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

\+ CS(COMM) 159/2024 & I.As. 4196/2024, 4198/2024, 5827/2024

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

Through: Mr. Mukul Rohatgi and Mr. Sandeep Sethi, Senior Advocates with Mr. Pravin Anand, Ms. Archana Shanker, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Devinder Rawat, Mr. Achyut Tewari, Mr. N. Mahabir and Ms. Riya Kumar, Advocates.

versus

ZYDUS LIFESCIENCES LIMITED ..... Defendant

Through: Mr. C.S. Vaidyanathan and Mr. Rajshekhar Rao, Senior Advocates with Ms. Bitika Sharma, Mr. P.S. Manjunathan, Ms. Sandhya Kukreti, Ms. Ahana Singh, Ms. Vanshika, Mr. Yogesh Khullar, Mr. Vinayaka Goel, Mr. Shivam and Ms. Karnika S. Pasayat., Advocates.

CORAM:
HON'BLE MR. JUSTICE SANJEEV NARULA

O R D E R

% 09.07.2024

I.A. ……../2024 *(to be numbered) (under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 seeking an interim injunction)*

1. The matter was last heard by this Bench on 13th May, 2024. Since then, the roster has changed. The matter has been taken up today at 04:43 PM on a mentioning made by Mr. Mukul Rohatgi and Mr. Sandeep Sethi, Senior Counsel representing the Plaintiffs, who have presented a copy of the

instant application, pressing for urgent interim reliefs against the Defendant. The afore-noted application has also been filed electronically through diary No. 2087607/2024, after advance service on the counsel for Defendant. Accordingly, the Registry is directed to allocate a number to the instant application.

2. Considering the fact that substantial arguments on the interlocutory application under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure, 1908 are yet to heard and the position of the board of the current roster, it is not feasible to retain the matter as part-heard. Consequently, the Court is inclined to release this matter from the category of part-heard. However, before proceeding, a significant concern raised by the Senior Counsel for the Plaintiffs must be addressed. It has come to the Court's attention that, amidst the ongoing deliberations on the grant of an interim injunction [in I.A. 4196/2024], the Defendant has launched a product named "Sigrima," a biologic similar to Plaintiffs' "Perjeta®," which comprises of "Pertuzumab." Further, it is pointed out that Defendant has entered into a commercial licensing arrangement with Dr. Reddy's Laboratories, a third party, for co-marketing their "Sigrima" product in India. In such circumstances, through the instant application under Order XXXIX Rules 1 and 2, the Plaintiffs seek injunctive reliefs against the sale and distribution of the said product, which purportedly infringes the claims of Plaintiffs' patents numbered IN 268632 and IN 464646.

3. Senior Counsel for the Plaintiffs emphasize that during the hearings on I.A. 4196/2024 conducted on 23rd February, 04th April, 24th April, and 13th May 2024, concerns were repeatedly voiced regarding the potential launch of the impugned product by the Defendant. It was stressed that

according to the Plaintiffs' information, the biosimilar in question was still pending regulatory approval, and there was a lack of transparency about the processes employed by the Defendant in manufacturing their biologic, as well as the status of their application for regulatory approvals. Given these uncertainties, the Senior Counsel had explicitly requested the Court to direct the Defendant not to launch their product in the market. Despite this, the Defendant's counsel indicated that there was no pressing urgency, asserting that the approval process was likely to take more time. Mr. Sethi argues that the Defendant should have kept the Court informed of the expected timelines for obtaining regulatory approvals. Their failure to do so and the subsequent launch of the product amount to overreaching the court process. Had complete and accurate timelines been disclosed to the Court, it would have allowed the Court to schedule the hearings more effectively, and issue timely and appropriate orders.

4. Indeed, during the hearings, in response to the Plaintiffs' expressed apprehensions, the Court had specifically inquired from Mr. C.S. Vaidyanathan, Senior Counsel representing the Defendant, about the status of their application for drug approvals. At that time, Mr. Vaidyanathan assured the Court that the regulatory authority was expected to take at least three months before making a final decision. Contrarily, today, Mr. Vaidyanathan has presented a different stance, stating that the Defendant never specified a timeframe. According to him, the Defendant had merely indicated that the regulatory approval would take 'some time.' He seeks time to file a response to the present application.

