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

+ **CS(COMM) 605/2025**

**ASTELLAS PHARMA INC & ANR.**

.....Plaintiffs

Through: Mr. Pravin Anand, Ms. Archana Shankar, Mr. Dhruv Anand, Ms. Udit Patro, Ms. Vidisha Garg, Ms. Nimrat Singh, Mr. Dhananjay Khanna, Ms. Sampurnaa Sanyal and Ms. Aakansha Parashar, Advocates

versus

**LUCIUS PHARMACEUTICAL LUCIUS PHARMACEUTICALS  
LAO CO LTD & ORS.**

.....Defendants

Through: None.

**CORAM:**

**HON'BLE MR. JUSTICE SAURABH BANERJEE**

**ORDER**

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**30.05.2025**

**I.A. 14624/2025** (*Section 149 read with Section 151 CPC, 1908*)

1. The plaintiffs, *vide* the present application under *Section 149* and *Section 151* of the Code of Civil Procedure, 1908 (*CPC*), seek an extension of time for filing the deficit, Court Fee.

2. Learned counsel for the plaintiffs seeks and is granted *one day time* to file the deficit court fees.

3. Accordingly, the present application is allowed and disposed of.

**I.A. 14625/2025** (*Exemption from pre-litigation mediation*)

4. *Vide* the present application under *Section 12A* of the Commercial Courts Act, 2015, read with *Section 151* of the *CPC*, the plaintiffs seek exemption from pre-litigation mediation.



5. Considering the averments made in the present application, as also since the plaintiffs are seeking *ex parte ad interim* injunction in an accompanying application, and in view of the judgment passed by the Hon'ble Supreme Court in ***Yamini Manohar v. T.K.D. Krithi*** 2024 (5) SCC 815, which has been followed by a Division Bench this Court in ***Chandra Kishore Chaurasia v. R. A. Perfumery Works Private Limited*** 2022:DHC:4454-DB, the plaintiffs are exempted from instituting pre-litigation mediation.

6. Accordingly, the present application stands disposed of.

**I.A. 14623/2025** (*Exemption*)

7. Exemption allowed, subject to all just exceptions.

8. The application stands disposed of.

**I.A. 14621/2025** (*Seeking discovery, production and inspection of the defendants' documents*).

9. *Vide* the present application under *Order XI Rule 1, 3 and 5* read with *Section 151* of the CPC, the plaintiffs seek a direction to the defendants to discover on affidavit the documents/ details as mentioned in paragraphs 9 to 11 of the present application and.

10. Upon the plaintiffs taking appropriate steps, issue notice to the defendants returnable before the learned Joint Registrar on 08.09.2025.

11. Reply(ies), if any, be filed within four weeks. Rejoinder thereto, if any, be filed within two weeks thereafter.

12. Renotify before the learned Joint Registrar on 08.09.2025.

**I.A. 14626/2025** (*Seeking time for filing the required certificate under 63(4)(c) of BSA.*)

13. *Vide* the present application under *Section 151* of the CPC, the



plaintiffs seek *four weeks* for filing the required certificate under *Section 63(4)(c)* of the Bharatiya Sakshiya Adhiniyam, 2024.

14. For the reasons stated in the application, the same is allowed and the present application stands disposed of.

**I.A. 14622/2025** (*for additional documents*)

15. *Vide* the present application under *Order XI Rule 1(4)* read with *Section 151* of the CPC, the plaintiffs seek leave of this Court to file additional documents within *thirty* days.

16. The plaintiffs will be at liberty to file additional documents within *thirty* days, *albeit*, after initiating appropriate steps, strictly as per the provisions of the Commercial Courts Act, 2015 read with *Section 151* of the CPC and the Delhi High Court (Original Side) Rules, 2018.

17. Accordingly, the present application stands disposed of.

**CS(COMM) 605/2025**

18. The plaintiffs, by way of the present plaint, seeks permanent injunction against the defendants for infringement of its Indian Patent No.292990.

19. Let the plaint be registered as a suit.

20. Upon filing of the process fee, issue summons of the suit to the defendants through all permissible modes returnable before the learned Joint Registrar on 08.09.2025.

21. The summons shall state that the written statement(s) be filed by the defendants within a period of *thirty days* from the date of the receipt of the summons. Written statement(s) be filed by the defendants along with affidavit of admission/ denial of documents of the plaintiff, without which the written statement(s) shall not be taken on record.



22. Replication(s) thereto, if any, be filed by the plaintiff within a period of *fifteen days* from the date of receipt of written statement(s). The said replication(s), if any, shall be accompanied by with affidavit of admission/ denial of documents filed by the defendants, without which the replication(s) shall not be taken on record within the aforesaid period of fifteen days.

