licensing has been sought. However, as the issue of whether the Defendant's biologic formulation is identical to the Plaintiff's remains to be thoroughly examined, it is directed that the Defendant shall submit the aforementioned information in a sealed envelope with the Court. This***

> ***measure, in the Court's opinion, would ensure the preservation of sensitive information pending further deliberations. The Court will subsequently also assess the need for establishing a confidentiality club to manage the disclosed information, to ensure that access to such information is appropriately controlled and limited to authorized individuals."***
>
> [emphasis supplied]

5. Following the aforesaid order, the plaintiffs filed the present application on 11th March 2024 seeking constitution of a confidentiality club. By way of the present application, the plaintiffs seek access to the information filed by the defendant under a sealed cover by the members of the confidentiality club for effectively mapping the defendant's formulation(s) as well as process(es).

6. Notice in the present application was issued and accepted on behalf of the defendant on 13th March 2024.

7. Pursuant to the aforesaid, the defendant, on 22nd March 2024, filed its manufacturing process in a sealed cover.

8. Amidst the ongoing deliberations on the grant of an interim injunction, the defendant launched a product, namely, 'Sigrima', a similar biologic of the plaintiffs' Perjeta, which comprises *Pertuzumab*. The plaintiffs therefore filed another application under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 (hereinafter '***CPC***'), being I.A. 33509/2024, seeking interim injunction restraining the sale and distribution of the aforesaid product.

9. On 9th July 2024, an *ad interim* injunction was passed by the predecessor bench against the defendant in the following terms:

> *"10. In light of these considerations – fairness, equity, and the balance of convenience – the Court finds compelling reasons to issue an injunction. Accordingly, till the next date of hearing, the Defendants are restrained from marketing / selling their product "Sigrima", which is a biological similar of Plaintiffs' "Perjeta®"/ "Pertuzumab"."*

10. *Vide* judgment dated 9th October 2024, the predecessor bench of this Court dismissed I.A. 33509/2024. The aforesaid judgment was taken in appeal by the plaintiffs and the said judgment was set aside by the division bench on 16th October 2024, and the matter was remanded back before this Court.

11. On 5th November 2024, senior counsel appearing on behalf of the defendant requested that the hearing in the applications for interim injunction be deferred on the ground that the defendant has filed a Special Leave Petition (hereinafter '***SLP***') before the Supreme Court against the aforesaid order dated 16th October 2024 passed by the division bench. The Court ordered that the *ad interim* injunction granted on 9th July 2024 shall continue in the interregnum.

12. On 18th November 2024, the Supreme Court disposed of the aforesaid SLP with a request that I.A. 4196/2024 and I.A. 33509/2024 in the present suit be decided expeditiously by this Court.

13. The defendant also filed an appeal against the Order dated 5th November 2024 before the division bench, and the same was set aside *vide* order dated 21st November 2024 insofar as it extended the *ad interim* injunction dated 9th July 2024.

14. As a result, there is no interim injunction in favour of the plaintiffs as on date. However, at this stage, counsel for the plaintiffs does not wish to press I.A. 4196/2024 and I.A. 33509/2024, the applications for interim injunction. Instead, counsel for the plaintiffs presses the present application, I.A. 5827/2024, seeking disclosure of the defendant's manufacturing process to the members of the confidentiality club.

15. Submissions on behalf of counsel for the parties were heard on 2nd December 2024, 7th January 2025, 14th January 2025, 14th February 2025 and

4th March 2025 and the judgment was reserved on 27th March 2025. Both the parties have filed their respective written submissions.

SUBMISSIONS ON BEHALF OF THE PLAINTIFFS

16. Mr. Arvind Nigam and Mr. Sandeep Sethi, learned senior counsel appearing on behalf of the plaintiffs, have made the following submissions:

16.1. *Pertuzumab* is commercialized by the plaintiffs under the trade mark Perjeta which, as is currently sold by the plaintiffs, uses both the suit patents. The process covered by IN'646 is for making *Pertuzumab* and its variants, (commercially known as Perjeta). This specific and precise manufacturing process determines the quality of the composition comprising *Pertuzumab* and its variants.

16.2. Section 104A of the Act is concerned with the burden of proof and not with discovery. The said burden has to be established during the course of trial and not at an interim stage wherein discovery of the defendant's process is sought by the plaintiffs. Thus, Section 104A of the Act may be invoked only at the stage of final arguments and not at this stage.

16.3. The defendant's argument that the pre-requisite of Section 104A of the Act has not been satisfied as it requires the products of the parties to be identical whereas the defendant's product is only a similar biologic of the plaintiffs' product is a complete red herring. If such an argument made on behalf of the defendant is accepted, there can never be a process patent infringement of a biologic drug.

16.4. Unlike the case with chemical compounds, a similar biologic can never be an exact replica of the innovator reference biologic, given the intrinsic nature of the biologic product. Nonetheless, a similar biologic is nearly identical to its reference biologic and the same is evident from the Guidelines

on Similar Biologics, 2016 issued by the Department of Biotechnology (Ministry of Science and Technology) and CDSCO (Ministry of Health and Family Welfare), Government of India.

16.5. Considering that the defendant has claimed its product to be a similar biologic of the plaintiffs' *Pertuzumab* (Perjeta®, Genentech Inc.) and has used the same as the reference drug in its application for clinical trials before the CDSCO, the defendant admits that it is manufacturing a similar biologic of the plaintiffs' reference biologic *Pertuzumab*, which covers the formulation claims of IN'632 as well as the process claims of IN'646. Further, since no methodology for production of the defendant's similar biologic has been disclosed, the plaintiffs apprehend that the process employed by the defendant is identical to that of Perjeta, and thus infringes the registered patent IN'646.

16.6. As regards the defendant's formulation, the plaintiffs filed a claim mapping with their rejoinder to the defendant's reply to I.A. 4196/2024, which establishes infringement of IN'632.

16.7. The defendant's process of manufacturing the similar biologic of the plaintiffs' product *Pertuzumab* (Perjeta) is within the special knowledge of the defendant only. Considering the defendant's use of the plaintiffs' product *Pertuzumab* (Perjeta®, Genentech Inc.) as a reference drug/ comparator in its application filed with the CDSCO, it is imperative that the defendant discloses its process to the members of the confidentiality club set up by this Court.

