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

\+ CS(COMM) 306/2026

CHUGAI SEIYAKU KABUSHIKI KAISHA & ANR. .....Plaintiffs

Through: Mr. Pravin Anand, Mr. Shrawan Chopra, Mr. Achyut Tewar, Ms. Krisha Baweja, Mr. Parth Malhotra and Mr. N. Mahabir, Advocates.

versus

BASIL DRUGS AND PHARMACEUTICALS PRIVATE LIMITED .....Defendant

Through:

CORAM:
HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

O R D E R

% 24.03.2026

I.A. 7844/2026 (Additional Documents)

1. The present application has been filed on behalf of the plaintiffs under Order XI Rule 1(4) of the Code of Civil Procedure, 1908 (*'CPC'*) as applicable to commercial suits under the Commercial Courts Act, 2015 (*'CC Act'*) seeking leave to place on record additional documents.

2. The plaintiffs are permitted to file additional documents in accordance with the provisions of the CC Act and the Delhi High Court (Original Side) Rules, 2018.

3. Accordingly, the application stands disposed of.

I.A. 7845/2026 (Pre-Institution Mediation)

4. This is an application filed by the plaintiffs seeking exemption from instituting pre-institution mediation under Section 12A of the CC Act.

5. As the present matter contemplates urgent interim relief, in light of the judgment of the Supreme Court in ***Yamini Manohar vs. T.K.D. Keerthi: (2024) 5 SCC 815,*** exemption from the requirement of pre-institution

mediation is granted.

6. The application stands disposed of.

I.A. 7846/2026 (Exemption)

7. This is an application filed on behalf of the plaintiffs under Section 151 of CPC seeking exemption from filing clearer copies, redacted copies and certified copies of the documents.

8. Exemption is allowed, subject to just exceptions. The clear/typed/translated copies, redacted and certified copies of the documents with proper margins of the dim annexures be filed within four weeks with an advance copy to the defendant.

9. The application stands disposed of.

I.A. 7847/2026 (Direction to Defendant to disclose and produce document)

10. The present application has been filed on behalf of the plaintiffs under Order XI Rules 1 and 5 of CPC as amended by the CC Act, 2015 and Chapter IV, Rule 1(f) of the Delhi High Court (Original Side) Rules, 2018 read with Section 151 of CPC seeking a direction to the defendant to disclose and produce documents/information as listed in para 14 of the application, i.e., (i) market authorization received by the defendant for the generic Alectinib, or its salt soon, or any other product(s) that infringes the claims of the suit patent, if any; and/ or (ii) process of manufacturing of the defendant of generic Alectinib, or its salt soon, or any other product(s) that infringes the claims of the suit patent, if any.

11. Issue notice.

12. Let a reply be filed within four weeks from the date of service. Rejoinder thereto, if any, be filed within two weeks thereafter.

I.A. 7848/2026 (Leave to file unredacted affidavit of independent investigator in a sealed cover)

13. The present application has been filed on behalf of the plaintiffs under

Section 151 of CPC seeking leave to file the unredacted affidavit of the independent investigator in a sealed cover.

14. The plaintiffs are permitted to file the unredacted affidavit of the independent investigator in a sealed cover within four weeks from date.

15. The application stands disposed of.

I.A. 7843/2026 (Order XXXIX Rules 1 & 2, CPC)

16. Present application has been filed on behalf of the plaintiffs under Order XXXIX Rules 1 & 2 of CPC, 1908 seeking *ex-parte ad-interim* injunction against the defendant.

17. Plaintiff no.1 is a company headquartered in Japan and was established in the year 1925. It claims to be a leading innovator in the healthcare industry. The plaintiff no.2 was founded in the year 1986 and is a company organised and existing under the laws of Switzerland. Plaintiff no.2 claims to be a research focused healthcare group in the fields of pharmaceuticals and diagnostics and has been involved in the discovery, development, production and marketing of novel healthcare solutions for over the last 120 years.

18. The suit patent is titled "Tetracyclic Compound" (Patent No. IN 294424), and the said compound, salts or solvates thereof, according to the patent, are useful in the treatment of diseases including cancer such as lung cancer. Plaintiff no.1 is the patentee of the suit patent and plaintiff no.2 is the exclusive licensee by virtue of License Agreement dated 31.10.2012. The bibliographic details of the suit patent are as under:-

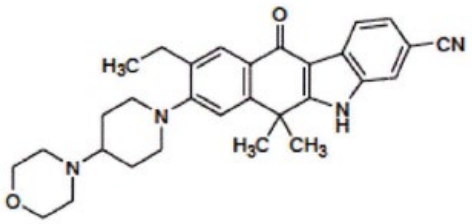
Indian Patent Number	294424
Patent Application Number	152/CHENP/2012
Applicant/Patentee	Plaintiff No. 1
Title	Tetracyclic Compound
National Phase entry-filing date of Indian Application	04.01.2012
International Application No.	PCT/JP2010/059785
International Filing Date (Date of Patent)	09.06.2010
Date of Priority	10.06.2009

