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

Reserved on: September 06, 2024

% ***Pronounced on: October 09, 2024***

\+ **CS(COMM) 159/2024**

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

Through: Mr. Sandeep Sethi and Mr. Arvind Nigam, Sr. Advs. with Mr. Pravin Anand, Mr. Shrawan Chopra, Ms. Archana Shankar, Mr. Devinder Rawat, Ms. Prachi Agarwal, Mr. Achyut Tewari, Ms. N. Mahavir, Ms. Riya Kumar, Ms. Shreya Sethi and Mr. Agnish Aditya, Advocates.

Versus

ZYDUS LIFESCIENCES LIMITED ..... Defendant

Through: Mr. Dushyant Dave, Sr. Adv. with Ms Bitika Sharma, Mr. Aadarsh Ramanujan, Ms. Vrinda Pathak, Ms. Sandhya Kukreti, Mr. Rajnish Kumar, Ms. Vanshika Puri and Ms. Ahaana Singh Rana, Advocates

Ms. Rupali Bandopadhya with Mr. Abhijeet Kumar, Advocates

CORAM:
HON'BLE MR. JUSTICE SAURABH BANERJEE

J U D G M E N T

I.A. 33509/2024 (*Order XXXIX rules 1 & 2, CPC*)

1. In a suit for permanent injunction of patents infringement, the plaintiffs

have filed the present application under *Order XXXIX rules 1 & 2* of the Civil Procedure Code, 1908[1] seeking the following reliefs:-

> "*a. Directing the Defendant, all its employees, agents, distributors, licensees, and all others acting for, through, or under them, to recall all of the stocks of the product "Sigrima" and/ or any similar biologic/ biosimilar of Pertuzumab, infringing the claims of IN 268632 and IN 4646464, from the market;*
>
> *b. Restrain the Defendant, and all its employees and/ or agents, and all others acting for, through, or under them, from releasing any stocks of the product "Sigrima" and/ or any similar biologic/ biosimilar of Pertuzumab, infringing the claims of IN 268632 and IN 4646464, in the market;*
>
> *c. Direct the Defendant to disclose on an affidavit, the extent of its sales of the product "Sigrima" and/ or any similar biologic/ biosimilar of Pertuzumab, infringing the claims of IN 268632 and IN 4646464, including the Batch No. wise quantities manufactured, sold, dates of such manufacturing and sale(s), held in stock, sale price, and details of parties it was sold to;*"

Narrative Background:

2. The learned predecessor bench of this Court, after issuing notice in the present application and for the reasons stated therein, on 09.07.2024, passed an order of injunction directing that "*... ...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... ...*"

2.1. The plaintiff no.1 F. Hoffmann-La Roche AG founded in 1896, is a company organized and existing under the laws of Switzerland. Being in the business of pharmaceuticals and diagnostics, it has been involved in the discovery, development, production, and marketing of novel healthcare

[1] Hereafter referred to as "***CPC***"

solutions for over 120 years.

2.2. The plaintiff no.2 Genentech Inc. founded in 1976, is an American corporation incorporated in the State of Delaware, USA. It has since been acquired by the plaintiff no.1 in March 2009 as its wholly owned independent subsidiary.

2.3. The plaintiffs' group of companies has presence in over 100 countries and employs over one million people worldwide and has invested CHF 13,237 in research and development in 2023.

2.4. The plaintiffs have instituted the present suit *inter alia* pertaining to its Indian Patent No.IN 464646[2] titled as "PERTUZUMAB VARIANTS AND EVALUATION THEREOF" which relates to the method for making a composition comprising Pertuzumab, which is a monoclonal antibody (MAb) biologic and is the first of its class in a line of agents called "HER Dimerization Inhibitors". The plaintiff no.1 is the patentee of the patent IN '646 and by virtue of an exclusive License Agreement dated 08.02.2024 entered into *inter se* the plaintiffs, the plaintiff no.2 is the exclusive licensee thereof.

2.5. The bibliographic details of patent IN '646 are entailed as under:-

Title	***Pertuzumab variants and evaluation thereof***
Patentee	plaintiff no.1
Application No.	6979/CHENP/2015
Patent No.	464646
Priority Date	16.04.2013

[2] Hereafter referred to as "***patent IN '646***"

PCT International Filing Date (Date of patent)	15.04.2014
PCT International Application Number	PCT/US2014/034200
National Phase entry-filing date in India	112.11.2015
Date of Publication under Section 11A	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. The said patent IN '646 has the following 8 claims:-

"*1. 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 heovy amino acid sequences in SEQ ID NOs. 7 and 8, respectively, and the method comprises:*

a. expressing Pertuzumab and the variant(s) from a recombinant Chinese Hamster Ovary GHO) cell at mandacturing scale of at least 12,000 liter and purfying the composition comprising the Pertuzumab and the variant(s):

b. subjecting the composition to analytical assays to evaluate the amount of the variant(s) therein, wherein the variant(s) comprise:

i. unpaired cysteine variant comprising Cys23/Cys88 unpaired cysteines in one or both variable light domains of Pertuzumab in the composition in an amount <_ 4.9% as determined by hydrophobic interaction chromatography (HIC) of the intact antibody;

ii. both a low-molecular-weight-species (LMWS) and high-molecular w eight-species (H MWS), where in the amount of LMWS is 3.6% of the composition as measured by size-exclusion high performance liquid chromatography

(SE-HPLC), and the amount of HMWS is <1.7% of the composition as measured by size-exclusion high performance liquid chromatography (SE-HPLC);

iii. an afucoslated variant in the range from > 2% to 4.1% of the composition as measured by capillary electrophoresis-laser-induced fluorescence (CELIF);

iv. Pertuzumab Peak I fragment in an amount of < 0.5% or Pertuzumab Peak 2 fragment in an amount of <1.0% as measured by reduced capillary electrophoresis sodium dodecyl sulphate (R-CE-SDS).

2. The method as claimed in claim l, wherein the amount of the heterodimer variant in the composition is from 13% to l8% as determined by hydrophobic interaction chromatography (HIC) of intact antibody.