16.8. Discovery/ disclosure of the defendant's process also ought to be granted under the provisions of Order XI Rules 1(7), 1(12) and 5 of the CPC as amended by the Commercial Courts Act, 2015. No *prima facie* case is required to be established by the plaintiffs for being permitted discovery of the defendant's manufacturing process. In this regard, the plaintiffs place

reliance on the judgment of this bench in ***F-Hoffmann-La Roche* v. *Drugs Controller General of India***[1].

16.9. Mere filing of the manufacturing process by the defendant in a sealed cover will serve no purpose, as the question whether the process employed by the defendant for making its similar biologic is identical to the plaintiffs' process cannot be ascertained until the defendant's process is disclosed to the plaintiffs.

16.10. No prejudice would be caused to the defendant if the present application is allowed and disclosure of the defendant's process is permitted.

SUBMISSIONS ON BEHALF OF THE DEFENDANT

17. Mr. Dushyant Dave and Mr. Rajshekhar Rao, learned senior counsel appearing on behalf of the defendant, have made the following submissions:

17.1. The present application does not make out any ground for disclosure and is only an afterthought and a backhanded attempt to seek access to the defendant's proprietary process, as the plaintiffs failed to establish a *prima facie* case of infringement of patent against the defendant.

17.2. The only ground for seeking constitution of a confidentiality club in the pleadings of the present application is that the proprietary process of the defendant is needed to conduct 'claim mapping' of the process patent IN'646 as directed by this Court *vide* order dated 23rd February 2024. However, the said averment is false and misleading as the aforesaid order directed the plaintiffs to conduct claim mapping only of the product patent IN'632 with the defendant's patent application, which was already in the public domain and was filed with the suit.

[1] 2025 SCC OnLine Del 934

17.3. The plaintiffs, in I.A. 4196/2024 and their rejoinder to the defendant's reply to I.A. 4196/2024, baldly asserted that the grounds for invoking Section 104A of the Act are satisfied. However, during the oral arguments, the plaintiffs altered their stance, arguing that Section 104A is not attracted at the stage of constitution of the confidentiality club and is only relevant at the final adjudication stage. The plaintiffs' aforesaid stance is contrary to the statute as well as their own pleaded case.

17.4. The satisfaction of the pre-requisites prescribed under Section 104A of the Act is mandatory prior to directing the defendant to disclose its process to the members of the confidentiality club. The purpose of invoking Section 104A is to seek disclosure from the defendant in a proceeding where a plaintiff has discharged its initial onus. Thus, Section 104A cannot be ignored at the time of seeking disclosures from the defendant.

17.5. The plaintiffs' reliance on Order XI of the CPC as amended by the Commercial Courts Act, 2015 and the argument that its provisions will prevail over the specific requirements under a sector-specific law is erroneous and does not inure to their benefit. It is a settled position of law that the Patents Act is a self-contained code and the pre-requisites of Section 104A cannot be diluted by the introduction of the Commercial Courts Act, 2015.

17.6. The plaintiffs' product obtained from IN'646 for the purpose of Section 104A of the Act is admittedly not *Pertuzumab* (Perjeta) but *Pertuzumab* (Perjeta) + variants, wherein the variants have been specifically claimed to be a product feature. Pertinently, the said variants are the basis on which the prior art has been sought to be distinguished in IN'646. Therefore, the products of the parties have not proven to be identical, as the defendant has only sought

to make a similar biologic of *Pertuzumab* (Perjeta) and not *Pertuzumab* (Perjeta) + variants.

17.7. Even assuming that the plaintiffs' product obtained from IN'646 is *Pertuzumab* (Perjeta) *per se*, it cannot be said that the products are identical only on the basis that the defendant's product is similar biologic of the plaintiffs' reference biologic *Pertuzumab*. Similar biologics, as per the Guidelines on Similar Biologics, 2016, only refers to similarity in terms of 'safety', 'efficacy' and 'quality' of the product and does not mean that their formulation is identical. The aforesaid Guidelines makes no reference to patent infringement.

17.8. Thus, the pre-requisites under Section 104A of the Act have not been satisfied in the present case.

ANALYSIS AND FINDINGS

18. I have heard counsel for the parties and examined the materials on record.

19. The present application concerns enabling the confidentiality club and permitting the members of the confidentiality club to access the process used by the defendant for manufacturing its product 'Sigrima', which has been filed by the defendant on 22nd March 2024 in a sealed cover.

20. Since the present application is concerned with the infringement of the plaintiffs' process patent and both sides have made submissions with regard to the applicability of Section 104A of the Act, one of the key issues in deciding the present application would be to determine the scope and interpretation of Section 104A of the Act. Section 104A was inserted in the Act in the year 2002 in compliance with India's obligations under the

Agreement on Trade-related Aspects of Intellectual Property Rights[2] (hereinafter '***TRIPS Agreement***').

Scope and ambit of Section 104A of the Act

21. For the sake of convenience, Section 104A of the Act is set out below:

> *"**104A. Burden of proof in case of suits concerning infringement.** –(1) In any suit for infringement of a patent, where the subject matter of patent is a process for obtaining a product, the court may direct the defendant to prove that the process used by him to obtain the product, **identical to the product of the patented process**, is different from the patented process if,–*
>
> *(a) **the subject matter of the patent is a process for obtaining a new product**; or*
>
> *(b) **there is a substantial likelihood that the identical product is made by the process**, and the patentee or a person deriving title or interest in the patent from him, has been unable through reasonable efforts to determine the process actually used:*
>
> ***Provided that the patentee or a person deriving title or interest in the patent from him first proves that the product is identical to the product directly obtained by the patented process.***
>
> *(2) **In considering whether a party has discharged the burden imposed upon him by sub-section (1), the court shall not require him to disclose any manufacturing or commercial secrets, if it appears to the court that it would be unreasonable to do so.**"*
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> [emphasis supplied]

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[2] Article 34 – Process Patents: Burden of Proof – 1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, **if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.** Therefore, Members shall provide, in at least one of the following circumstances, that **any identical product** when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) If the product obtained by the patented process is new;
(b) If there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3**. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.**

22. Section 104A of the Act represents a calibrated departure from the general evidentiary principle that the burden of proof lies upon the party asserting a fact. It carves out a statutory exception only in suits involving infringement of process patents, where the patentee is often handicapped in proving the infringing process due to its inherently concealed nature. However, this exception is neither automatic nor routine. Section 104A applies only when the plaintiff discharges the following threshold requirements:

a. The defendant's product is identical to the product directly obtained by the patented process; and
b. The subject matter of the process patent is for obtaining a new product or there is a substantial likelihood that the identical product is made by the said process, and it is difficult for the plaintiff to determine the process used by the defendant.

