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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**
+ **CS(COMM) 376/2024, & I.A. 10537/2024**

E. R. SQUIBB AND SONS, LLC & ORS. Plaintiffs

Through: Mr. Mukul Rohatgi, Sr. Advocate with
Mr. Pravin Anand, Ms. Archana
Shankar, Ms. Preeti Agarwal, Ms. Nidhi
Bajaj, Advocates.

versus

ZYDUS LIFESCIENCES LIMITED Defendant

Through: Mr. C.S. Vaidyanathan, Sr. Counsle
with Mr. Rajiv Naiyar, Mr. Adarsh
Ramanujan, Ms. Bitika Sharma, Ms.
Vrinda Pathak and Ms. Shandhya
Kukreti, Advocates.

CORAM:
HON'BLE MR. JUSTICE ANISH DAYAL

% **ORDER**
08.05.2024

I.A. 10537/2024 (Seeking leave to file Additional Documents)

1. The present application has been filed on behalf of the plaintiff under Order 11 Rule 1(4) of the Code of Civil Procedure, 1908 (“CPC”) as applicable to commercial suits under the Commercial Courts Act, 2015 seeking to place on record additional documents.
2. Plaintiff, if it wishes to file additional documents at a later stage, shall do so strictly as per the provisions of the Commercial Courts Act, 2015 and the Delhi High Court (Original Side) Rules, 2018.



3. Accordingly, the present application is disposed of.

I.A. 10534/2024 (Exemption from pre-institution mediation)

1. Having regard to the facts of the present case and in light of the judgement of Division Bench of this Court in ***Chandra Kishore Chaurasia v. R.A. Perfumery Works Private Ltd.***, FAO (COMM) 128/2021, exemption from attempting pre institution mediation is allowed.
2. Accordingly, the application stands disposed of.

I.A. 10535 /2024 (Exemption from filing certified, typed copies of documents annexures etc)

1. Exemption is granted, subject to all just exceptions.
2. Applicant shall file legible, clear, and original copies of the documents on which the applicant may seek to place reliance before the next date of hearing.
3. Accordingly, the present application is disposed of.

CS (COMM) 376/2024

1. Let the plaint be registered as a suit.
2. Upon filing of process fee, issue summons to defendant by all permissible modes. Summons shall state that written statement be filed by defendant within 30 days from the date of receipt of summons. Along with the written statements, defendant shall also file affidavit of admission/denial of the plaintiffs' documents, without which the written statement shall not be taken on record. Liberty is given to plaintiffs to file a replication within 30 days of the receipt of the written statements. Along with the replication, if any, filed by the plaintiffs, affidavits of admission/denial of documents filed by the



defendant, be filed by the plaintiffs, without which the replication 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.

3. List before Joint Registrar for marking of exhibits on 12th August, 2024.
4. It is made clear that any party unjustifiably denying documents would be liable to be burdened with costs.

I.A. 10533/2024 (Application under Order XXXIX Rules 1 & 2 of CPC)

1. This application has been filed under Order XXXIX Rules 1 & 2 of CPC as part of the accompanying suit filed by plaintiff for permanent injunction restraining the infringement of Indian Patent No. 340060, and other attendant relief.
2. Plaintiff is the patent holder for the suit patent which was granted to them in 2020, date of application being 02nd May, 2006 for International filing, and 09th November, 2007 for National Phase application.
3. The three dates of priority claimed for the suit patent are 09th May 2005, 21st November, 2005 and 08th December, 2005.
4. Mr. Mukul Rohatgi, Senior Counsel for plaintiff, submits that the patent was granted after four pre-grant oppositions, which were dismissed, and one post grant opposition, which was filed by the subsidiary of defendant no.1, and is still pending.
5. Mr. Rohatgi submits that the pharmaceutical product is 'NIVOLUMAB' and the drug is marketed in India under the brand name 'OPDYTA', internationally under the name 'OPDIVO'.
6. The patent expires on 02nd May, 2026 and therefore they only have a couple of years to benefit from the suit patent



7. The grievance is against the defendant, who are seeking to process a biosimilar version of plaintiff's drug, and sought a license to manufacture it in India, for the purposes of conducting clinical trials, for which they received permission.

8. The reference drug stated by the defendants for the purpose of the clinical trial was the plaintiff's drug. This fact is not denied by Senior Counsel for defendant.

9. Plaintiff's concern is that the defendant should not be launching their product in the market in these circumstances, since it would amount to infringement of the suit patent.

10. Mr. C.S. Vaidyanathan, Senior Counsel for defendant, submits that he has a preliminary objection on the maintainability of the suit considering that the Hon'ble High Court of Madras in W.P. No. 8451 of 2023 *vide* judgment dated 15th March, 2024, set aside the Opposition Board Recommendation (OBR), against which an appeal has been filed.

11. Mr. C.S. Vaidyanathan, submits that he is challenging the validity of the patent and their proposed drug does not infringe the suit patent. He further states that they have applied for a license to manufacture their drug in April, 2024 to the Subject Expert Committee (SEC) and don't expect it to be granted till August, 2024.

12. In these circumstances, counsel for defendant accepts notice and will file a response within the next six weeks, with copies to the opposing side.

13. In the meantime, till the next date of hearing, defendant shall not place its products in the market without the prior permission of the Court.

14. It is made clear that nothing stated in this order shall be considered as an observation on the merits of the matter, and the issue will be considered on the



basis of party's pleadings on the next date of hearing.

15. List on 25th July, 2024.

16. Order be uploaded on the website of this Court.

ANISH DAYAL, J

MAY 8, 2024/RK/rj