3. The method as claimed in claim 1, wherein the amount of LMWS of Pertuzumab in the purified composition is <1.2% as determined by SE-HPLC, and the amount of HMWS of Pertuzumab in the purified composition < 1.4% as determined by SE-HPLC.

4. The method as claimed in claim l, wherein the amount of LMWS of Pertuzumab in the purified composition is <0.6% as determined by SE-HPLC and the amount of HMWS of Pertuzumab in the purified composition is< 0.8% as determined by SE-HPLC.

5. The method as claimed in claim l, wherein the purified composition comprises Pertuzumab Peak I fragment or Pertuzumab Peak 2 fragment in the amount specified in iv.

6. The method as claimed in claim 5, wherein the purified composition comprises both Pertuzumab Peak I fragment and Pertuzumab 2 fragment in the specified amounts.

7. The method as claimed in any one of the preceding claims further comprising combining the purified composition with one or more pharmaceutically acceptable excipients to make a pharmaceutical composition.

8. The method as claimed in any one of the preceding claims, wherein the Pertuzumab and the variant(s) each comprise the light chain omino acid sequence in SEQ ID No. I I and the heavy chain amino acid sequence

in SEQ ID No. 12."

2.7. Human Epidermal growth factor Receptor (HER) is a family of receptor tyrosine kinases, which are important mediators of cell growth, differentiation, and survival. This receptor family includes four distinct members including epidermal growth factor receptor HER1, HER2, HER3 and HER4. The overexpression of HER2 gene is a primary cause for breast cancer tumours and is one of the most aggressive forms of cancer. Overexpression of HER2 has also been observed to cause extensive breast cancer and ovarian cancers. Over expression of HER2 can also cause other cancers such as stomach, endometrium, salivary gland, lung, kidney, colon, thyroid, pancreas, and bladder. The breast cancer patients with HER2 overexpression show aggressive clinical course, including poor disease-free and overall survival, chemoresistance, and shorter time to relapse.

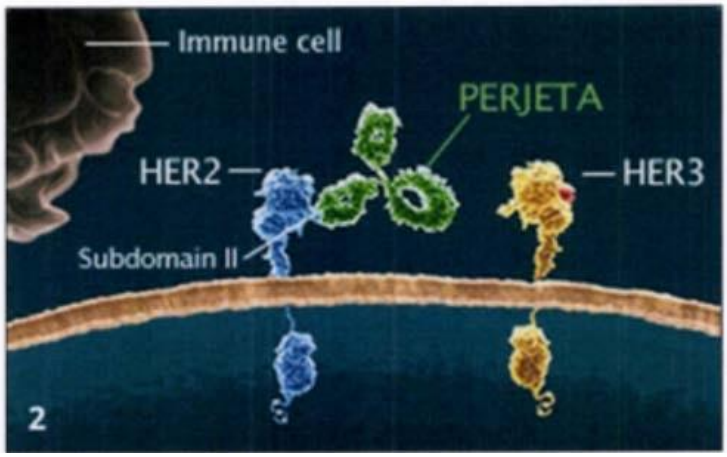
2.8. The said Pertuzumab is a monoclonal antibody which is the first in its class in line of agents called the "HER2 dimerization inhibitors". Accordingly, Pertuzumab by binding to HER2, inhibits dimerization of HER2 with other HER receptors, thus inhibiting tumour growth.

2.9. The said Pertuzumab and its variant(s) comprise 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 patent 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.

2.10. The said Pertuzumab blocks one of the methods of signalling so that one HER2 receptors are unable to pair with another HER2. The said Pertuzumab is designed to bind to subdomain II of HER2 receptors and blocks its ligand-dependent heterodimerization:-

a. The said Pertuzumab inhibits HER2:HER3 dimer formation and downstream signalling, suppressing HER2-mediated cell proliferation. It also augments antibody-dependent cell mediated cytotoxicity. A pictorial representation of which is reproduced below:-



2.11. The plaintiffs have also instituted the present suit *inter alia* pertaining to its other Indian Patent No.IN 268632[3] titled as "PHARMACEUTICAL FORMULATION COMPRISING HER2 ANTIBODY" and relates to an aqueous pharmaceutical formulation comprising Pertuzumab and is in relation to a Pertuzumab formulation comprising Pertuzumab and excipients such as sucrose, histidine acetate buffer, polysorbate, such that the pH of the

[3] Hereafter referred to as "***patent IN '632***"

formulation is from 5.5-6.5. The plaintiff no.2 is the patentee of patent IN '632 and by virtue of an exclusive License Agreement dated 08.02.2024 entered into *inter se* the said plaintiffs, the plaintiff no.1 is the exclusive licensee thereof.

2.12. The bibliographic details of patent IN '632 are entailed as under:-

Title	Pharmaceutical Formulation comprising HER2 antibody
Patentee	Plaintiff No.2
Application No.	1730/DELNP/2007
Patent No.	268632
Priority Date	20.10.2004
PCT International Filing Date (Date of patent)	19.10.2005
PCT International Application Number	PCT/US2005/037471
National Phase entry-filing date in India	05.03.2007
Date of Publication under Section 11A	24.08.2007
FER Issue Date	26.08.2010
FER Response Date	18.05.2011
Date of grant	09.09.2015
Date of expiry	19.10.2025

2.13. The said patent IN '632 has 4 claims, wherein Claim 1 is an independent claim. The plaintiffs assert independent Claim 1, along with the dependent Claims 2 to 4. The said patent IN '632 has the following 4 claims:-

> "*1. An aqueous pharmaceutical formulation comprising pertuzumab in an amount from 20mg/mL to 41mg/mL, histidine-acetate buffer at a concentration from 10mM to 40mM, sucrose at a concentration from 60mM to 250mM, and polysorbate 20 at a concentration from 0.01 % to 0.1 %, wherein the pH of the formulation is from 5.5 to 6.5.*

> *2. The formulation as claimed in claim l, comprising about 30mg/mL pertuzumab, about 20mM histidine-acetate buffer, about l20mM sucrose, and about 0.02%polysorbate 20, wherein the pH of the formulation is about 6.0.*
>
> *3. The formulation as claimed in claim l, wherein pertuzumab comprises a light chain amino acid sequence shown as SEQ ID NO.15 and a heavy chain amino acid sequence shown as SEQ ID NO. 16.*
>
> *4. The formulation as claimed in claim l, wherein the pH of the formulation is from about 5.8 to about 6.2.*"

2.14. The defendant i.e., Zydus Lifesciences Limited is a company incorporated under the Companies Act, 1956. As per its website https://zyduslife.com, it was formerly known as Cadila Healthcare Limited. The defendant is an Indian pharmaceutical company *inter alia* seemingly engaged in the manufacture and sale of drugs, oral and injectable, active pharmaceutical ingredients, tablets, capsules, etc.

