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

+ **CS(COMM) 347/2024**

HELSINN HEALTHCARE SA & ANR. Plaintiffs

Through: Mr. Sudhir Chandra Aggarwal, Sr.
Adv. with Mr. Pravin Anand, Mr.
Dhruv Anand, Ms. Nimrat Singh, Mr.
Dhananjay Khanna, Ms. Udit Patra
& Mr. Sampurna Sanyal, Advs.

versus

HETERO HEALTHCARE LIMITED Defendant

Through: Mr. Ajay Sahni, Mr. Ankit Sahni &
Mr. Chirag Ahluwalia, Advs.

**CORAM:
HON'BLE MR. JUSTICE ANISH DAYAL**

**ORDER
30.04.2024**

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I.A. 9525/2024 (Exemption from filing certified, clear copies of documents)

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.

I.A. No.9524/2024 (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. The 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 DHC (Original Side) Rules, 2018.
3. Accordingly, the present application is disposed of.

I.A. No.9523/2024 (Order XI Rule 1, 3 & 5 of the CPC)

1. This application has been filed on behalf of plaintiffs seeking discovery, production and inspection of defendant's documents.
2. Issue notice. Notice accepted by the counsel for defendant. Reply, if any, be filed within three weeks with advance copy to the counsel for plaintiffs, who may file rejoinder thereto, if so desired, before the next date of hearing.

I.A. No.9527/2024 (exemption from instituting pre-litigation 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. No.9526/2024 (seeking extension of time for filing court fee)

1. This application has been filed by plaintiffs seeking extension of time for filing court fee.
2. Counsel for plaintiffs undertakes to file court fee within a period of one week from today.
3. Accordingly, this application stands disposed of.



CS(COMM) 347/2024

1. Let the plaint be registered as a suit.
2. Upon filing of process fee, issue summons to the defendant by all permissible modes. Summons shall state that the written statement be filed by the defendant within 30 days from the date of receipt of summons. Along with the written statements, the defendant shall also file affidavit of admission/denial of 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 statement. Along with the replication, if any, filed by the plaintiffs, affidavits of admission/denial of documents filed by the defendant, be filed by 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 the Joint Registrar for marking of exhibits on 2nd August 2024.
4. It is made clear that any party unjustifiably denying documents would be liable to be burdened with costs.

I.A. 9522/2024 (under Order XXXIX Rule 1 & 2 CPC)

1. This application under Order XXXIX Rules 1 and 2 CPC, seeking *ex parte ad interim* injunction is part of the accompanying suit seeking a decree of permanent injunction restraining defendant from infringement of plaintiffs' right in suit patent No.426553 (hereinafter referred to as "**suit patent**") and restraining them from manufacturing, selling, promoting or dealing with defendant's products under the brand name 'NETUPIN'.
2. Plaintiff no.1 is a Swiss pharmaceutical group, while plaintiff no. 2 is



an Indian incorporated company, being the exclusive licensee of plaintiff no.1. The suit patent was granted in “*Compositions and methods for treating Centrally Mediated Nausea and Vomiting*”, with the following details:

- a) *Indian Patent No.:* 426553
- b) *Title:* COMPOSITIONS AND METHODS FOR TREATING CENTRALLY MEDIATED NAUSEA AND VOMITING
- c) *Patentee:* Helsinn Healthcare SA (Plaintiff No. 1)
- d) *Indian Application No.:* 1009/MUMNP/2012
- e) *Priority dates:* 18th November, 2009 and 14th September, 2010
- f) *International filing date:* 18th November, 2010
- g) *International Application No.:* PCT/IB2010/003106
- h) *India filing date:* 20th April, 2012
- i) *Date of publication u/s 11A:* 31st August, 2012
- j) *Date of grant:* 23rd March, 2023
- k) *No. of claims:* 6
- l) *Claims being asserted:* All claims

3. The suit patent is valid and will expire on 18th November 2030.

4. Pre-grant oppositions had been filed against the suit patent by two pharmaceutical companies viz., ‘*Panacea Biotech*’ and ‘*Zydus Healthcare Limited*’. Both these pre-grant oppositions were rejected by the Assistant Controller of Patents and Designs (hereinafter referred to as “**Assistant Controller**”) and vide order dated 23rd March 2023, the suit patent was



granted.

5. Mr. Sudhir Chandra Aggarwal, Senior Counsel for plaintiff has drawn attention to the said detailed 80-page order of 23rd March 2023, passed by the Assistant Controller, dealing with both pre-grant and post grant oppositions.

6. Plaintiff sells the said products under the brand 'AKYNZEO'/'



since April 2018. The suit patent concerns an oral dosage form comprising of 'Netupitant' (200 to 400 mg, in particular 300 mg) and 'Palonosetron hydrochloride' (0.56 mg), for treating nausea and vomiting induced by chemotherapy. The claimed combination/formulation provides unexpected synergy and enhanced efficacy.

