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

+ **CS(COMM) 691/2024**

ASTRAZENECA AB & ANR.

.....Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Shivang Sharma and Mr. Gursimran, Advs.

versus

BEACON PHARMACEUTICALS PLC & ORS.Defendants

Through: Mr. Naman Joshi, Ms. Seema Joshi, Ms. Ritika Vohra, Mr. Rahul and Ms. Amba Tickoo, Advs. for D-4

CORAM:

HON'BLE MR. JUSTICE SAURABH BANERJEE

ORDER

% **14.08.2024**

I.A. 36542/2024 (*Pre litigation mediation 12A CCA*)

1. The plaintiffs vide the present application seek exemption from instituting pre-litigation mediation.

2. Considering the averments made in the present application and the plaintiffs seek urgent ad-interim reliefs and in view of ***Yamini Manohar vs. T.K.D. Krithi*** 2023 SCC OnLine 1382 and ***Chandra Kishore Chaurasia vs. R. A. Perfumery Works Private Limited***. 2022:DHC:4454-DB, the plaintiffs are exempted from instituting pre-litigation mediation.

I.A. 36540/2024 (*Addl.doc*)

3. The plaintiffs vide the present application seek time to file additional documents.

4. For the reasons stated in the application, the plaintiffs will be at

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liberty to file additional documents, *albeit*, strictly as per the provisions of the Commercial Courts Act, 2015 and Delhi High Court (Original Side) Rules, 2018.

5. Accordingly, the present application is allowed and disposed of.

I.A. 36543/2024 (*Exp*)

8. Exemption allowed as sought, subject to all just exceptions.

9. The application stands disposed of.

I.A. 36545/2024 (*Exp from advance service on D-3*)

10. The plaintiffs vide the present application seek exemption from advance service on the defendant no.3.

11. Learned counsel for the plaintiffs submits that since there is an urgency in the matter, plaintiffs may be are exempted from serving advance notice on the defendant no.3 herein.

12. For the reasons stated in the application as also taking into account the aforesaid factors and in the interest of justice, the plaintiff is granted exemption from effecting advance service upon the defendant no.3.

13. The application is disposed of.

I.A. 36544/2024 (*Extension of time for court fee*)

14. The plaintiffs vide the present application seek extension of time for filing the deficient Court fee.

15. Learned counsel for the plaintiffs seeks four weeks' time for filing the court fees of INR 2,00,000/- and process fee of INR 1000/-.

16. For the reasons stated in the present application and the arguments advanced by the learned counsel for the plaintiffs, the present application is allowed, subject to the plaintiffs depositing the remaining court within a period of four weeks.



17. The Registry is directed to place the matter before the Court, in case the remaining court fees is not deposited within the stipulated period of four weeks.

18. The application is disposed of.

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19. By virtue of the present suit, the plaintiffs seek a permanent injunction against defendants from infringing plaintiffs patent IN 297581.

20. Let the plaint be registered as a suit.

21. Upon filing of the process fee, issue summons of the suit to the defendants through all permissible modes returnable before the Joint Registrar on 21.11.2024.

22. The summons shall state that the written statement(s) be filed by the defendants within a period of *thirty days* from the date of the receipt of the summons. Written statement(s) be filed by the defendants along with affidavit(s) of admission/ denial of documents of the plaintiff, without which the written statement(s) shall not be taken on record.

23. Replication(s) thereto, if any, be filed by the plaintiffs within a period of fifteen days from the date of receipt of written statement(s). The said replication(s), if any, shall be accompanied by with affidavit(s) of admission/ denial of documents filed by the defendants, without which the replication(s) shall not be taken on record within the aforesaid period of fifteen days.

24. If any of the parties wish to seek inspection of any document(s), the same shall be sought and given within the requisite timelines.

25. List before the Joint Registrar for marking exhibits of documents on 21.11.2024. It is made clear that if any party unjustifiably denies any



document(s), then it would be liable to be burdened with costs.