2.15. As per the plaint, in January 2023, the defendant had procured 480 vials of the original innovator biologic reference product Pertuzumab (Perjeta) from the plaintiffs' affiliate, Roche Products (India) Pvt. Ltd. As a responsible corporate, the Roche Group, has always supported innovation, research, and development of new drugs in India. Therefore, plaintiff no.1's Indian affiliate Roche Products (India) Pvt. Ltd. supplied its products for clinical studies of several companies for development of similar biologic/ biosimilar products in India, including supply of 478 vials of Perjeta for clinical trials of the defendant.

2.16. In the first week of February 2024, the plaintiffs came across the

Recommendations of the Subject Expert Committee (SEC) (Oncology) of the Central Drugs Standard Control Organization (CDSCO), which were made in the Committee's 2nd/24 SEC meeting held on 23.01.2024 and 24.01.2024 at CDSCO Headquarters, New Delhi whereby defendant appears to have filed an application having reference no. BIO/CT2l/BO/2023/40418 for grant of permission to manufacture New Drug Formulation for sale or the distribution of Pertuzumab as per New Drugs and Clinical Trails 2019 in Form CT-21. The SEC Committee 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. The same is reproduced below:-

20.	BIO/CT21/BO/2023/40418 Pertuzumab 30 mg/ml	M/s Zydus Lifesciences Limited	The firm presented their proposal for grant of permission to manufacture and market Pertuzumab 30mg/mL concentrate solution for infusion (420 mg / 14 mL single-dose vial) based on the results of comparative Phase III clinical trial conducted in India to establish the efficacy, safety, pharmacokinetics and immunogenicity of the drug product. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Pertuzumab 30mg/mL concentrate solution for infusion (420 mg / 14 mL single-dose vial) for the indication of metastatic breast cancer subject to the condition that the firm shall conduct Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture

SEC (Oncology) meeting dated 23.01.2024& 24.01.2024
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2.17. Against the aforesaid backdrop, the plaintiffs instituted the present suit along with an application under *Order XXXIX rules 1 & 2* CPC being I.A.

4196/2024[4] seeking the following reliefs:-

> *"a. An order for interim injunction restraining the Defendant, its associates and group entities, its directors, employees, officers, servants, agents, stockists, retailers, semi stockists, wholesalers, marketers, distributors, affiliates and subsidiaries, any other entity / person in the chain of supply and all others acting for and on its behalf from using, making, manufacturing, selling, distributing, advertising, exporting, offering for sale, importing or dealing in any other manner, directly or indirectly, in a similar biologic / biosimilar of Pertuzumab, and / or any other product(s) that infringes the claims of the Indian Patent Nos. IN 268632 and IN 464646, or doing any other 23 act which violates the Plaintiff's rights under Section 48 of the Patents Act, 1970;*"

2.18. When the earlier application was listed before the learned predecessor bench on 23.02.2024, after hearing the submissions advanced by the learned senior counsel/s of the plaintiffs as also those advanced by the learned senior counsel/s for the defendant, by way of an elaborate order, the plaintiffs were unable to obtain any injunction against the defendant. One of the grounds being lack of '*claim mapping*' being present on record on that date, which, however as per the submissions advanced by the learned senior counsel/s for the plaintiffs was not possible as the defendant was yet to commercially launch its impugned product '*Sigrima'* in the market.

Submissions advanced by plaintiffs:

3. Based on the pleadings and arguments addressed by the learned senior counsel/s for the plaintiff in support thereof, the case of the plaintiffs briefly, is as under:-

3.1. Though the earlier application under *Order XXXIX rules 1 & 2* CPC after its initial listing on 23.02.2024 was also listed on 04.04.2024,

[4] Hereinafter referred as "***earlier application***"

24.04.2024 and 13.05.2024 thereafter. However, during the course of various hearings and in response to specific queries raised by the learned predecessor bench, the defendant made statements about it having not received any regulatory approvals for its impugned product '*Sigrima'* so far and it would take a few months. Also, in the interregnum, the plaintiffs were able to file '*claim mapping*' along with their rejoinder to the earlier application on 02.04.2024, however, the plaintiffs were unable to procure any order of injunction in their favour.

3.2. In the spate of these, the plaintiffs came to know that the defendant appeared to have received regulatory approvals, at least, as far back as April 2024 or may be earlier, for its impugned product, '*Sigrima'* and it was available in the market.

3.3. This, prompted the plaintiffs to file the present application seeking appropriate reliefs mentioned in para 1 hereinabove, since the defendant appeared to have entered into a semi-exclusive licensing agreement with Dr. Reddy's Laboratories Limited for co-marketing the alleged Pertuzumab biosimilar/ similar biologic '*Sigrima'*. For this, heavy reliance was placed upon the press release submitted by Dr. Reddy's Laboratories Limited to the Bombay Stock Exchange dated 28.06.2024, wherein it categorically stated as under:-

