2025:BHC-OS:8657

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
ORDINARY AND ORIGINAL CIVIL JURISDICTION
IN ITS COMMERCIAL DIVISION

NOTICE OF MOTION NO. 305 OF 2016
IN
COMMERCIAL SUIT NO. 272 OF 2016

ROCHE PRODUCTS (INDIA) PRIVATE LIMITED AND OTHERS)...APPLICANTS /)ORI. DEFENDANTS 1 TO 3

IN THE MATTER OF

CADILA HEALTHCARE LTD.)...PLAINTIFF

V/s.

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

Dr.Birendra Saraf, Senior Advocate a/w. Mr.Ishwar Nankani a/w. Mr.Huzefa Khokhawala and Mr.Abhishek Tiwari i/by M/s.Nankani & Associates, Advocate for the Applicants/Defendants No.1 to 3.

Dr.Veerendra Tulzapurkar, Senior Advocate a/w. Mr.Bijal Chhatrapati, Mr.Pratik Pawar, Ms.Shanaya Cyrus Irani, Mr.Siddhesh S. Pradhan i/by J.Sagar Associates, Advocate for the Respondent/Plaintiff.

Mr.Rajesh Singh, Advocate for the Defendant no.4 – Union of India.

CORAM : ABHAY AHUJA, J.
RESERVED ON : 28th APRIL 2025
PRONOUNCED ON : 9th JUNE 2025

ORDER. :

1. This Notice of Motion has been filed at the behest of the Defendants no.1 to 3 seeking the following reliefs:

(a) This Hon'ble Court be pleased to pass an order of dismissal of the above Suit, being Suit No.1073 of 2015 as barred by law;

In the alternative:

(b) Suit No.1073 of 2015 be rejected/dismissed under the provisions of Order VII Rule 11 of the Code of Civil Procedure, 1908.

2. On 6th January 2025, when the matter was called out, the following order was passed:

> *"1. Pursuant to the order dated 12th July, 2024, today when the matter is called out, Ms.Irani, learned Counsel appears for the Plaintiff and submits that Dr. Virendra Tulzapurkar, learned Senior Counsel has been engaged to appear in the matter and he has requested that the matter be listed on 20th January, 2025.*
>
> *2. Mr.Nankani, learned Counsel appearing for the Defendants No. 1 to 3 submits that on the earlier occasion when the matter had come up, after brief discussions the order dated 12th July, 2024 came to be passed and that the Plaintiff was to take instructions on the withdrawal of the Suit in as much as the suit is already been worked out. Mr. Nankani submits that admittedly the Plaintiff has already launched his product in the market and therefore, the prayer Clause (a) has already been worked out.*
>
> *3. As regards the prayer Clause (b), Mr. Nankani, learned Counsel for the Defendants No. 1 to 3 submits that since the Suit has already been filed by the Defendants in the Delhi High Court, questioning the approvals and licenses granted to the Plaintiff, this Court cannot pass orders with respect to the prayer Clause (b) or even (c).*
>
> *4. Let appropriate instructions be taken by the Plaintiff in the matter by the next date. List on 20th January, 2025."*

3. Thereafter, on 20th January 2025, when the matter was called out, the following order was passed :

> *"1. Pursuant to earlier orders of this Court ending with order dated 6th January 2025, when the matter is called out today, Dr.Tulzapurkar, learned Senior Counsel appearing for the Plaintiff submits that if the Defendants do not interfere in the marketing of the Plaintiff's product, then he can take instructions from the Plaintiff if the Suit can be withdrawn as the Defendants no.1 to 3 have already filed a Suit in the Delhi High Court questioning the approvals and licenses granted to the Plaintiff.*
> *2. Dr.Birendra Saraf, learned Senior Counsel and Advocate General of the State, appearing for the Defendants submits that since the product has already been launched, as submitted earlier, prayer clause (a) would not survive. As regards prayer clauses (b) and (c), Dr.Birendra Saraf submits that the Defendants no.1 to 3 have already filed a Suit in the Delhi High Court with regard to the approvals and licenses granted to the Plaintiff and nothing would really survive in this Suit.*
> *3. Having heard the learned Senior Counsel, for Dr.Tulzapurkar, learned Senior Counsel for the Plaintiff, to take instructions, list on 30th January 2025 under the caption 'for directions'."*

4. However, when the matter was called out on 30th January 2025, Dr.Tulzapurkar, learned Senior Counsel appearing for the Plaintiff, submitted that he had instructions to go ahead with the matter to pursue the Suit, after which the following order was passed :

"1. Pursuant to earlier orders of this Court, ending with order dated 20th January, 2025, today when the matter is called out, Dr. Tulzapurkar, learned Senior Counsel appearing for the Plaintiff submits that he has instructions to state that the Plaintiff would be going ahead with the proceedings in this Court and that an Application under Section 10 of the Code of Civil Procedure, 1908 ("CPC") has been filed before the Delhi High Court seeking stay of the Suit in the Delhi High Court.

2. Dr. Saraf, learned Senior Counsel and Advocate General of the State appearing for the Defendant takes strong exception to the conduct of the Plaintiff and submits that although on 20th January, 2025 the Plaintiff was to give instructions that the Suit can be withdrawn as the Defendants No. 1 to 3 have already filed a Suit in the Delhi High Court questioning the approvals and licenses granted to the Plaintiff and that before the next date, which is today, the Plaintiff has gone ahead and filed an Application under Section 10 of the CPC in the Delhi High Court.

3. Dr. Saraf, however, submits that if the Plaintiff is desirous of proceeding with the Suit, the Notice of Motion filed under Section Order VII Rule 11 of the CPC be heard first.

4. Both the learned Senior Counsel submit that the Notice of Motion be fixed for hearing as the pleadings are complete.

5. Accordingly, at their joint request, list on 17th March, 2025 at 3.00 p.m. for hearing of the Notice of Motion."

5. Thereafter, on 17th March 2025, Dr.Saraf, learned Senior Counsel, had concluded his arguments on behalf of the Applicants and the matter was listed on 8th April 2025 for Dr.Tulzapurkar, learned Senior Counsel, on behalf of the Plaintiff to respond. On 8th April 2025, Dr.Tulzapurkar for the Plaintiff concluded his arguments and the matter

was listed for Dr.Saraf to rejoind on 28th April 2025. On 28th April 2025 arguments in rejoinder were heard and order was reserved and liberty was granted to file written submissions, if any, within a period of two weeks.

6. I have heard the learned Senior Counsel at length and considered the rival contentions. Written submissions on behalf of the Plaintiff-Respondent have been filed on 8th April, 2025 and on behalf of the Applicants/Defendants on 8th May, 2025.

7. In 1990, Genentech Inc., the Defendant No. 2, developed a biologic drug "Trastuzumab", which was approved for the treatment of certain kinds of cancer. The drug was manufactured by F. Hoffman-La Roche AG, the Defendant No. 3, and has been imported and marketed in India by Roche Products (India) Limited who is the Defendant No.1, (collectively referred to as "Roche") since 2002. It has been submitted that Roche did not have a patent for biologic Trastuzumab *per se* in India.

8. That, certain manufacturers, after obtaining approval of the Drugs Controller General of India (“DCGI”), launched their version of

Trastuzumab, claiming their drug to be biosimilar to Roche's Trastuzumab. Roche had during the years 2014/2015 filed suits in Hon'ble Delhi High Court against these manufacturers, challenging, *inter alia*, their claims that their drugs are biosimilars to Roche's Trastuzumab as well as challenging the manner in which DCGI granted approvals to these manufacturers.

9. It has been submitted on behalf of the Applicants that in 2015, when the Plaintiff was in the process of launching a drug named 'Vivitra' claiming it to be a biosimilar of Roche's Trastuzumab, the present suit came to be filed by the Plaintiff in this Court (the "Suit") on 30 November 2015 in which the Plaintiff has pleaded its cause of action in paragraphs 45 to 51 of the plaint. The relevant paragraphs of the plaint are set out below:

> *"45. The Plaintiff states that Roche has aggressively initiated and pursued proceedings against other Indian companies who have launched/proposed to launch biosimilars of Trastuzumab in India. It has been Roche's case, in substance, in those proceedings, that the Defendant Nos. 4 & 5 have incorrectly granted manufacturing and marketing authorizations to the Indian companies despite alleged lapses in their clinical trials conducted by such Indian Companies. The Plaintiff craves leave to refer to the said proceedings, if and when produced. The Plaintiff submits that Roche has been aggressively acting to perpetuate its monopoly and*

obstruct the manufacture and sale of biosimilar versions of Trastuzumab after the lapse of its patent rights to the same. Roche's attempts to evergreen its expired patents has included the adoption of frivolous and vexatious proceedings against Indian drug manufacturers such as the Plaintiff. The Plaintiff submits that such obstructive actions by Roche are also against public interest and block the launch of more cost effective treatment.

46. The Plaintiff apprehends that Roche is very likely to initiate some similar action against it in an attempt to thwart the launch and marketing of the Plaintiff's biosimilars of Trastuzumab despite Defendant No.4 & 5 having carefully and appropriately examined and considered the Plaintiff's applications and granted the necessary license, entitling the Plaintiff to launch and market its biosimilars of Trastuzumab.

47. The Plaintiff's drug is a biosimilar to Roche's Trastuzumab. It has the same composition, therapeutic quality, safety and efficacy as the Roche's Trastuzumab.

48. The Plaintiff states that any action by Roche seeking to interfere and/or restrain in the Plaintiff's launch and marketing of its biosimilar of Trastuzumab would be misconceived and unsustainable given that the Plaintiffs has already obtained the necessary license after detailed scrutiny by the authorities concerned, Roche has no locus standi and/or cause of action to file any suit against the Defendant No.4 & 5 and/or the Plaintiff in the manner it has chosen to do against other Indian companies. The Plaintiff submits that Roche has no right to sue so as to restrain the Plaintiff's launch and marketing of its biosimilar of Trastuzumab, Assuming whilst denying that Roche is aggrieved by the decision of Defendant No. 4 & 5, even then, there is a provision for appeal to the Central Government, under Rule 122 DC of the Drugs and Cosmetics Rules, 1945. Despite the above, Roche has already demonstrated its alacrity and willingness to adopt aggressive legal action to, in effect,

somehow prevent products competing with its own reaching the Indian market.

49. The Plaintiff further states that:

(a) Trastuzumab does not enjoy patent protection and thus it is in public domain - No civil suit can be filed for patent infringement;

(b) There is no data exclusivity and the data relating to Trastuzumab is publicly available as India has not adopted the data exclusivity provision as the same is a TRIPS-plus provision and India only follow TRIPS. Thus, no suit can be filed for any violation of data exclusivity provision;

(c) The name TRASTUZUMAB is an international non-proprietary name which is 'public property' - Thus, no suit can be filed for Trade Mark infringement or passing off for using the name "TRASTUZUMAB";

(d) The WHO Guidelines on Similar Biotherapeutics approve of abbreviated pathways for approval of biosimilars;

(e) No monopoly can exist on publicly available data, or even confidential data;

(f) Consequently, Roche has no right under any provision of Intellectual Property law to restrain the Plaintiff against the launch of its biosimilar of TRASTUZUMAB.'

50. The facts and contentions set forth in this plaint constitute the cause of action for the present suit. The principal cause of action has arisen against Defendant No. 1, Defendant No. 2, the innovator of Trastuzumab and trade mark holder of Herceptin under which name it markets Trastuzumab globally and Defendant No. 3, the manufacturer of Trastuzumab indirectly carry out their business of marketing and sale of Trastuzumab through Defendant No. 1. As Defendant No. 1 has its registered office in Mumbai, the principal and material cause of action in the present suit

arises in Mumbai. Thus, Hon'ble court can therefore entertain and try the present suit. The Plaintiff submits that Defendant No. 4 and 5 are formal defendants and no reliefs are sought against them. Defendant Nos. 2 and 5 are situate outside India. As such, a petition for leave under Clause 12 of the letters patent has been filed for grant of reliefs as detailed in the said Petition.