23. If the plaintiff is able to satisfy both the aforesaid conditions, the Court has the discretion to direct the defendant to prove that the process adopted by it to obtain its product is different from the patented process.

24. In order to protect the legitimate commercial interests of the defendant, sub-section (2) of Section 104A of the Act provides that a defendant would not be required to disclose any manufacturing or commercial secrets if it appears to the Court that the same is unreasonable to do so.

25. Section 104A of the Act came up for consideration before the High Court of Karnataka in ***Natural Remedies Pvt. Ltd.* v. *Indian Herbs Research***

and Supply Co. Ltd.[3]. The observations of the Court with regard to scope and ambit of Section 104A of the Act are set out below:

> *"69. Now by amended Act and by virtue of introduction of Section 104-A of the Act, the burden is sought to be shifted on the defendant. That is the purpose and object of insertion of Section 104-A of the Act.* ***A reading of the aforesaid provisions makes it very clear that, in a suit for infringement of a process, if the patentee proves that the product of the defendant is identical to the product of the patented process, then the burden of proving that the process used by the defendant in obtaining his product is different from the patented process lies on the defendants. Therefore, the condition precedent for application of the provisions is that the product of the plaintiff and defendant should be identical. If the products are not identical, a suit for infringement of a patent of the process would not lie and Section 104-A of the Act is not [] attracted.*** *Once the plaintiff proves that his product and the product of the defendant are identical, then, the Court may direct the defendant to prove that the process used by the defendant to obtain the product is different from the patented process. Therefore, in the event of the product of both the plaintiff and the defendant being identical, the burden shifts on the defendant to prove that the process adopted by him to obtain the product is totally different from the process adopted by the plaintiff in obtaining his product.* ***The word used is identical and not similar. The definition of 'identical' in Oxford Dictionary is, similar in every detail exactly alike. Therefore, the meaning of the word 'identical' means being the same, exactly equal and alike having such a close similarity or resemblance as to be essentially equal or interchangeable. Matching, equal, twin, equivalent, synonymous, coinciding exactly when superimposed. Two things are identical if one can be substituted for the other without affecting the truth.*** *However, the definition of similar in Oxford Dictionary means, having a resemblance in appearance, character, or quantity, without being identical. Showing resemblance in qualities, characteristics, or appearance; alike but not identical. Resembling or similar; having the same or some of the same characteristics often used in combination expressing closely related meanings. Meaning the same or nearly the same.*
>
> *70.* ***Therefore, from the aforesaid meaning attributed to these two words, similar is not identical. The word used in Section 104-A is identical and not similar. Therefore, unless the two products are identical, Section 104-A is not attracted. The products being identical is sine qua non for applicability of Section 104-A of the Act.***

[3] 2011 SCC OnLine Kar 4561

> *71.* ***Insofar as Section 104-A is concerned, it is not a weapon in the hand of the plaintiff. It is a shield in the hand of the defendant. The question of the defendant disclosing the process by which his product is manufactured in defence to a claim for infringement for a patent would not arise either at the stage of pleadings or at the stage of evidence. It arises only when this Court holds the patent is valid and consequently it comes to the conclusion that there is an identical product manufactured by the defendant similar to that of the plaintiff and then the Court can call upon the defendant to produce the particulars of the process by which his product is manufactured.*** *It is only then, if the defendant refuses to furnish the particulars of the process, the Court may draw adverse inference and invoke Section 104(a).* ***If the Court comes to the conclusion that the plaintiffs patent is valid and the product of the defendant is identical with that of the plaintiff the Court may call upon the defendant to disclose the process by which his, product is manufactured and the defendant may be ready and willing to place the process, before the Court subject to the Court protecting the trade secret of the defendants.*** *The trade secrets in India are protected under the, common law. There is no statute as such, protecting that right. In either case, if the defendant has to disclose either in the written statement or by way of evidence through trial, the process by which he manufactures his product that would violate the protection, which is given to the defendant, under the common law and, therefore, any interpretation to be given by this Court, should bear in mind, that when the plaintiffs interest is protected under the statute and the defendant interest is also protected by common law. These two have to be harmoniously interpreted so that either of the, parties are not put to disadvantage. Other wise the protection given to the defendant under common law is completely taken away.* ***It is in this background the amendment to Section 104(a) which overrides the provisions of the [] Indian Evidence Act contained in Sections 100 to 104 of the Evidence Act is to be understood and construed."***
>
> [emphasis supplied]

26. The aforesaid judgment was followed by the High Court of Andhra Pradesh in ***Bristol-Myers Squibb Holdings Ireland* v. *Mylan Laboratories Limited***[4]. The observations of the Court with regard to interpretation of Section 104A of the Act are set out below:

> *"21.* ***A reading of Section 104-A of the Act of 1970 makes it clear that in a suit for infringement of a process, if the patentee proves that the product of the respondent is identical to the product of the patented***