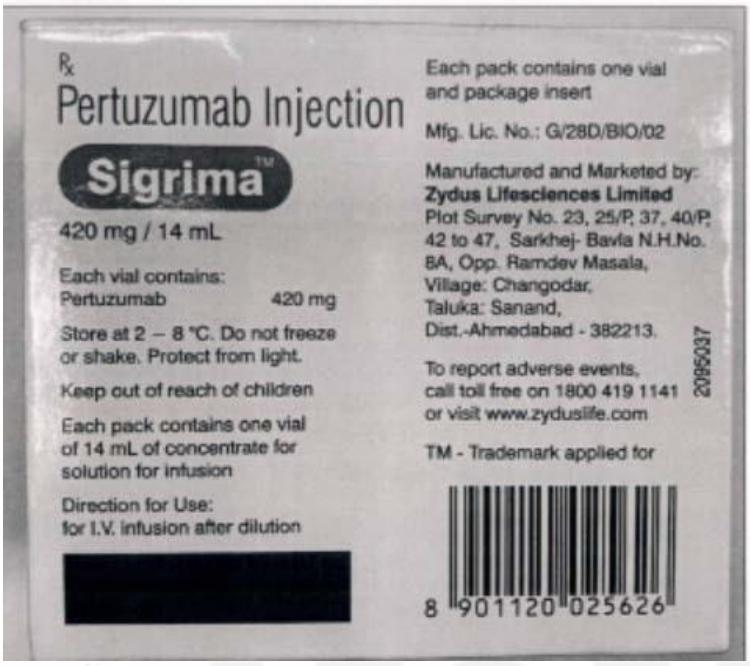
> "*Pertuzumab biosimilar developed by Zydus is a critical treatment for HER2 positive breast cancer and is being launched jointly by Zydus and Dr. Reddy 's in India. The product will be marketed by Zydus under the brand name Sigrima while Dr. Reddy 's will market it under the brand name Womab™.*"

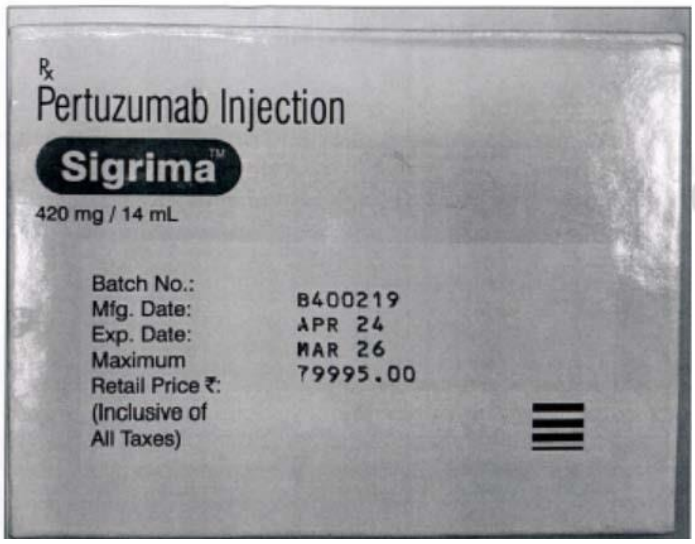
3.4. As per plaintiffs, the defendant is guilty of breach of its assurance given to this Court on 13.05.2024, though there was nothing recorded to that effect in any of the orders passed by the learned predecessor bench.

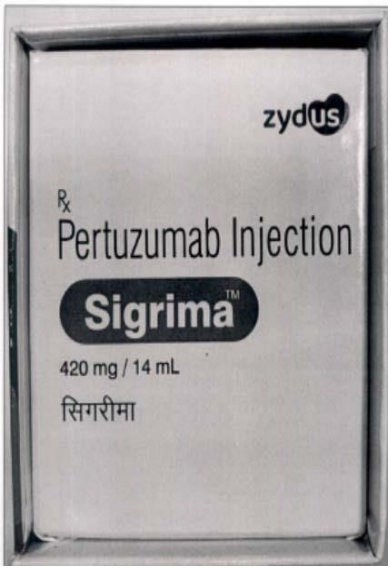
3.5. The plaintiffs alleged that despite receiving approval in early April 2024 and the on-going hearings before the learned predecessor bench, the defendant never informed the plaintiffs or this Court qua the drug approval or its process.

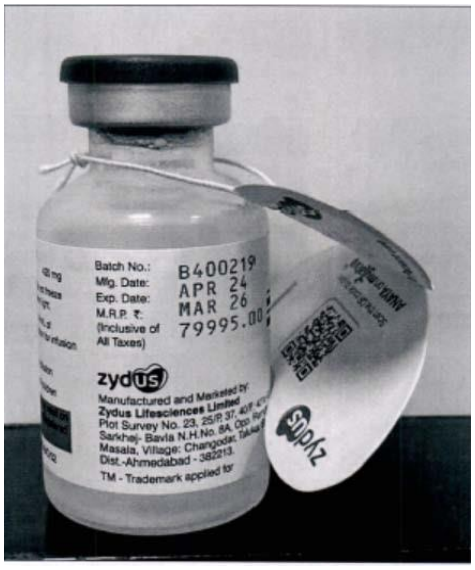
3.6. As such, plaintiffs contended that the defendant is guilty of over-reaching this Court and has abused the trust reposed by this Court in the parties to the *lis*. Also, that this has inflicted insurmountable damage upon the plaintiffs, which according to the plaintiffs is incalculable in monetary terms.

3.7. The plaintiffs also contended that the impugned product '*Sigrima'* was available in the market and the defendant dumped almost two years' worth of stock in the market before the order dated 09.07.2024 came to be passed. To substantiate the same, the plaintiffs have filed a sample of the said impugned product '*Sigrima'* of the defendant which was purchased by them on 04.07.2024 i.e. prior to filing of the present application, which was shown to this Court during the course of hearings, which is as under:-









3.8. In support of their arguments, reliance was placed upon ***Balwantbhai Somabhai Bhandari vs Hiralal Somabhai Contractor (Deceased) Rep. Lrs & Ors.***[5], ***Gujarat Bottling Co. Ltd. vs Coca Cola & Ors.***[6], ***State of Maharashtra vs Ramadas Shrinivas Nayak & Anr.***[7], ***Roop Kumar vs Mohan Thedani***[8] wherein it has been held that a party is bound by the undertaking given in Court and if an order of a competent Court is standing/ subsisting, the veracity thereof cannot be questioned. In effect, the case of the plaintiffs was that even though the predecessor bench had not granted an injunction in favour of the plaintiffs due to the factum that the defendant had given an assurance to the Court that concerned drug approvals will take time and hence there was no urgency, the defendant cannot be allowed to side track it and/ or take benefit thereof, much less, during the pendency of the

[5] C.A.4955/202 dated 06.09.2023 Supreme Court
[6] (1995) 5 SCC 545
[7] (1982) 2 SCC 463
[8] (2003) 6 SCC 595

present suit and earlier application to launch the impugned product '*Sigrima'*.

