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WP (IPD) No. 24 of 2



IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 12-02-2026

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THE HON'BLE MR JUSTICE N. ANAND VENKATESH

W.P. (IPD) No. 24 of 2025

and

W.M.P.(IPD) Nos.19 and 20 of 2025

Merck Sharp & Dohme B.V
Represented by its Authorized Singnatory
Laura M Ginkel Waarderweg 39 Nl -2031 BN Haarlem,
Netherlands.

..Petitioner(s)

Vs

1. The Union Of India
Represented By Its Secretary, Ministry Of
Finance, Department Of Revenue, New Delhi
2. The Office of Controller General Of Patents,
Designs And Trademarks
Intellectual Property Office Building, G.S.T
Road, Guindy Chennai 600 032
3. The Joint Controller Of Patents And Designs
Intellectual Property Office Building, G.S.T
Road, Guindy Chennai 600 032
4. J. Sridharan
13/2 Viswanathan Street, West Mambalan
Chennai 33
5. Natco Pharma Limited
Natco House, Road No 2 Banjara Hills
Hyderabad 34



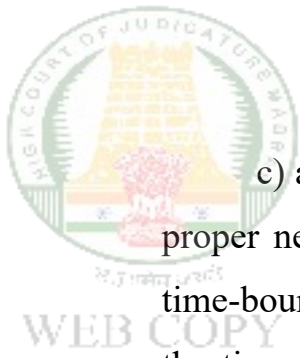
6. Mahima Gupta
99 Men Bazar S S Inter College Hasanpur,
Majhra Majhara, Dataganj Budaun, Uttar
Pradesh 243 635
7. Mansi Verma
91/3 Aditya World City Ghaziabad 201 002 U.P.
India

..Respondent(s)

PRAYER: This Writ Petition is filed under Article 226 of the Constitution of India for the issuance of Writ of Certiorarified Mandamus

a) to call for the records of the impugned Notice No POC / Pregrant Oppn. / 408 / CHEN / 2014 / C 1808 C 1809 under Rule 55 (3) (b) of the Patent Amendment Rules 2024 dated 6th September 2024 passed by the 3rd Respondent in respect of the fourth pre-grant opposition and quash the same thereby dismissing the fourth pre-grant opposition as being a *benami* and a frivolous opposition lacking any merit and further direct the 3rd respondent to close prosecution of and decide upon the first, second, and third pre-grant opposition filed against, the present patent application i.e., Indian Patent Application No 408 / CHENP / 2014 in a time bound manner within the time period as directed by this Court,

b) to direct the 3rd respondent to summarily dismiss any and ever further pre-grant opposition that is filed during the pendency of the present Application and asserting any prior art document of petitioner ground that has already been asserted in any of the first, second, third, or fourth pre-grant oppositions filed against the present Application,



c) alternatively to direct the 3rd respondent to record credible reasons in a proper new Rule 55 (3) (b) notice with respect to said fourth opposition in a time-bound manner and to hear and decide upon said fourth opposition within the time period as directed by this Court, and to follow the same in any and every new pre-grant opposition filed during the pendency of the present application that has not been summarily dismissed as duplicating any prior art or ground asserted in any prior pre-grant opposition, and

d) to set guidelines as how a prima facie assessment has to be made by the office of 2nd respondent and 3rd respondent and any controller of the Patent office in general, while assessing pre-grant oppositions under Rule 55 (3) of the Patents Rules 2003.

For Petitioner(s): Ms. Vindhya S. Mani

For Respondent(s): Mr. K.V.Muthu Visakan
Senior Panel Counsel for R1 to R3

Mr. R. Sathish Kumar for R5

Ms.S.Suba Shiny for R7

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ORDER

This Writ Petition has been filed challenging the impugned notice issued by the 3rd respondent dated 06.09.2024 in respect of the 4th pre-grant opposition and for a consequential direction to the 3rd respondent to decide upon the 1st, 2nd and 3rd pre-grant oppositions filed against the Patent Application



No.408/CHENP/2014 in a time-bound manner within the period stipulated by this Court. The petitioner has also sought for a further direction to the 3rd respondent to summarily dismiss every other pre-grant opposition received in the pending application and also to properly apply his mind on Rule 55(3)(b) of the Patents (Amendment) Rules, 2024, whenever a new pre-grant opposition is filed during the pendency of the present Patent Application filed by the petitioner.

2. Heard the learned counsel appearing on either side and perused the materials placed before this Court.

3. The petitioner submitted a Patent Application in Indian Patent Application No.408/CHENP/2014, which claims the compound acalabrutinib, the active ingredient in the pharmaceutical product Calquence. The further case of the petitioner is that the said pharmaceutical product Calquence has been marketed in India since October, 2020 and it is approved for certain cancer treatments.