26. List before the Court on 08.01.2025

I.A. 36539/2024 (*Leave to plaintiffs to serve defendants with interrogatories*)

27. By way of the present application under Order XI Rule 2 of the Code of the Civil Procedure, 1908 the plaintiffs are seeking leave of the Court to serve interrogatories to the defendants which are filed along with application under Form 2 of the Order XI Rule (4) CPC.

28. The learned counsel for the plaintiffs submits that the interrogatories under Chapter IV, Rule 1(f) of the Delhi High Court (Original Side) Rules, 2018 are for understanding the claim of the plaintiffs better since the plaintiffs are not completely aware to what extent the defendants are infringing the suit patent.

29. Issue notice.

30. Learned counsel appearing for the defendant no.4 on advance notice accept notice.

31. Issue notice to the remaining defendants by all permissible modes returnable before the Joint Registrar on 21.11.2024.

32. Reply, if any, be filed within a period of four weeks. Rejoinder thereto, if any, be filed within two weeks thereafter.

33. List before Court on 08.01.2025.

I.A. 36541/2024 (*O-2, R-2, CPC*)

34. By way of the present application, plaintiffs seek the following reliefs:-

i) “Grant leave to the Plaintiffs to add or amend claims as prayed for in the plaint filed in the present proceedings, including



a claim for infringement of additional patents held by the Plaintiffs which are found to be infringed by the Defendant's impugned drug;

ii) Grant leave to the Plaintiffs to enhance their claim for damages to a quantum higher than INR 2, 00, 00, 000 at a later stage in the present proceedings."

35. Learned counsel for the plaintiffs submits that the plaintiffs apprehend that the defendants may not only be selling Osimertinib in India, but also may be exporting it to other countries furthermore, it is also the apprehension of the plaintiffs that the defendants may be selling and exporting a Fixed Dose Combination (FDC) comprising Osimertinib which will also be infringing plaintiffs' patents other than the suit patents.

36. Issue notice.

37. Learned counsel appearing for the defendant no.4 on advance notice accept notice.

38. Issue notice to the remaining defendants by all permissible modes returnable before the Joint Registrar on 21.11.2024.

39. Reply, if any, be filed within a period of four weeks. Rejoinder thereto, if any, be filed within two weeks thereafter.

40. List before Court on 08.01.2025.

I.A. 36538/2024 (Stay)

41. By way of present application, the plaintiffs are seeking :-

"a. An order of temporary injunction restraining the Defendants, including their directors, employees, officers, servants, agents, affiliates, dealers, distributors, stockists, and all others acting on their behalf, as well as third parties involved with the impugned drugs manufactured by the Defendants and sold to dealers, stockists, or online retailers, whether on an exclusive or principal-to-principal basis, from using, manufacturing, selling, distributing, advertising, exporting, or offering for sale—whether through liaising with medical practitioners or through offline or online channels, directly or indirectly—any product containing the compound Osimertinib, its



pharmaceutically acceptable salts, or its finished formulations, under the brand name TAGRIX, or any other brand; and/or engaging in any activities related to any other product that infringes upon the subject matter of Indian Patent No. IN 297581

b. An order directing the Defendants or any other third party platform offering a listing, to delist and delete all listings on its platform, which advertise and offer for sale infringing versions of Osimertinib under the brand TAGRIX, including but not limited to the following URLs:

- i. <https://www.indiamart.com/proddetail/osimert-80mgtablets-osimertinib-80mg-tablets-22664565173.html>,
- ii. <https://www.indiamart.com/proddetail/tagrix-80-mgtablet-23177970248.html>
- iii. <https://www.indiamart.com/proddetail/tagrix-80-mgosimertinib-tablets-beacon-2853346138030.html>
- iv. <https://www.indiamart.com/proddetail/tagrix-tablet-21587412497.html>
- v. <https://www.indiamart.com/proddetail/tagrixosimertinib-80-mg-tablet-2853972266073.html>
- vi. <https://www.indiamart.com/proddetail/osimertinib-80mg-tablet-export-only-22274507991.html?pos=1&DualProdscape>
- vii. <https://www.indiamart.com/proddetail/tagrix-80-mgtablet-2852511449148.html?pos=2&DualProdscape>
- viii. <https://www.indiamart.com/proddetail/tagrix-80-mgtablet-20714955933.html?pos=3&DualProdscape>
- ix. <https://www.indiamart.com/proddetail/tagrix-80-mgtablet-2848987037062.html?pos=4&DualProdscape>
- x. <https://www.indiamart.com/proddetail/80-mg-tagrixtablets-23112309133.html?pos=8&DualProdscape>
- xi. <https://www.indiamart.com/proddetail/beaconosimertinib-tagrix-80-mg-tablets-2851649236912.html?pos=6&DualProdscape>
- xii. <https://www.indiamart.com/proddetail/tagrix-80mgosimertinib-tablet-2849077203791.html?pos=7&DualProdscape>
- xiii. <https://www.indiamart.com/proddetail/tagrix-80-mgosimertinib-mesylate-tablet-2851802274873.html?pos=11&DualProdscape>
- xiv. <https://www.indiamart.com/proddetail/tagrix-80-mg-2852086423273.html?pos=12&DualProdscape>
- xv. <https://www.indiamart.com/proddetail/80-mg-tagrixosimertinib-tablet-2851865266130.html?pos=15&DualProdscape>
- xvi. <https://www.indiamart.com/proddetail/osimertinibtagrix-80-mg-2852540707230.html?pos=16&DualProdscape>
- xvii. <https://www.indiamart.com/proddetail/tagrix-80-mgosimertinib-mesylate-tablet-2852305924833.html?pos=14&DualProdscape>
- xviii. <https://www.indiamart.com/proddetail/tagrix-tablet-21491643433.html?pos=13&DualProdscape>
- xix. <https://www.exportersindia.com/product-detail/silversnow-white->



tagrix-osimertinib-80mg-5459810.htm

xx. <https://www.exportersindia.com/product-detail/tagrixtablets-osimertinib-3304530.htm>

xxi. <https://www.exportersindia.com/product-detail/tagrix-80-mg-tablets-6931537254.htm>

xxii. <https://www.littlebons.com/search.html?ss=Tagrix+Osimertinib+80+Mg+Tablet>

and to ensure that no product comprising Osimertinib, which does not connote the Plaintiffs as the manufacturer or marketer, is advertised or offered for sale on the abovementioned website(s), mobile app, platform, during the pendency of the patent IN 297581;

c. An order directing the Defendants individually to render accounts of quantity of Osimertinib manufactured, sales revenues accrued and the profits made from the said manufacture, sale, offer for sale, import, export etc. of the products comprising Osimertinib or its pharmaceutically acceptable salts and finished formulations, or any other product that infringes the subject matter of Indian Patent No.IN 297581.

d. An order directing the Defendant No. 1 to takedown/restrict access to the impugned website being made available on the domain name www.tagrix.net;

e. An order allowing the Plaintiffs' to write to the Domain Name Registrar to take down the website(s) and/or specific URL(s) of the impugned listing(s) should the Defendants fail to comply with the order(s) of the Hon'ble Court or provide reasons in writing as prescribed under law;

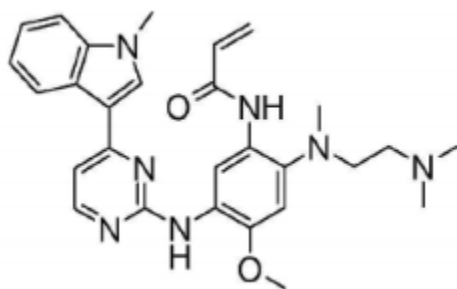
f. An order directing freeze of accounts of Defendant No. 3 being Account No. 50200076739438, IFSC Code HDFC0001739 and UPI id dr.arb3-3@okhdfcbank and any other bank account linked with such UPI ID."

42. The plaintiff no.1 AstraZeneca AB, is a Swedish company having registered office at SE- 151 85 Södertälje, Sweden and the plaintiff no. 2 is the Indian subsidiary of AstraZeneca and markets pharmaceutical products in India. The plaintiffs are innovation-driven biopharmaceutical business companies engaged in the discovery, development, and commercialization of prescription medicines, including oncology products and operates in over 100 countries.