23. If any of the parties wish to seek inspection of any document(s), the same shall be sought and given within the requisite timelines.

24. List before the learned Joint Registrar for marking exhibits of documents on 08.09.2025. It is made clear that if any party unjustifiably denies any document(s), then it would be liable to be burdened with costs.

**I.A. 14620/2025** (*Order XXXIX Rule 1 and 2 CPC, ad interim injunction*)

25. *Vide* the present application under *Order XXXIX Rules 1 and 2* of the CPC the plaintiffs seek ad interim injunction against the defendants for infringement of its Indian Patent No.292990.

26. As per the pleadings and the arguments advanced by the learned counsel for the plaintiffs, the plaintiff no.1 is a Japanese multinational pharmaceutical formed on 01.04.2005 from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujiawa Pharmaceutical Co., Ltd. The Company has its headquarters in Tokyo, with research centers in Tsukuba and Osaka and clinical development centered in Northbrook, Illinois; La Jolla, California and Leiden, Netherlands.

27. The plaintiff No. 2 is a Japanese pharmaceutical company founded in 1949 and has a long history of manufacturing and selling pharmaceuticals and has expanded its operations internationally, including selling its products in China and in India.



28. The plaintiff nos. 1 and 2 have in collaboration developed a New Chemical Entity, GILTERITINIB, which is the subject matter of the suit patent, IN 292990. GILTERITINIB is manufactured and marketed by the plaintiffs internationally and in India under the brand name XOSPATA®, which is a registered trademark in India owned by the plaintiff No. 1.

29. The present suit relates to Indian Patent No. 292990, which covers and claims, a molecule which is a new chemical entity: 6-Ethyl-3-((3-methoxy-4-(4-(4-methylpiperazin-1-yl)piperidin-1-yl)phenyl)amino)-5-((tetrahydro-2H-pyran-4-yl)amino)pyrazine-2-carboxamide. The said molecule has been assigned an International Non-Proprietary Name (INN), **GILTERITINIB**. The said molecule has been invented by the plaintiffs, who have obtained patents corresponding to the suit patent in more than 34 countries of the world. The bibliographic details of the suit patent as under:-

- a) *Indian Patent No.292990*
- b) *Patentees: ASTELLAS PHARMA INC. (Plaintiff No. 1) and KOTOBUKI PHARMACEUTICAL CO., LTD. (Plaintiff No. 2).*
- c) *Indian Application No.: 8996/CHENP/2011*
- d) *Date of filing in India: 02nd December 2011*
- e) *Date of publication under Section 11A: 15th February 2013*
- f) *Date of filing of international application: 06th May 2010.*
- g) *PCT Application No.: PCT/JP2010/057751.*
- h) *Priority application nos. and dates: JP 2009-113936 (08<sup>th</sup> May 2009).*
- i) *Date of grant: 16th February 2018*
- j) *Title: DIAMINO HETEROCYCLIC CARBOXAMIDE COMPOUND.*
- k) *Drug covered: GIL TERITINIB (WHO INN*



Nomenclature) - used for treatment of Relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation.

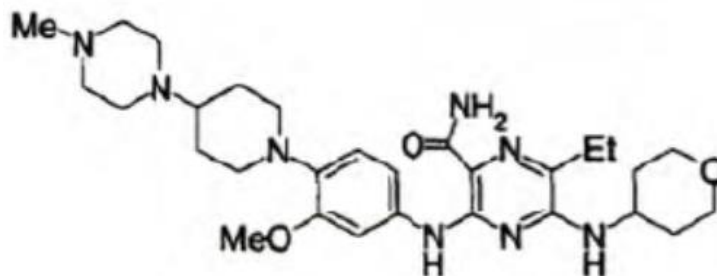
l) No. of claims: 5

m) Claims claiming / covering GILTERITINIB: Specifically claimed in Claims 1, 2 and 3.

n) The suit patent discloses the compound GIL TERITINIB in Example 547, the HFM salt (hemifumaric acid salt) of GILTERITINIB is exemplified in Example 577, a general process of preparation in paragraphs [0120][0129] of the granted specification and the Biological assays to demonstrate the biological activity of GIL TERITINIB are provided in Test Examples 1 and 2.

o) IUPAC name of GILTERITINIB: 6-Ethyl-3-((3-methoxy-4-(4-(4-methylpiperazin-1-yl)piperidin-1-yl)phenyl)amino)-5-((tetrahydro-2H-pyran-4-yl)amino)pyrazine-2-carboxamide.

p) Structure of GIL TERITINIB: As provided at internal specification page 235 (Example 547):