51. The cause of action has arisen in October, 2015 when the Plaintiff has obtained approval for manufacture and marketing its Biosimilar of Trastuzumab and further when the Plaintiff has now obtained license to manufacture its biosimilar of Trastuzumab on 27th November 2015 from the Defendant No.5 and when the Plaintiff has come to know of the successive suits and vexatious proceedings filed by the Defendant Nos. 1 to 3 against various Indian Companies. Furthermore, Roche has publicly announced and made the Plaintiff aware in Mumbai, through an internationally published position paper, that it intends to take "all necessary steps" so as to prevent the manufacture and sale of legitimately approved and licensed biosimilars on purported grounds of patient safety. A copy of the aforementioned position paper is annexed hereto and marked as Exhibit "G". The present suit is therefore filed within the period of limitation and no part of the cause of action there of is barred by limitation"

(emphasis supplied)

10. On the basis of the aforesaid cause of action, the Plaintiff has prayed for the following reliefs in paragraph 60 of the Plaint:

(a) that this Hon'ble Court be pleased to declare and confirm that the Plaintiff is entitled and has a right to launch and market is biosimilar of Trastuzumab;

(b) that this Hon'ble Court be pleased to order and declare that the Defendant Nos. 1 to 3 is not entitled to question the approvals and licenses granted by the Defendant No. 4 & 5, to the Plaintiff in respect to the Plaintiff's biosimilar of Trastuzumab;

(c) that this Hon'ble Court be pleased to pass a permanent order of injunction restraining Defendant Nos. 1 to 3 from interfering with and/or preventing the Plaintiff from launching and marketing its biosimilar of Trastuzumab.

11. Dr.Saraf, learned Senior Counsel for the Applicants/Defendants no.1 to 3 has submitted that it is apparent that the entire cause of action and the apprehension on the basis of which the Suit was filed was that Roche had filed legal proceedings against other biosimilar manufacturers, which according to the Plaintiff was an obstructive action undertaken by Roche and that the Plaintiff apprehended that Roche is likely to initiate "similar actions" against the Plaintiff in an attempt to thwart the launch and marketing of the Plaintiff's product.

12. It is further submitted that the Plaintiff's cause of action is further that :

(a) any action by Roche to interfere/restrain the Plaintiff from launching its product would be misconceived and unsustainable.

(b) Roche has no *locus standi* or cause of action to file a suit against the Plaintiff in the manner it has chosen to do against other Indian companies.

(c) Roche has no right to sue or restrain the Plaintiff's launch and marketing of the Plaintiff's product.

(d) Assuming that Roche was aggrieved by the decision of the regulatory authorities granting permission, their remedy is by way of an appeal under Rule 122 DC of the Drugs and Cosmetics Rules, 1945 ("Drugs Rules").

(e) Despite the available remedy, Roche has adopted aggressive legal action in order to prevent products, competing with its own products, from reaching the Indian market.

13. Dr.Saraf has submitted that Roche's actions against the other companies and the legal action apprehended by the Plaintiff are unfounded. Learned Senior Counsel submits that the Plaintiffs have in paragraph 49 of the plaint pleaded as to how a legal proceeding that may be filed by the Defendants No.1 to 3 would not be maintainable.

14. Dr.Saraf submits that the Plaintiff has asserted in Paragraph 50 of the plaint that the facts and contentions set forth earlier in the plaint

constitute the cause of action in the present Suit, however, paragraph 50 primarily contains submissions relating to territorial jurisdiction.

15. It is submitted that the Plaintiff asserts in Paragraph 51 of the plaint that the cause of action arose when the Plaintiff came to know of the Suits filed by Roche against other manufacturers, however, paragraph 51 primarily relates to limitation.

16. Dr.Saraf further submits that the Plaintiff has also referred to a stand taken by Roche in an internationally published position paper that Roche intends to take all necessary steps to avoid related misunderstandings and will oppose the use of misleading claims that are unsubstantiated due to lack of reasonable data. The Plaintiff has, however, at Paragraph 51 of the Plaint, selectively quoted and misrepresented Roche's position paper with an intent to mislead and prejudice this Court.

17. It is submitted that a reading of the plaint as a whole makes it apparent that the entire cause of action pleaded in the plaint is that Roche has initiated legal proceedings against other Indian manufacturers, and that, therefore, the Plaintiff apprehended that

Roche will initiate similar proceedings against the Plaintiff. That, the entire essence of the plaint was a grievance and apprehension that Roche was not entitled to initiate legal proceedings, and the prayers in the Suit have to be considered in that context.

18. Dr.Saraf has submitted that the Plaintiff launched its drug in 2015 shortly after filing this Suit and since then has been marketing and selling their drug. That, Roche, thereafter, filed a suit in the Delhi High Court against the Plaintiff being Civil Suit (Commercial) No. 1119 of 2016 *inter alia* challenging the permission granted by the regulatory authorities to the Plaintiff (the "Cadila Delhi Suit"). It is stated that during the pendency of the Cadila Delhi Suit and the present Suit, the Plaintiff changed its name to Zydus Lifesciences Limited, which is reflected in the orders of the Delhi High Court. That, Cadila (Plaintiff herein and Defendant in the Cadila Delhi Suit) filed an application under Order VII Rule 11 of the Code of Civil Procedure, 1908 ("CPC") for rejection of Roche's plaint before the Delhi High Court and the said application has been rejected by an order of the Delhi High Court dated 11 September 2023, in which the Delhi High Court held the Cadila Delhi Suit to be maintainable, and has also rejected the arguments made by Cadila in paragraphs 48 and 49 of the present plaint.

19. Dr.Saraf has submitted that in its order of 11th September 2023, the Delhi High Court held that the alternate remedy under Rule 122 DC of the Drugs Rules (i) was not available to Roche, and (ii) was no longer available as Rule 122 DC had been deleted from the statute book in 2019. That, the Delhi High Court also held that Roche cannot be prevented from enforcing its rights or challenging the permissions granted to Cadila and held the Cadila Delhi Suit to be maintainable and dismissed Cadila's application under Order VII Rule 11 of the CPC.

20. Dr.Saraf submits that, therefore, this application has been filed under Order VII Rule 11 of the CPC on 16th September 2016 seeking rejection of the plaint on the basis that:

(a) the reliefs sought in the Plaint disclose that the Suit is barred by law;

(b) the Suit does not disclose a cause of action;

(c) the purported cause of action sought to be made out against the Defendant Nos. 1-3 in the Suit does not survive, and the Suit has become infructuous.

21. Dr.Saraf submits that prayer clause (b) of the plaint is barred by law. Learned Senior Counsel submits that the plaint clearly sets out

that the cause of action is an apprehension that Roche will initiate legal proceedings against the Plaintiff and the prayers in the plaint have to be read in that light. The entire endeavour of the Plaintiff was to prevent a legal action by Roche, which has now been instituted. The entire cause of action in the plaint is nothing but the Plaintiff seeking to prevent Roche from initiating legal action. That, therefore, the Suit is clearly barred by Section 41(b) of the Specific Relief Act, 1963, ("SRA") as amended which bars a court from restraining any person from initiating or prosecuting proceedings.

22. It is submitted on behalf of the Applicants that the Plaint in the present Suit has to be read as a whole and the prayers therein have to be read in conjunction with the averments made in the plaint, where the only apprehension expressed was that Roche has initiated legal proceedings against the other entities and was likely to initiate similar legal proceedings against the Plaintiff. It is submitted that through clever drafting, the Plaintiff seeks to camouflage the cause of action - to seek a restraint on initiation of legal proceedings. That the Plaintiff's suit is a clear example of clever drafting meant to create the illusion of a cause of action. That when a plaint merely gives the impression of a cause without substance, this Court must reject it to prevent frivolous

litigation. And that the Plaintiff cannot cloak the plaint in such a manner as to create a fictitious cause of action. That, therefore, prayer clause (b) is barred by law.

23. Dr.Saraf reiterates that the Defendant no.1 has filed a Suit in the Delhi High Court and the Hon'ble Delhi High Court has held the Cadila Suit to be maintainable.

24. As far as prayer clauses (a) and (c) of the plaint are concerned, Dr.Saraf submits that the said prayers are infructuous. Learned Senior Counsel submits that the prayer clauses (a) and (c) relate to the Plaintiff's right to launch and market the drug and an apprehension that Roche will initiate legal proceedings against the Plaintiff and that the grant of these prayers has now become infructuous for two reasons:

(i) The Plaintiff admittedly launched its drug "Vivitra" on 25 December 2015, and this drug has been marketed and sold by the Plaintiff for more than 9 years, without any interference from Roche. That, there is, accordingly, no basis now for the Plaintiff to seek an injunction against Roche from interfering with the launch/marketing of Vivitra.

(ii) Roche has filed the Cadila Delhi Suit challenging the approvals granted by DCGI to the Plaintiff as these approvals have not been

granted in accordance with applicable law. That, the said Cadila Delhi Suit is at an advanced stage, with parties having completed their pleadings, and the Plaintiff's application under Order VII Rule 11 of the CPC also has been dismissed on 11 September 2023 by the Delhi High Court. A Division Bench of the Delhi High Court has also subsequently dismissed Cadila's appeal against this order. The Plaintiff has actively defended the Cadila Delhi Suit since 2016, but has taken no steps to expedite the prosecution of the Suit before this Court in the past nine years.

25. Dr.Saraf submits that the Plaint does not disclose any actionable right or a cause of action in favour of the Plaintiff at the time of filing the Suit. That the Suit is based on a sole cause of action - the Plaintiff's apprehension that Roche is likely to initiate legal proceedings against the Plaintiff in relation to the launch and interfere with marketing of the Plaintiff's drug. That, this is not a valid cause of action.

26. Dr.Saraf has relied upon the following decisions in support of his contentions :

(i) *Frost International Limited Vs. Milan Developers and Builders Private Limited and Another*[1]

1 (2022) 8 SCC 633

(ii) *Cotton Corporation of India Vs. United Industrial Bank Limited*[2]

(iii) *T. Arivandandam Vs. T.V. Satyapal & Another*[3]

(iv) *Sopan Sukhdeo Sable Vs. Assistant Charity Commissioner and Others*[4]

(v) *Dahiben Vs. Arvindbhai Kalyanji Bhanushali*[5]

27. On the other hand, Dr.Tulzapurkar, learned Senior Counsel, appearing on behalf of the Plaintiff / Respondent submits that the Application is entirely misconceived and is based on an incorrect reading of the plaint, tied in with imaginary averments which are not even in the Plaint.

28. Learned Senior Counsel for the Plaintiff/Respondent submits that it is well settled that while considering an application under Order VII Rule 11 of the CPC, the Court is required to solely read the Plaint as it stands, and the documents referred to in the plaint or annexed to the plaint. That, consequently, any misreading of the plaint or arguments advanced based on imaginary averments suitable to the Defendants which are not even in the plaint or for that matter, ignoring the reliefs sought in the plaint ought not to be countenanced by this Court.