43. The plaintiffs' compound, Osimertinib, is used for the treatment of



non-small cell lung cancer (NSCLC). Osimertinib is the International Non-proprietary Name (INN) assigned by the World Health Organization to the plaintiffs' compound N-(2-{2- dimethylaminoethyl-methylamino}-4-methoxy-5-{[4-(1- methylindol-3-yl)pyrimidin-2yl]amino}phenyl)prop-2-enamide. A two-dimensional representation of the chemical structure of Osimertinib is enumerated below:-



44. The plaintiffs' compound, emphasizes on a "mutant selective profile" of the inhibitor vis a vis wild type (WT) EGFR, both types of EGFR kinase exist within a cancer patient's body, but only the mutated form(s) represent the therapeutic target. In order to minimize unwanted side-effects, such as skin rash, diarrhoea and/or dose-limiting toxicity problems, Osimertinib achieves high selectivity profile for both the single (i.e., sensitising mutation only) and double mutant forms of EGFR versus the wild-type receptor. Thus, Osimertinib represents a new generation (third generation) of EGFR TKIs, and showing high potency against both single (i.e., sensitising mutation only) and double mutant EGFR while having a suitable margin of selectivity between both mutant forms versus the wild-type receptor. Osimertinib's thus has a novel potential for use in treatment of cancers, especially non-small cell lung cancers, in human beings. Furthermore, sale qua said compound for last three preceding



years has been INR 82,92,00,000/-, INR149,10,30,000/-, INR 219,09,00,000 respectively.

45. The details of patent of the plaintiff no.1 are enumerated below:

Application Number	9461/CHENP/2013	Compound patent
Title	2-(2,4,5- SUBSTITUTED ANILINO) PYRIMIDINE DERIVATIVES AS EGFR MODULATORS USEFUL FOR TREATING CANCER	
Applicant Name	AstraZeneca AB	
Date of Filing in India	26/11/2013	
PCT International Filing Date	25/07/2012	
Priority Date	27/07/2011 27/01/2012	
Publication Date (u/s 11A)	28/11/2014	
Date of Grant	11/06/2018	
Date of Patent Expiry	25/07/2032	

46. The claims granted to the plaintiff no.1 in suit patent IN 297581 are as follows:-

Claim 1: The compound: N-(2-{2-dimethylaminoethylmethylamino}-4-methoxy-5-{[4-(1-methylindol-3-yl)pyrimidin-2-yl]amino}phenyl)prop-2-enamide: or a pharmaceutically acceptable salt thereof.

Claim 2: The compound: N-(2-{2-dimethylaminoethylmethylamino}-4-methoxy-5-{[4-(1-methylindol-3-yl)pyrimidin-2-yl]amino }phenyl)prop-2-enamide, as claimed in claim 1.

Claim 3: A pharmaceutically acceptable salt as claimed in claim



1, which is the mesylate salt of N-(2-{2-dimethylaminoethylmethylamino}-4-methoxy-5-{[4-(1-methylindol-3-yl)pyrimidin-2-yl]amino}phenyl)prop-2-enamide.

Claim 4: A pharmaceutical composition comprising the compound or a pharmaceutically acceptable salt thereof as claimed in any one of claims 1 to 3, in association with a pharmaceutically acceptable diluent or carrier.