30. **GILTERITINIB** is an orally available small molecule receptor Tyrosine Kinase Inhibitor (TKI) for the treatment of Acute Myeloid Leukemia (AML) with a FL T3 mutation. AML is a cancer that impacts blood and bone marrow and its incidence increases with age. It is the double inhibition of Tyrosine Kinases that provides for a surprising and unexpected property profile of **GILTERITINIB**, and which allows for double blocking of leukaemia (AML). The two said key Tyrosine Kinase Inhibitors targeted by **GILTERITINIB** are:



- i. FLT3 (FMS-like tyrosine kinase 3); and
- ii. AXL (another receptor kinase involved in resistance and survival pathways - that AML cells use to bypass FL T3 inhibition)

31. The commercial product protected under the suit patent has developed by the plaintiffs collaboratively under the brand name XOSPATA®. XOSPATA® (**GILTERITINIB**), as is an orally targeted therapy, used to treat acute myeloid leukemia (AML) in adults when the disease has returned or has not improved after prior treatments. A pictorial representation of the product of the plaintiffs is enumerated below:-



32. The defendant No. 1, Lucius Pharmaceutical Co. Ltd., as per its own website <https://luciuspharmaceuticals.com/>, was established in 2020 in Vientiane, the capital of Laos and the defendant No.1 is involved in manufacturing 200+ generic drugs in diverse therapeutic fields.

33. The defendant No. 1 is involved in the manufacture and sale/supply of the infringing **GILTERITINIB** product under the brand 'LUCIGIL'.

34. The defendant Nos. 2 to 6 are Indian entities which have been found offering for sale the defendant No.1 's infringing **LUCIGIL** product in



India through the online marketplace of the defendant No. 7.

35. The defendant No. 7, India MART InterMESH Ltd., is a company incorporated under the Companies Act, 1956, and claims to be India's largest online B2B marketplace connecting buyers to suppliers.

36. The plaintiffs during a routine online reconnaissance in late April, 2025, to check for availability of infringing **GILTERITIN1B** products in India, came across an infringing product LUCIGIL of the defendant No.1. A pictorial representation of the product of the defendant no.1 as also listing on its website is enumerated below:-



A screenshot from the Defendant No. 1's website – infringing Gilteritinib product under the brand LUCIGIL

37. The defendant no.2, Keshavdas and Sons Med Exports (Nagpur), was found advertising for sale the defendant No. 1's infringing LUCIGIL product on its IndiaMart page, a pictorial representation of the same is



enumerated below:-



38. Upon a telephonic conversation inter-se the defendant no.2's and the investigator of the plaintiffs, the defendant no.2 confirmed that they could provide the LUCIGIL product to the investigator in Delhi for personal use.

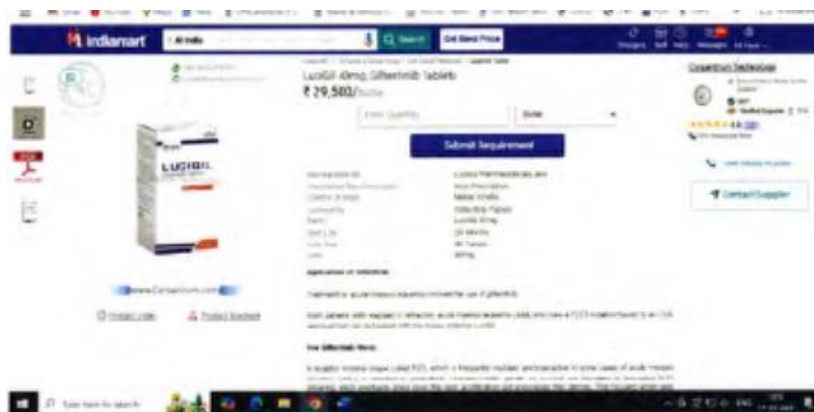
39. The defendant no.3, Ujwala Pharmaceutical (Pune), was found advertising for sale the defendant No. 1's infringing LUCIGIL product on its IndiaMart page, who also on inquiry informed the plaintiffs investigator to provide the impugned product in Delhi for personal use, a pictorial representation of the listing of the defendant no.3 is enumerated below:-



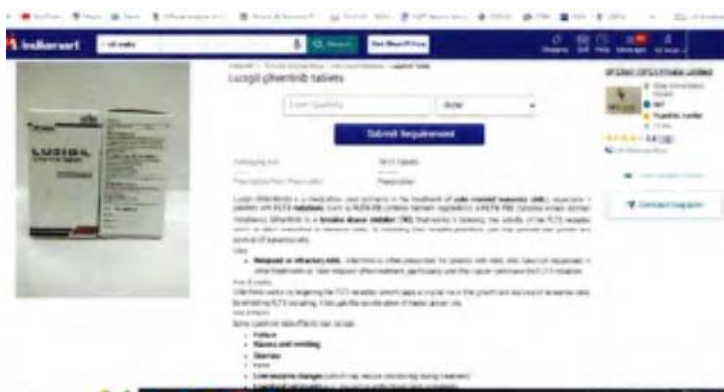
40. The defendant no. 4, Corsantrum Technology (Surat), was found advertising for sale the defendant No. 1's infringing LUCIGIL product on its IndiaMart page, who also on inquiry informed the plaintiffs



investigator to provide the impugned product in Delhi for personal use, a pictorial representation of the listing of the defendant no.4 is enumerated below:-



