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

\# **CNR No. DLHC010546852026**

\+ CS(COMM) 1219/2026 I.A. 31247-31255/2026

HELSINN HEALTHCARE SA & ANR. ....Petitioners

Through: Mr. Amit Sibal, Sr. Adv. with Mr. Pravin Anand, Mr. Dhruv Anand, Mr. Dhananjay Khanna, Ms. Bhavya Verma, Mr. Saksham Dhingra, Ms. Smriti Nair and Ms. Sudit Batra, Advs.

versus

INTAS PHARMACEUTICAL LIMITED .....Respondent

Through: Mr. Sandeep Sethi, Ms. Vrinda Pathak, Mr. Rajnish Kumar, Mr. Ritwik Sharma, Ms. Shreya Sethi and Mr. Krishna Gambhir, Advs.

CORAM:
HON'BLE MS. JUSTICE MANMEET PRITAM SINGH ARORA

O R D E R

% 10.11.2026

I.A. 31248/2026

1. This is an application filed by the Plaintiffs under Order XI Rule 1, 3 and 5 of the Code of Civil Procedure, 1908 [‘CPC’] seeking discovery, production and inspection of Defendant’s documents.

2. Issue Notice.

3. Notice accepted by the counsel for the Defendant. Reply be filed within four (4) weeks with an advance copy to the counsel for the Plaintiffs,

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who may file rejoinder thereto, if so desired, within four (4) weeks from service of reply.

I.A. 31249/2026

4. This is an application filed by the Plaintiffs under Order 11 Rule 1(4) CPC seeking leave to file additional documents.

5. Mr. Anand seeks leave to withdraw this application. The application is disposed of as withdrawn.

I.A. 31250/2026

6. This is application filed by the Plaintiffs under Section 149 CPC seeking extension of time for filing Court Fees.

7. Subject to Plaintiffs filing the Court Fees on or before 20.11.2026, the application is allowed. In case, the Plaintiffs fail to deposit the Court Fees within the time granted hereinabove, the plaint will be liable to be rejected as per Order VII Rule 11(b), CPC.

8. With the aforesaid directions, the application stands disposed of.

I.A. 31251/2026

9. This is an application filed under Section 12A of the Commercial Courts Act, 2015 read with Section 151 CPC seeking exemption from institution of pre-litigation mediation.

10. Having regard to the facts that the present suit contemplates urgent interim relief, on the assertion that the Defendant is infringing the suit patent

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and is likely to launch its impugned product imminently in the market, this Court is of the considered opinion that in light of the judgment of the Supreme Court in **Yamini Manohar v. T.K.D. Keerthi**[1] and **Novenco Building and Industry A/S v. Xero Energy Engineering Solutions Private Ltd.**[2], exemption from the requirement of pre-litigation mediation is granted to the Plaintiffs.

11. Accordingly, the application stands allowed.

I.A. 31252/2026

12. This is an application filed under Section 151 CPC seeking time for filing the required certificate under Section 63(4)(c) of the Bharatiya Sakshya Adhiniyam, 2023 ['BSA'].

13. Subject to the Plaintiffs filing certificate under Section 63(4)(c) of the BSA within four (4) weeks, the time for filing the said affidavit is extended, failing which the said documents will not be admissible and not taken on record.

14. With the aforesaid directions, the application stands disposed of.

I.A. 31253/2026

15. This is an application filed under Section 151 CPC for exemption from filing duly executed Power of Attorney ['PoA'] in favour of Mr. Vikas Gaur from Plaintiff No. 1.

[1] (2024) 5 SCC 815
[2] 2025 SCC OnLine SC 2278

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16. For the reasons recorded in the application, time for placing on record the duly executed PoA is hereby extended by a period of four (4) weeks, failing which the suit will deemed to have not been properly instituted on behalf of Plaintiff No. 1.

17. With the aforesaid directions, the application stands disposed of.

I.A. 31254/2026

18. This is an application filed under Order XXVI Rules 4, 9 and 10 of CPC seeking appointment of Local Commissioner.

19. Mr. Anand seeks leave to withdraw this application. The application is disposed of as withdrawn.

I.A. 31255/2026

20. This is an application filed under Section 151 CPC seeking exemption from advance service to the defendants.

21. The Defendant has been served with the advance copy of the suit paper-book and is represented at the hearing today.

22. Thus, the application is disposed of as infructuous.

I.A. 31247/2026

23. This application under Order XXXIX Rules 1 and 2 read with Section 151 of the CPC, has been filed by the Plaintiffs seeking an ex-parte ad-interim injunction restraining the Defendant from infringing Indian Patent No. 426553 [‘suit patent’], including by manufacturing, selling, distributing,

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advertising, offering for sale or otherwise dealing in its product 'NO-CINV' ['impugned product'].