2 (1983) 4 SCC 625
3 (1977) 4 SCC 467
4 (2004) 3 SCC 137
5 (2020) 7 SCC 366

29. Dr.Tulzapurkar, learned Senior Counsel, has submitted that despite the above, the Defendants No.1 to 3 have made a feeble attempt to misconstrue the plaint to seek reliefs under Order VII Rule 11 of the CPC and the same is demonstrated from the following :

(a) Defendant No.1 is an importer and marketer of "Trastuzumab" in India. Defendant No.2 claims to be an inventor of the Drug.

(b) A formulation patent was granted to Defendant No.1 in respect of the Drug in India with effect from 3rd May, 1999 which expired on 3rd May, 2013. The Invention in respect of the said patent, upon its expiration, became available in the public domain. The Defendants wish to perpetuate the monopoly of manufacturing and marketing the Drug in India even after the patent had expired on 3rd May, 2013.

(c) The Defendants did not desire any Indian Company to manufacture and market a similar drug in India. Consequently, attempts were made by filing proceedings against other companies so as to prevent other companies from manufacturing and selling a similar drug. The Plaintiff was one of such companies who, after obtaining necessary approvals from the concerned authorities, intended to market similar drug.

30. As the Plaintiff apprehended interference and obstruction of the launch and marketing of the similar drug in India, the Plaintiff filed the present Suit for the following reliefs:

(a) that this Hon'ble Court pleased to declare and confirm that the Plaintiff is entitled and has a right to launch and market its biosimilar of Trastuzumab;

(b) that this Hon'ble Court be pleased to order and declare that Defendant Nos.1 to 3 are not entitled to question the approvals and licenses granted by the Defendant Nos.4 and 5 (i.e. the authorities), to the Plaintiff in respect of the Plaintiff's bio similar of Trastuzumab;

(c) that this Hon'ble Court be pleased to pass a permanent order of injunction restraining Defendant Nos.1 to 3 from interfering with and/or preventing the Plaintiff from launching and marketing its bio similar of Trastuzumab.

(d) After the filing of the present Suit, the Plaintiff filed Notice of Motion No.2093 of 2015 before this Court seeking interim relief of injunction. However, since the Plaintiff was able to launch its product, the Plaintiff did not pursue this Notice of Motion and withdrew the same with liberty to approach this Court.

(e) Subsequent to the Plaintiff filing the present Suit before this Court, Defendants No. 1 to 3 filed a Suit, namely, Civil Suit

(Commercial No. 1119 of 2016) before the Hon'ble Delhi High Court *inter alia* challenging the approvals granted to the Plaintiff herein. In this Suit before the Hon'ble Delhi High Court, the Plaintiff (as Defendant No. 1) filed an application for rejection of the plaint under Order VII Rule 11 which came to be rejected. More importantly, in the Suit filed on behalf of Defendants No.1 to 3 before the Hon'ble Delhi High Court, the present Plaintiff (as Defendant No. 1 in that Suit) has filed an application for stay of Delhi Suit under Section 10 of the CPC. This application remains pending as on date. However, the filing of the Delhi Suit has no bearing on the present proceedings and cannot be looked into at all. The Delhi Suit was subsequent to the filing of the Plaint of the present proceeding and naturally does not find any mention in the Plaint of the present proceeding.

(f) Dr.Tulzapurkar has submitted that upon a bare perusal and reading of all the averments in the plaint, it is clear that the reference to the Suits filed by the Defendants No.1 to 3 against Indian companies by way of historical narration supports the Plaintiff's case and contention in the present Suit that the Defendants are desirous of preventing competition and preventing the Plaintiff from launching and marketing the similar drug. The averments made in paragraphs 44, 45,

46, 47, 48 and 51 of the plaint are relevant for the purpose of considering the Application filed on behalf of the Defendants. Sufficient cause of action has been made out.

(g) More specifically, it is clearly stated in paragraph 46 of the present plaint that the Plaintiff apprehends that Roche is very likely to initiate some similar action against it in an attempt to thwart the launch and marketing of the Plaintiff's similar drug.

(h) In paragraph 48 of the plaint, the Plaintiff has specifically stated that any action by Roche seeking to interfere and/or restrain in the Plaintiff's launch and marketing of its similar drug would be misconceived and unsustainable.

(i) In paragraph 51, the Plaintiff has categorically averred as follows :

> *"Furthermore, Roche has publicly announced and made the Plaintiff aware in Mumbai, through an internationally published position paper, that it intends to take all necessary steps' so as to prevent the manufacture and sale of legitimately approved and licensed biosimilars on purported grounds of patent safety."*

(j) The Plaintiff has annexed a copy of the abovementioned position paper at Exhibit "G" at page 103 of the plaint. More particularly, on page 105 of the Plaint, the following statement appears in the said paper :

> *"Unless a manufacturer provides all necessary evidence qualifying its products as the biosimilar, any approval of an NCB should be reassessed by the National Health Agency because of the potentially significant differences in regard quality, safety and efficacy between the NCB and the reference biotherapeutic product. Manufactures who bring a biotherapeutic product to the market and claim their product is "biosimilar" without being able to provide the necessary scientific evidence are not acting in a transparent and responsible manner. Roche will continue to take all necessary steps to avoid related misunderstanding and will oppose the use of misleading claim that are unsubstantiated due to lack of reasonable data".*
>
> *(Emphasis supplied)*

(k) Significantly, paragraph 51 and Exhibit "G" were not pointed out to this Court during the submissions of the Defendant.

(l) From the reading the plaint as a whole and the aforesaid annexure (Exhibit "G"), the following becomes abundantly clear:

(i) There is no averment that the Defendants herein should be restrained from filing or adopting or prosecuting any proceeding against the Plaintiff herein in respect of the similar drug of the Plaintiff.

(ii) There is no submission in support of any prayer for injunction against the Defendants from adopting any legal proceedings.

(iii) There is no prayer seeking any injunction restraining the Defendants herein from taking any legal proceedings.

(iv) The entire argument of the Defendants in support of their Application under Order VII Rule 11 of the CPC is untenable as the

averments in the Plaint clearly show bona fide apprehension of the Defendants' interference with the launch and marketing of the similar drug.

(v) The entire argument that the Plaintiff is seeking injunction against prosecution of any proceedings against the Defendants is incorrect in light of the fact that there is no such prayer. As stated hereinabove, the reference to the proceedings is by way of historical narration of facts which caused apprehension in the mind of the Plaintiff of interference and obstruction by the Defendants.

(m) Moreover, the Defendants are not entitled to imagine the averments in the Plaint and argue that because of those averments, the Plaintiff is seeking injunction against adoption of legal proceedings. It is submitted that an application under Order VII Rule 11 of CPC is required to be considered only on the basis of the averments as they exist in the plaint, and the documents. The justification of the apprehension is a matter of evidence. The Defendants cannot travel beyond and/or rely on something outside the Plaint to base their Application under Order VII Rule 11 of CPC. It is solely the averments in the Plaint that are to be looked into and considered by this Hon'ble Court.

31. In support of the above submission, learned Senior Counsel for the Plaintiff has relied upon ***Eldeco Housing & Industries Ltd. vs. Ashok***

Vidyarthi & Ors.[6] and on the observations made by the Hon'ble Supreme Court in the earlier case viz. *Liverpool & London SP & I Association Ltd. versus M.V.Sea Success I and Anr*[7].

32. Dr.Tulzapurkar submits that the reliefs prayed for in the Plaint are also required to be considered. In the present case, the relief of injunction is not against adopting any legal proceedings by the Defendants. The prayer simpliciter states that the Defendants should be restrained from interfering with and/or preventing the Plaintiff from launching and marketing its biosimilar of Trastuzumab. However, the Defendants are deliberately reading in the words 'from instituting any legal proceedings' in the said prayer when the same is not even there.

33. Dr.Tulzapurkar, further submits that no addition can be made in support of the claim that the relief is barred by law viz. Section 28 of the Indian Contract Act and the very case relied upon by the Defendants viz. *Sopan Sukhdeo Sable vs. Assistant Charity Commissioner and Others (supra)* clearly states that the reliefs sought in the suit have to be considered. That, therefore, the relief of injunction is not for seeking restraint of legal proceedings but against

6 (2023) SCC Online SC 1612
7 (2004) 9 SCC 512

interference with the launch and marketing. The fact that the Defendants will indulge in such an action is clear from the paper at page 105 where it said that:

> *"Roche will continue to take all necessary steps....and will oppose the use of misleading claims that are substantiated due to lack of reasonable data".*

The said document is not disputed by the Defendants anywhere at any time.

34. Dr.Tulzapurkar submits that, therefore, the plaint discloses a valid cause of action and is not barred by any law viz. Section 28 of the Indian Contract Act, 1872 or Section 41 (b) of the Specific Relief Act, 1963. Dr.Tulzapurkar has relied upon the decision in the case of ***Madanuri Sri Rama Chandra Murthy vs. Syed Jalan***[8] cited by the Defendants where in paragraph 7 at pages 178 & 179 the Hon'ble Supreme Court observed that:

> *"Since the power conferred on the court to terminate civil action at the threshold is drastic, the conditions enumerated under Order VII Rule 11 CPC to the exercise of power of rejection of plaint have to be strictly adhered to".*

35. Dr.Tulzapurkar submits that in the third case relied upon by the Defendants viz. *Dahiben vs. Arvindbhai Kalyanji Bhanusali (dead)*

8 (2017) 13 SCC 174

through Lrs (supra), in paragraph 23.6, the Hon'ble Supreme Court of India observed as follows:

> *"Under Order VII Rule 11, a duty is cast on the court to determine whether the plaint discloses a cause of action by scrutinizing the averments in the plaint, read in conjunction with the documents relied on or whether the suit is barred by any law".*

36. Dr.Tulzapurkar further submits that in the fourth case relied on by the Defendants viz., *Frost International Ltd. vs. Milan Developers & Builders Pvt. Ltd. And Anohter (supra)*, the Court referred to the case of *Dahiben vs. Arvindbhai Kalyanji Bhanusali (dead) through Lrs (supra)*, where it was observed clearly in paragraph 23.5 of *Dahiben vs. Arvindbhai Kalyanji Bhanusali (dead) through Lrs (supra)* that the power conferred on the court to terminate the civil action is, however, a drastic one, and conditions enumerated in Order VII Rule 11 are required to be strictly adhered to.

37. Dr.Tulzapurkar, accordingly, submits that the Defendants' attempt to sustain the Application by referring to documents and judgments should not be countenanced. That, the only documents that this Court is required to consider is the Plaint and the documents referred to or annexed thereto.

38. The learned Senior Counsel on behalf of the Plaintiff / Respondent submits that the reliance by the Defendants on the judgment of the Delhi High Court in the Application under Order VII Rule 11 filed by the Plaintiff herein (who was Defendant No. 1 in the Delhi Suit) is entirely misplaced, apart from the fact that the said decision is wholly irrelevant for the purpose of adjudicating the present Notice of Motion.

39. Dr.Tulzapurkar would submit that the other ground taken by the Defendants is that the suit has become infructuous. Learned Senior Counsel submits that this is not a ground contemplated under Order VII Rule 11 of the CPC. That, subsequent events cannot make a suit infructuous and in any event, the argument of the Defendants that the suit has become infructuous since the Plaintiff has already launched its product must be rejected. That, the apprehension that the Defendants will take steps to prevent marketing still subsists. Dr.Tulzapurkar submits that it is settled position in law that a plaint cannot be rejected based on subsequent events and relies upon the decision in the case of ***Mehtabi v. Ghulam Mohammad Sheikh & Ors.***[9].