WO Publication No.	WO2010/143664
International Publication date	16.12.2010
Publication Date (u/S 11A)	26.10.2012
Date of Grant	16.03.2018
Publication Date (u/S 43(2))	23.03.2018
Date of Expiry	09.06.2030
Pre-Grant Opposition	None
Post-Grant Opposition	20.02.2019
Post-Grant Opposition Decision	09.11.2020
Revocation	None

19. The suit patent is valid and subsisting and expires on 09.06.2030. A post-grant opposition was filed by one Dr. Reddy's Laboratories Limited challenging the grant of the suit patent, which was however, rejected. Thus, the suit patent has been granted after having undergone multiple levels of scrutiny including examination and a robust post-grant opposition proceeding which was rejected, thereby upholding the validity of the suit patent.

20. It is claimed that the suit patent specifically discloses and claims a novel and 2nd generation Anaplastic Lymphomas Kinase (ALK) – inhibitor compound, 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl) piperidin-1-yl]-11-oxo-6, 11-dihydro-5H-benzo [b]carbazole-3-carbonitrile, that is effective for prophylaxising or treating a disease accompanied by abnormality in ALK, such as non-small cell lung cancer (NSCLC). The suit patent is claimed to disclose and cover a compound having an International Non-proprietary Name (INN) being 'Alectinib' assigned by the World Health Organization (WHO) in the year 2013.

21. It is stated that Alectinib is a new chemical entity (NCE), with its chemical name as 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-l-yl]-11-oxo-6,11-dihydro-5H-ben zo[b] carbazole-3-carbonitrile. Alectinib is a kinase inhibitor for oral administration and has the molecular formula - C30H34N4O2. The chemical structure as mentioned in the WHO recommended INN List is reproduced hereunder:-



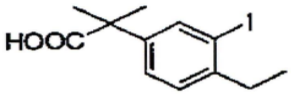
22. It is stated that Claim 1 of the suit patent specifically claims the compound Alectinib or its salt or solvate thereof whereas Claims 2 and 3 pertain to the intermediate compounds. Claims 4 and 5 of the suit patent are, *inter alia,* in respect of the free base and monohydrochloric acid salt, respectively of Alectinib. Claims 1 to 5 of the suit patent are reproduced hereunder:-

Claim 1:

1. A compound wherein the compound is 9-Ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile or salt or solvate thereof.

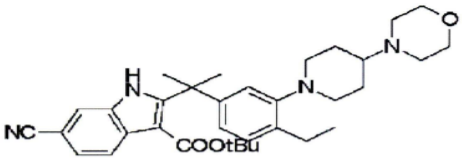
Claim 2:

2. An intermediate compound of the following Formula:



Claim 3:

3. An intermediate compound of the following Formula



Claim 4:

4. The compound as claimed in claim 1, wherein the compound is the free base of 9-Ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile.

Claim 5:

The compound as claimed in claim 1, wherein the compound is the monohydrochloric acid salt of 9-Ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile.

23. Plaintiff states that Alectinib is the Active Pharmaceutical Ingredient (API) in the commercial product, marketed under the brand 'Alecensa®', of which plaintiff no.1 is the registered proprietor in India under TM No.2475036 registered for pharmaceutical preparation, namely anti-cancer drug for Anaplastic Lymphoma Kinase (ALK)-positive advanced/metastatic non- small cell lung cancer (mNSCLC) in Class-5.

24. It is stated that 'Alecensa®' (Alectinib Hydrochloride) has been approved by regulatory authorities in several countries throughout the world and was granted breakthrough therapy designation and priority review status by the Food and Drug Administration (FDA), USA. It is stated to have been granted an accelerated approval by US FDA on 11.12.2015 for treatment of people with advanced (metastatic) ALK-positive non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.

25. It is stated that the Central Drugs Standard Control Organisation (CDSCO) had granted approval for import and marketing of Alectinib capsules (150 mg) equivalent to Alectinib Hydrochloride (161.3 mg) on 23.01.2017. The suit patent is stated to have been worked in India and Form 27 (working statements) has been duly filed by the plaintiffs before the Indian Patent Office for the calendar years 2023 and 2024.

26. Plaintiff claims that the suit patent is an 'old patent' since it was filed in India in the year 2012 claiming priority since 2009 and was granted in the year 2018 which is still valid and subsisting. The post-grant opposition under Section 25(2) of the Patents Act, 1970 having been held in favour of the plaintiffs, the said suit patent enjoys a strong presumption of validity. The patent for Alectinib has been granted in more than 60 countries and has neither been revoked nor invalidated in any jurisdiction.

27. The plaintiffs have protected the valuable intellectual rights by filing law suits which are enlisted in para 45 of the plaint, some of which are enlisted

hereunder:-

i. Order dated 02.09.2021 in CS(COMM) 404/2021.

ii. Order dated 13.09.2021 in CS(COMM) 427/2021.

iii. Order dated 18.03.2026 in CS(COMM) 265/2026.

