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

% **Date of Decision: 12th November, 2024**

+ CS(COMM) 101/2022 & I.A. Nos. 2392/2022, 1079/2023 &
14102/2023

ASTRAZENECA AB & ANR.Plaintiffs

Through: Mr. Pravin Anand with Ms. Vaishali
R. Mittal, Mr. Siddhant Chamola, Mr.
Karan Kr. Kamra, Mr. Shivang
Sharma and Mr. Gursimran Singh
Narula, Advocates.
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versus

WESTCOAST PHARMACEUTICAL WORKS
LIMITEDDefendant

Through: Mr. Abhishek Kotnala, Advocate.
(M): 8860292115

CORAM:
HON'BLE MS. JUSTICE MINI PUSHKARNA
MINI PUSHKARNA, J (ORAL)

I.A. 1079/2023

1. The present application has been filed seeking summary judgment under Order XIII-A, Rules 3, 6(1)(a) & 8 of the Civil Procedure Code, 1908 ("CPC"), read with Order VIII Rule 10 CPC, read with Section 151 CPC.
2. Present suit has been filed by the plaintiffs seeking permanent injunction restraining infringement of patent bearing number IN 297581; damages; costs of the proceedings etc.

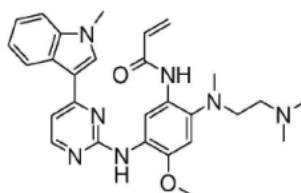


3. The plaintiffs seek a summary judgment against the defendants, on the ground that the defendants have no prospect of defending the plaintiff's claims.

4. The facts as canvassed in the plaint, are as follows:

4.1 The plaintiffs along with AstraZeneca group of companies ("AstraZeneca") are actively engaged in the discovery, development and commercialization of prescription medicines. The plaintiffs operate in over 100 countries and its innovative medicines are used by millions of patients worldwide.

4.2 The plaintiffs' novel compound, Osimertinib, is useful for the treatment of cancer, especially specific types of non-small cell lung cancers (NSCLC) which have underlying mutations in a protein known as Epidermal Growth Factor Receptor (EGFR). Osimertinib is the chemical name of the plaintiffs' 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). A two-dimensional representation of the chemical structure of Osimertinib, is reproduced as under:



4.3 The said novel compound, Osimertinib, is protected by the plaintiffs' patent IN 297581 [IN '581], which was granted on 11th July, 2018 and is valid till 25th July, 2032. Therefore, the plaintiffs have the exclusive right to manufacture, use, offer for sale, import or sell Osimertinib in India.



4.4 The plaintiffs' Osimertinib 40mg and 80mg, is marketed as part of finished formulations under the brand Tagrisso in India and in several other countries across the globe. The plaintiffs received their first regulatory approval for Tagrisso in India in 2017, and since then, the plaintiffs' drug has become very popular for the treatment of those specific types of non-small cell lung cancers, toward which it is directed.

4.5 The defendant, Westcoast Pharmaceutical Works Limited, having its registered office at *F.P. No. 17 & 16/5 Meldi Estate, Near Prasang Party Plot, Opposite Sola Bhagwat, Sayona City Road, Gota, Ahmedabad-382481, Gujarat, India*, is a company engaged in the manufacture and sale of pharmaceutical drugs across India, and is also engaged in contract manufacturing of pharmaceuticals for third-party entities.

4.6 In the first week of January 2022, the plaintiffs' representatives came across a flyer issued by the defendant, in which, it offered to manufacture and sell Osimertinib in extremely high quantities on a contract-manufacturing basis. This offer to sell Osimertinib, amounts to infringement of the plaintiffs' patent IN '581.

4.7 The defendant was soliciting large orders, upwards of 1,00,000 tablets of infringing Osimertinib, and was claiming to deliver such infringing tablets within 7-8 weeks from *inter alia* receiving payment in advance. The defendant's offer was not restricted to any particular entities but was targeted at the marketing or contract-manufacturing divisions of all pharmaceutical companies in India.

4.8 Thus, the present suit came to be filed.

5. This Court on 11th February 2022, issued an *ex parte ad interim* injunction, after being *prima facie* satisfied about the plaintiffs' claim,



restraining the defendant from dealing in Osimertinib, or its pharmaceutically acceptable salts, formulations or any other product, which infringed the plaintiffs' patent IN '581. Pursuant to the said *ex parte ad interim* order, the defendant was served with summons of the present proceedings on 16th February 2022.