[4] 2014 SCC OnLine Hyd 1511

process, then the burden of proving that the process used by the respondent in obtaining his product is different from the patented process lies on the respondent. Therefore, the condition precedent for application of the provisions is that the product of the appellant and respondent should be identical and if the products are not identical, a suit for infringement of a patent of the process would not lie and Section 104-A of the Act of 1970 is not attracted. *Once the plaintiff proves that his product and the product of the defendant are identical, then the Court may direct the defendant to prove that the process used by the defendant to obtain the product is different from the patented process. Therefore, in the event of the product of both the plaintiff and the defendant being identical, the burden shifts on the defendant to prove that the process adopted by him to obtain the product is totally different from the process adopted by the plaintiff in obtaining his product. The word used is identical and not similar. The definition of 'identical' in Oxford Dictionary is, similar in every detail 'exactly alike'. Therefore, the meaning of the word 'identical' means being the same, exactly equal and alike having such a close similarity or resemblance as to be essentially equal or interchangeable, matching, equal, twin, equivalent, synonymous, coinciding, exactly when superimposed. Two things are identical if one can be substituted for the other without affecting the truth. However, the definition of 'similar' in Oxford Dictionary means, having a resemblance in appearance, character, or quantity, without being identical. Showing resemblance in qualities, characteristics or appearance; alike but not identical. Resembling or similar, having the same or some of the same characteristics often used in combination, expressing closely related meanings. Meaning the same or nearly the same.* ***Therefore, the word used in Section104-A is identical and not similar and that unless the two products are identical, Section 104-A is not attracted. The products being identical is sine quo non for applicability of Section 104-A of the Act. Only when the court comes to the conclusion that there is an identical product manufactured by the defendant similar to that of the plaintiff, then the Court can call upon the defendant to produce the particulars of the process by which his product is manufactured. It is only then, if the defendant refuses to furnish the particulars of the process, the Court may draw adverse inference and invoke Section 104-A.*** *If the Court comes to the conclusion that the plaintiff's patent is valid and the product of the defendant is identical with that of the plaintiff the Court may call upon the defendant to disclose the process by which his product is manufactured and the defendant must be ready and willing to place the process before the Court subject to the Court protecting the trade secret of the defendant. [Judgment of Karnataka High Court in Natural Remedies Private Limited v. Indian Herbs Research & Supply Co. Ltd., in O.S. No. 1 of 2004, dated 09.12.2011].”*

[emphasis supplied]

27. From a reading of the aforesaid judgments, the following legal principles emerge with regard to the scope and ambit of Section 104A of the Act:

a. Only when the plaintiff proves that the plaintiff's product and the defendant's product are identical, the Court may direct the defendant to disclose its process to show that the same is different from the patented process.

b. The products of the plaintiff and the defendant being identical is a *sine qua non* for the applicability of Section 104A of the Act. Mere similarity between the two products would not suffice.

c. While directing the defendant to disclose its process, the Court would protect the trade and commercial secrets of the defendant.

d. Where the products are found to be identical and the defendant nonetheless refuses to furnish the particulars of its process, the Court may draw adverse inference and invoke Section 104A of the Act.

28. I am in respectful agreement with the position of law elucidated by the aforesaid judgments. The intent behind Section 104A of the Act is to shift the onus of proof from the plaintiff to the defendant in cases involving infringement of process patents. This is premised on the fact that the process adopted by a defendant in manufacturing its product would only be known to the defendant and would be difficult for the plaintiff to determine. However, this is subject to certain pre-conditions, one of which is that the plaintiff has to show that the product of the defendant is identical to the product that is directly obtained from the process patent of the plaintiff.

29. In ***Centrient Pharmaceuticals* v. *Dalas Biotech***[5], a coordinate bench of this Court was deciding an application filed on behalf of the plaintiffs seeking discovery by interrogatories. While discussing the plaintiffs' burden of proving infringement of a process patent by the defendant, the Court noted that under Section 104A of the Act, the plaintiffs must first establish that the defendant's product is identical to the product obtained by the patented process. The Court dismissed the aforesaid application and held that by way of the said application, the plaintiffs were attempting a fishing and roving inquiry, under the guise of interrogatories, which is impermissible. The relevant extracts of the said decision are set out below:

> *"25. Insofar as the plea that written statement is vague, it was the submission of Mr. Kohli that the written statement filed by the defendant explain its position that the process does not infringe the patent of the plaintiffs. In other words, the written statement filed by the defendant is not vague. Mr. Kohli has primarily stated that since the regulatory approvals procured by the defendant for manufacturing of Amoxicilin Trihydrate is not the subject matter of the present suit, such an information cannot be sought for, by the plaintiffs. Though, the plea of Mr. Kohli is not appealing,* ***what is important is, there is a burden on the plaintiffs to prove that the patent infringement lies on the plaintiffs by first proving that the product obtained by the defendant is identical to the product obtained by the patented process.***
>
> *26. It was submitted by Mr. Kohli that the plaintiffs have filed a manipulated test report to discharge its burden, which is challenged by the defendant. That apart,* ***I find, the attempt of the plaintiffs is to discover the fact, what constitute the exclusive evidence of the opponent's case. Further, the attempt is also for doing a roving and fishing inquiry, which cannot be allowed through the process of interrogatories.***
>
> *27. The plea of Mr. Lall that the defendant has added optionality to the process to contend that the patent has not been infringed, can be taken care of by the plaintiffs through the process of cross examination of the defendant's witness to test the credibility of the stand of the defendant. In other words,* ***interrogatories by the plaintiffs to extract something, which it could do so in the course of cross examination, cannot be allowed.***

[5] 2021 SCC OnLine Del 157

> *28. Under such circumstances, this Court is of the view that the application filed by the plaintiffs calling upon the defendant to file response to the interrogatories cannot be allowed. I do not see any merit in the application. The same is dismissed."*
>
> [emphasis supplied]

Whether Section 104A of the Act can be invoked at the present stage of the suit

30. The plaintiffs have argued that Section 104A of the Act cannot be invoked by the defendant at this stage of the suit and the same comes into play only at the stage of final adjudication of the suit. The plaintiffs have also sought to distinguish the decision in ***Natural Remedies*** (supra) on the ground that the same was given at the stage of final hearing of the suit and not at the interim stage.

31. From a plain reading of Section 104A of the Act, there is nothing to suggest that Section 104A cannot be invoked at an earlier stage, particularly when the plaintiffs are seeking disclosure of the defendant's process by way of an interlocutory application.

32. In ***Natural Remedies*** (supra), the High Court of Karnataka, at the final adjudication of the suit, held that the defendant cannot be called upon to disclose its process without fulfilling the requirement of Section 104A of the Act. If the Court can refuse disclosure at the final stage relying upon Section 104A of the Act, it can surely refuse to direct the defendant to disclose its process at an earlier stage if the conditions of Section 104A of the Act are not met.

33. The decision in the ***Natural Remedies*** (supra) was followed in ***Bristol-Myers*** (supra) which was in the context of an appeal against an order passed by the Trial Court refusing to grant an *ad interim* injunction in favour of the

plaintiff (appellant). Clearly, the said judgement was not at the stage of final disposal of the suit and yet, the Court invoked Section 104A of the Act.