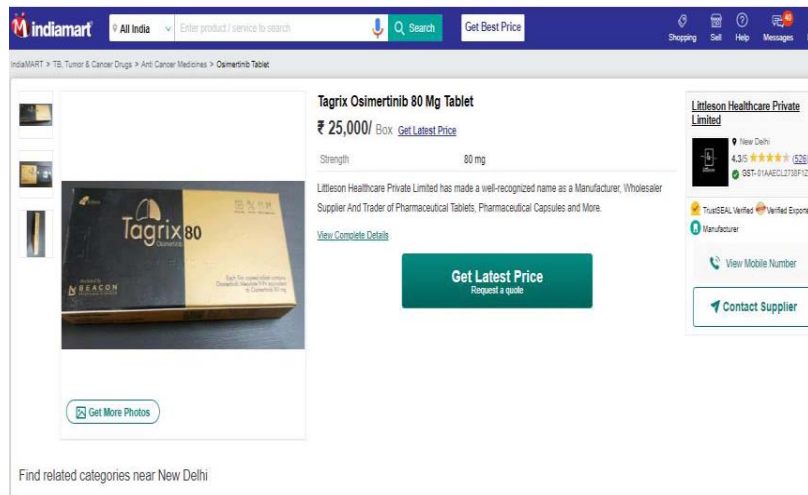
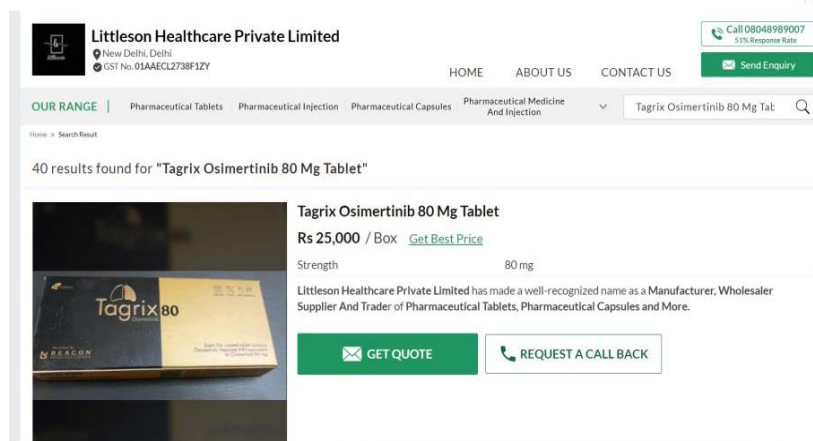
47. Learned counsel for the plaintiffs submits that the defendant no. 1, Beacon Pharmaceuticals PLC is operating under the name of Beacon Pharmaceuticals Ltd. from Dhaka, Bangladesh and also through its website <https://old.beaconpharma.com.bd/> claiming therein to have developed several oncology drugs including generic version of Osimertinib under the brand Tagrix. A pictorial representation is reproduced below:-



48. Learned counsel submits that the defendant no. 2 is exclusive global marketing and distribution partner of the defendant no.1. She submits that as per the website of defendant no. 2, it is involved in exporting the drugs