9 2020 SCC Online J&K 695

40. Learned Senior Counsel reiterates that it is settled law that for the purpose of an Order VII Rule 11 application, a Court is only required to determine whether the plaint discloses a cause of action from the allegations made out in the plaint. The strength of the pleaded cause of action and the defence raised by the Defendants in the Suit are irrelevant to the enquiry under Order VII Rule 11 of CPC. It is submitted that it is clear from a reading of the plaint that the same discloses a cause of action for restraining the Defendants from interfering in the marketing of the Plaintiff's biosimilar and for seeking a declaration that the Plaintiff's drug has been approved as per law. Therefore, in as much as the allegations in the plaint disclose a cause of action, the plaint cannot be rejected.

41. Learned Senior Counsel has submitted on behalf of the Plaintiff / Respondent that, therefore, no case has been made out for any relief under Order VII Rule 11 of the CPC and that the Notice of Motion be dismissed.

42. In rejoinder, Dr.Saraf has submitted that by relying on certain judgments, the Plaintiff contends that the plaint ought to be read as it stands without any addition and or deletion and that the Defendants

are in effect seeking to add words to the plaint. That, far from it, what the Defendants seek is the reading of the plaint as a whole and a meaningful and purposeful reading of the plaint. On doing so, it is apparent that the entire cause of action pleaded in the plaint are apprehended legal proceedings and the Suit is nothing but an attempt to prevent the Defendants to avail their legal remedies by initiating legal proceedings.

43. Dr.Saraf submits that the position paper at Exhibit 'G' to the plaint is being selectively and inaccurately interpreted by the Plaintiff and being used in these proceedings out of context. That, on the contrary, the following relevant text of the said Position Paper contradicts the Plaintiff's submissions that Roche's conduct is purportedly anticompetitive and merely reflects Roche's intention to take all lawful measures available to protect their rights and reputation, including the initiation of legal proceedings :

> *"Roche supports the development of regulatory frameworks for the introduction of biosimilars and continue being actively engaged in stakeholder dialogue. Such frameworks help to ensure that there is a high and consistent level of public health protection that applies to biosimilars, on the same basis as it applies to innovator/originator products. In addition, it is out strong belief that regulations relating to biosimilar shoud not impede, but rather promote and give*

> *incentive for, innovative reasearch towards the development of new medicines.*
> *The approval of biosimilar via a specific regulatory pathway can only be justified when based on the principle of similarity i.e. comparision with a defined reference product for which extensive experience is available.....*
> *If a biotherapeutic product intended to be a copy of a reference product is approved but does not meet WHO criteria for biosimilars, i.e. has not been demonstrated to be similar with regard to quality or non-clinical and clinical properties, it should not be called a biosimilar. Rather it should be called a non-comparable biologic (NCB)....*
> *..... Manufacturers who bring a biotherapeutic product to the market and claim their product is a "biosimilar" without meeting the WHO criteria for biosimilars are not acting in a transparent and responsible manner.* ***We will continue to take all necessary steps to avoid related misunderstandings and will oppose the use of misleading claims*** *that are unsubtantiated due to lack of reasonable data."*
>
> *(emphasis supplied)*

44. It is further submitted in rejoinder that the Plaintiff argues that the ground that the Suit has become infructuous *"is not a ground contemplated under Order VII Rule 11 of the CPC"*. That, as submitted above, prayer clauses (a) and (c) in the plaint are no longer capable of being granted since the drug has already been launched and marketed. That, prayer clause (b) cannot be granted because it seeks to restrain Roche from initiating legal action, which is barred by law. In any event, the Hon'ble Supreme Court and the Delhi High Court have already

upheld the maintainability of the Roche's challenge to the approvals granted to the Plaintiff and other similarly placed manufacturers of biosimilars of Roche's Trastuzumab. If none of the remedies sought in the plaint can be granted, and the Suit itself is based only on an apprehension that no longer exists because the Plaintiff has already launched its drug without any interference from Roche, then the case does not reveal a valid cause of action.

45. It is further reiterated by Dr.Saraf that the plaint clearly shows *bona fide* apprehension of the Defendants' interference with the launch and marketing of the similar drug. Admittedly, the Suit rests entirely on a mere apprehension that the Defendants No.1 to 3 might interfere with the drug's launch and marketing. That, a Suit cannot be sustained on such speculative grounds, especially when the Plaintiff's drug was not only launched in 2015, but is also being marketed and sold since 2015 without any interference. Moreover, Roche's suit against the Plaintiff in the Delhi High Court has been held to be maintainable, and the Plaintiff's submissions as to future interference, through legal proceedings, are vague, without any legal or factual basis and unsubstantiated.

46. Further, Dr.Saraf submits that contrary to the Plaintiff's assertion, Roche has not asserted patent rights in their claims against the Plaintiff and other manufacturers of biosimilars of Trastuzumab. That, Roche did not have a patent over the biologic Trastuzumab *per se* in India which argument has been rejected by the Delhi High Court in its order of 11th September 2023 in the Cadila Delhi Suit. That, in other suits, pending before the Delhi High Court, challenging approvals granted to manufacturers of biosimilars of Trastuzumab, similar arguments have been rejected by the Delhi High Court and by the Hon'ble Supreme Court in the following terms:

(a) In the Cadila Delhi Suit, a single judge of the Delhi High Court, while rejecting Cadila's application under Order VII Rule 11 of the CPC observed *"it is the pleaded case of the Plaintiffs that they are not asserting rights under the patent, which has expired in 2013."* The Delhi High Court further observed that *"contrary to Cadila's assertions in the application, Plaintiffs have not asserted any rights premised on the patent, which has expired in 2013..... Since Plaintiffs claim does not emanate from its patent, the question of ever-greening of patent or stifling competition does not arise..."*. A Division Bench of the Delhi High Court subsequently dismissed Cadila's appeal against this order on

30th November 2023. Cadila has not further challenged the Single Judge's order and this order has attained finality.

(b) In Roche's Suit against Reliance Life Sciences (Civil Suit (Commercial.) No. 234 of 2022), formerly Civil Suit (OS) No. 3284 of 2015) in connection with the same drug - Trastuzumab, the Delhi High Court noted that patent linkage is not relevant to the issues involved in the Suit since Roche's patent has lapsed. This order was upheld by the Supreme Court in *Genentech Inc. & others v DCGI & others* (2020) 13 SCC 371), wherein the Supreme Court observed that Roche's suit against Reliance Life Sciences *"is not a trademark action, nor is it an attempt to enforce the appellants' patent, which admittedly expired in 2013."*

47. Dr.Saraf submits that the order dated 11th September 2023 in the Cadila Delhi Suit, along with similar orders in related proceedings including the reliance on the judgment of the Delhi High Court in the application under Order VII Rule 11 of the CPC filed by the Plaintiff in the Cadila Delhi Suit is relevant for adjudicating the present application to demonstrate that arguments the Plaintiff is making in support of its Suit in this Court have been rejected by other Courts.

48. Finally, Dr.Saraf submits that it is well established that, for the purpose of deciding an application under Order VII Rule 11 of the CPC, this Court must examine the averments in the plaint. However, this does not mean that the Court should allow an infructuous proceeding to continue. That, subsequent events are relevant, as much as they go to the root of the matter and demonstrate that the very foundation of the Suit does not survive.

49. Dr.Saraf, accordingly, submits that the Notice of Motion be allowed as prayed for.

50. The facts in the matter are not in dispute. As noted above, when the matter was called out on 20th January 2025, the learned Senior Counsel appearing for the Plaintiff / Respondent had submitted that if the Defendants do not interfere in the marketing of the Plaintiff's product, then he can take instructions from the Plaintiff whether the Suit can be withdrawn as the Defendants no.1 to 3 have already filed a Suit in the Delhi High Court questioning the approvals and licenses granted to the Plaintiff.

51. On the said date, Dr.Saraf appearing for the Applicants had submitted that since the product had already been launched, prayer clause (a) would not survive and as regards prayer clauses (b) and (c), since the Applicants had already filed a Suit in the Delhi High Court, nothing would really survive in the Suit filed in this Court. Accordingly, for the learned Senior Counsel for the Plaintiff / Respondent to take instructions, the matter was adjourned and directed to be listed on 30th January 2025 under the caption 'for directions'. However, when the matter was called out on 30th January 2025, surprisingly, the learned Senior Counsel appearing for the Plaintiff / Respondent submitted that he had instructions to go ahead with the matter and also that an application under Section 10 of the CPC had been filed before the Delhi High Court seeking a stay to the Suit filed by the Applicants in the Delhi High Court. Dr.Saraf had taken strong objection to this conduct of the Plaintiff / Respondent, as, it is after the statement made and time taken on 20th January 2025 on behalf of the Plaintiff / Respondent to take instructions in terms of paragraph 1 of the said order, that an application under Section 10 of the CPC had been filed in the Delhi High Court. Dr.Saraf for the Applicants had, however, requested that if the Plaintiff / Respondent was desirous of proceeding with the Suit filed in this Court, then this Notice of Motion under Order VII Rule 11

of the CPC be heard first. That is how, this Notice of Motion has been heard.

52. It is settled law that an application under Order VII Rule 11 of the CPC has to be decided on the basis of pleadings. As can be seen from paragraphs 44 and 45 of the plaint, the Plaintiff's entire cause of action and the apprehension as set out in paragraphs 45 to 51 on the basis of which the Suit was filed was that it is clearly on the basis of an apprehension that the Defendant no.1 had filed legal proceedings against other Indian companies who have launched/proposed to launch biosimilars of Trastuzumab which according to the Plaintiff was an obstructive action taken by the Defendant no.1. Further, from paragraph 46 of the plaint it can be seen that the Plaintiff apprehended that Roche is likely to initiate "similar actions" against the Plaintiff in an attempt to thwart the launch and marketing of the Plaintiff's product.

53. The Plaintiff has pleaded the following further cause of action in paragraph 48 of the plaint:

(a) any action by Roche to interfere/restrain the Plaintiff from launching its product would be misconceived and unsustainable.

(b) Roche has no *locus standi* or cause of action to file a suit against the Plaintiff in the manner it has chosen to do against other Indian companies.

(c) Roche has no right to sue or restrain the Plaintiff's launch and marketing of the Plaintiff's product.

(d) Assuming that Roche was aggrieved by the decision of the regulatory authorities granting permission, their remedy is by way of an appeal under Rule 122 DC of the Drugs and Cosmetics Rules, 1945 ("Drugs Rules").

(e) Despite the available remedy, Roche has adopted aggressive legal action in order to prevent products, competing with its own products, from reaching the Indian market.

54. In paragraph 49, the Plaintiff has pleaded as to how a legal proceeding that may be filed by the Defendants no.1 to 3 would not be maintainable.

55. In paragraph 50 it has been stated that the facts and contentions set forth earlier in the plaint constitute cause of action in the present Suit although the said paragraph primarily contains averments relating to territorial jurisdiction.

56. In paragraph 51 it is stated that the cause of action arose when the Plaintiff came to know of the Suits filed by the Defendant no.1 against other manufacturers and paragraph 51 primarily relates to limitation. The stand taken by the Defendants in an internationally published position paper that the Defendants intend to take all necessary steps to avoid related misunderstandings and will oppose the use of misleading claims that are unsubstantiated due to lack of reasonable data, has also been referred to.

57. In my view, from a reading of the plaint as a whole it is clear that the entire cause of action pleaded in the plaint is that Roche has initiated legal proceedings against other Indian manufacturers, and that the Plaintiff apprehended that Roche will initiate similar proceedings against the Plaintiff. That, the entire essence of the plaint was a grievance and apprehension that Roche was not entitled to initiate legal proceedings, and the prayers in the Suit have to be considered in the said context.