34. It has been pointed out on behalf of the defendant that the plaintiffs have themselves admitted to the applicability of Section 104A of the Act. In I.A. 4196/2024 filed on behalf of the plaintiffs seeking relief of interim injunction, the plaintiffs have specifically stated that they have discharged their onus under Section 104A of the Act by proving that the products of the plaintiffs and the defendant are identical based on the defendant's citation of Perjeta as a reference drug before the CDSCO and the burden of proof now rests with the defendant (*refer paragraphs 27 and 28 of I.A. 4196/2024 and paragraph 5 of rejoinder to the defendant's reply to I.A. 4196/2024*). The aforesaid stand of the plaintiffs was also reiterated in their rejoinder to the defendant's reply to the present application (*refer paragraphs 4 and 8 of rejoinder to the defendant's reply to I.A. 5827/2024*). It is only at the stage of oral arguments that the plaintiffs have taken a contrary stand that Section 104A of the Act is not applicable at the present stage of the suit. Clearly, a party cannot be permitted to take contrary stands at different point of time as per its own convenience.

35. The predecessor bench, in the order dated 23rd February 2024, observed that Section 104A of the Act would be applicable insofar as the process patent IN'646 is concerned. The relevant observations of the predecessor bench in the aforesaid order are set out below:

> *"27.* ***The Plaintiffs have a process patent IN'646, as discussed above. Thus, to determine the allegations of process infringement, the Court intends to invoke Section 104A of the Patents Act.*** *Under this provision, when a patent covers a process for obtaining a product, the Court is empowered to require the Defendant to demonstrate that their method for creating an identical product diverges from the patented process, subject*

> *to certain pre-requisites. This shift in the burden of proof is predicated on the novelty of the product and the patentee's disclosure of the process in the patent document in a sufficiently detailed manner for replication by a person skilled in the art."*
>
> [emphasis supplied]

36. The aforesaid observation was also reiterated in the order dated 13th March 2024, the relevant extracts of which are set out below:

> *"5.* ***The previous order is clear as to the court's observations regarding the creation of confidentiality club and section 104A of the Patent Act, 1970 and thus no further observations are necessary. Right now, the Court is simply setting up the confidentiality framework; precise terms of access to sensitive process information aren't yet under deliberation. Creating the confidentiality club now would save crucial time without prejudicing either party. This proactive step would only ensure that upon the Court's eventual decision, the confidentiality club can be enabled to immediately access relevant information, if so required.*** *Therefore, the instant application must be viewed in this context."*
>
> [emphasis supplied]

37. Neither of these orders were challenged by the plaintiffs. Therefore, the plaintiffs at this stage cannot be permitted to submit that Section 104A of the Act has no applicability at the present stage of the suit.

38. For all the aforesaid reasons, I am unable to accept the submission of the plaintiffs that Section 104A of the Act would not be applicable at the present stage of the suit.

Whether Section 104A of the Act would apply to 'disclosure' of the process adopted by the defendant

39. Section 104A of the Act provides that the burden of proof to show that the process adopted by the defendant is different from that of the plaintiff, can be shifted to the defendant.

40. The main requirement for discharging the aforesaid burden of proof by the defendant would be the disclosure of its process of manufacturing. Once the defendant is directed to disclose its manufacturing process, the Court only

has to compare/ map the same with the process claimed in the process patent to see if they are identical/ similar. Therefore, disclosure of its manufacturing process by the defendant is the key mandate under Section 104A of the Act. This is also borne out from the language of sub-section (2) of Section 104A of the Act, which specifically uses the term 'disclose' in relation to the confidential aspects of the defendant's process.

41. Therefore, in my considered view, the aspect of disclosure of the defendant's process to the plaintiffs is covered within the scope of Section 104A of the Act and accordingly, I am not inclined to accept the plaintiffs' submission that Section 104A of the Act would have no application in cases where the plaintiff seeks disclosure/ discovery.

Whether Section 104A of the Act would prevail over the discovery provisions under CPC as amended by the Commercial Courts Act, 2015

42. Counsel for the plaintiffs has placed reliance on the provisions of Order XI Rules 1(7), 1(12) and 5 of the CPC as amended by the Commercial Courts Act, 2015 to submit that discovery/ disclosure of the defendant's process ought to be allowed. Counsel for the plaintiffs submits that the two judgments cited by the defendant, *i.e.*, ***Natural Remedies*** (supra) and ***Bristol-Myers*** (supra) were delivered prior to the coming into force of the Commercial Courts Act, 2015, which has liberal provisions for allowing discovery of documents. Therefore, the provisions relating to discovery under Order XI Rules 1(7), 1(12) and 5 of the CPC as amended by the Commercial Courts Act, 2015 should prevail over the provisions of the Patents Act.

43. The Patents Act is a specialized legislation dealing with cases relating to patents including patent infringement cases, whereas the Commercial Courts Act, 2015 is a general legislation dealing with all commercial disputes.

It is a settled position of law that provisions of a special statute would always prevail over the provisions of general law. Therefore, Section 104A of the Act would prevail over the discovery provisions under the CPC as amended by the Commercial Courts Act, 2015. This issue was extensively discussed in ***Telefonaktiebolaget LM Ericsson (PUBL)* v. *Competition Commission of India***[6], where a division bench of this Court examined whether the provisions of the Competition Act, 2002 would prevail over the provisions of the Patents Act. The division bench held that a general law such as the Competition Act, 2002 cannot override a special law like the Patents Act. In this regard, the relevant extract from the aforesaid judgement is reproduced below:

> "55. *Therefore, when assessed, by the* ***maxim generalia specialibus non derogant*** *[General law will not override special law] or by the maxim lex posterior derogat priori, the Patents Act must prevail over the Competition Act on the issue of exercise of rights by a patentee under the Patents Act.* ***Even assessed by the rigours of Ashoka Mktg. Ltd. case [ASHOKA Mktg. Ltd. v. Punjab National Bank, (1990) 4 SCC 406], which require the conflict to be resolved by reference to the purpose and policy underlying the two enactments and the clear intendment conveyed by the language of the relevant provisions therein, the Patents Act must necessarily prevail over that of the Competition Act.***"
>
> [emphasis supplied]

44. Reference may also be made to a judgement of this bench in ***Telefonaktiebolaget LM Ericsson (PUBL)* v. *Lava International***[7]. It was reiterated that the provisions of the Patents Act, being a specialized legislation, would prevail over the general law of limitation. The relevant observations in the aforesaid judgment are set out below:

> *"816. Section 11A (7) of the Patents Act categorically states that the rights of a patentee originate from the date of publication of the patent application. First proviso to Section 11(A)7 provides that the suit for infringement cannot be instituted before the date of grant of patent. Section*

[6] 2023 SCC OnLine Del 4078
[7] 2024 SCC OnLine Del 2497

> *45 of the Patents Act provides that the suit can only be filed in respect of an infringement that took place after the date of publication of the patent application. Therefore, the position that emerges is that a suit for infringement can only be filed after the grant of the patent. However, the damages can be claimed from the date of publication of the patent application. The rationale behind this appears to be that the grant of patent may take considerable time and the patentee should not be denied his right to claim damages, in respect of infringement that occurs post publication of the patent. Thus, the period of limitation as prescribed under Article 88 of the Schedule of Limitation Act, 1963 will not be applicable in the present case.* ***In any event, it is a settled position of law that the provisions of special law, i.e., Patents Act would prevail over the provisions of general law, i.e., Limitation Act, 1963.****"*
>
> [emphasis supplied]

45. The plaintiffs have placed reliance in this regard on the judgment of this bench dated 18th February 2025 in their own case, *i.e.*, ***F-Hoffmann-La Roche* v. *Drugs Controller General of India*** (supra). In the said judgment, the application seeking discovery was allowed relying upon various provisions of the CPC as amended by the Commercial Courts Act, 2015. However, it was specifically noted in the said judgment that Section 104A of the Act would have no relevance in the said case as the patents in question had already expired. The relevant observations of the Court in ***F-Hoffmann-La Roche*** (supra) are set out below:

> *"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.****"*
>
> [emphasis supplied]

46. Therefore, the observations made in the aforesaid decision would have no bearing in the present suit.

47. In light of the above discussion, in my considered view, Section 104A of the Act would prevail over the discovery provisions under the CPC as amended by the Commercial Courts Act, 2015.

Whether Section 104A of the Act would apply in respect of biological drugs?

48. Another contention of the plaintiffs is that Section 104A of the Act will have no application in respect of biological drugs, as two different biological drugs, by their very nature, cannot be identical to each other. In this regard, reliance is placed on the observations made in the judgment of a coordinate bench of this Court in ***Roche Products* v. *Drugs Controller General of India***[8]. Paragraphs 180 and 184 of the aforesaid judgment are set out below:

> *"180. It is undisputed fact that biological drugs are synthesised by cells of living organisms, as opposed to chemical drugs which are produced by chemical synthesis. 'Biosimilars' are biological drugs that are similar to the innovator biological drug. Due to Owing to the complexity in the molecular arrangement and manufacturing process of a biological drug, it is not possible to replicate the structure and steps involved in the manufacture of the innovator biological drug and to produce an identical follow-on biological drug. Biosimilars, therefore, cannot be generic equivalents of the innovator biological drug. The generic drugs are characterised by their chemical and therapeutic equivalence to the original, low molecular weight chemical drugs. These are identical to the original product and are sold under the same chemical name.*
>
> *** *** ***
>
> *184. In order to avoid any confusion, it is mentioned (as admitted by the parties also) that the approval process for generic drugs is not the same as the approval process for biosimilars. Biological drugs are synthesised by cells of living organisms, as opposed to chemical drugs which are produced by chemical synthesis. The 'Biosimilars' are biological drugs that are similar to the innovator biological drug. It is admitted by all parties that it is not possible to replicate the structure and steps involved in the manufacture of the innovator biological drug and to produce an identical follow-on biological drug. Thus, biosimilars cannot be generic equivalents of the innovator biological drug."*

[8] 2016 SCC OnLine Del 2358

49. There is nothing in the language of Section 104A of the Act to suggest that it would not apply in cases pertaining to infringement of biological drugs. In ***Roche Products*** (supra), the applicability of Section 104A of the Act was not an issue before the Court and hence, no observation was made with regard to Section 104A of the Act.

50. While the Biosimilar Guidelines use the term 'similar' as sufficient for regulatory approval, the legal burden under Section 104A remains one of proving identity in substance and composition, as held in ***Natural Remedies*** (supra). This threshold cannot be diluted in biologic cases merely because absolute replication is scientifically difficult. The statutory use of the term 'identical' reflects the legislature's conscious choice, and to read the same in a lower threshold would amount to judicial dilution of the requirement.

51. Therefore, the plaintiffs' contention with respect to inapplicability of Section 104A of the Act in cases involving biological drugs is devoid of merits.

Whether the plaintiffs have fulfilled the requirements of Section 104A of the Act?

52. Now, I proceed to examine whether the plaintiffs have satisfied the requirements of Section 104A of the Act and made out a case for the defendant to disclose its manufacturing process. The plaintiffs contend that the defendant's product is identical to the plaintiffs' product as the defendant itself has used the plaintiffs' product, *i.e*, Perjeta as a reference biologic in its application before the CDSCO for approval of a similar biologic (*refer paragraph 54 of the plaint*). In the said application, the defendant has admitted that it is manufacturing a drug which is similar biologic of the plaintiffs' aforesaid product.

53. The predecessor bench, in the order dated 23rd February 2024, has discussed the scope and relevance of the Guidelines on Similar Biologics, 2016. Relevant paragraphs from the aforesaid order are set out below:

> *"20. A biologic pharmaceutical, often simply called a 'biologic', is a type of medication derived from living organisms or their cells. The inherent complexity of biologics stems from their molecular size, structure, and the intricacies of their development process. Unlike traditional pharmaceuticals, which are typically synthesized through chemical processes to create small molecule drugs, biologics are produced using biotechnological methods involving recombinant DNA technology, controlled gene expression, and antibody production. Biologic medicines represent a paradigm shift from traditional small molecule pharmaceuticals, introducing a new spectrum of challenges for the intellectual property architecture designed to safeguard them.*
>
> *21. …There are no clinically meaningful differences between a Similar Biologic and an approved reference biological product. Similar Biologics can only be developed against the Reference Biologic that has been approved using a complete data package in India. A product can only be considered as a Similar Biologic if it is proven to be Similar using extensive quality characterization against the Reference Biologic and further product development should only be considered once the Similar Biologic is demonstrated to be similar in quality to a Reference Biologic…*
>
> *** *** ***
>
> *24.* ***Biosimilars are designed to be highly similar to the reference product, but not identical. As discussed above, the Guidelines lay out the pathway for approval of biosimilar, however, these focus on the approval process and do not directly address patent issues. The determination of infringement must begin with understanding the scope of the patent(s) held by the reference biologic. We know that Patents can cover a wide range of protectable subject matter, including the biologic's molecular structure, the process by which it is manufactured, formulations, methods of use, and more. If the biosimilar or similar biologic utilizes or embodies any aspect that is patented by the reference biologic, only then there could be a case for patent infringement.****"***
>
> [emphasis supplied]