24. Case set-up by the Plaintiffs in the application is as under: -

24.1 Plaintiff No. 1 is a pharmaceutical group incorporated in Switzerland and is the proprietor of the suit patent, whereas Plaintiff No. 2 is an Indian company and the exclusive licensee thereof. The suit patent, titled 'COMPOSITIONS AND METHODS FOR TREATING CENTRALLY MEDIATED NAUSEA AND VOMITING', was granted on 23.03.2023 and is stated to be valid and subsisting until 18.11.2030.

24.2 The suit patent relates to an orally administered dosage form comprising Netupitant, in the range of 200 to 400 mg, and Palonosetron hydrochloride 0.56 mg, equivalent to 0.5 mg of Palonosetron free base, for the treatment of Chemotherapy-Induced Nausea and Vomiting ['CINV']. The Plaintiffs contend that the patented combination provides enhanced efficacy in treating both acute and delayed phases of CINV. The Plaintiffs commercialised the patented formulation under the brand name 'AKYNZEO', which was launched in India in May 2018.

24.3 The grievance of the Plaintiffs is that on 7.11.2026, they learnt through a market surveyor that the Defendant was preparing to launch a generic product under the brand name 'NO-CINV'. The Plaintiffs thereafter obtained photographs of the Defendant's product, which, according to them, reveals that it is a combipack comprising two tablets, namely, one film-coated tablet of Netupitant 300 mg and one uncoated tablet of Palonosetron 0.5 mg. The packaging describes the product as a 'COMBIPACK' and

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mentions '1 + 1 Tabs'. The product is also stated to be intended for the prevention of CINV.

24.4 The Plaintiffs contend that the Defendant's product falls within the scope of Claims 1 to 4 of the suit patent, as it comprises the same active ingredients in the claimed dosage strengths and is intended to be administered orally for the same therapeutic purpose. The Plaintiffs further state that upon becoming aware of the Defendant's proposed launch, they issued a cease-and-desist notice dated 07.11.2026, calling upon the Defendant to furnish an undertaking not to infringe the suit patent. However, no response to the said notice has been received.

25. Mr. Sandeep Sethi, learned senior counsel appearing on behalf of the Defendant, submits that the Defendant has already launched the impugned product countrywide on 07.11.2026.

25.1 He states that, at this short notice, the Defendant has been able to provide the instructing counsel with two invoices evidencing dispatches to a single entity in Patna and one invoice evidencing dispatch to an entity in Meerut. The sum total of the invoices is Rs. 14 lakhs approximately. He submits that the Defendant seeks an opportunity to file its response to the present application before the prayer for ad-interim injunction is considered. In this regard, he relies upon the order dated 06.09.2023 passed by the Coordinate Bench in **HELSINN HEALTHCARE SA & ANR. v. ZYDUS HEALTHCARE LIMITED & ANR.**[3] ('ZYDUS'), wherein an opportunity was granted to the defendant therein to file a reply before consideration of

[3] CS (COMM) 629/2023, order dated 06.09.2023

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the prayer for ad-interim or interim relief. He submits that the product of the said defendant i.e. ZYDUS is still available in the market.

25.2 He also relies upon the judgment dated 26.09.2025 passed by the Coordinate Bench in **HELSINN HEALTHCARE SA v. AET LABORATORIES P. LTD.**[4] ('AET') dismissing the injunction application.

25.3 He submits that the ad-interim injunction order dated 30.04.2024 passed by the Coordinate Bench in **HELSINN HEALTHCARE SA & ANR. v. HETERO HEALTHCARE LIMITED**[5] ('HETERO'), relied upon by the Plaintiffs, only expresses a prima facie view and cannot be treated as a precedent for grant of an ad-interim injunction in this suit.

25.4 He submits that the Defendant's product comprises Netupitant 300 mg and Palonosetron 0.5 mg, which are being sold as two separate tablets in a combipack. He contends that the patent covering Netupitant expired on 23.02.2020, similarly the patent covering Palonosetron has also expired. He states that thus both the constituent substances Netupitant and Palonosetron are known substances. He states that merely combining two known substances cannot be construed as invention, and the suit patent is, therefore, vulnerable to challenge on the ground of lack of novelty.

25.5 He, however, fairly admits that the Defendant has not instituted any legal proceedings challenging the validity of the suit patent.