7. Senior Counsel has pointed out to the principal claims of the application in which the suit patent was granted:



Claim 1: An orally administered dosage form comprising:

- a combination of palonosetron and netupitant or a pharmaceutically acceptable salt thereof;
- comprising 0.56 mg of palonosetron hydrochloride and
- from 200 to 400 mg of netupitant or a pharmaceutically acceptable salt thereof.

Claim 2: The dosage form as claimed in claim 1, comprising 300 mg of netupitant or a pharmaceutically acceptable salt thereof.

Claim 3: The orally administered dosage form claimed in claim 1, wherein said netupitant comprises 300 mg of netupitant as free base and said palonosetron comprises 0.56 of palonosetron hydrochloride, corresponding to 0.5 mg of palonosetron as a free base.

8. Grievance is against defendant which is an Indian incorporated company having its registered office in Hyderabad in Telangana and also carries on business in Delhi. Plaintiffs became aware sometime in mid-April 2024, that defendant was promoting a soon to be launched product 'NETUPIN'. Plaintiffs even obtained a pamphlet from their market-sources, which defendant was using to promote their product. The promotional pamphlet as obtained by plaintiff is reproduced hereunder:



9. It is contended by plaintiffs' counsel that it is obvious from the said pamphlet that defendant's proposed product 'NETUPIN' was a combination pack of 'Netupitant 300 mg' and 'Palonosetron 0.5 mg' and comprises of a pack of one single capsule for oral use- "1 x 1 Capsule". The Abbreviated Product Information ("ABPI") also mentions that the combination was being sold for the purposes of prevention of '*Chemotherapy-Induced Nausea and Vomiting*'. It is stated that neither did defendant file any pre-grant opposition of the suit patent nor did they "*clear the way*" by seeking a declaration for any other mechanism, before launching their product.

10. As per a market survey conducted by plaintiffs (which is detailed in para 37 of the plaint), the product of defendant has not yet been launched in various territories of the country.



11. Mr. Ajay Sahni, counsel appearing on behalf of defendant on advance notice, has however contended that the product is already being sold by defendant and has produced an invoice dated 27th April 2024, showing dispatch to distributor of the said product. Further, he has produced the packaging of the product, in which it is proposed to be launched, which shows that it is a combi-pack of 'Netupitant 300 mg' and 'Palonosetron 0.5 mg capsule' ('1 X 2 capsule') in the following manner:



12. He therefore states that since patent for 'Netupitant' had expired on 23rd February 2020, they are entitled to sell that separately from other compound 'Palonosetron' and considering that they are two separate capsules, there is no infringement of patent. He accordingly relies on pending writ petition filed by Zydus Healthcare Ltd. Before this Court, being *Zydus Healthcare Ltd. v Assistant Controller of Patents and Designs & Anr., WP (C)-IPD 23/2023*, in which notice has been issued by this Court, however, stay has not been granted.

13. This Court has considered facts and circumstances of the case and opines that *prima facie* defendant's product is nothing but an integrated combination of both 'Netupitant 300 mg' and 'Palonosetron 0.5 mg' which is the subject matter of the suit patent and despite it being provided as twin-capsules, it is packaged as an integrated pack to be taken together. Separating the two compounds but packaged in an integrated manner and sold as a comb-



pack, does not make the defence of the defendant tenable, at least *prima facie*. Invoices shown by the defendant are dated 27th April 2024, only two days back, and there is no substantive proof to show that defendant had been selling the same for a reasonable / substantial time.

14. In this view of the matter, in the opinion of this Court, plaintiffs have made out a *prima facie* case for grant of an *ad interim* injunction till the next date of hearing. Balance of convenience lies in favour of plaintiffs, and plaintiffs are likely to suffer irreparable harm in case the injunction, as prayed for, is not granted and defendant's product is allowed to be disseminated in the market.

15. Accordingly, till the next date of hearing, an *ad interim* injunction is passed restraining defendant and all those acting for or on their behalf from selling, distributing or promoting, directly or indirectly in any manner, defendant's product 'NETUPIN' or any other medicinal or pharmaceutical product which infringes plaintiff's suit patent.

16. Issue notice. Notice accepted by the counsel for defendant. Reply, if any, be filed within three weeks with advance copy to the counsel for plaintiffs, who may file rejoinder thereto, if so desired, before the next date of hearing.

17. Compliance with Order XXXIX Rule 3, CPC be effected within a week's time.

18. List on 12th July 2024.

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

ANISH DAYAL, J

APRIL 30, 2024/sm/na

[Click here to check corrigendum, if any](#)