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

+ **CS(COMM) 106/2024**

**ASTRAZENECA AB & ANR.**

..... Plaintiffs

Through: Mr. Pravin Anand, Ms. Vaishali R. Mittal, Mr. Siddhant Chamola and Mr. Shivang Sharma, Advocates.

versus

**AZISTA INDUSTRIES PVT LTD & ORS.**

..... Defendants

Through: Mr. Ajay Sahni and Mr. Chirag Ahluwalia, Advocates for D-1 to 5. Mr. Dattatray Vyas and Mr. Ashish Mukhi, Advocates for D-8.

**CORAM:**

**HON'BLE MR. JUSTICE SANJEEV NARULA**

**ORDER**

% **06.02.2024**

**I.A. 2572/2024 (seeking leave to file additional documents)**

1. This is an application seeking leave to file additional documents under the Commercial Courts Act, 2015 (“CCA”).
2. Plaintiffs, if they wish to file additional documents at a later stage, shall do so strictly as per the provisions of CCA.
3. Accordingly, the application stands disposed of.

**I.A. 2574/2024 (seeking exemption from requirements of Section 12A of the Commercial Courts Act, 2015)**

4. As the present suit contemplates urgent interim relief, in light of the



judgment of Supreme Court in *Yamini Manohar v. T.K.D. Krithi*,<sup>1</sup> exemption from attempting pre-institution mediation as per Section 12A of the CCA is granted.

5. Disposed of.

**I.A. 2575/2024** *(for exemption from filing clear copies or documents with exact margins and/or which are on A4 size paper, typed-copies of handwritten documents, English translations and from filing originals of the relevant documents at this stage)*

6. Exemption is granted, subject to all just exceptions.

7. Plaintiffs shall file legible and clearer copies of exempted documents, compliant with practice rules, before the next date of hearing.

8. Accordingly, the application stands disposed of.

**I.A. 2576/2024** *(seeking extension of tie to file court fees)*

9. For the grounds and reasons stated therein, the application is allowed. Plaintiffs are granted two weeks' time to file court fees.

10. The application is disposed of.

**CS(COMM) 106/2024**

11. Let the plaint be registered as a suit.

12. Issue summons. Summons are accepted by Mr. Ajay Sahni, counsel for Defendant Nos. 1 to 5 (Azista Industries Pvt. Ltd., Azista Bhutan Healthcare, Hetero Healthcare Limited, Hetero Drugs Limited and Hetero Labs Limited, respectively) and Mr. Dattatray Vyas, counsel for Defendant No. 8 (Hegde & Hegde Pharmaceuticals LLP). They confirm the receipt of

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<sup>1</sup> 2023 SCC OnLine SC 1382.



the suit-paper book and dispense with the requirement of service of formal summons by the registry. The written statements shall be filed by the Defendants within 30 days from today. Upon filing of process fee, issue summons to the remaining Defendants, by all permissible modes. Summons shall state that the written statement shall be filed by the remaining Defendants within 30 days from the date of receipt of summons. Along with the written statement, Defendants shall also file an affidavit of admission/denial of the documents of the Plaintiffs, without which the written statements shall not be taken on record.

13. Liberty is given to Plaintiffs to file replications within 15 days of the receipt of the written statements. Along with the replications, if any, filed by the Plaintiffs, an affidavit of admission/denial of documents of the Defendants must be filed by the Plaintiffs, without which the replications shall not be taken on record. If any of the parties wish to seek inspection of any documents, the same shall be sought and given within the timelines.

14. List before the Joint Registrar for marking of exhibits on 10<sup>th</sup> April, 2024. It is made clear that any party unjustifiably denying documents would be liable to be burdened with costs.

15. List before Court for framing of issues on 4<sup>th</sup> July, 2024.

**I.A. 2571/2024 (seeking administration of interrogatories)**

16. Issue notice. Mr. Ajay Sahni, counsel for the Defendant Nos. 1 to 5 and Mr. Dattatray Vyas, counsel for Defendant No. 8, accept notice. They are permitted to file a reply to the application within four weeks from today. Rejoinder if any, within two weeks thereafter.

17. Issue notice to the remaining Defendants, by all permissible modes,



upon filing of process fee, returnable on the next date of hearing. Reply, if any, be filed within four weeks from the date of service. Rejoinder thereto, if any, be filed within two weeks thereafter.

**I.A. 2573/2024** *(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 and for grant leave enhance their claim for damages to a quantum higher than INR 2,00,00,000 at a later stage)*

18. Issue notice. Mr. Ajay Sahni, counsel for the Defendant Nos. 1 to 5 and Mr. Dattatray Vyas, counsel for Defendant No. 8, accept notice. They are permitted to file a reply to the application within four weeks from today. Rejoinder if any, within two weeks thereafter.