58. As can be seen, the plaint clearly sets out that the cause of action is an apprehension that Roche will initiate legal proceedings against the Plaintiff and the prayers in the plaint have to be read in that light. The

endeavour of the Plaintiff was to prevent a legal action by Roche, which has now been instituted. The entire cause of action in the plaint is nothing but the Plaintiff seeking to prevent Roche from initiating legal action. Accordingly, the Suit is clearly barred by Section 41(b) of the Specific Relief Act, 1963, ("SRA"), as amended, which bars a court from restraining any person from initiating or prosecuting proceedings in the following terms:

> *"41. Injunction when refused—*
> *An injunction cannot be granted—*
> *(a)…. …. …*
> *(b) to restrain any person from instituting or prosecuting any proceeding in a court not subordinate to that from which the injunction is sought:"*

59. The Plaint in the Suit has to be read as a whole and the prayers have to be read in conjunction with the averments made in the plaint. The only apprehension expressed is that Roche has initiated legal proceedings against the other entities and was likely to initiate similar legal proceedings against the Plaintiff.

60. In *Frost International Limited v. Milan Developers and Builders Private Limited and Another (supra) (paragraph 34 onwards and paragraph 50)* the Hon'ble Supreme Court has observed that the plaint

should be given a meaningful reading when read as a whole, and if it is found that the reliefs sought by the plaintiff in effect seek restraint of a legal remedy, the application under Order VII Rule 11 ought to be allowed. The Hon'ble Supreme Court has also noted that where a plaintiff that seeks injunction of legal proceedings under the garb of declaratory relief, as is the case in the present Suit, then such a suit is barred under Section 41(b) of the SRA.

61. In *Cotton Corporation of India v. United Industrial Bank Limited (supra) (paragraph 8),* the Hon'ble Supreme Court held that the underlying intendment of Section 41(b) of the SRA ought to be considered before awarding any injunction. The Court held that the litigant must always be unhindered and must have uninterrupted access to courts. That, through clever drafting, the Plaintiff sought to camouflage its only cause of action - to seek a restraint on initiation of legal proceedings and Plaintiff's suit was a clear example of clever drafting meant to create the illusion of a cause of action. It is well settled that when a plaint merely gives the impression of a cause without substance, this Court must reject it to prevent frivolous litigation. The Plaintiff cannot cloak the plaint in such a manner as to create a fictitious cause of action.

62. In my view therefore prayer clause (b) of the Plaint is barred by law.

63. As far as prayer clauses (a) and (c) to the Suit are concerned, in my view, the said prayers have become infructuous. Prayer clauses (a) and (c) relate to the Plaintiff's right to launch and market the drug and an apprehension that Roche will initiate legal proceedings against the Plaintiff. The grant of these prayers has now become infructuous for two reasons:

(i) The Plaintiff admittedly launched its drug "Vivitra" on 25 December 2015, and this drug has been marketed and sold by the Plaintiff for more than 9 years, without any interference from Roche. There is, accordingly, no basis now for the Plaintiff to seek an injunction against Roche from interfering with the launch/marketing of Vivitra.

(ii) Roche has filed the Cadila Delhi Suit challenging the approvals granted by DCGI to the Plaintiff as these approvals have not been granted in accordance with applicable law. The Cadila Delhi Suit is at an advanced stage, with parties having completed their pleadings, and the Plaintiff's application under Order VII Rule 11 of the CPC having been dismissed on 11 September 2023 by the Delhi High Court. A Division Bench of the Delhi High Court subsequently dismissed Cadila's

appeal against this order. The Plaintiff has actively defended the Cadila Delhi Suit since 2016, but has taken no steps to expedite the prosecution of the Suit before this Court in the past nine years.

64. The Plaint does not disclose any actionable right or a cause of action in favour of the Plaintiff at the time of filing the Suit. As submitted above, the Suit is based on a sole cause of action viz. the Plaintiff's apprehension that Roche is likely to initiate legal proceedings against the Plaintiff in relation to the launch and interfere with marketing of the Plaintiff's drug. Although there cannot be any dispute on the principles laid down in the case of *Eldeco Housing & Industries Ltd. vs. Ashok Vidyarthi & Ors. (supra)* and *Liverpool & London SP & I Association Ltd. versus M.V.Sea Success I and Anr (supra)* that whether a plaint disclosed a cause of action or not is essentially a question of fact and the same must be found out from the reading of the plaint itself and for that purpose, the averments in the plaint in their entirety have to be seen without addition or subtraction of words and that so long as the claim discloses some cause of action or raises some question fit to be decided by the Judge, the mere fact that the case is weak and not likely to succeed is not a ground for striking it out. Only, that is the law. However, in the facts of this case, as noted above, the entire cause

of action in the plaint is nothing but the Defendant having initiated proceedings against other entities entities and the apprehension that the Defendant is likely to initiate similar legal proceedings against the Plaintiff. That, in my view, cannot be said to be a cause of action, although it does create an impression or an illusion of the same as is settled law that cause of action is a bundle of facts which the Plaintiff must prove to demonstrate its right to the relief. It is a foundation upon which a claim is built and must be established before a trial can proceed. It consists of two elements : existence of a legal right and violation of the same and existence of a right to file a civil Suit for violation of the said right. In the facts of the case, there is no presenti of violation of a legal right. In ***Coke v. Gill***[10], it was held that cause of action means every fact which would be necessary for the plaintiff to prove if traversed to support his right to the judgment of the court in his favor. None of these ingredients are satisfied. There has been no breach of a duty that the Defendant owes to the Plaintiff and therefore, no legal right in *praesenti* have been breached giving rise to a cause to file this Suit.

10 (1873) LR 8 CP 107

65. The plaint merely gives an impression of cause without substance creating an illusion of cause of action and does not really disclose any cause of action. Although this Court does not deem it necessary to go into the aspect of the litigation being vexatious or not or an abuse of process of law.

66. In *T. Arivandandam v. T.V. Satyapal & Anr. (supra)*, *(paragraph 5),* the Hon'ble Supreme Court held that filing plaints by clever drafting which creates an illusion of cause of action is a depreciable practice which cannot be permitted. It is to be seen on a meaningful reading of the plaint and not only on a formal reading whether the plaint discloses an actual cause of action.

67. In *Sopan Sukhdeo Sable v. Assistant Charity Commissioner & Others (supra),* the Hon'ble Supreme Court held that if on a meaningful and not only a formal reading of the plaint, the plaint appears to be vexatious and meritless in the sense of not disclosing a clear right to sue, then the court should exercise its power under Order VII Rule 11 of the CPC. Further, if by clever drafting, an illusion of cause of action is created in the plaint, then it should be nipped in the bud by rejecting the plaint. The Court held that there cannot be any

compartmentalization, dissection, segregation and inversions of the language of the various paragraphs in the plaint and it is not permissible to cull out a sentence or passage and to read it out of the context in isolation. The plaint has to be read without addition or subtraction of words and the intention of the party has to be gathered from the tenor and terms of its pleadings taken as a whole. The Court held that the real object of the Order VII Rule 11 of the CPC is to keep irresponsible suits out of Courts and the Court should carry out a searching examination as to whether the litigation is an irresponsible litigation, i.e., if the filing of the suit is an abuse of process. Paragraphs 12 to 17 of the said decision in the case of *Sopan Sukhdeo Sable vs. Assistant Charity Commissioner and Others (supra),* are relevant and are usefully quoted as under :

> *"12. The trial court must remember that if on a meaningful and not formal reading of the plaint it is manifestly vexatious and meritless in the sense of not disclosing a clear right to sue, it should exercise the power under Order 7 Rule 11 of the Code taking care to see that the ground mentioned therein is fulfilled. If clever drafting has created the illusion of a cause of action, it has to be nipped in the bud at the first hearing by examining the party searchingly under Order 10 of the Code. (See T. Arivandandam v. T.V. Satyapal (1977 4 SCC467).*
> *13. It is trite law that not any particular plea has to be considered, and the whole plaint has to be read. As was observed by this Court in Roop Lal Sathi v. Nachhattar Singh Gill (1982) 3 SCC 487) only a part of the plaint cannot be*

rejected and if no cause of action is disclosed, the plaint as a whole must be rejected.

14. In Raptakos Brett & Co. Ltd. v. Ganesh Property ((1998) 7 SCC 184 it was observed that the averments in the plaint as a whole have to be seen to find out whether clause (d) of Rule 11 of Order 7 was applicable.

15. There cannot be any compartmentalisation, dissection, segregation and inversions of the language of various paragraphs in the plaint. If such a course is adopted it would run counter to the cardinal canon of interpretation according to which a pleading has to be read as a whole to ascertain its true import. It is not permissible to cull out a sentence or a passage and to read it out of the context in isolation. Although it is the substance and not merely the form that has to be looked into, the pleading has to be construed as it stands without addition or subtraction or words or change of its apparent grammatical sense. The intention of the party concerned is to be gathered primarily from the tenor and terms of his pleadings taken as a whole. At the same time it should be borne in mind that no pedantic approach should be adopted to defeat justice on hair-splitting technicalities.

16. Submission of the learned counsel for Respondent 2 Trust was that requirement of law being reading the plaint in its totality, the appellants cannot take the plea that they would give up or relinquish some of the reliefs sought for. That would not be permissible. The plea clearly overlooks the basic distinction between statements of the facts disclosing cause of action and the reliefs sought for. The reliefs claimed do not constitute the cause of action. On the contrary, they constitute the entitlement, if any, on the basis of pleaded facts. As indicated above, Order 6 Rule 2 requires that pleadings shall contain and contain only, a statement in a concise form of the material facts on which the party pleading relies for his claim. If the plea of Mr Savant, learned counsel for the respondent Trust is accepted, the distinction between

the statement of material facts and the reliance on them for the claim shall be obliterated. What is required in law is not the piecemeal reading of the plaint but in its entirety. Whether the reliefs would be granted on the pleaded facts and the evidence adduced is totally different from the relief claimed. All the reliefs claimed may not be allowed to a party on the pleadings and the evidence adduced. Whether part of the relief cannot be granted by the civil court is a different matter from saying that because of a combined claim of reliefs, the jurisdiction is ousted or no cause of action is disclosed. Considering the reliefs claimed vis-a-vis the pleadings would not mean compartmentalisation or segregation, in that sense. The plea raised by the respondent Trust is therefore clearly unacceptable.

17. Keeping in view the aforesaid principles, the reliefs sought for in the suit as quoted supra have to be considered. The real object of Order 7 Rule 11 of the Code is to keep out of courts irresponsible law suits. Therefore Order 10 of the Code is a tool in the hands of the courts by resorting to which and by a searching examination of the party, in case the court is prima facie of the view that the suit is an abuse of the process of the court, in the sense that it is a bogus and irresponsible litigation, the jurisdiction under Order 7 Rule 11 of the Code can be exercised."