Submissions advanced by defendant:

4. As per the pleadings and arguments addressed by the learned senior counsel/s for the defendant in support thereof, the case of the defendant briefly, is as under:-

4.1. The plaintiffs had full knowledge that the defendant will soon be launching its impugned product '*Sigrima'*. Besides this, the plaintiffs had been repeatedly pressing for the interim relief as sought in the earlier application on 23.02.2024, 04.04.2024, 24.04.2024 and 13.05.2024 before the learned predecessor bench, however, they were unsuccessful in obtaining any *ad-interim* injunction in their favour.

4.2. Though it is nowhere denied that the defendant launched the impugned product '*Sigrima',* however, placing reliance upon the order dated 23.02.2024 passed by the learned predecessor bench on the very first day of listing of the present suit in the earlier application, wherein it is clearly recorded that the plaintiffs had failed to establish a *prima facie* case as there was no evidence, expert's or otherwise nor was '*claim mapping*' done to show patent infringement, it was contended that the situation is the same as of now as well. Moreover, at no stage, did the learned predecessor bench, in the present case, ask the defendant not to launch its impugned product '*Sigrima'* as also that the defendant never gave any undertaking of any kind to the learned predecessor bench qua launch of its impugned product '*Sigrima'* and it was thus not bound to keep informed about the progress of its application for a Drug License of the said impugned product to the learned

predecessor bench. In any event, since there was no interim injunction in favour of the plaintiffs and against the defendant, nothing of that sort was called for.

4.3. The *ad-interim* injunction granted by the learned predecessor bench on 09.07.2024 is against the settled principles with respect to irreparable loss/ mischief to ensue the plaintiffs; refusal of an injunction involving greater injustice than the grant; absolute good faith of the party seeking the injunction; alongwith *prima facie* case and balance of convenience as promulgated by the Hon'ble Supreme Court in ***Morgan Stanley Mutual Funds vs Kartick Das***[9].

4.4. Furthermore, placing reliance upon ***Chengalvaraya Naidu vs Jagannath***[10], it was contended that since the plaintiffs in any event have approached this Court with unclean hands and are guilty of making false statements, they are not entitled to any relief/s, much less grant of an *ad-interim* injunction by this Court, at this stage.

4.5. Then, placing reliance upon *Section 83* of the Patent Act, 1970 as also on ***F. Hoffmann-La Roche Ltd. & Anr. vs Cipla Ltd.***[11] wherein a Division Bench of this Court has held that general public access to life saving drugs assumes greater significance, learned senior counsel/s for the defendant contended that as per well settled law, public interest is of paramount importance in patent matters especially those relating to drugs.

4.6. The case of the plaintiffs in the present application is outside/ beyond

[9] (1994) 4 SCC 225
[10] (1994) 1 SCC 1
[11] 2009 (110) DRJ 452 (DB)

the scope as set out by the plaintiffs in the plaint, particularly, since there is no such prayer of the present nature qua the SEC clearance and/ or approval by the Drug Controller either in the plaint or in the earlier application or in the present application.

4.7. Placing reliance upon *Order VIII rule 8* CPC which is qua "*reliefs founded on separate grounds*"; and *Order XI Rule(1)(6)* of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 which specifically deals with disclosure of documents; and *Order XI rule 2* CPC which is dealing with "*Particular interrogatories to be submitted.*" and *Order XI rule 4* CPC which is dealing with "*Form of interrogatories*", it was contended that since the plaintiffs failed to mention anything qua the proceedings before the SEC or the Drug Controller and/ or seek any specific reliefs qua that at any stage before, the defendant had no duty and/ or obligation to produce such documents.

Reasonings and Analysis:

5. This Court has heard the learned senior counsel/s for the parties who have argued *in extenso* on various dates and also perused the pleadings, the relevant documents on record as well as the written synopsis filed from time to time along with the judgments cited by both sides.

6. Prior to proceeding further, this Court would like to express its token of appreciation for the learned senior counsel/s appearing for both sides, who, I must say, were ably assisted by the counsel/s briefing them, for their able assistance.

7. Before adverting to the merits involved herein, it is clarified that being

only a successor to the learned predecessor bench, I need not to adjudicate upon the correctness of the order dated 09.07.2024[12] passed in the present application, more so, whence neither of the parties have challenged the said order. The said order dated 09.07.2024 has only been modified/ amended/ interfered/ changed vide order dated 15.07.2024 of this Court only to the extent of paragraph 4 thereof, which was pertaining to Mr. C.S. Vaidyanathan, learned senior counsel for the defendant. Barring that, rest of the contents of the said order dated 09.07.2024 has remained unchanged.

8. *Admittedly*, since the said order dated 09.07.2024 is neither in review nor appeal, it is final, binding and sacrosanct for all purposes and is thus obligatory upon the parties to follow it in letter and spirit. None of the parties can thus question and/ or seek to interpret the said order dated 09.07.2024. This Court finds able support in ***D.P. Chadha vs Triyugi Narain Mishra & Ors***.[13], wherein the Hon'ble Supreme Court has held as under:-

> *"18. The record of the proceedings made by the court is sacrosanct. The correctness thereof cannot be doubted merely for asking. In State of Maharashtra v. Ramdas Shrinivas Nayak [(1982) 2 SCC 463 : 1982 SCC (Cri) 478 : AIR 1982 SC 1249] this Court has held: (AIR Headnote)*
> *"[T]he Judges' record was conclusive. Neither lawyer nor litigant may claim to contradict it, except before the Judge himself, but nowhere else. The court could not launch into inquiry as to what transpired in the High Court.*
> *The Court is bound to accept the statement of the Judges recorded in their judgment, as to what transpired in court. It cannot allow the statement of the Judges to be contradicted by statements at the Bar or by affidavit and other evidence. If the Judges say in their judgment that something was done, said or admitted before them, that has to be the last word on the subject. The principle is well settled that statements of facts as to what transpired at the hearing, recorded in the judgment of the court, are conclusive of the facts so stated and no one can*