6. On 22nd April 2022, the defendant entered appearance through its counsel, wherein, additional time was sought to file the Written Statement. However, the same was not filed, till the expiry of 120 days.

7. As the defendant failed to file its written statement, the defendant filed an affidavit dated 29th August, 2022, of Mr. Kamlesh C. Patel, Director of the defendant, wherein, it claimed that regulatory approval to manufacture Osimertinib was obtained under a mistaken belief that it was not patented in India, attributing the error to Government authorities responsible for preventing approvals for patented drugs.

8. The defendant argued that there is no legal mechanism in India to verify patent protection during regulatory licensing. It further asserted that it had only published a promotional flyer post-approval, had not manufactured Osimertinib, and did not intend to do so until the expiry of the suit patent IN '581 on 25th July, 2032, having requested cancellation of the regulatory approval on 10th August, 2022. Additionally, the defendant raised objections regarding this Court's territorial and pecuniary jurisdiction and non-compliance with pre-litigation mediation. An undertaking was also given not to launch any infringing product during the patent's term.

9. On 30th November, 2022, this Court confirmed the *ex parte ad interim* injunction in favour of the plaintiffs and against the defendant, till the pendency of the suit. The plaintiffs consequently submitted that in light of



the aforesaid undertaking, the suit be decreed in terms of the prayers sought by the plaintiffs, which was objected to by the defendant.

10. The defendant filed an application being, *I.A. 21995/2022* under Order VII Rule 11 CPC for rejection of the plaint, which was dismissed vide judgment dated 15th May, 2023. Subsequently, the defendant filed another application, being *I.A. 14102/2023*, wherein, the defendant stated that it has not manufactured the infringing product and will not do so.

11. As already noted, vide order dated 11th February, 2022, an *ex parte ad interim* injunction was passed in favour of the plaintiffs and against the defendant, whereby, the defendant was restrained from dealing in Osimertinib or its pharmaceutically acceptable salts, formulations or any other product, which infringes the plaintiffs' suit patent IN '581.

12. Further, it is noted that despite service of summons on 16th February, 2022 upon the defendant, the written statement was not filed within the maximum statutory period of 120 days. Hence, the right of the defendant to file written statement was closed and the *ex parte ad interim* injunction order was also made absolute vide order dated 30th November, 2022.

13. This Court in its order dated 30th November, 2022, further recorded that, the only submission of the defendant is that they are not marketing any infringing product. The relevant portion of the said order is reproduced as under:

“xxx xxx xxx

5. **The only submission of the defendant is that they are not marketing any infringing product.**

6. *Accordingly, the interim order passed by this Court on 11th February 2022 is made absolute pending disposal of the suit.*

xxx xxx xxx”

(Emphasis Supplied)



14. Pursuant to the closing of the aforesaid right of the defendant, the defendant filed an affidavit dated 29th August, 2022, wherein, Director of the defendant has undertaken that he has never manufactured the drugs under the subject patent and has no intention to use the same till the validity of the alleged patent, i.e., till 25th July, 2032. The relevant portion of the said affidavit, is reproduced as under:

“xxx xxx xxx

8. That the Defendant after getting the product permission from the Drugs Authority and believing that there was no patent, published the flyer. **It is pertinent to note that the Defendant has not manufactured any drugs under the subject patent.** It is submitted that if the Drugs Department had not given the product permissions to the Defendant, the Defendant would have not published the flyer of the alleged drugs. **In any case, the Defendant has never manufactured the drugs and has no intention to use the same till the validity of alleged patent.** The Defendant has already filed request on 10/08/2022 before Food & Drugs Department for cancellation of product permissions.

xxx xxx xxx”

(Emphasis Supplied)

15. This Court takes note of the aforesaid statement made in the affidavit filed on behalf of the defendant. The defendant is held bound by the said statement.

16. In view of the aforesaid undertaking of the defendant and the fact that no written statement has been filed by the defendant, it is manifest that there is no defence raised by the defendant. In the absence of any credible defence, and in the absence of any argument or evidence by the defendant that could justify a trial, it is held that the present is a fit case for passing summary judgment. Accordingly, it is held that the plaintiff is entitled to decree in its favour.