19. Issue notice to the remaining Defendants, by all permissible modes, upon filing of process fee, returnable on next date. Reply, if any, be filed within four weeks from the date of service. Rejoinder thereto, if any, be filed within two weeks thereafter.

**I.A. 2570/2024** *(u/Order XXXIX Rule 1 & 2 r/w Section 151 of the Code of Civil Procedure, 1908)*

20. Issue notice. Mr. Ajay Sahni, counsel for the Defendant Nos. 1 to 5 and Mr. Dattatray Vyas, counsel for Defendant No. 8, accepts notice.

### **Plaintiff's Contentions**

21. Mr. Pravin Anand, counsel for Plaintiffs, presents the following facts and circumstances while pressing the present application for grant of ad-interim relief:

21.1 The present suit relates to infringement of Plaintiff No. 1's patent



bearing no. IN 297581 (“**Suit Patent**”) in relation to Plaintiff’s drug comprising Osimertinib. Plaintiff No. 1 (AstraZeneca AB), a company incorporated in Sweden, forms a part of the AstraZeneca group of companies. Plaintiff No. 2 (AstraZeneca Pharma India Limited) is incorporated in India. Plaintiffs’ compound Osimertinib is a second-line treatment, useful for the treatment of non-small cell lung cancers which have underlying mutations in a protein known as Epidermal Growth Factor Receptor. Osimertinib is the International Nonproprietary Name assigned by World Health Organisation to Plaintiff’s compound N-(2-{2-dimethylaminoethyl-methylamino}-4-methoxy-5-[[4-(1-methylindol-3-yl)pyrimidin-2yl]amino}phenyl)prop-2-enamide (or pharmaceutically acceptable salts thereof). Osimertinib is protected in the Suit Patent, which was granted on 11<sup>th</sup> July, 2018 and is valid till 25<sup>th</sup> July, 2032. Plaintiffs have the exclusive right to manufacture use, offer for sale, import or sell Osimertinib in India.

21.2 Defendants are allegedly engaged in clandestine operations, acting in concert to manufacture, smuggle and sell unlawful drugs, which are infringing versions of Osimertinib in India. On the basis of the investigations carried out by the Plaintiffs, they uncovered the *modus* used by Defendants for such activities:

(a) The packaging of the product procured by the Plaintiffs discloses that Defendant No. 2 manufactures Osimertinib in Bhutan under the brand OSITAB. As import-export data of Defendants over the last few years revealed no imports of the impugned drug, and because the patent for compound Osimertinib is not registered in Bhutan, it is quite possible that the drugs are manufactured locally in India while the packaging of these



drugs mention the place of manufacture as Bhutan. A photograph of the product is as follows:



(b) Defendant No. 1 is involved in the marketing and selling of these drugs within India, which can be surmised from the fact that Defendant Nos. 1 & 2 are affiliated companies and Defendant No. 1 is the Indian arm of Defendant No. 2, which admittedly has manufacturing plants in Bhutan.

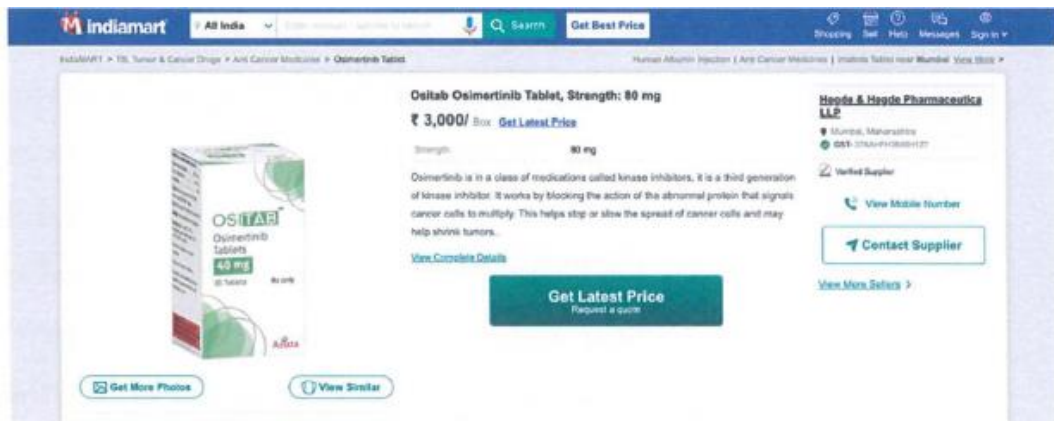
(c) The sale of the drugs in India are being promoted through doctors and medical practitioners by the Hetero Group (Defendant Nos. 3-5). Copies of undated prescriptions without letterheads have been annexed to the plaint, purportedly given by doctors, showing that the products under the brand name OSITAB can be allegedly purchased through Hetero's employees.