68. In *Dahiben v. Arvindbhai Kalyanji Bhanushali (Gajra) (supra),* the Hon'ble Supreme Court crystallized the parameters of consideration under Order VII Rule 11 of CPC and held that if the assertions made in the plaint are contrary to the law or judicial dicta, the court can exercise power under Order VII Rule 11 of CPC. The Court once again emphasized that it is not permissible to cull out a sentence or a passage

and it is to read in isolation, but the plaint should be read as a whole and, if on a meaningful reading of the plaint, it is found the suit is manifestly vexatious and without any merit and does not disclose a cause of action, the plaint should be rejected. The Hon'ble Supreme Court highlighted that the Courts must be vigilant against any camouflage or suppression and to determine whether the litigation is utterly vexatious and an abuse of the process. Paragraphs 23 and 24 of the said decision are usefully quoted as under :

> *"23. We have heard the learned counsel for the parties, perused the plaint and documents filed therewith, as also the written submissions filed on behalf of the parties.*
> *23.1. We will first briefly touch upon the law applicable for deciding an application under Order 7 Rule 11 CPC, which reads as under:*
> > *"11. Rejection of plaint.-The plaint shall be rejected in the following cases-*
> > *(a) where it does not disclose a cause of action;*
> > *(b) where the relief claimed is undervalued, and the plaintiff, on being required by the court to correct the valuation within a time to be fixed by the court, fails to do so;*
> > *(c) where the relief claimed is properly valued but the plaint is written upon paper insufficiently stamped, and the plaintiff, on being required by the court to supply the requisite stamp paper within a time to be fixed by the court, fails to do so;*
> > *(d) where the suit appears from the statement in the plaint to be barred by any law;*
> > *(e) where it is not filed in duplicate;*
> > *(f) where the plaintiff fails to comply with the provisions*

of Rule 9:

Provided that the time fixed by the court for the correction of the valuation or supplying of the requisite stamp-papers shall not be extended unless the court, for reasons to be recorded, is satisfied that the plaintiff was prevented by any cause of an exceptional nature from correcting the valuation or supplying the requisite stamp-papers, as the case may be, within the time fixed by the court and that refusal to extend such time would cause grave injustice to the plaintiff."

(emphasis supplied)

23.2. The remedy under Order 7 Rule 11 is an independent and special remedy, wherein the court is empowered to summarily dismiss a suit at the threshold, without proceeding to record evidence, and conducting a trial, on the basis of the evidence adduced, if it is satisfied that the action should be terminated on any of the grounds contained in this provision.

23.3 The underlying object of Order 7 Rule 11(a) is that if in a suit, no cause of action is disclosed, or the suit is barred by limitation under Rule 11(d), the court would not permit the plaintiff to unnecessarily protract the proceedings in the suit. In such a case, it would be necessary to put an end to the sham litigation, so that further judicial time is not wasted.

23.4. In Azhar Hussain v. Rajiv Gandhi (1986 SUPP SCC 315) this Court held that the whole purpose of conferment of powers under this provision is to ensure that a litigation which is meaningless, and bound to prove abortive, should not be permitted to waste judicial time of the court, in the following words: (SCC p. 324, para 12)

"12. ... The whole purpose of conferment of such powers is to ensure that a litigation which is meaningless, and bound to prove abortive should not be permitted to occupy the time of the court, and exercise the mind of the respondent. The sword of Damocles need not be kept hanging over his head unnecessarily without point or purpose. Even in an

ordinary civil litigation, the court readily exercises the power to reject a plaint, if it does not disclose any cause of action."

23.5. The power conferred on the court to terminate a civil action is, however, a drastic one, and the conditions enumerated in Order 7 Rule 11 are required to be strictly adhered to.

23.6 Under Order 7 Rule 11, a duty is cast on the court to determine whether the plaint discloses a cause of action by scrutinising the averments in the plaint, read in conjunction with the documents relied upon, or whether the suit is barred by any law.

23.7. Order 7 Rule 14(1) provides for production of documents, on which the Plaintiff places reliance in his Suit, which reads as under:

"14. Production of document on which plaintiff sues or relies.—(1) Where a plaintiff sues upon a document or relies upon document in his possession or power in support of his claim, he shall enter such documents in a list, and shall produce it in court when the plaint is presented by him and shall, at the same time deliver the document and a copy thereof, to be filed with the plaint.

(2) Where any such document is not in the possession or power of the plaintiff, he shall, wherever possible, state in whose possession or power it is.

(3) A document which ought to be produced in court by the plaintiff when the plaint is presented, or to be entered in the list to be added or annexed to the plaint but is not produced or entered accordingly, shall not, without the leave of the court, be received in evidence on his behalf at the hearing of the suit.

(4) Nothing in this Rule shall apply to document produced for the cross-examination of the plaintiff's witnesses, or, handed over to a witness merely to refresh his memory."

(emphasis supplied)

23.8. Having regard to Order 7 Rule 14 CPC, the documents filed along with the plaint, are required to be taken into consideration for deciding the application under Order 7 Rule 11(a). When a document referred to in the plaint, forms the basis of the plaint, it should be treated as a part of the plaint.

23.9. In exercise of power under this provision, the court would determine if the assertions made in the plaint are contrary to statutory law, or judicial dicta, for deciding whether a case for rejecting the plaint at the threshold is made out.

23.10. At this stage, the pleas taken by the defendant in the written statement and application for rejection of the plaint on the merits, would be irrelevant, and cannot be adverted to, or taken into consideration.

23.11. The test for exercising the power under Order 7 Rule 11 is that if the averments made in the plaint are taken in entirety, in conjunction with the documents relied upon, would the same result in a decree being passed. This test was laid down in Liverpool & London S.P. & I Assn. Lid. v. M.V. Sea Success I (2004) 9 SCC 512 which reads as: (SCC p. 562, para 139)

> *"139. Whether a plaint discloses a cause of action or not is essentially a question of fact. But whether it does or does not must be found out from reading the plaint itself. For the said purpose, the averments made in the plaint in their entirety must be held to be correct. The test is as to whether if the averments made in the plaint are taken to be correct in their entirety, a decree would be passed."*

23.12. In Hardesh Ores (P) Ltd. v. Hede & Co. [(2007) 5 SCC 614] the Court further held that it is not permissible to cull out a sentence or a passage, and to read it in isolation. It is the substance, and not merely the form, which has to be looked into. The plaint has to be construed as it stands, without addition or subtraction of words. If the allegations in the plaint prima face show a cause of action, the Court cannot

embark upon an enquiry whether the allegations are true in fact. D. Ramachandran v. R.V. Janakiraman (1999) 3 SCC 267.

23.13. If on a meaningful reading of the plaint, it is found that the suit is manifestly vexatious and without any merit, and does not disclose a right to sue, the court would be justified in exercising the power under Order 7 Rule 11 CPC.

23.14. The power under Order 7 Rule 11 CPC may be exercised by the court at any stage of the suit, either before registering the plaint, or after issuing summons to the defendant, or before conclusion of the trial, as held by this Court in the judgment of Saleem Bhai v. State of Maharashtra (2003) 1 SCC 557. The plea that once issues are framed, the matter must necessarily go to trial was repelled by this Court in Azhar Hussain case.

23.15. The provision of Order 7 Rule 11 is mandatory in nature. It states that the plaint "shall" be rejected if any of the grounds specified in clauses (a) to (e) are made out. If the court finds that the plaint does not disclose a cause of action, or that the suit is barred by any law, the court has no option, but to reject the plaint.

24. "Cause of action" means every fact which would be necessary for the plaintiff to prove, if traversed, in order to support his right to judgment. It consists of a bundle of material facts, which are necessary for the plaintiff to prove in order to entitle him to the reliefs claimed in the suit.

24.1. In Swamy Atmananda v. Sri Ramakrishna Tapovanam (2005) 10 SCC 51, this Court held: (SCC p. 60, para 24)

> *"24. A cause of action, thus, means every fact, which, if traversed, it would be necessary for the plaintiff to prove in order to support his right to a judgment of the court. In other words, it is a bundle of facts, which taken with the law applicable to them gives the plaintiff a right to relief against the defendant. It must include some act done by the defendant since in the absence of such an act, no cause*

of action can possibly accrue. It is not limited to the actual infringement of the right sued on but includes all the material facts on which it is founded."

(emphasis supplied)

24.2. In T. Arivandandam v. T.V. Satyapal [(1977) 4 SCC 467] this Court held that while considering an application under Order 7 Rule 11 CPC what is required to be decided is whether the Plaintiff discloses a real cause of action, or something purely illusory, in the following words: (SCC p. 470, para 5)

"5……The learned Munsif must remember that if on a meaningful - not formal - reading of the plaint it is manifestly vexatious, and meritless, in the sense of not disclosing a clear right to sue, he should exercise his power under Order 7 Rule 11 CPC taking care to see that the ground mentioned therein is fulfilled. And, if clever drafting has created the illusion of a cause of action, nip it in the bud at the first hearing…."

(emphasis supplied)

24.3. Subsequently, in ITC Ltd. v. Debts Recovery Appellate Tribunal [(1998) 2 SCC 70] this Court held that law cannot permit clever drafting which creates illusions of a cause of action. What is required is that a clear right must be made out in the plaint.

24.4. If, however, by clever drafting of the plaint, it has created the illusion of a cause of action, this Court in Madanuri Sri Rama Chandra Murthy V. Syed Jalal [(2017) 13 SCC 174] held that it should be nipped in the bud, so that bogus litigation will end at the earliest stage. The Court must be vigilant against any camouflage or suppression, and determine whether the litigation is utterly vexatious, and an abuse of the process of the court."

69. In the facts of this case, the Plaintiff launched its drug in 2015 shortly after filing this Suit and since then has been marketing and selling their drug. Roche, thereafter, filed a suit in the Delhi High Court against the Plaintiff being Civil Suit (Commercial) No. 1119 of 2016 *inter alia* challenging the permission granted by the regulatory authorities to the Plaintiff ("Cadila Delhi Suit") and the Hon'ble Delhi High Court has held the Cadila Delhi Suit to be maintainable.

70. Cadila (Plaintiff herein and Defendant in the Cadila Delhi Suit) filed an application under Order VII Rule 11 of the Code of Civil Procedure, 1908 ("CPC") for rejection of Roche's plaint before the Delhi High Court. That, the said application was rejected by an order of the Delhi High Court dated 11 September 2023, in which the Delhi High Court held the Cadila Delhi Suit to be maintainable, and also rejected the arguments made by Cadila in paragraphs 48 and 49 of the present plaint. Paragraph 7 of the order dated 11 September 2023 in the Cadila Delhi Suit which is relevant is usefully quoted as under :

> *"7. No cause of action arises in favour of the Plaintiffs and they have no locus standi to file the present Suit. Plaintiffs have no statutory or common law rights or any other intellectual property rights in the drug 'Trastuzumab' and in the absence of any valid and subsisting rights the plaint deserves to be rejected. It is an admitted position that the*

> *drug 'Trastuzumab' does not enjoy patent protection since 03.05.2013, when the Plaintiffs' patent lapsed and the drug is in the public domain. Therefore, no Suit can be filed for patent infringement."*

71. In its order of 11th September 2023, the Delhi High Court held that the alternate remedy under Rule 122 DC of the Drugs Rules (i) was not available to Roche, and (ii) was no longer available as Rule 122 DC had been deleted from the statute book in 2019. The Delhi High Court also held that Roche cannot be prevented from enforcing its rights or challenging the permissions granted to Cadila and held the Cadila Delhi Suit to be maintainable. Accordingly, Cadila's application under Order VII Rule 11 of the CPC was dismissed Paragraphs 44, 54, 57, 76, 78, 81, 91, 93, 95 of the Delhi High Court's order dated 11th September, 2023 are also usefully quoted as under :