26. In response, learned counsel appearing on behalf of the Plaintiffs, submits that the order dated 06.09.2023 in **ZYDUS** (supra) is

[4] CS (COMM) 1188/2024

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distinguishable on facts. He submits that, at the relevant time, the writ petition, being W.P.(C)-IPD 23/2023, filed by Zydus Healthcare Limited challenging the order of the Controller rejecting its pre-grant opposition was pending consideration before this Court, which was a relevant circumstance taken into account by the Coordinate Bench. He submits that the said writ petition has since been dismissed by this Court vide judgment dated 24.12.2025. He further points out that although an appeal against the said judgment, being LPA No. 44/2026, is pending, no order staying the operation of the grant of the suit patent has been passed by the Division Bench.

26.1 He states that similarly, the products of **AET** are not available in the Indian market. He states that the injunction application in **AET laboratories P. Ltd.** (supra) was dismissed on a prima facie view with respect to lack of territorial jurisdiction of this Court and not on merits.

27. This Court has heard the learned senior counsel for the parties and perused the record.

28. At this stage, the Court is concerned with the limited question of whether an ad-interim injunction ought to be granted so as to preserve the subject matter of this application and not permit a situation, where the ground reality changes irreversibly pending the hearing of grant or denial of an ad-interim injunction.

29. The Plaintiffs have approached this Court on 09.11.2026, within two days of acquiring knowledge of the Defendant's proposed launch of the

[5] CS(COMM) 347/2024

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impugned product on 07.11.2026. The Plaintiffs have also placed on record the cease-and-desist notice dated 07.11.2026, which, admittedly, has not received any response from the Defendant. The Plaintiffs have therefore acted with alacrity and approached the Court at the earliest without any delay.

30. The Defendant's contend that they have launched the product on 07.11.2026 and have handed across three invoices for an approximate value of Rs. 14 lakhs sold to two entities. Perusal of the invoices show business to business sales (B2B). Scale of launch and sales completed prior to 10.11.2026 will be examined after supporting documents are filed with the reply.

31. The Defendant's product, as is evident from the photographs placed on record, comprises Netupitant 300 mg and Palonosetron 0.5 mg, packaged together as a combipack containing two separate tablets intended for oral administration. The infringement of the Claims 1 to 4 of the suit patent is thus prima facie evident and is not contested by the Defendant during arguments. In this regard, the reasoning adopted by the Coordinate Bench in **Hetero Healthcare Limited** (supra), while granting an ad-interim injunction in respect of a combipack comprising Netupitant and Palonosetron, is relevant. The Coordinate Bench observed as under:

> "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

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but packaged in an integrated manner and sold as a combi-pack, does not make the defence of the defendant tenable, at least prima facie.

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."

Similarly, the Defendant's product, though comprising two separate tablets, is packaged as a single combipack containing the very combination of Netupitant and Palonosetron, which forms the subject matter of the suit patent. The facts of this case a para-materia with the aforesaid order in **Hetero Healthcare Limited** (supra).

32. As regards the Defendant's plea that the suit patent is invalid on the ground of lack of novelty, before the tenability of this plea is evaluated at this ad-interim stage, it is relevant to note that the suit patent was granted on 23.03.2023, after two pre-grant oppositions filed by 'Panacea Biotech' and 'Zydus Healthcare Limited' were considered and rejected by the Assistant Controller of Patents and Designs. 'Zydus Healthcare Limited' thereafter challenged the said order before this Court by way of W.P.(C)-IPD 23/2023. The said writ petition was dismissed vide judgment dated 24.12.2025. It is, noted that the writ petition was dismissed on the ground of lack of territorial jurisdiction and the validity of the suit patent was not adjudicated on merits therein. Although LPA No. 44/2026 is stated to be pending, no order staying the operation of the grant of the suit patent has been brought to the notice of this Court.

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33. The aforesaid facts show that the application of the Plaintiffs' seeking grant of suit patent was widely known in the pharmaceutical industry and was contested by other pharma companies.

34. This Court cannot lose sight of the material fact that the Defendant itself is an established pharmaceutical company. The suit patent was granted on 23.03.2023 and it has full knowledge of the grant of the suit patent in favour of the Plaintiffs. Despite the availability of statutory remedies to challenge the validity of the suit patent on the plea of alleged lack of novelty, the Defendant has admittedly not instituted any legal proceedings challenging the said grant of patent. The Defendant has, therefore, proceeded to manufacture and launch the impugned product without first seeking to '*clear the way*' as contemplated in law (Re: **Merck Sharp and Dohme Corporation v. Glenmark Pharmaceuticals**[6] and **FMC Corporation & Ors. v. Natco Pharma Limited**[7]). This circumstance weighs heavily against the Defendant at this ad-interim stage, where the infringement is not in dispute and the defense plea is based on the challenge to the validity of the suit patent, which requires consideration and cannot be accepted on a demurer on this first date of listing. The Defendant itself is a party to several litigations *qua* infringement in the High Court and is therefore well-versed with legal process to be followed by a defendant for challenging validity of a granted patent.