[12] Hereinafter referred to as "***said order***"
[13] (2001) 2 SCC 221

> *contradict such statements by affidavit or other evidence. If a party thinks that the happenings in court have been wrongly recorded in a judgment, it is incumbent upon the party, while the matter is still fresh in the minds of the Judges, to call the attention of the very Judges who have made the record to the fact that the statement made with regard to his conduct was a statement that had been made in error. That is the only way to have the record corrected. If no such step is taken, the matter must necessarily end there.""*

9. Even otherwise, this Court is not sitting either in review or contempt or appeal over the said order dated 09.07.2024 and thus has to adjudicate upon the merits of the present application based on the records before it and arguments addressed in relation thereto. More so, since the said order dated 09.07.2024 was only "… … *till the next date of hearing*, … …".

10. When the earlier application being I.A. 4196/2024 came up for hearing before the predecessor bench on 23.02.2024, the circumstances were different from that when the present application was listed before the same bench on 09.07.2204 due to the subsequent developments. So, the yardstick applied by the predecessor bench, while passing the two order/s as aforesaid, was entirely different. Today, the situation is as such as it was prevalent on 23.02.2024 when the predecessor bench was adjudicating the earlier application without any '*claim mapping*', the same is the situation in the present application.

11. Interestingly, for an *ad-interim* injunction under *Order XXXIX rules 1 & 2* CPC in any other suit for infringement unlike the present one before a Court of law, a party like the plaintiffs herein has to make out a *prima facie* case with the *balance of convenience* in its favour and that there is a likelihood of *irreparable harm, loss and injury* being caused to it. Since, this

is well established and settled law, there are no qualms about it, there is no requirement for this Court to dwell and/ or emphasize upon it, at this stage.

12. However, when a party like the plaintiffs herein approaches a Court of law in a suit for infringement of patent which is accompanied by an application under *Order XXXIX rules 1 & 2* CPC wherein also the said party like the plaintiffs herein is seeking an *ad interim injunction,* there is a fourth limb as well i.e. '*claim mapping*' or like whereby it is necessary for such a party to establish and cross the hurdle of showing that the impugned product like '*Sigrima'* of the defendant in the present case is likely to and/ or is actually infringing their suit patents IN '646 and IN '632.

13. To establish the above, the only mechanism available to a party like the plaintiffs, was/ is to establish their case of '*claim construction*' as well as '*claim mapping*'. Since defining scope of the patents involved is very necessary because broad interpretation of the patents might cover more subject matter, increasing the chance of infringement. Thus, narrow interpretation restricts the scope of patent. Therefore, both '*claim construction*' and '*claim mapping*' form the very fulcrum of a patentee like the plaintiffs herein for alleging that the claim/s made by it in its patent is/ are indeed being infringed by a rank outsider like the defendant herein without having any authority to do so.

14. *'Claim construction'* is primarily for interpreting the meaning and scope of the claim/s made by a patentee like the plaintiffs herein in their suit patents IN '646 and IN '632 whereas *'claim mapping'* of the claim/s in any registered patent is a process to map the feature/s, type/s, component/s,

composition/s, function/s of all the said claim/s therein of the patentee like the plaintiffs herein with those of another product which is actually nearly similar or can be said to be similar to that of the said registered patent of the patentee like the plaintiffs herein for determining if the two products are indeed similar and, if so, the extent of likeness and similarity *inter-se* the two.

15. In fact, *'claim mapping'* is a process generally referring to the comparison of a patent's claim to a product, process or another patent. The goal of this process is to examine whether the product or process claim infringes or overlaps with another patent. This process requires focus on matching features of a product with the claim elements i.e., each element of a claim is matched against corresponding features of the product or method to see if the product contains each and every element described in the patent claim or to what extent do they overlap.

16. Both '*claim construction*' and '*claim mapping*' generally refer to the legal interpretation of the meaning, scope, intent and language of the claim/s made by a patentee in the patent in order to define/ clarify as to what is/ are covered by in the said particular patent. It embarks upon the interpretation of the exclusive rights of a patentee and the broad contours and boundaries of the said patentee in the patent. They, being are essential steps in the field of patent litigation play crucial roles in determining the scope and applicability of a patent, but they both serve two distinct purposes in the field.

17. In any suit for infringement of a patent wherein while considering an application under *Order XXXIX rules 1 & 2* CPC, the Court has to be

cautious about the fact that defining scope of the patent is very necessary because broad interpretation of the patent might cover more subject matter, increasing the chance of infringement.

18. Mere registration of a patent in favour of a patentee like the plaintiffs is not itself sufficient for seeking the grant of an *ad interim* injunction in an application under *Order XXXIX rules 1 & 2* CPC of the present nature in a suit for infringement of a patent. After all, an *ad interim* injunction with respect to the suit patents IN '646 and IN '636 on the mere basis of preponderance of probabilities hypothetically without any basis cannot be granted. Doing so will mean that any patentee who is holding a valid subsisting registration of a/ any patent shall be automatically entitled to an *ad interim* injunction whence it/ they approach a/ any Court of law. Meaning thereby, such a patentee would be entitled to an *ad interim* injunction axiomatically as what will be registered, in that case merely a stamp/ seal (of confirmation) from a/ any Court of law.

19. Reliance is placed upon ***Bilcare Ltd. v. Supreme Industries Ltd.***[14], wherein it has been held as under:-

> *" In Hindustan Lever Ltd. v. Godrej Soaps Limited [1997 PTC (17) 756], it was held,*
> *24. xxxxxxxxx*
> *In patent cases the onus of showing a prima facie case justifying the grant of an injunction is a heavy one and it is comparatively easy for the Respondent to establish a defence sufficient to prevent the grant of such an injunction in Hubbard v. Vosper, (1972) 1 All ER 1023 at 1029, Lord Denning observed:*
> *In considering whether to grant an interlocutory injunction, the right course for a Judge is to look at the whole case. He must have regard not only to the strength of the claimant but also to the strength, of the defence and then decide what is best to*

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be done. Sometimes, it is best to grant an injunction so as to maintain the status quo until the trial. At other times, it is best not to impose a restraint on the Defendant, but leave him free to go ahead. For instarice, in Frazer v. Evans, (1969) 1 All ER 8, although the Plaintiff owned the copyright, we did not grant an injunction, because the Defendant might have a defence of fair dealing. The remedy by interlocutory injunction is so useful that it should be kept flexible and discretionary. It must not be made the subject of strict rules.