28. Plaintiff claims that in December, 2025, the plaintiffs' representative was informed that during a routine survey at the CPHI event held in November, 2025, information was received that the defendant may be dealing in the API 'Alectinib'. It was on the said basis that investigations were conducted. The investigator is stated to have received the information that the defendant was found to have its profile listed on platforms such as IndiaMart and JustDial. It was further confirmed from the defendant's representative that API 'Alectinib' is currently under development and the tentative schedule for its launch is the first quarter, between April to May, 2026. The said information has raised reasonable apprehension in the mind of the plaintiffs that the defendant appears to be at an advanced stage of development of generic Alectinib and in the process of launching the generic Alectinib or its salt soon or any other product that infringes the suit patent.

29. In order to support the aforesaid apprehension, the plaintiffs placed on record the screenshots of the defendant's website which clearly depict the API 'Alectinib' as one of the APIs under development. The same is reproduced hereunder:-

https://www.basilpharmaceutical.com/

Download APIs Under Development Brochure

Oncology API's

General API's

API's Ready To Be Commercialized

APIs Under Development

Search

Sr No	Products
1	Upadacitinib
2	Lumateperone
3	Orforglipron

Sr No	Products
4	Vibegron
5	Avatrombopag Maleate
6	Remogliflozin Etabonate
7	Abemaciclib
8	Alectinib
9	Ceritinib
10	Encorafenib
11	Niraparib
12	Pemigatinib
13	Ribociclib

30. The plaintiffs have also filed alongwith its documents the report of the investigator, which is appended as Document-A, at page 1447 of the plaintiffs' documents, claiming to be the transcript of the call between the representative of the defendant and the investigator. The said information arrived at from the transcript and the apprehension giving rise to the present *quia timet* action suit is clearly stated in para 53 and 55 of the plaint.

31. The plaintiff states that the notice of the present suit has also been issued to the defendant, however, there has been no response thereto or even appearance before the Court today. Apprehending infringement of its suit patent, the present application seeks *ex-parte ad-interim* injunction.

32. Having regard to the arguments of Mr. Pravin Anand, learned counsel appearing for the plaintiffs, perusing the pleadings and examining the documents on record, it appears that a limited *ex-parte ad-interim* injunction

would be in order.

33. As per the claim in the suit, the suit patent is registered and is valid till 09.06.2030. Having regard to the said fact, it appears that the plaintiffs' rights under Section 48 of the Patents Act need to be protected. As per the screenshot of the website of the defendant, it appears that the API Alectinib is under development. The report of the investigator and the transcript enclosed therewith, though may require proof at the stage of trial, however, at this stage, in the peculiar facts of the present case, tend to lend credence to the assertion that the defendant may possibly launch its products based on API Alectinib sometime in the month of April-May, 2026. Since the website of the defendant has listed Alectinib at Srl. No.8 as 'APIs under development', this Court needs to also protect the defendant to the extent as envisaged and postulated in Section 107(a) of the Act.

34. Therefore, till the time the defendant enters appearance and files its reply and Written Statement to the present suit, it appears appropriate to direct that the defendant, its associates and group entities, its directors, employees, officers, servants, agents, stockists, retailers, semi-stockists, wholesalers, marketers, distributors, affiliates and subsidiaries, any other entity/person in the chain of supply and all others acting for and on its behalf are restrained from using, making, manufacturing, selling, distributing, advertising, exporting, offering for sale, importing or dealing in any other manner, directly or indirectly, in any product including but not limited to generic Alectinib or its salt or solvates or intermediate(s) thereof that infringes the subject matter of Indian Patent No.IN 294424. However, the defendant may continue the actions envisaged in Section 107(a) of the Patents Act, 1970, till the next date of listing.

35. Issue notice.

36. Let a reply to this application be filed by the defendant within four weeks from service. Rejoinder, thereto, if any, be filed within two weeks thereafter.

37. Compliance of Order XXXIX Rule 3 of CPC shall be done within ten days from date.

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38. Let the plaint be registered as a suit.

39. Upon filing of the process fee, issue summons of the suit to the defendant through all permissible modes.

40. The summons shall state that the Written Statement shall be filed by the defendant within 30 days from the date of the receipt of summons. Alongwith the Written Statement, the defendant shall also file Affidavit of Admission/Denial of the documents of the plaintiffs, without which the Written Statement shall not be taken on record.

41. Liberty is granted to the plaintiffs to file Replication, if any, within 30 days from the receipt of the Written Statement. Along with the Replication filed by the plaintiffs, an Affidavit of Admission/Denial of the documents of defendant be filed by the plaintiffs, without which the Replication shall not be taken on record.

42. In case any party is placing reliance on a document, which is not in their power and possession, its details and source shall be mentioned in the list of reliance, which shall also be filed with the pleadings.

43. If any of the parties wish to seek inspection of any documents, the same shall be sought and given within the prescribed timelines.

44. List before the Joint Registrar (Judicial) on 08.07.2026 for completion of service and pleadings.

45. List before the Court on 28.09.2026.

TUSHAR RAO GEDELA, J

MARCH 24, 2026/*sh*