(d) The availability of the infringing drugs is evident from multiple third-party entities that are selling infringing versions of Osimertinib under the brand OSITAB in India on portals such as Defendant No. 7 (IndiaMART InterMESH Ltd). Defendant No. 7, a marketplace e-commerce platform, is facilitating the advertisement and sale of infringing drugs by third-parties. These drugs are not meant for sale on online websites and require a prescription by a registered medical practitioner, and therefore Defendant No. 7 is not acting in consonance with law.

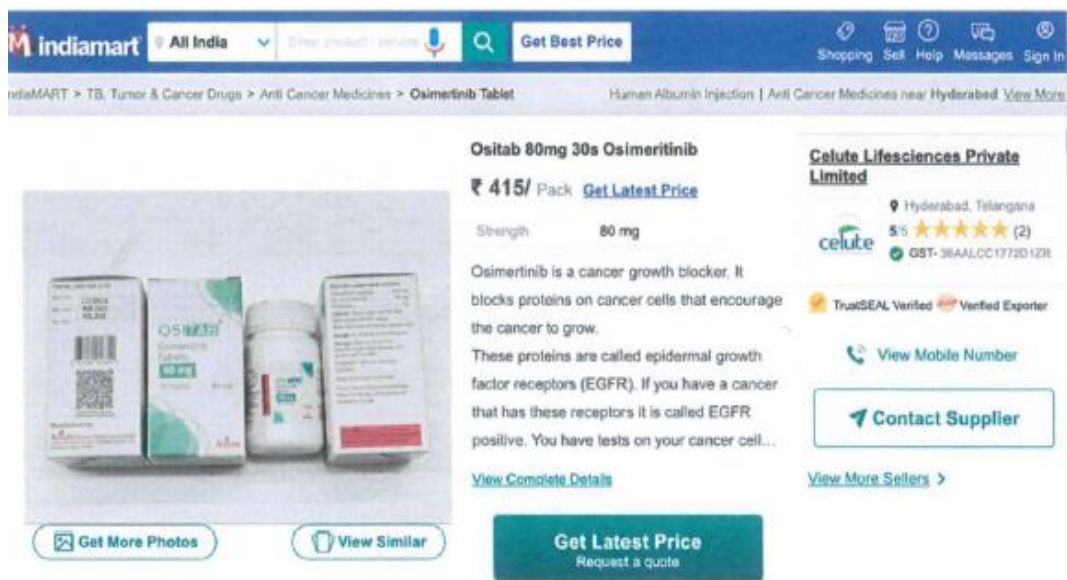
(e) Defendant No. 8 (Hegde & Hegde Pharmaceutical LLP) and



Defendant No. 9 (Celute Lifesciences Private Limited) are the third-party entities that engage in the supply and sale of infringing Osimertinib on the merchant platform operated by the Defendant No. 7. Screenshots of the listing for OSITAB made by the Defendant No. 7 and Defendant No. 8 on Indiamart are as follows:



(Defendant No. 8)



(Defendant No. 9)



(f) Plaintiffs have received information that several unidentified persons are engaged in the trade and supply of infringing versions of Osimertinib, facilitating smuggling of drugs across the Indo-Bhutan border, or supply of such smuggled drugs further inland or the distribution of these drugs to various medical stores in India. These actors have been impleaded as John Does.

(g) Plaintiffs have placed on record an affidavit, indicating that the products manufactured by Defendant No. 2 are readily available at the retail outlets/ pharmacies such as that of Defendant No. 6 (Mor Chemists Banjara Hills).

21.3 The Plaintiffs have secured several orders protecting their suit patent before this Court, copies whereof have been placed on record. They are: *AstraZeneca AB v West-Coast Pharmaceuticals*<sup>2</sup>, *AstraZeneca AB v Zee Laboratories Ltd.*<sup>3</sup> and *AstraZeneca AB v. MSN Laboratories Pvt. Ltd.*<sup>4</sup>.

21.4 There was no pre-grant opposition to the Suit Patent, however, there were two post-grant oppositions. The post-grant opposition filed by Natco Pharma Ltd. was subsequently withdrawn. The other post grant opposition filed by Sunshine Organics Pvt. Ltd. is pending adjudication, and as things stand, Plaintiffs enjoy exclusive rights to *inter alia* manufacture, offer for sale and sell Osimertinib.

### **Defendant's Submissions**

22. Mr. Ajay Sahni, counsel for Defendant Nos. 1 to 5, on instructions at the outset denies the allegations made in the plaint as false and incorrect. He

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<sup>2</sup> CS(COMM) 101/2022, order dated 11<sup>th</sup> February, 2022.