> *"44. I have heard learned Senior Counsels for the parties and learned Central Government Standing Counsel for DCGI and examined their respective contentions.*
>
> *54. Relevant it is to note that this very objection of failure to resort to the remedy of appeal under Rule 122DC was raised by the Defendant in the Reliance suit, questioning the maintainability and was negated by the Court in the judgment in* ***Genentech INC and Others v. Drugs Controller General of India and Others, 2016 SCC OnLine Del 2572,*** *deciding an application under Order XXXIX Rules 1 and 2 CPC. It is important to highlight that the Court had recorded a concession given by the learned Additional Solicitor General,*

appearing on behalf of the Regulator that Rule 122DC does not protect or enforce the rights of the manufacturer of the innovator drug and the procedure of granting approvals to manufacturers of biosimilar drugs does not involve a lis between the manufacturer of an innovator drug and a biosimilar drug. It was conceded that since DCGI does not determine the rights of innovators at the time of granting approvals to new drug manufacturers, Plaintiffs were entitled to file a civil suit to protect their rights in relation to their drug 'Trastuzumab', in the absence of any other alternative and efficacious remedy being available. This Court is persuaded to concur with the view taken in the said judgment, as an added reason, to hold that remedy of appeal under Rule 122DC was not a path available to the Plaintiffs and there is no other alternative remedy under the Drugs Rules/Act, precluding them from approaching this Court. Suits are thus not barred by law and plaints cannot be rejected on this ground. Relevant paragraphs from the judgment in ***Genentech INC and Others v. Drugs Controller General of India and Others, 2016 SCC OnLine Del 2572,*** *are as follows :-*

> *"109. With regard to the objection raised by the defendants about the exclusivity of civil jurisdiction impliedly bar under Rule 122DC. Rule 122DC does not cover appeals against approvals granted under Part XA - this rule is limited to appeals against orders passed by the DCGI under Part XA of the Rules. The terms "order" and "approval"/"permission" have distinct meanings under Part XA of the Drugs Rules (refer to Rule 122DAB(3), Rule 122DAB(7), 122DAC(3), 122DAC(4), 122DB and Rule 122B(2A)). In the present suit, the plaintiffs have not challenged any "order" passed by defendant No. 1 under Part XA of the Drugs Rules. It does not confer a right on a third party to challenge an approval granted under Rule 122B - Rule 122DC applies to a person who is immediately*

and directly aggrieved by an order of the licensing authority, inter alia, refusing to grant licence to himself or to renew licence, and not to one who is consequently aggrieved, like the plaintiffs in the present case.

110. No doubt as Rule 122DC contains the appeal provision, the benefit of the appeal would be accrued only to a person who is before the regulator in the first instance and who would, therefore, have the knowledge of the order issued by the regulator. The said party is expected to file an appeal within 60 days from the date of the order, as contemplated under Rule 122DC. In the present case, approval for drug of defendant No. 3 was not made available to the plaintiffs. Accordingly, this provision is not applicable to the plaintiffs in the present case. The approvals of biosimilar in favour of defendant No. 3 of innovator drugs are admittedly never notified of approvals granted or given any information available to manufacturers of innovator drugs. As far as bar of Section 37 of the Act is concerned, as argued by the defendants, there is no force as the suit has not been filed against any Government employee who may have involved in the process of approvals.

111. The said Rule does not protect or enforce the right of the innovator drugs. Even Mr. Sanjay Jain, learned ASG appearing on behalf of the defendants No. 1 and 2, has admitted that the procedure of granting approvals to manufacturers for biosimilar drugs does not involve a lis between the manufacturer of the innovator drug and the manufacturer of the biosimilar drug. Defendant No. 1 does not determine the rights of such parties at the time of granting approvals to drug manufacturers. Therefore, the plaintiffs (i.e. the manufactures of the innovator drug in the present case) are entitled to file a civil suit to protect their rights in relation to the plaintiffs' Trastuzumab as efficacious remedy under this Rule is not available. (See

Ganga Ram Hospital v. Municipal Corporation of Delhi (2001 (60) DRJ 549 at paragraph 20).”

57. In view of the wealth of judicial precedents referred to above, there is no substance in the contentions of Cadila and Hetero that this Court lacks the jurisdiction to entertain the present suits and plaints be rejected under Order VII Rule 11(d) being barred in law. It is not the case of the Defendants that in order to claim biosimilarity, a drug is not required to be rigorously tested in accordance with the procedures laid down in the Drugs Act, Drugs Rules and the Biosimilar Guidelines to establish its similarity or near similarity to the innovator reference biologic on every parameter. Plaintiffs have questioned the validity of clinical trials conducted by Cadila and Hetero and grant of approvals by the regulator as being non-compliant with the prescribed mandatory procedure under the applicable laws. Plaintiffs seek declaration that the approvals are non est as well as restraint orders against representation of the impugned drugs as biosimilars till appropriate tests are conducted, raising concerns of safety and efficacy in public interest and dilution of their goodwill due to passing off. Plaintiffs have categorically averred that they do not question the competence or discretion of the Regulatory Authority to grant approvals to biosimilars but lay a siege to the manner in which the approvals have been granted i.e. the decision making process, within the contours of the legal and statutory framework regulating the same. It is not disputed by any of the Defendants that there is no specific bar of Civil Court jurisdiction under the Drugs Act or Rules. It is an admitted position that the regulatory regime does not envisage a procedure for cross-notice or grant of opportunity to the drug innovator at the pre-grant stage of approvals to bring to the attention of the Authority that the mandatory pre-clinical /clinical trials have not been properly conducted and/or any other violation of the procedure. Therefore, if in a given case

approvals are questioned, then as observed by the Court in the Reliance suit, Plaintiffs cannot be prevented from enforcing a right to enjoin the defendants till they accomplish the onerous task of establishing that the approvals for manufacturing, distributions and sales were in consonance with the biosimilar regime in the form of Drugs Act/Rules and Guidelines. In these circumstances, Civil Court's powers can be invoked to interdict the resultant consequences of impugned actions.

76. With regard to Cadila's drug, which is the subject matter of the suit, it is averred that after the suit was filed by Cadila before the Bombay High Court, Plaintiffs researched and became aware that on 30.03.2012, Cadila purportedly received permission from RCGM to conduct pre-clinical toxicity studies in Wistar rats and New Zealand rabbits and the results were approved on 18.09.2012, even though Cadila failed to conduct pre-clinical pharmacology studies in relation to its drug and despite the fact that Plaintiffs conducted pre-clinical trials on pregnant monkeys, with no scientific justification for a deviation in the choice of animal model. There is no record of an application to DCGI for permission to conduct clinical trials and record shows that permission was sought to carry out only Phase III clinical trials, without first conducting Phase I and II trials. On 10.03.2014, DCGI purportedly approved the clinical trial protocol for Phase III only and the protocol was registered on 19.05.2014. Cadila's CTR was finalized and approved after Biosimilar Guidelines became effective on 15.09.2012. Rule 122DA mandates that all three phases of clinical trials are to be carried out for a 'new drug' and para 2(7)(i) of Schedule Y provides that trials should be conducted in a sequential manner i.e. data generated in phase I should form the basis of phase II trial and the latter should form the basis of phase III clinical trial. This mandate is also found in Clause 8 which provides that all three phases of human clinical trials must be carried out for a

biosimilar drug. Several other violations of the applicable provisions of law have been pleaded extensively in the plaint, most of which are similar to the ones in the other suit and are not repeated for the sake of brevity.

78. Plaintiffs allege that Cadila has misrepresented its drug as a biosimilar to 'Trastuzumab', which is illegal and factually and scientifically flawed, in the absence of requisite trials for all three indications. The misrepresentation before the regulatory authorities and the SEC is likely to continue before the public, doctors and patients using 'Trastuzumab' and is in the nature of extended passing off. Cadila is also appropriating the business reputation of the Plaintiffs in relation to 'Trastuzumab' which provides an accepted and well-known treatment for certain forms of cancer worldwide and enjoys a global reputation. It is apparent that the misrepresentation is with a view to encash on the reputation of the Plaintiffs and take unfair advantage of the same. In the absence of sufficient independent data for Cadila's drug and in view of the incorrect claim of comparability between Cadila's drug and 'Trastuzumab', Cadila will use data relating to Plaintiffs' 'Trastuzumab' including data regarding manufacturing process, clinical trials, safety and efficacy in the package insert and other promotional materials in order to publicize its drug and create a market for it, which ought to be restrained.

81. When the averments in the present plaints are considered and tested on the anvil of the above stated principles, the inexorable conclusion is that the plaints do not merit rejection at this stage. Meaningfully and holistically read, the causes of action set out in the plaints, on which Plaintiffs may or may not finally succeed, are:

(a) drugs of Cadila/Hetero have been approved for manufacturing and distribution by the regulatory authority without following the procedures under Drugs Act, Drugs Rules and Biosimilar Guidelines;

(b) Cadila and Hetero claim similarity with Plaintiffs' 'Trastuzumab'/'Bevacizumab', respectively without establishing biosimilarity through appropriate tests and conditions laid down in the applicable laws; (c) in view of inherent differences in the compositions of alleged biosimilar drugs and innovators' biological drugs and inadequate testing, drugs of Cadila/Hetero should not have been approved and thus they should be restrained from promoting and marketing their respective drugs; (d) impugned actions of Cadila/Hetero are classic textbook cases of extended passing off and amount to dilution of the formidable and globally known reputation and goodwill of the Plaintiffs' drugs, at the same time giving unfair and undue advantage to Cadila/Hetero; (e) potential deficiencies in the drugs of Cadila/Hetero will not only dilute and damage Plaintiffs' reputation but will be detrimental to public interest as doctors, patients and other stakeholders in the medical community will be misled into believing that the drugs of Cadila/Hetero, claimed to be biosimilar are associated with Plaintiffs' world known innovator drugs; and (f) in the absence of enough data of adequate testing pertaining to safety, efficacy, quality, composition, use of the INNs is not only legally impermissible but is adding to public confusion.

91. Almost similar defences were taken by Cadila and Hetero in the present suits, respectively. Relevance of mentioning the previous litigation is only to highlight that while Division Bench had stayed the judgment dated 25.04.2016 in the Reliance suit, the Supreme Court set aside the order of the Division Bench and vacated the stay and unequivocally held that the judgment dated 25.04.2016 is made operational. The logical inference is that the Supreme Court did not consider the suit to be devoid of cause of action or wholly vexatious or meritless, else the Supreme Court would not have passed a direction to continue the interlocutory injunction order as

against a stay order passed by the Division Bench. Defendants contend that the Supreme Court was not examining the maintainability of the plaint and the observations cannot be used in the present suits. Be it ingeminated that this Court is not referring to the observations to decide the present applications on merits and the reference is solely for the purpose of bringing forth that the order of the Single Judge was upheld dealing with similar pleas as in the present suits and categorically noting two vital facts that the patent of the Plaintiffs had expired in 2013 and the Plaintiffs were not enforcing their patent rights but enforcing the common law right of extended passing off. The pleas in the present plaint thus cannot be brushed aside by a simplistic argument of the Defendants that no cause of action is made out. Relevant paragraphs from the order of the Supreme Court for the limited purpose of showing that the order of learned Single Judge was made operational are as follows :-

> *"13. The Division Bench of the High Court thereafter considered FAO(OS) No. 181 of 2016 and CM Appln. No. 22510 of 2016 filed by Respondent 3 against the interim order passed by the learned Single Judge on 25-4-2016 [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] whereunder, Respondent 3 was permitted to launch and market their product "TrastuRel" without projecting the same as biosimilar to the appellants' drugs Herceptin, Herclon and Biceltis. Under the impugned order dated 18-9-2019 [Reliance Life Sciences (P) Ltd. v. Genentech Inc., 2019 SCC OnLine Del 10151] , the Division Bench allowed the application of Respondent 3 and granted interim stay of the learned Single Judge orders dated 25-4-2016 [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] , [Roche Products (India) (P) Ltd. v. Drugs Controller General of India, 2016 SCC OnLine Del 2358] in terms of the orders dated 28-4-2016 and as clarified vide order*

dated 3-3-2017 [Biocon Ltd. v. Roche Products (India) (P) Ltd., 2017 SCC OnLine Del 12793] , in FAOs (OS) Nos. 132 and 133 of 2016, filed by Biocon and Mylan. The Court justified the interim order by observing that the regulatory authorities have granted their approval to the biosimilar drug of Respondent 3 and prima facie the said approval cannot be considered to be illegal. But it was not possible to determine at that stage, whether Respondent 3 has conducted the requisite trials as are prescribed for a biosimilar drug. The Division Bench held that in the face of the expiry of the patent in favour of the plaintiff, their locus standi to file the suit was considered to be relevant issue to be determined and the possibility of the suit being filed with the objective of stifling competition was taken into account and accordingly relief was granted to Respondent 3 in marketing their product "TrastuRel" on the same terms, as was granted to Biocon and Mylan.