17. Holding that if the Court comes to a conclusion that the defendant lacks a real prospect of successfully defending the claim, a Commercial



Court is entitled to pass a summary judgment in terms of the summary procedure in The Commercial Courts Act, 2015, this Court in the case of *Su-Kam Power Systems Ltd. Versus Kunwer Sachdev and Another, 2019 SCC OnLine Del 10764*, has held as follows:-

“xxx xxx xxx

90. To reiterate, the intent behind incorporating the summary judgment procedure in the Commercial Court Act, 2015 is to ensure disposal of commercial disputes in a time-bound manner. In fact, the applicability of Order XIII A, CPC to commercial disputes, demonstrates that the trial is no longer the default procedure/norm.

91. Rule 3 of Order XIII A, CPC, as applicable to commercial disputes, empowers the Court to grant a summary judgement against the defendant where the Court considers that the defendant has no real prospects of successfully defending the claim and there is no other compelling reason why the claim should not be disposed of before recording of oral evidence. The expression “real” directs the Court to examine whether there is a “realistic” as opposed to “fanciful” prospects of success. This Court is of the view that the expression “no genuine issue requiring a trial” in Ontario Rules of Civil Procedure and “no other compelling reason.....for trial” in Commercial Courts Act can be read mutatis mutandis. Consequently, Order XIII A, CPC would be attracted if the Court, while hearing such an application, can make the necessary finding of fact, apply the law to the facts and the same is a proportionate, more expeditious and less expensive means of achieving a fair and just result.

92. Accordingly, unlike ordinary suits, Courts need not hold trial in commercial suits, even if there are disputed questions of fact as held by the Canadian Supreme Court in Robert Hryniak (supra), in the event, the Court comes to the conclusion that the defendant lacks a real prospect of successfully defending the claim.

xxx xxx xxx”

(Emphasis Supplied)

18. Considering the aforesaid discussion, this Court is of the view that the plaintiffs are entitled to a decree under Order XIII-A of the Commercial Courts, Commercial Division and Commercial Appellate Division of the



High Courts Act, 2015, as the said provision empowers this Court to pass a summary judgment, without recording evidence, if it appears that the defendant has no real prospect of defending the claim.

19. As regards the plea of the plaintiff for cost, it is to be noted that despite being granted multiple opportunities by this Court, the defendant intentionally chose not to file a written statement. Further, the defendant repeatedly moved frivolous applications, on account of which, the present proceedings prolonged. Further, this Court also notes the submission of learned counsel for the plaintiffs that the defendant has been found to be guilty of similar infringing activities on previous occasions. Submission made in the plaint, in this regard, reads as under:-

“xxx xxx xxx

43. *Furthermore, the Defendant has previously been engaged in litigation with the Plaintiffs, as the Defendants had secured a marketing and manufacturing license for the anti-diabetes drug Dapagliflozin, which was protected by separate patents of the Plaintiffs. The Plaintiff had secured information that the Defendants had received approval for manufacturing of 45 lakh tablets of the infringing drug. The Plaintiffs had instituted a civil suit for infringement of patent against the said Defendant before this Hon'ble Court being AstraZeneca AB & Anr. v, West Coast Pharmaceuticals Works Ltd., CS (COMM) 155 of 2020. By an order dated June 03, 2020, the Defendant was restrained from manufacturing, selling, offering for sale etc. the said infringing drug, Thereafter, on account of an express undertaking given by the Defendant-that inter alia it acknowledged the Plaintiffs' exclusive rights in the patents for Dapagliflozin; it would refrain from manufacturing, importing, selling, offering for sale, exporting etc, Dapagliflozin - this Hon' ble Court passed a permanent injunction restraining in infringement of patent in favour of the Plaintiffs, and the suit was decreed vide order dated August 25,2020.*

xxx xxx xxx”

20. Further, this Court also notes the averments made by the plaintiffs in their written submissions, which read as under:-



“xxx xxx xxx

13. *It is submitted that the Defendant is a habitual infringer, with a history of infringing upon the intellectual property rights of various patent holders. Evidence of the Defendant's prior infringements, as documented in previous cases, clearly establishes a pattern of unlawful behaviour. It is submitted that the Defendant, on its website claims to be to be in the business of pharmaceuticals since 1965. It further boasts that it has a strong oncology division and that it exports its products on a large scale. It is submitted that it is not possible for the Defendant to have not known about the Plaintiffs, its Indian patent [IN'581] and the availability of its products in India.*