35. In the considered opinion of this Court, the plea of the Defendant that the combination of two known substances lacks novelty and therefore the

[6] 2015 SCC OnLine Del 8227
[7] 2025 SCC OnLine Del 8582

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validity of suit patent is vulnerable to a credible challenge, would require a detailed examination of the complete specification, the claims of the suit patent as well as the orders passed by the Controller. This issue can be decided by the Court after the parties have exchanged their pleadings and the Defendant has placed its written objections and supporting material on record. The same cannot be determined at this initial stage on a demurer, particularly when the matter has been taken up today on an urgent basis during vacation. The Defendant has taken a calculated commercial risk in proceeding to manufacture the impugned product without first clearing the way and must therefore await adjudication of the merit of its defence plea.

36. The orders in the case of **ZYDUS** (supra) and **AET** (supra) have been rightly distinguished by the Plaintiff.

37. In view of the aforesaid facts and circumstances, this Court is of the *prima facie* opinion that the Plaintiffs have made out a case for grant of an ad-interim injunction.

38. The photographs of the Defendant's product placed on record further indicate that the product was manufactured in October 2026 and expiry date is of September 2028. Having regard to the limited nature of the ad-interim protection being granted until the next date of hearing, and the fact that the Defendant has only recently launched the product, no prejudice will be caused to the Defendant if the impugned product is restrained from being released in the market until the next date of hearing. The balance of convenience lies in favour of the Plaintiffs, and the Plaintiffs are likely to suffer irreparable harm in case the Defendant is permitted to continue

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dealing in the impugned product pending consideration of the present application until the next date of hearing.

39. Accordingly, till the next date of hearing, the Defendant, its directors, officers, employees, servants, agents, distributors, stockists and all others acting for or on its behalf are restrained from manufacturing, using, selling, offering for sale, distributing, advertising, exporting or otherwise dealing, directly or indirectly, in its product 'NO-CINV' or any other medicinal or pharmaceutical product which infringes the Plaintiffs' suit patent IN 426553.

40. Issue notice.

41. Learned Counsel appearing on behalf of the Defendant accepts notice.

42. Reply be filed on or before 17.11.2026. The Defendant along with his reply will place on record the invoices through which goods have been sold between 07.11.2026 and 10.11.2026 along with Airway bills proving dispatch and delivery. In addition, the Defendant will also file a detail of its existing stock as on 10.11.2026 along with batch numbers, date of manufacture and date of expiry. The pleading will be duly signed by a Director of the Defendant.

43. The time for filing reply has been fixed as 17.11.2026, in view of the grant of ad-interim injunction. In case, the Defendant wants additional time, it may seek such time from the Roster Bench.

44. The Plaintiffs will not seek any adjournment on 17.11.2026 and will remain ready to address arguments on the said date for continuation of the ad-interim injunction granted today.

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45. The observations herein, however, are only *prima facie* and shall not prejudice the Defendant's right to raise all permissible defences in response to the present application, which shall be adjudicated on the next date of hearing and at the time of deciding the present application.

46. List before the Roster Bench on 17.11.2026.

CS(COMM) 1219/2026

47. Let the plaint be registered as a suit.

48. The Defendant has entered appearance on advance service. Ms. Vrinda Pathak, accepts service of summons and waives formal service. She is directed to file her vakalatnama on or before 17.11.2026.

49. The Defendant will file its written statement within thirty (30) days. The Defendant shall also file affidavit of admission/denial of the documents filed by the Plaintiffs, failing which the written statement(s) shall not be taken on record.

50. The Plaintiffs are at liberty to file replication thereto within thirty (30) days after service of the written statement. The replication shall be accompanied by affidavit of admission/denial in respect of the documents filed by Defendant, failing which the replication shall not be taken on record.

51. It is made clear that any unjustified denial of documents may lead to an order of costs against the concerned party.

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52. Any party seeking inspection of documents may do so in accordance with the Delhi High Court (Original Side) Rules, 2018.

53. The next date of hearing before the learned Joint Registrar (J) for completion of pleadings, for marking of exhibits and for recording of admission/denial of documents will be fixed by the Roster Bench on the next date of hearing.

54. List before Roster Bench on 17.11.2026.

55. The digitally signed copy of this order, duly uploaded on the official website of the Delhi High Court, www.delhihighcourt.nic.in, shall be treated as a certified copy of the order for the purpose of ensuring compliance. No physical copy of order shall be insisted by any authority/entity or litigant.

MANMEET PRITAM SINGH ARORA, J

NOVEMBER 10, 2026/msh/AM

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