54. To appreciate the aforesaid submission made on behalf of the plaintiffs, a reference may be made to the Guidelines on Similar Biologics, 2016 issued by CDSCO and the Department of Biotechnology (hereinafter '***Biosimilar***

Guidelines'). The term 'reference biologic' has been defined in the glossary of the Biosimilar Guidelines in the following manner:

> *"**j. Reference Biologic***
> ***A Reference Biologic is used as a comparator for comparability studies with the Similar Biologic in order to show Similarity in terms of safety, efficacy and quality.** The Reference Biologic should be licensed / approved in India or ICH countries and should be the innovator's product. The Reference Biologic should be licensed based on a full safety, efficacy and quality data. Therefore another Similar Biologic cannot be considered as a choice for Reference Biologic."*
>
> [emphasis supplied]

55. Similarly, the term 'similar biologic' has been defined in the glossary of the Biosimilar Guidelines in the following manner:

> *"**l. Similar Biologic***
> *A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biologic product based on comparability."*
>
> [emphasis supplied]

56. Other relevant extracts from the Biosimilar Guidelines are set out below:

> *"5. Scope*
> *…*
> *Any product can be considered as a Similar Biologic, only if it is proven to be Similar using extensive quality characterization against the Reference Biologic. Further product development should only be considered once the similarity of the Similar Biologic is demonstrated **in quality** to a Reference Biologic.*
> *…*
> *6. Principles for Development of Similar Biologics*
> *…*
> *Although the extent of preclinical and clinical evaluation of the Similar Biologic is likely to be less than that required for the Reference Biologic, **it is essential that the testing of the Similar Biologic be sufficient to ensure that the product meets acceptable levels of safety, efficacy and quality** to ensure public health in accordance with international guidelines (WHO 2013).*
> *…*

Identification of any significant differences in safety, efficacy and quality studies would mean the need for a more extensive preclinical evaluation and the product will not qualify as a Similar Biologic.

…

6.1 Selection of Reference Biologic

…

The Reference Biologic has to be used in all the comparability exercises with respect to quality, preclinical and clinical considerations. The following factors should be considered for selection of the Reference Biologic:

• The Reference Biologic should be licensed / approved in India or ICH countries and should be the innovator's product. ***The Reference Biologic should be licensed based on a full safety, efficacy and quality data.*** *Therefore another Similar Biologic cannot be considered as a choice for Reference Biologic.*

• In case the Reference Biologic is not marketed in India, the Reference Biologic should have been licensed in any ICH countries. ***The Reference Biologic product can be imported for developing the Similar Biologic for quality, pre-clinical and clinical comparability.***

• The same Reference Biologic should be used throughout the ***studies supporting the safety, efficacy and quality of the product (i.e. in the development Programme for the Similar Biologic)****.*

• The dosage form, strength and route of administration of the Similar Biologic should be the same as that of the Reference Biologic.

• The active drug substance (active ingredient) of the reference biologic and that of Similar Biologic must shown to be similar.

…

6.2 Manufacturing Process

The Similar Biologics manufacturer ***should develop the manufacturing process*** ***to yield a comparable quality product in terms of identity, purity and potency to the Reference Biologic. The manufacturing process for Similar Biologics should be validated and demonstrated to be highly consistent and robust.*** *If the host cell line used for the production of Reference Biologic is disclosed****, it is desired*** ***to use the same host cell line for manufacturing Similar Biologics.*** ***Alternatively*** ***any cell line that is adequately characterized and appropriate for intended use can be used to develop a Similar Biologic, with appropriate justification in order to minimize the potential for significant changes in quality attributes (QAs) of the product and to avoid introduction of certain types of process related impurities that could impact clinical outcomes and immunogenicity…***

The data requirements for review of manufacturing process at preclinical submission stage include a complete description of the manufacturing process from development and characterization of cell banks, stability of

clone, cell culture/ fermentation, harvest, excipients, formulation, purification, primary packaging interactions ***(if different from Reference Biologic)****, etc…"*

[emphasis supplied]

57. It is discernible from the above extracts of the Biosimilar Guidelines that for a similar biologic to be approved by the CDSCO, there is no requirement for the similar biologic to be identical to the reference biologic. The requirement is that the active ingredient used in similar biologic should be similar and the dosage form, strength and route of administration of the similar biologic should be same as that of the reference biologic. Regarding the process used for manufacturing a similar biologic, the Biosimilar Guidelines only require the process to yield a comparable quality product in terms of identity, purity and potency to the reference biologic. It is, however, open for a similar biologic manufacturer to come up with alternative manufacturing processes without compromising the safety, efficacy and quality of its product.

58. The phrase '*if different from Reference Biologic*' in the extract above suggests that the manufacturing process of a similar biologic developed by its manufacturer could be entirely different from that of the reference biologic. This aspect was also noted by the predecessor bench in the order dated 23rd February 2024 (*refer paragraphs 24 and 26 of the order dated 23rd February 2024*). Therefore, even if a drug is stated to be the similar biologic of a reference biologic, it does not naturally follow that the process of manufacturing the same is identical to that of the reference biologic.

59. In this regard, a reference may be made to the judgment of the Federal Court of Australia in ***Pfizer Ireland Pharmaceuticals* v. *Samsung Bioepis***[9], where it was observed that merely because the product is a similar biologic would not automatically lead to the conclusion that it was the outcome of the same process as that of the patented process. In other words, merely because the end products are similar, it does not lead to the conclusion that both were derived from the same process. The relevant extracts from the aforesaid judgement are reproduced hereinbelow:

> *"97. Ultimately, Dr Ibarra's evidence in this respect does not rise above speculation (Pfizer refers to it as an inference) that the similarities observed might mean that the BRENZYS Process is similar to the Pfizer Process. That speculation, in my view, clings tenuously to the coincidences identified in Cho.* ***These coincidences are cogently explained by a far more available inference; that the end products are biosimilar. That fact does not suggest similarity of process."***
>
> [emphasis supplied]

60. Therefore, the filing of the aforesaid application dated 9th September 2021 by the defendant with the CDSCO by itself would not fulfil the requirement of Section 104A of the Act that the defendant's product is identical to that of the plaintiffs. It also does not indicate that the defendant has used the plaintiffs' patented process.