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28. Mr. Chakraborty, learned Counsel has submitted that in view of the above decision of the House of Lords, the view taken by a Division Bench of this Court in Boots Pure Drug Co. v. May and Baker Ltd., 1948 (52) CWN 253 should be taken as not laying down the correct principle of law. In that case, it was held, that in order to get a temporary injunction against the infringement of a patent right, it is necessary that the Plaintiffs should prove three things:

(a) that they have a prima facie case, that is to say, they have such evidence as would lead the Court to come to the conclusion that the patent is prima facie a valid patent;

(b) they must prove by prima facie evidence that there has been an infringement on the part of the Defendant; and

(c) that the balance of convenience is in favour of the Plaintiffs.

29. As regards condition (a) it is a rule of practice that if a patent is a new one, a mere challenge at the Bar would be quite sufficient for the refusal of a temporary injunction, but if the patent is sufficiently old and has been worked, the Court would, for the purpose of a temporary injunction, presume the patent to be a valid one. If the patent is more than six years old and there has been actual user it would be safe for the Court to proceed upon this presumption.

xxxxxxxxx

48. Mr. Mukerjee, has also referred to the following passage at pp. 113 of Brain C.-Reid's "A, Practical Guide to Patent Law" 2nd Edition (1993):

Nevertheless, the grant of interlocutory relief is by no means automatic; it remains, at the end of the day, an exceptional remedy given at the Court's direction for which exceptional cause to be shown. The leading modern decision in this area of the law generally, American Cyanamid v. Ethico (Interlocutory was in fact enunciated in a patent dispute in 1974.)

49. But the learned author at pp. 116 of same treaties has drawn the attention to the danger inherent in mechanical application of the American Cyanamic approach; In particular, the Court will not allow the American Cyanamic approach (which in principle is quite favourable to the patentee) to become by over rigid application an engine of oppression. This is highlighted by the decision of the Court of appeal in Brupat v. Sandfod Maston Products (1983 RPC 61) where a Defendant of extremely modest financial standing (normally a good

reason for grant of relief since it gives rise to doubt as to their eventual capacity to pay damages if infringement is found at the trial) was allowed to continue provided that he pay in the interim into an escrow account a reasonably royalty."

20. Relevantly, I also find able support from Terrell on the Law of Patents (19th Edition) wherein it has been, quite explicitly explained and stated as under:-

"*Once the construction of the claims of a patent has been determined as a matter "normal interpretation", the question of whether or not there has been infringement, and whether or not a cited piece of prior art anticipates the claim, can often be answered immediately… …*"

21. In fact, the High Court of Delhi Rules Governing Patent Suits, 2022 also contains as under:-

"3.(ix) Precise claims versus product (or process) chart mapping or in the case of SEPs, claim chart mapping through standards;
(x) Infringement analysis explained with reference to the granted claims in the specification. Details of the allegedly infringing product or process, the manner in which infringement is being alleged including, if available, a description of the defendant's process"

22. Lastly, in ***Guala Closures Spa vs Agi Greenpac Limited***[15] a learned Single Judge of this Court has, while dealing with a similar application under *Order XXXIX rules 1 & 2* CPC in a suit for infringement of a patent, *albeit*, qua the issue of '*claim construction*' and not '*claim mapping*' observed as under:-

"40. Claim construction is generally the first and foremost exercise carried out in adjudicating patent infringement suits, especially when confronted with products like tamper-evident closures which are based on mechanical features. The same has also been highlighted in 'Chapter 9: Construction of the Specification and Claims', in Terrell on the Law of Patents, Eighteenth Edition. As

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> *per Terrell, determination of the actual scope of the Claims of a complete specification, is one of the most significant issues, in litigation involving patents. Once the scope of the claims is clarified, questions regarding infringement and invalidity often find swift resolution. Therefore, it has been highlighted that patentees must navigate a delicate balance, as they have to assert their claim in such a way that the Claim is broad enough to cover infringement while not excessively broad to avoid coverage by prior art. … …*"

23. Though the aforesaid observations in ***Guala Closures (supra)*** are pertaining to '*claim construction*' and not '*claim mapping*', however, in the considered opinion of this Court, the same analogy will be applicable whilst a Court is adjudicating the issue of an *ad interim injunction* in an application under *Order XXXIX rules 1 & 2* CPC in a suit for infringement of a patent of the present nature.

Conclusions:

24. Reverting to the said issue on hand in the present application before this Court for adjudication, interestingly when the same was being argued by the learned senior counsel/s for the plaintiffs, even though the earlier application under *Order XXXIX rules 1 & 2* CPC of the very same plaintiffs, which was listed before this Court on 23.02.2024 and wherein the plaintiffs had ultimately filed the '*claim mapping*' along with its rejoinder to the said application on 02.04.2024, was pending, no reference and/ or arguments qua '*claim mapping*' were ever advanced before this Court on any of the diverse dates.

25. Being the patentee of both the suit patents IN '646 and IN '632, the plaintiffs are the rightful owners to institute the present suit for infringement of the said patents against the defendant as also seek appropriate reliefs for

grant of an *ad interim* injunction qua them against the defendant as well, however, in view of the afore going analysis and reasonings specifically with regards to '*claim mapping*' as also the fact that there were no reference and/ or arguments advanced by either of the parties, particularly by the learned senior counsel for the plaintiffs, the relief of an *ad interim* injunction is not possible without there being any '*claim mapping*'.