14. *The Defendant has been involved in multiple litigations before this Hon'ble Court wherein it has submitted to the jurisdiction of this Hon'ble Court and where this Hon'ble Court has found it to be guilty of similar infringing activities. A brief list of the suits filed against the Defendant have been listed hereinbelow:*

i. AstraZeneca v. West Coast Pharma, CS (COMM) 155/2020- Dapagliflozin-restrained on 3 June 2020, settled the dispute [Doc 10]

ii. Pfizer v. West-Coast, CS (COMM) 94/2022- compounds Pablociclib and Crizotinib– interim injunction granted. Similar affidavit filed [Doc 11], Order [Doc 12 colly.]

iii. Dr. Reddy's Laboratories v. West-Coast Pharmaceuticals, CS (COMM) 242/2021 – The Defendant adopted a trademark OMES, which was identical to the Plaintiff therein's trademark OMEZ for same drug. costs of INR 11,000 granted [Doc 13]

xxx xxx xxx”

21. It is to be noted that the plaintiffs have been compelled to incur significant legal expenses due to the defendant's infringing activities, and their subsequent conduct in these proceedings. The statement of costs has been duly filed by the plaintiffs, as per which, the plaintiffs have incurred costs of ₹ 7,19,014/-.

22. On the aspect of costs, holding that costs should be awarded, which ought to be realistic and should serve the purpose of curbing vexatious



litigation, Supreme Court, in the case of *Uflex Limited Versus Government of Tamil Nadu and Ors.*, (2022) 1 SCC 165, has held as follows:-

“xxx xxx xxx

55. We may note that the common thread running through all these three cases is the reiteration of salutary principles : (i) costs should ordinarily follow the event; (ii) realistic costs ought to be awarded keeping in view the ever-increasing litigation expenses; and (iii) the costs should serve the purpose of curbing frivolous and vexatious litigation. [Report No. 240 of the Law Commission of India.]

56. We may note that this endeavour in India is not unique to our country and in a way adopts the principle prevalent in England of costs following the event. The position may be somewhat different in the United States but then there are different principles applicable where champerty is prevalent. No doubt in most of the countries like India the discretion is with the court. There has to be a proportionality to the costs and if they are unreasonable, the doubt would be resolved in favour of the paying party [UK Civil Procedure Rule 44.2.]. As per Halsbury's Laws of England, the discretion to award costs must be exercised judicially and in accordance with reason and justice. [Vol.10, 4th Edn. (Para 15)]. The following principles have been set out therein:

“In deciding what order (if any) to make about costs, the court must have regard to all the circumstances, including:

(i) The conduct of all the parties;

(ii) Whether a party has succeeded on part of his case, even if he has not been wholly successful; and

(iii) Any payment into court or admissible offer to settle made by a party which is drawn to the court's attention.

The conduct of the parties includes:

(a) Conduct before, as well as during, the proceedings and in particular the extent to which the parties followed any relevant pre-action protocol;

(b) Whether it was reasonable for a party to raise, pursue or contest a particular allegation or issue;



(c) The manner in which a party has pursued or defended his case or a particular allegation or issue; and

(d) Whether a claimant who has succeeded in his claim, in whole or in part, exaggerated his claim.” [0th Vol. 4th Edn. (Para 17).]

xxx xxx xxx”

(Emphasis Supplied)

23. Accordingly, the plaintiffs are entitled to costs in their favour.
24. Considering the aforesaid detailed discussion, the following directions are issued:-
 - I. The suit is decreed in favour of the plaintiffs and against the defendant in terms of Para 67(a) of the plaint.
 - II. The plaintiffs are entitled to cost of ₹ 7,00,000/-, to be paid within a period of six weeks, by the defendant to the plaintiffs, through the plaintiffs’ counsel.
25. Decree sheet be drawn up.
26. Learned counsel appearing for the plaintiffs shall be at liberty to remit the Costs to their clients based out of the country, in accordance with law.
27. The suit, along with the pending application, stands disposed of.

MINI PUSHKARNA, J

NOVEMBER 12, 2024

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