61. There is another aspect of the matter to be considered. The defendant contends that the product in its application dated 9th September 2021 filed with the CDSCO refers to *Pertuzumab* (Perjeta®, Genentech Inc.), which is in public domain and is different from the product obtained from the process patent of the plaintiffs, *i.e.*, a composition comprising *Pertuzumab* and one or more variants.

[9] MANU/AUFC/0847/2017

62. The plaintiffs have averred in the plaint that *Pertuzumab* is sold under the brand name Perjeta (*refer paragraph 42 of the plaint*). At several other places in the plaint, the plaintiffs have interchangeably used the terms *Pertuzumab* and Perjeta (*refer paragraphs 11 and 41 of the plaint*).

63. However, a perusal of the plaint would also show that the product that is manufactured using the process patent IN'646 is not *Pertuzumab per se* but *Pertuzumab* along with variants. A reference in this regard may again be made to paragraph 11 read with paragraph 12 of the plaint, which are set out below:

> "*11.* ***The present suit inter alia pertains to Indian Patent No. IN 464646 titled as "PERTUZUMAB VARIANTS AND EVALUATION THEREOF"*** *(also known as "suit patent IN'646").* ***The said patent IN'646 relates to the method for making a composition comprising Pertuzumab and one or more variants. Pertuzumab (commercially known as (Perjeta®)*** *is a monoclonal antibody (MAb) biologic and is the first of its class in a line of agents called "HER Dimerization Inhibitors". Pertuzumab, by binding to HER2 cells, inhibits the dimerization of HER2 cells with other HER receptors and thus inhibits tumour growth.*
>
> *12.* ***The inventiveness of IN'646 resides in the method of making a composition having Pertuzumab and its variant(s) comprising unpaired cysteine variants, low-molecular-weight-species (LMWS), high-molecular weight-species (HMWS), afucoslated variant, Pertuzumab Peak l, and Pertuzumab Peak 2*** *and quantifying the said variants within the range disclosed and claimed by IN'646, resulting in a much safer and efficacious drug and further also has a positive impact on the anti-proliferative qualities. This specific and precise manufacturing process determines the quality of the composition comprising Pertuzumab and its variants.*"
>
> [emphasis supplied]

64. Similar averments have been made by the plaintiffs in their rejoinder to the defendant's reply to I.A. 4196/2024, paragraph 8 of which is set out below:

> *"8. It is stated that none of the cited prior arts relied on by the Defendant in paragraph 11 of their reply (item no. 1 to 7 and 9) are relevant. The Defendant's argument that Pertuzumab and its process are publici juris is completely baseless and legally untenable, at the outset.* ***The invention of the suit patents relates to Pertuzumab and its variants thereof.*** *However, there has been no disclosure of the variants manufactured, identified, and*

characterized in the suit patent, IN'646, in any of the prior arts cited by the Defendant."

[emphasis supplied]

65. This is also evident from the background and summary of the invention and claims of the complete specification of IN'646 wherein *Pertuzumab* (Perjeta) has been identified as the prior art and it is stated that the invention is in respect of "*a method for making a composition comprising Pertuzumab and one or more variants wherein the Pertuzumab and variant(s) each comprise the variable light and variable heavy amino acid sequences in SEQ ID NOs. 7 and 8*".

66. Therefore, it can be inferred that *Pertuzumab* (Perjeta) was already known in the prior art and the end product of the process patent IN'646 is a distinct composition comprising *Pertuzumab* and one or more variants.

67. Based on the aforesaid discussion, it cannot be said that the reference made by the defendant in its aforesaid application filed with the CDSCO is to the product obtained from the patented process IN'646. Therefore, on the said basis, the plaintiffs cannot argue that the defendant's product is identical to the plaintiffs' product directly obtained from the patented process, as mandated under Section 104A of the Act.

68. Besides placing reliance on the aforesaid application of the defendant referring to *Pertuzumab* (Perjeta®, Genentech Inc.) as the reference drug, the plaintiffs have not filed any other documents to demonstrate that the product manufactured by the defendant is identical to the product of the plaintiffs covered under IN'646.

Claim mapping filed by the plaintiffs

69. As the defendant's product was not launched at the time of filing of the present suit and the present suit was filed as a *quia timet action*, the predecessor bench, on 23rd February 2024, directed the plaintiffs to do the claim mapping in respect of IN'632, the product patent, with claims of the defendant's patent application no. 2021079337. Admittedly, the product of the defendant was launched in the market in June 2024. Yet the plaintiffs have not conducted any analytical characterisation or a reverse engineering of the defendant's product to show that the defendant's product is identical, or even similar, to the plaintiffs' product manufactured using the process patent, which is a statutory requirement under section 104A of the Act.

70. The claim mapping filed on behalf of the plaintiffs pertains to a product patent and claims of the defendant's patent application, and is therefore not directly relevant to the adjudication of the present application which, as noted above, concerns the process patent.

71. Even otherwise, upon examination of the claim mapping of IN'632 in comparison with the claims of the defendant's patent application, it is evident that the defendant's product relates to a composition comprising *Pertuzumab* and excipients, specifically an arginine citrate buffer. In contrast, the plaintiffs' product employs a histidine acetate buffer.

72. Therefore, even in terms of the claim mapping filed on behalf of the plaintiffs, it cannot be concluded that the composition described in the plaintiffs' product patent and the defendant's patent application are identical.

Conclusion

73. Based on the aforesaid discussion, in my considered view, the plaintiffs have failed to fulfil the mandatory requirements of Section 104A of the Act.

Therefore, no direction can be issued to the defendant to disclose its manufacturing process filed in a sealed cover.

74. Hence, I do not see any merit in the present application and the same is dismissed.

75. Needless to state, any observations made in this judgment are only for the purposes of deciding the present application and would have no bearing on the final adjudication of the suit.

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76. List before the Joint Registrar on 23rd September, 2025, the date already fixed.

AMIT BANSAL
(JUDGE)

JULY 23, 2025
Vivek/-/ds/at/Rzu