26. Without any '*claim mapping*' there is no basis for this Court to render any finding and/ or draw any final conclusion against the defendant. As such, without commenting on the merits involved, even though the plaintiffs may have set out a good case based on the conduct/s of the defendant as recorded in the order dated 09.07.2024, however, since there is no '*claim mapping*' qua the two patents IN '646 and IN '632 of the plaintiffs with the impugned product '*Sigrima'* of the defendant, this Court is unable to pass any order in favour of the plaintiffs merely because the composition comprising Pertuzumab is same or they are biosimilar.

27. More so, since in terms of *Section 3* of the Patents Act, 1970, there are more than one factor/s which governs grant of a patent. In the considered opinion of this Court, it is too bold for it to grant an order of *ad interim* injunction on the basis of probabilities.

28. In fact, under similar circumstances, the predecessor bench in order dated 23.02.2024 refused to grant an *ad interim* injunction in favour of the plaintiffs specifically in view of the observations made as under:-

> "*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.

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.

26. The Court also acknowledges the dual aspects of intellectual property concerning biologic medicines, which encompass not only the molecular structure of the biologic but also the sophisticated processes required for its reliable, safe, and consistent large-scale manufacturing within living systems. This recognition aligns with the detailed stipulations of the Indian regulatory guidelines for similar biologics, as outlined in Clause 6.2 of the Guidelines, according to which, manufacturers of Similar Biologics are mandated to refine their manufacturing processes to ensure that the resultant product closely matches the Reference Biologic in terms of identity, purity, and potency. Furthermore, the Guidelines stress the importance of process validation as well as the demonstration of a manufacturing procedure that is both highly consistent and robust. In scenarios where the host cell line utilized in the production of the Reference Biologic is publicly disclosed, there is a strong preference for employing the same host cell line in the manufacturing of Similar Biologics. This requirement underscores the balance between innovating within the framework of existing biologics and

> *adhering to the stringent standards set forth to maintain the integrity and efficacy of these therapeutic products.*
>
> *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."*

29. Even otherwise, granting an injunction merely on the basis of a registered patent to a/any/every patentee like the plaintiffs without putting it to the test of '*claim mapping*' or like, cannot be the intention of the legislature. In such circumstances, allowing the present application of the plaintiffs would amount to an *ad-interim* injunction to them simply because they have two suit patents IN '646 and IN '632 subsisting in their names. The same shall render the purpose of the existence of the provisions of the Patent Act, 1970 otiose.

30. Holistically, the issue qua conduct of the defendant is hardly of any significance since it is the plaintiffs, who have been unable to demonstrate anything qua '*claim mapping*' or like. Since the plaintiffs' have not averred/ referred/ argued anything qua '*claim mapping*' or like, in the present application under *Order XXXIX rules 1 and 2* CPC which is an integral part for consideration of grant of an *ad interim* injunction in favour of the plaintiffs and against the defendant in the present suit for infringement of suit patents IN '646 and IN '632. Even otherwise, it is highly improbable for this

Court to conclude anything merely on the basis of the SEC Meeting held on 23/24.01.2024 or what was stated to the SEC by the defendant or otherwise that the defendant is actually infringing the suit patents, IN '646 and IN '632 of the plaintiffs, and that too, at this stage.

31. In view of the aforesaid reasonings and analysis, this Court is refraining to go into the aspect of alleged breach of assurance given by the defendant or that it did not inform this Court about the launch or that it allegedly over-reached this Court or that the plaintiffs have suffered damages as well.

32. Qua the involvement of Dr. Reddy's Laboratories Limited and the dealings of the defendant qua the two registered patents IN '646 and IN '632 is a different cause of action qua which the plaintiffs have already instituted a separate suit against both of them and cannot be adjudicated herein in the present suit and application as it is a totally different cause of action involving a third party.

33. In view of the aforesaid and even otherwise, since the Hon'ble Supreme Court in ***Morgan Stanley (Supra)*** was dealing with a case with respect to Consumer Protection Act, 1986 which was not involving the issue qua infringement of a patent like the present one, in the considered opinion of this Court, it is not necessary for taking into account the conduct of the defendant as well.

34. Having said as aforesaid, this Court is not in agreement with the submissions of the learned senior counsel/s for the defendant qua there being no specific prayer/s qua the Drug Controller and/ or that it was not bound to

apprise/ inform this Court since there was no such order/s or the service of the applications in accordance with law upon the defendant. Though there may have not been any specific order, but from the order/s passed by the predecessor bench, there seems to have been an implied understanding. Even otherwise, *principles of natural justice* demand the defendant to act judicially and with utmost care, prevention and precaution, more so, whence *admittedly* the defendant is not a fly by night operator and it claims to be one of the pioneer entities. The defendant is well aware of the far-reaching impact when it is involved in proceedings pending adjudication before a Court of law and when the actions of the defendant have a corollary effect on the outcome/ decision thereof.

35. The contention of the learned counsel/s for the defendant that the order dated 09.07.2204 deserves to be vacated since the defendant was served with an advance copy of the present application late in the day and the same was taken up by the learned predecessor bench late in the day, and that too upon urgent mentioning, needs not to be gone into.

36. Lastly, the grant of relief of *an-injunction* is of a discretionary nature, for grant of which the party like the plaintiffs herein have to satisfy a Court of law by setting out that it has a *prima-facie case* in their favour with the *balance of convenience* also in their favour and that they are likely to suffer *irreparable loss and injury* as well as '*claim mapping*' or like in a suit of patent infringement of the present nature, in terms of the aforesaid, the plaintiffs have been unable to make out any case in their favour and against the defendants in the absence thereof.

37. Under the aforesaid circumstances, to the mind of this Court, the plaintiffs are not entitled for the reliefs prayed for in the present application.

38. Accordingly, the present application under *Order XXXIX rules 1 & 2* CPC of the plaintiffs is dismissed in the above terms and the *ad interim* order dated 09.07.2024 passed by the predecessor bench is vacated.

CS(COMM) 159/2024, I.A. 4196/2024-Stay, I.A. 4198/2024-Exp. from pre-institution mediation, I.A. 5827/2024-constitution of Confidentiality club, I.A. 33509/2024-Stay & I.A. 36101/2024-O-39,R-2A CPC

39. Renotify before the roaster bench for further proceedings on 02.12.2024.

SAURABH BANERJEE, J.

OCTOBER 09, 2024
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