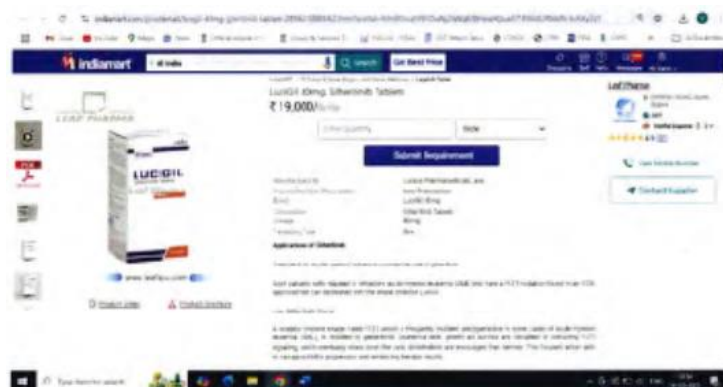
41. The defendant no. 5, SP Elixir (OPC) private ltd. (Ahmedabad), was found advertising for sale the defendant No. 1's infringing LUCIGIL product on its IndiaMart page, who also on inquiry informed the plaintiffs investigator to provide the impugned product in Delhi for personal use, a pictorial representation of the listing of the defendant no.5 is enumerated below:-



42. The defendant no. 6, Leaf pharma (Surat), was found advertising for sale the defendant No. 1's infringing LUCIGIL product on its IndiaMart page, who also on inquiry informed the plaintiffs investigator to provide the impugned product in Delhi for personal use, a pictorial representation



of the listing of the defendant no.6 is enumerated below:-



43. In view of the above the learned counsel for the plaintiffs pray that an *ex-parte ad interim* injunction may be passed in the favour of the plaintiffs.

44. This Court has heard the learned counsel for the plaintiffs and perused the documents on records as well.

45. A bare perusal of listings qua of impugned good of the defendants reveals that the impugned good/ medicine 'LUCIGIL' is comprising of the compound 'GILTERITINIB', qua which is the plaintiff no.1 has a valid patent registration granted by the Indian Patent Office on 16.02.2018, which is valid and subsisting till date.

46. In view thereof as also in view of the various averments and assertions made by the plaintiffs in the plaint as also the submissions made by the learned counsel for the plaintiffs, the plaintiffs have made out a *prima-facie* case with the *balance of convenience* for grant of an *ad interim ex-parte injunction* in their favour and against the defendants. The defendants, if not restrained by way of an *ad interim ex-parte* injunction may lead to a likelihood of confusion and deception amongst the minds of the general public at large which needs to be stopped. The same may also



lead to the plaintiffs suffering *irreparable harm, loss, injury* and prejudice.

47. Accordingly, till the next date of hearing:-

a) The defendants, their directors, employees, officers, servants, agents, stockist, retailers, wholesalers, distributors, associate and group companies and all others acting for and on their behalf are restrained from using, making, selling, distributing, advertising (including on the defendants' website and third party websites), exporting, importing and offering for sale, or in any other manner, directly or indirectly, dealing in any product (in any form), including GILTERITINIB, either as API or any of its pharmaceutically acceptable salt/s, or finished formulation or in any other form including under the brand name LUCIGIL or any other brand name, that infringes the subject matter of Indian Patent No. IN 292990.

b) Upon the plaintiffs approaching the defendant no.7 and providing links/ listings of the impugned products on their website, the defendant no.7 is directed to de-list and remove the aforesaid links/ listings relating to the infringing GILTERITINIB product, including 'LUCIGIL', sold by the defendant nos. 1 to 6, or any of their directors, employees, officers, servants, agents, associate and group companies and all others acting for and on their behalf, or by any other third party from its platform and/ or websites managed by it.

48. Upon filing of process fee, issue notice to the defendants through all permissible modes, including through *email*, returnable before the Court on 16.10.2025.



49. Reply(ies), if any, be filed within four weeks. Rejoinder(s) thereto, if any, be filed within two weeks thereafter.
50. The provisions of *Order XXXIX Rule 3* of the CPC be complied with within one week.
51. List before Court on 16.10.2025.

**SAURABH BANERJEE, J**

**MAY 30, 2025/So**