5. Be that as it may, the present suit was filed by the Defendant as a *quia timet* action, seeking to restrain the apprehended release of a similar biologic

by the Defendant, which they perceive as infringing their afore-noted patents. During the course of submissions on 23rd February, 2024, the Senior Counsel representing the Defendant had confirmed that they had applied for a drug license for their formulation. Despite specific inquiries in subsequent hearings, the Court was not informed that regulatory approval was imminent. It has now come to light, through this application, that the Defendant received approval from the Central Drug Standard Control Organisation,[1] Ministry of Health and Family Welfare on 04th April, 2024. Pertinently, in the hearings conducted after this approval – on 24th April, 2024 and 13th May, 2024 – the Defendant chose not to disclose this significant development to the Court.

6. Today, after the Plaintiffs have brought these facts to the Court's notice, Mr. Vaidyanathan clarifies that the approval from CDSCO was only a conditional approval. The permission to market the drug in question was only obtained on 27th June, 2024 from the National Institute of Biologicals.

7. Regardless of the above circumstances, given that this matter was actively under consideration by the Court, it was reasonable to expect that the Defendant would provide timely updates about significant developments. Specifically, when the Court explicitly inquired about the timeframe for regulatory approvals during the hearings, the Defendant had a duty to disclose any pertinent information regarding the launch of the impugned product. Such transparency is crucial in legal proceedings, particularly in a *quia timet* case of this significance, where timely and accurate information could potentially influence the Court's decisions and the Plaintiff's responses.

[1] "CDSCO."

8. The principles of fairness in procedural conduct, especially in commercial disputes is crucial. In this case, the Defendant's failure to transparently communicate significant regulatory developments during the Court's deliberations raises serious concerns about fairness. This lack of disclosure directly impacts the equitable treatment of the parties involved, as it deprived the Plaintiff and the Court of critical information that could influence the Court's directions. Moreover, the principle of equity must also be weighed in. Equity demands that no party gains an undue advantage by withholding information or acting in a manner that could be construed as contrary to the spirit of fair legal proceedings. Here, the Defendant's recent undisclosed approval and subsequent commercial launch, bolstered by their business venture with Dr. Reddy's Laboratories, of the impugned product on 27th and 28th June, 2024 exemplifies a potential to undermine the equitable handling of the case. The Court is thus inclined to restrain the Defendant from marketing their product "Sigrima" whilst a decision is rendered on the interlocutory application.

9. The balance of convenience in favour of the Plaintiffs further supports the Court's inclination to grant an injunction. The timing of the product's launch suggests a strategic move by the Defendant to establish a market presence before any potential judicial restrictions could be imposed. Allowing the Defendant to continue the sale and distribution of the impugned product could alter the market situation, which would significantly disadvantage the Plaintiffs, especially if the product is later found to infringe upon the Plaintiffs' patents. An injunction serves as a preventive measure to avoid the market from being flooded with the infringing product, thus protecting the Plaintiffs' interests while the

substantive issues are conclusively resolved. Therefore, the balance of convenience suggests that the potential harm to the Plaintiffs from denying the injunction far outweighs any inconvenience to the Defendant, who will merely be delayed from benefiting from a product whose legality is yet to be fully adjudicated.

10. In light of these considerations – fairness, equity, and the balance of convenience – the Court finds compelling reasons to issue an injunction. Accordingly, till the next date of hearing, the Defendants are restrained from marketing / selling their product "Sigrima", which is a biological similar of Plaintiffs' "Perjeta ®"/ "Pertuzumab."

11. Issue notice. Ms. Bitika Sharma, counsel for Defendant, accepts notice.

12. Reply to the application, if any, be filed within two weeks from today. Rejoinder thereto, if any, be filed within one week from today.

13. List before Roster Bench for further consideration on 18th July, 2024.

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14. As observed above, considering the position of the current board and that substantial hearing is required for rendering a decision on the injunction application, which would entail hearings spanning several dates, the Court is not in a position to retain the matter and accordingly, the same is released from the category of part heard.

15. List before the Roster Bench on 18th July, 2024.

SANJEEV NARULA, J

JULY 9, 2024/*nk*