4. The grievance of the petitioner is that after the present application was published in the Patent Journal as early as on 03.04.2015 and the First



Examination Report was issued in 2017, for which the petitioner had filed a response, the 4th respondent came up with a pre-grant opposition on 28.01.2019.

Immediately, notice was issued to the petitioner and the petitioner submitted a reply to the pre-grant opposition. Subsequently, hearing notices were issued and the matter was adjourned from time to time till 2022. Thereafter, the 2nd pre-grant opposition was filed by the 5th respondent on 18.04.2022. Notice was issued and the petitioner submitted a reply to the opposition and hearing notices were issued and the matter was adjourned from time to time and the written submissions were ultimately filed on 09.09.2023. By the time the final order was passed, the 3rd pre-grant opposition was filed by the 6th respondent on 02.02.2024. Once again, the 3rd respondent issued notice based on the 3rd pre-grant opposition. On receipt of the same, the petitioner filed a reply and thereafter hearing notices were issued. When this process was going on, the 4th pre-grant opposition was filed by the 7th respondent on 12.07.2024.

5. It is under these circumstances that the petitioner knocked the doors of this Court mainly on the ground that the inaction on the part of the authorities to decide the application based on the oppositions that has already been made, has resulted in one pre-grant opposition after another being filed, and this process has been going on from 2019 onwards. As a result, even if ultimately the petitioner is able to get the patent after rejection of all the oppositions, it can



have effect only up to the year 2032, since the petitioner submitted the application during the year 2012. Thus, it is alleged by the petitioner that the petitioner is being denied the advantage of getting patent on account of the filing of one pre-grant opposition after another and the official respondents, without any application of mind are issuing notices in a mechanical fashion. Therefore, the petitioner has sought to challenge the present impugned notice dated 06.09.2024, which was issued pursuant to the 4th pre-grant opposition, under Rule 55(3)(b) of the Patents (Amendment) Rules, 2024.

6. The learned counsel for the petitioner submitted that the four pre-grant oppositions basically raised the very same grounds against the application submitted by the petitioner and that the official respondents, who are expected to apply their mind under Rule 55(3) of the Patents Rules, 2003, as to whether the same should be entertained and notice should be ordered under Rule 55(3)(b), are failing in their duty, as a result of which the petitioner has suffered irreparable loss. Apart from that, the notice that has been issued in respect of the 4th pre-grant opposition does not reflect any application of mind and therefore, the same requires the interference of this Court.



7. The learned counsel for the petitioner further submitted that there were unreasonable delays on the part of 2nd and 3rd respondents in not adhering to the time lines fixed under the relevant Rules and that they have handled the applications submitted by the petitioner in a lackadaisical manner. The learned counsel submitted that insofar as the 2nd respondent is concerned, an unreasonable delay was caused by issuing the FER 2 years and 7 months after publication of the present application instead of within 6 months after publication. Similarly, the 2nd respondent also caused a further delay of 1 year and 4 months to issue the hearing notice after petitioner filed the reply statement to the 1st pre-grant opposition. Once again, the 3rd respondent caused an unreasonable delay of 8 months and 15 days to issue notice under Rule 55(3) with respect to the 2nd pre-grant opposition and there was a further delay of 2 months and 15 days to act on the first adjournment requested by the 5th respondent. Thus, with respect to the 1st and 2nd opposition, there was a substantial delay of 4 years and 6 months after filing of the 1st opposition, and the learned counsel alleged that each of the oppositions was filed by the alter ego of the same person who came up with the 1st pre-grant opposition.

8. The learned Senior Panel Counsel appearing on behalf of the official respondents, by relying upon the counter affidavit, submitted that the impugned notice was issued strictly in accordance with Rule 55(3)(b) of the Rules and that



the official respondents have not violated any statutory provisions or procedural mandates and therefore, the present Writ Petition is devoid of merits.

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9. The learned counsel for the 5th and 7th respondents submitted that they are given a statutory right under Section 25(1) of the Patents Act, 1970, to submit their opposition to the patent. It was further submitted that if at all there is any delay on the part of the official respondents, they cannot be blamed for that and they also want this Court to issue appropriate directions to the official respondents to deal with the pre-grant oppositions in accordance with law and take a decision within a time frame fixed by this Court.

10. The learned counsel for the private respondents submitted that the pre-grant opposition made by them cannot be summarily rejected and the same will take away a statutory right that has been guaranteed under the Act and Rules.

11. In the considered view of this Court, it is not necessary for this Court to go into the merits or otherwise of the specific opposition that has been raised on the side of the private respondents. As on today, the opposition is confined to five grounds that have been raised by the 5th and 7th respondents. Even insofar as



the documents that are relied upon by the 7th respondent, except two documents, which over laps, the other six documents are specifically relied upon by the 7th respondent.