<sup>3</sup> CS(COMM) 105/2022, order dated 22<sup>nd</sup> March, 2022.



argues that his clients are not infringing the suit patent. He emphasises that Defendant Nos. 1, 3, 4 and 5 have never dealt in or intend to deal with any product that would infringe Plaintiffs' Suit Patent. He further states that none of the aforementioned Defendants have any stock of the product OSITAB or any other such product which infringes the Suit Patent, nor will they deal with any infringing drug till the time the Suit Patent is valid and subsisting. The statements made by Mr. Sahni are taken on record and shall bind the said Defendants. As regards Defendant No. 2, Mr. Sahni, on instructions, states that the said Defendant while denying the allegations made in the plaint, clarifies that Defendant No. 2 is manufacturing OSITAB in Bhutan, which does not infringe the Suit Patent.

23. Mr. Sahni explains that the only 'import' the aforesaid Defendants are aware of are the ones made in terms of Rule 36 of the Drugs and Cosmetics Rules, 1945 ("**Rules**"). Rule 36 stipulates that import of small quantities of drugs, which are otherwise prohibited<sup>5</sup> can be imported for personal use, subject to certain conditions. The licensing authority is empowered by the Rules to permit import of drugs for personal use on an application made to it, in terms of Form 12-B annexed to the Rules. It is therefore stated that any export to India made by Defendants is only after due approval from the licensing authority i.e., Central Drugs Standard Control Organization (CDSCO). To bolster this submission, copies of two such permits granted by CDSCO has been handed across the board, which is taken on record. Mr. Sahni further assures the Court, on instructions, that no export of OSITAB shall be made to India except under the permission granted by CDSCO

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<sup>4</sup> CS(COMM) 248/2022, order dated 11<sup>th</sup> July, 2022.

<sup>5</sup> Under Section 10 of the Drugs and Cosmetics Act, 1940, import of certain medicines is prohibited,



under the Drugs and Cosmetics Act, 1940 under Rule 36 and for the purposes stipulated therein. The said statement made on behalf of Defendant No. 2 by Mr. Sahni is taken on record, and shall bind the said Defendant.

24. Similarly, Mr. Dattatray Vyas, counsel for Defendant No. 8, on instructions also denies the allegations made in the plaint states that his client has never dealt in nor does it intend to deal with any product infringing the Suit Patent. He further states that none of the aforementioned Defendants have any stock of the product OSITAB or any other such product which infringes the Suit Patent, nor will they deal with any infringing drug till the time the Suit Patent is valid and subsisting. The said statement is taken on record and shall bind Defendant No. 8. He further states that the listing of the products on Defendant no. 7's website has not been made by or authorised by Defendant No. 8, and expresses surprise upon noting the said listings. Nonetheless, he undertakes to take appropriate action to remove the listings on the website of Defendant No. 7.

### **Directions**

25. Defendant No. 7 is directed to delist and delete all listings on its platform which advertise and offer for sale infringing versions of Osimertinib under the brand OSITAB, including but not limited to the URLs <<https://www.indiamart.com/proddetail/ositab-osimertinib-tablet-2853117310348.html>> and <<https://www.indiamart.com/proddetail/ositab-80mg-30sosimeritinib-2852859799962.html>>. In the event the Plaintiffs come across any other listing of the said product on Indiamart, they shall be permitted to give the details of such listings/URLs to Defendant No. 7, who

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including medicines which are patented.



shall then take steps to have the said listings removed.

26. Defendant Nos. 6 and 9 are not present despite advance service of a copy of the suit paperbook. Be that as it may, considering the aforementioned submissions advanced by Mr. Anand, the Court finds a *prima facie* case in Plaintiff's favour; balance of convenience also lies in favour of the Plaintiffs and irreparable loss would be caused in case an *ex-parte ad interim* injunction is not granted. Accordingly, Defendant Nos. 6 and 9, and all others acting for and on their behalf are restrained from directly or indirectly dealing in, manufacturing, selling, distributing, advertising, exporting, offering for sale, through liaising with medical practitioners, and/or through offline or online channels, including but not limited to [www.indiamart.com](http://www.indiamart.com);; products comprising the compound Osimertinib and its pharmaceutically acceptable salts and its finished formulations, under the brand OSITAB, or any other brand, or any other product that infringes the Suit Patent.

27. Issue notice to the unrepresented Defendants, by all permissible modes, upon filing of process fee, returnable on the next date of hearing. Reply, if any, be filed within four weeks from the date of service. Rejoinder thereto, if any, be filed within two weeks thereafter.

28. Compliance of Order XXXIX Rule 3 of CPC be done with one week from today.

29. List before the Court thereafter.

**SANJEEV NARULA, J**

**FEBRUARY 6, 2024/as**