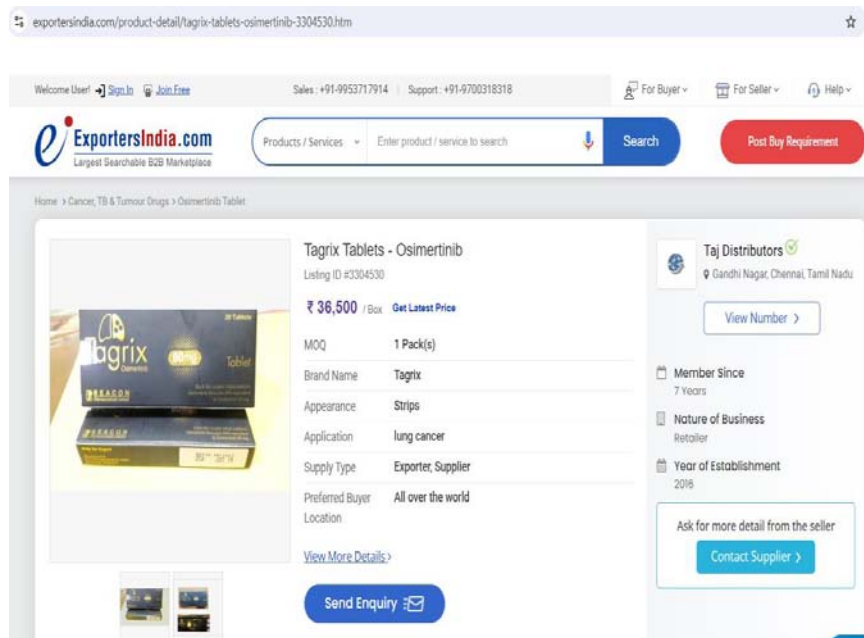


manufactured by defendant no.1 under the brand name Tagrix in India which is a plaintiffs compound 'Osimertinib'. As per learned counsel, the defendant no.3 operates as a seller, exporter and manufacturer of pharmaceuticals and operates through its own website <https://www.littleasons.com/> and lists products on third party website of the defendant no.4, Indiamart, and is a verified seller by defendant no. 4. The plaintiffs have purchased infringing Osimertinib of the defendant nos. 1 and 2, under the brand Tagrix from the defendant no. 3, very recently in July 2024. A pictorial representation of defendant nos. 3 and 4's website is reproduced below:-





49. Learned counsel also submits that the defendant no. 5 is an online merchant platform, which provides online space to allow sellers or suppliers of goods or services to connect with potential buyers and its platform <https://www.exportersindia.com/> contains several advertisements and offers for sale of infringing Osimertinib, including the infringing product. A pictorial representation of which is reproduced below:-



50. Learned counsel submits that the infringing drug ‘Tagrix’ manufactured by defendant nos. 1 and 2 is wrongly available in India since they do not possess any import-export licence or an approval from the Indian Drug Control Authorities for proceeding with the same in India.

51. Learned counsel submits that the defendants are wrongly dealing in the infringing versions of Osimertinib since till date they have neither filed nor secured any licence, voluntary or compulsory, from the plaintiff and further that the plaintiff is the holder of a valid and subsisting patent till to date.

52. Learned counsel then submits that the defendant no. 6, John Doe(s)



are several un-identified persons who are engaging in the trade, supply and sale of infringing versions of Osimertinib, either under the brand Tagrix or otherwise, at various levels along the supply chain/ operations of the defendant nos.1 and 2.

53. Learned counsel for the defendant no.4, appearing on advance notice, on instructions undertakes to delist and delete all listings on its platform as mentioned at para 70(b)(i-xviii) of plaint, www.indiamart.com, which advertise and offer for sale infringing versions of Osimertinib under the brand Tagrix.

54. This Court has heard the learned counsel for the parties and perused the records as well.

55. A bare perusal of listings qua impugned good reveals that the impugned drug 'Tagrix' is comprising of the compound 'Osimertinib', qua which is the plaintiff no.1 has a valid patent registration granted by the Indian Patent Office on 25.07.2012, which is valid and subsisting at this stage.

56. In view of the averments and assertions made by the plaintiffs in the plaint as also the submissions made by the learned counsel for the plaintiffs, the plaintiffs have made out a *prima facie* case with the *balance of convenience* for grant of an *ad interim ex-parte injunction* in their favour and against the defendants. The defendants, if not restrained by way of an *ad interim ex-parte injunction* may lead to a likelihood of confusion and deception amongst the minds of the general public at large which needs to be estopped. The same may also lead to the plaintiffs suffering *irreparable harm, loss, injury and prejudice*.

57. Accordingly, till the next date of hearing, anyone, who is not



authorised by the plaintiffs vide an agreement is restrained from selling, manufacturing, distributing, advertising, exporting or offering for sale the plaintiffs' compound 'Osimertinib' in any form or manner so as to infringe plaintiff no.1 patent IN 297581. Furthermore, defendant no.4 shall remain bound by the undertaking given before this Court.

58. Issue notice.

59. Learned counsel appearing for the defendant no.4 on advance notice accept notice.

60. Issue notice to the remaining defendants by all permissible modes returnable before the Joint Registrar on 21.11.2024.

61. Reply, if any, be filed within a period of *thirty days* from the date of service. Rejoinder thereto, if any, be filed within a period of *fifteen days* thereafter.

62. The provisions of *Order XXXIX Rule 3 CPC* be complied within two weeks.

63. List before the Court on 08.01.2025.

Dasti.

SAURABH BANERJEE, J

AUGUST 14, 2024/rr