12. Before issuing directions, this Court has to necessarily take into consideration the inaction on the part of the official respondents which has resulted in the present fiasco. The process of submission of application seeking for patent started its journey on 11.07.2012 and that journey has not even reached its culmination till the year 2026. The pre-grant oppositions started coming from the year 2019 when it was submitted by the 4th respondent. The 2nd pre-grant opposition from the 5th respondent emanated in the year 2022. It is quite understandable if there was a delay during this period considering the fact that the entire world was afflicted with Covid pandemic. Therefore, it has to be seen as to what happened after the year 2022. The 2nd pre-grant opposition was filed by the 5th respondent on 18.04.2022. After the reply statement filed by the petitioner for the pre-grant opposition, hearing notices were issued and the hearing was scheduled on 26.07.2023. Thereafter, it was adjourned for filing of written submission and the written submission was filed by the 5th respondent on 09.09.2023 and the petitioner filed the written submission on 10.09.2023. From October, 2023, till February, 2024, there was a lull. No decision was taken and during February, 2024, the 3rd pre-grant opposition was filed by the 5th



respondent. The 3rd respondent, on receipt of the pre-grant opposition, immediately issued a notice to the petitioner dated 04.03.2024. Again, a reply was filed, hearing notice was issued and the date of hearing was fixed and this process went on till 12.07.2024. At which point of time, the 4th pre-grant opposition was filed by the 7th respondent.

13. It is clear from the above that the official respondents were not acting upon the application and taking a final decision and by postponing the same for one reason and the other, pre-grant oppositions were accumulated. Whether these are genuine pre-grant oppositions is a matter into which this Court does not want to go into. It was the duty of the official respondents, who have to apply their mind whenever they get such pre-grant opposition, since it is mandated under Rule 55(3). If the official respondents are going to take their own time in deciding the application and also mechanically issue summons/notices whenever a pre-grant opposition is made, it is very easy to defeat the rights of someone who files an application seeking for patent. This is in view of the fact that anyone can oppose the grant of patent and therefore, the opposition can emanate from any part of the world and therefore, the rule-making authority thought it fit to impose a mandate that the controller must be *prima facie* satisfied on the pre-grant opposition received and that the controller



cannot mechanically issue notice as and when pre-grant oppositions are received.

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14. Keeping this in mind, now the amendment has been brought forth to the relevant Rules by prescribing time limits and now the authority is mandated to pass orders within a time frame on receiving their pre-grant opposition, which must reflect application of mind. At every stage, time limit is now prescribed. It has been done only to attend to the problem of patent application being kept pending endlessly, which results in pre-grant opposition being filed one after the other without allowing the authority to take a final decision on the patent application.

15. In the counter affidavit that has been filed by the 2nd and 3rd respondents, there is absolutely no explanation as to why the authority did not expeditiously take up the pre-grant opposition that was earlier filed by the 4th and 5th respondent and pass orders. The official respondents have merely taken a stand that they strictly went by the provisions and followed the procedural mandate. It does not really answer the question as to whether there was proper application of mind while issuing notice as and when the 2nd and 3rd respondents received pre-grant opposition from various parties.



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16. In order to bring to an end the present impasse, this Court is inclined to dispose of the Writ Petition in the following terms:-

(a) there shall be a direction to the petitioner to file their reply for the pre-grant opposition submitted by the 7th respondent within a period of four (4) weeks from the date of receipt of a copy of this order;

(b) there shall be a direction to the 3rd respondent to decide upon 1st, 2nd, 3rd and 4th pre-grant oppositions filed to the patent application submitted by the petitioner after affording an opportunity to the petitioner and the 7th respondent within a period of three (3) months thereafter;

(c) during the interregnum, if any further pre-grant opposition is received by the 3rd respondent, the 3rd respondent shall strictly deal with the same in line with Rule 55(3) of the Patents (Amendment) Rules, 2024, and if no *prima facie* case is made out in terms of bringing out any fresh ground, the same shall not be entertained and it shall be notified to the opponent accordingly; and

(d) the 3rd respondent shall strictly comply with the time lines fixed by this Court and pass final orders in the application submitted by the petitioner on its own merits and in accordance with law.



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There shall be no order as to costs. Consequently, connected Miscellaneous Petitions are also closed.

12-02-2026

Index : Yes / No
Speaking Order : Yes / No
Neutral Citation : Yes / No

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To

1. The Secretary, Union of India
Ministry Of Finance, Department Of Revenue,
New Delhi
2. The Office of Controller General Of Patents,
Designs And Trademarks
Intellectual Property Office Building, G.S.T
Road, Guindy Chennai 600 032
3. The Joint Controller Of Patents And Designs
Intellectual Property Office Building, G.S.T
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4. J. Sridharan
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5. Natco Pharma Limited

Natco House, Road No 2 Banjara Hills
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6. Mahima Gupta

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N. ANAND VENKATESH, J.

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W.M.P.(IPD) Nos.19 and 20 of 2025**

12-02-2026

Page 15 of 15