xxx xxx xxx

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

xxx xxx xxx

17. Before we consider the rival contentions, at the outset it is noted that the Reliance suit is now pending for final disposal in the High Court. In the detailed interim order recorded on 25-4-2016 [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] , the submissions of the learned ASG to the effect that the clinical trials of Phase I and Phase II for the drug manufactured by Respondent 3, are not registered with DCGI but approvals were accorded on the basis of the justification given by Respondent 3 was noted by the

Court. Whether the injunction suit filed by the appellants is an abuse of the process of law and whether the approval was granted to the similar drug manufactured by Respondent 3, without following 2012 Guidelines was also borne in mind. The possibility of the attempt by the defendants to pass off their drug as biosimilar product "Trastuzumab", marketed by the appellants was thought out. After careful consideration of all those aspects including the projection from DCGI, the learned Single Judge felt that the process of obtaining approval was flawed due to non-adherence to the statutory provisions of the Act and the Rules as also of the 2012 Guidelines. Then reflection was made on the protective conditions which can be imposed for allowing Respondent 3 to launch their product. Upon due assessment, the interim order dated 25-4-2016 [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] was then passed.

xxx xxx xxx

24. As regards the contention made by Mr Poovayya that the condition imposed by the learned Single Judge on the packaging/labelling is contrary to the statutory prescriptions, it must be borne in mind that the arrangement ordered [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] by the learned Single Judge has been in operation since 25-4-2016. Therefore without a final decision on the suit on the basis of relevant evidence, the continuing arrangement in our opinion should not have been disturbed, on this count.

xxx xxx xxx

25. The appellants' suit before the Delhi High Court is not a trade mark action nor is it an attempt to enforce the appellants' patent, which admittedly expired in 2013. The suit is an action for extended passing off and to prevent the respondent from using the appellants' data and improper reference to its drug "Trastuzumab". Therefore,

the expiry of the appellants' patent right on the drug "Trastuzumab" may not have any direct bearing on the contention raised in the Reliance suit.

xxx xxx xxx

29. In view of the aforesaid, the impugned order is set aside and appeal is allowed. The interim direction given by the learned Single Judge on 25-4-2016 [Genentech Inc. v. Drugs Controller General of India, 2016 SCC OnLine Del 2572] is accordingly made operational. At the same time, as the Reliance's suit is pending since 2016, the High Court is requested to dispose of CS(OS) No. 3284 of 2015 expeditiously and preferably within 12 months of receipt of this order. In the meantime, to avoid prejudice to Respondent 3, whenever government procurement is proposed for the drug by its generic name "Trastuzumab", Reliance should be allowed to participate with their biosimilar product, without any impediment. It is made clear that the views expressed here are only for the purpose of this appeal and should have no bearing in the proceeding pending in the High Court."

93. Cadila and Hetero have urged that: (a) Plaintiffs have no statutory rights to claim injunction, their patent having expired in 2013; (b) data relating to 'Trastuzumab'/ 'Bevacizumab' is available in the public domain and in the absence of right in the patent, no monopoly can be claimed and moreover, Indian law does not recognize data exclusivity protection; (c) Plaintiffs in CS(COMM) 1119/2016 have been marketing 'Trastuzumab' in India under the brand names 'HERCEPTIN', 'HERCLON' and 'BICELTIS', whereas Cadila markets its biosimilar 'Trastuzumab' under the trademark 'VIVITRA' while in CS(COMM) 540/2016, Plaintiffs sell their drug 'Bevacizumab' under the trade name 'AVASTIN' which is not the trademark or tradename used by Hetero; (d) 'Trastuzumab' or 'Bevacizumab' are INNs i.e. International Non-Proprietary Names and therefore, no proprietary rights

can be claimed by the Plaintiffs by virtue of Section 13 of the 1999 Act and permitting an ex-patentee to claim any form of ownership in an INN on account of goodwill/reputation earned during currency of the patent, will entirely destroy the patent regime and will permit patentees to evergreen their patent by filing 'passing off suits' against manufacturers of generics/biosimilars; (e) concept of extended passing off only applies in an action brought by a class of traders sharing collective goodwill in a trademark and is inapplicable in the present suits; (f) no copyright can be claimed in a package insert of a drug; (g) in the absence of subsisting intellectual property rights, Plaintiffs are barred from filing suits under Section 2(1)(c) of the Commercial Courts Act, 2015; and (h) in the absence of any legal right or legally protected interests in 'Trastuzumab' or 'Bevacizumab', no cause of action can arise on the principle of damnum sine injuria. Reading of these objections fortifies the stand of the Plaintiffs that these are in the nature of defences raised by Cadila and Hetero and cannot lead to a conclusion that the plaints are devoid of cause of action. Applying the first principles of Order VII Rule 11 CPC, it is impermissible for the Court to travel outside the contours of the plaints and rely on the defences in the written statement. In ***Mayar (H.K.) Ltd. and Others (supra),*** *the Supreme Court held as follows :-*

> *"12. From the aforesaid, it is apparent that the plaint cannot be rejected on the basis of the allegations made by the defendant in his written statement or in an application for rejection of the plaint. The court has to read the entire plaint as a whole to find out whether it discloses a cause of action and if it does, then the plaint cannot be rejected by the court exercising the powers under Order 7 Rule 11 of the Code. Essentially, whether the plaint discloses a cause of action, is a question of fact which has to be gathered on the basis of the averments made in the plaint in its entirety taking those averments to be correct. A cause of action is a*

bundle of facts which are required to be proved for obtaining relief and for the said purpose, the material facts are required to be stated but not the evidence except in certain cases where the pleadings relied on are in regard to misrepresentation, fraud, wilful default, undue influence or of the same nature. So long as the plaint discloses some cause of action which requires determination by the court, the mere fact that in the opinion of the Judge the plaintiff may not succeed cannot be a ground for rejection of the plaint. In the present case, the averments made in the plaint, as has been noticed by us, do disclose the cause of action and, therefore, the High Court has rightly said that the powers under Order 7 Rule 11 of the Code cannot be exercised for rejection of the suit filed by the plaintiff-appellants."

95. The contention of Cadila that the plaint in CS(COMM) 1119/2016 ought to be rejected as Cadila has instituted a suit before the Bombay High Court, prior to the present suit, seeking declaration as also injunction restraining the Defendants therein (Plaintiffs in the present suit) from in any manner interfering with Cadila's regulatory processes / approvals/licences in respect of its biosimilar 'Trastuzumab', is without merit. Reading of Sections 10 and 11 CPC unequivocally suggests that the legislative intent behind enacting the said provisions is to avoid conflict of decisions on same issues by different Courts as also prevent multiplicity of proceedings. However, this to my mind, cannot be a ground for rejection of a plaint under Order VII Rule 11 CPC. Even assuming that Cadila is right that the two suits are predicated on an identical or similar cause of action, at the highest the present suit would be liable to be stayed till the disposal of the earlier suit and once the former suit is decided, the result may preclude this Court from adjudicating the present suit.

72. I also agree with Dr.Saraf, learned Senior Counsel appearing for the Applicants, that the Plaintiff is seeking to add words to the plaint. That, by relying on certain judgments, the Plaintiff contends that the plaint ought to be read as it stands without any addition and or deletion and that the Defendants are in effect seeking to add words to the plaint. That, far from it, what the Defendants seek is the reading of the plaint as a whole and a meaningful and purposeful reading of the plaint. On doing so, it is apparent that the entire cause of action pleaded in the plaint are apprehended legal proceedings and the Suit is nothing but an attempt to prevent the Defendants to avail their legal remedies by initiating legal proceedings.

73. Dr.Saraf is also right when he submits that the position paper at Exhibit G to the plaint is being selectively and inaccurately interpreted by the Plaintiff and is being used in these proceedings out of context. Even the submissions on behalf of the Plaintiff that the Suit has become infructuous is not a good ground under Order VII Rule 11 of the CPC is not tenable in as much as prayer clauses (a) and (c) in the plaint are no longer capable of being granted since the drug has already been launched and marketed. Prayer clause (b) cannot be granted because it seeks to restrain Roche from initiating legal action, which is barred by

law. In any event, the Hon'ble Supreme Court and the Delhi High Court have already upheld the maintainability of the Roche's challenge to the approvals granted to the Plaintiff and other similarly placed manufacturers of biosimilars of Roche's Trastuzumab. If none of the remedies sought in the plaint can be granted, and the Suit itself is based only on an apprehension that no longer exists because the Plaintiff has already launched its drug without any interference from Roche, then the case does not reveal a valid cause of action.

74. In my view, a Suit cannot be filed on the basis of an apprehension that legal proceedings would be initiated in future. In any event, the plaint does not indicate any cause of action that there will be Defendants' interference with the launch and marketing of the similar drug. Admittedly, the Suit rests entirely on a mere apprehension that the Defendants No.1 to 3 might interfere with the drug's launch and marketing. A Suit cannot be sustained on such speculative grounds, especially when the Plaintiff's drug was not only launched in 2015, but is also being marketed and sold since 2015 without any interference. Moreover, Roche's suit against the Plaintiff in the Delhi High Court has been held to be maintainable, and the Plaintiff's submissions as to

future interference, through legal proceedings, are vague, without any legal or factual basis and unsubstantiated.

75. Also no patent rights appear to have been asserted by the Defendants in their claims against the Plaintiff and other manufacturers of biosimilars of Trastuzumab as statedly Roche does not have a patent over the biologic Trastuzumab *per se* in India.

76. I also do not see any error in the Applicants' reliance upon the decision dated 11th September 2023 of the Delhi High Court holding the Cadila Delhi Suit to be maintainable or reliance upon subsequent events by the Defendants, as the said information only completes the picture. Moreover, this Court has given its findings on the basis of examination of the averments in the plaint. Therefore, the reliance by the Plaintiff on the decision in the case of *Mehtabi v. Ghulam Mohammad Sheikh & Ors. (supra)* would in my view not assist the case of the Plaintiff.

77. In my view, therefore, none of the arguments or contentions on behalf of the Plaintiff / Respondent are tenable.

78. The Notice of Motion accordingly deserves to be allowed and is hereby allowed in terms of prayer clauses (a) and (b) which read thus :

> *"(a) This Hon'ble Court be pleased to pass an order of dismissal of the above Suit, being Suit No.1073 of 2015 as barred by law;*
> *In the alternative:*
> *(b) Suit No.1073 of 2015 be rejected/dismissed under the provisions of Order VII Rule 11 of the Code of Civil Procedure, 1908."*

79. The Notice of Motion and the Suit accordingly stand disposed as above.

(ABHAY AHUJA, J.)

80. After pronouncement of order, Ms.Bijal Chhatrapati, learned Counsel appearing for the Plaintiff seeks stay of the order.

81. Mr.Ishwar Nankani, learned Counsel appearing for the Defendants No.1 to 3 opposes the same.

82. In view of what has been held in the order, this Court is not inclined to grant stay.

83. The request for stay is accordingly rejected.

(ABHAY AHUJA, J.)

avk