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

% *Judgment delivered on: 24.12.2025*

\+ **W.P.(C)-IPD 23/2023**

ZYDUS HEALTHCARE LTD. .....Petitioner

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS & ANR. .....Respondents

Advocates who appeared in this case

For the Petitioner : Mr. Dayan Krishnan, Senior Advocate with Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms. Vrinda Pathak, Mr. P.S. Manjunathan, Ms. Sandhya Kukreti, Mr. Shreedhar and Mr. Parth Singh, Advocates.

For the Respondents : Mr. Vikrant N. Goyal, Mr. Prince Balyan, Mr. Kunal Dixit and Mr. Sachit Sharma, Advocates for R-1.
Mr. Amit Sibal, Senior Advocate with Mr. Pravin Anand, Mr. Dhruv Anand, Ms. Udita Patro, Mr. Dhananjay Khanna, Ms. Nimrat Singh, Ms. Smriti Nair, Mr. Saksham Dhingra and Ms. Suditi Batra, Advocates for R-2.

CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA

JUDGMENT

TEJAS KARIA, J

INTRODUCTION

1. The present Writ Petition under Article 226 of the Constitution of India ("**Constitution**") is filed challenging the order dated 23.03.2023 ("**Impugned Order**") passed by the Assistant Controller of Patents and Designs ("**Respondent No. 1 / Controller**") granting Patent No. 426553 ("**Subject Patent**") for Respondent No. 2's Patent Application No. 1009/MUMNP/2012 ("**Subject Application**").

FACTUAL MATRIX

2. The Petitioner is a wholly owned subsidiary of a pharmaceutical company, *Zydus Lifesciences Limited*, which is a fully integrated, global healthcare provider, and forms part of the Zydus group companies. The Petitioner has in-depth expertise in the field of healthcare.

3. Respondent No. 2 herein is the Applicant of the Subject Application titled as '*COMPOSITIONS AND METHODS FOR TREATING CENTRALLY MEDIATED NAUSEA AND VOMITTING'*.

4. Respondent No. 2 filed the Subject Application on 20.04.2012, which consisted of a total of 51 claims, of which 5 claims being Claims Nos. 1, 16, 27, 34 and 42 were independent and the rest of the claims were dependant on the said 5 independent claims.

5. On 25.07.2013, Respondent No. 2 requested for a voluntary amendment of the originally filed claims ("**First Amendment**") under

Section 57 of the Patents Act, 1970 ("**Act**") *via* Form 13. The reason for the amendment given by Respondent No. 2 was that the invention was not clearly defined. The amendments undertaken by Respondent No. 2 are hereunder:

a. From the originally filed 51 claims, Claim Nos. 1 to 33 were deleted.
b. The originally filed independent Claim No. 34 was amended to create the new amended independent Claim No. 1.
c. Further, amendments and deletions in the originally filed claims were carried out to arrive at an amended claim set comprising a total of 14 claims.

6. Respondent No. 1 issued a First Examination Report on 21.09.2017 ("**FER**"). In response to the FER, Respondent No. 2 filed its Reply dated 19.03.2018 ("**Reply**"). Respondent No. 2 in its Reply further amended the claims, which were reduced to a set of 11 claims with 2 independent claims being Claim Nos. 1 and 7 ("**Second Amendment**").

7. The Petitioner, *vide* dated 06.09.2021 filed pre-grant opposition ("**Pre-Grant Opposition**") wherein it was submitted that the amendments undertaken by Respondent No. 2 had resulted in broadening the scope of amended set of claims. Another opponent namely, *M/s. Panacea Biotech Ltd.* had also filed its representation for pre-grant opposition on 22.06.2018, however, the said entity did not prosecute its representation.

8. On 20.05.2022, a hearing was held by Respondent No. 1 ("**Hearing I**") wherein the Petitioner and Respondent No. 2 made submissions in response

to Pre-Grant Opposition filed by the Petitioner. The Petitioner filed Written Submissions on 04.07.2022 pursuant to the Hearing I.

9. After reserving the order after Hearing I, Respondent No. 1 issued a hearing notice dated 17.02.2023 under Section 14 of the Act to Respondent No. 2 for hearing on 03.03.2023 ("**Hearing II**").

10. To comply with the objections raised in the hearing notice under Section 14 of the Act, Respondent No. 2 made another set of amendments ("**Third Amendment**"). On 03.03.2023, a hearing was held by Respondent No. 1 and no opportunity of a hearing was provided to the Petitioner.

11. Thereafter, the Impugned Order was passed whereby the Pre-Grant Opposition of the Petitioner was rejected and the patent was granted. Hence, this Petition.

SUBMISSIONS ON BEHALF OF THE PETITIONER

12. The learned Senior Counsel for the Petitioner made the following submissions:

12.1. The Impugned Order failed to exercise the statutory duty under Sections 57 and 59 of the Act. The Impugned Order has granted the Patent based on an amended set of claims, even though no order was passed by Respondent No. 1 to determine whether the amendment could be allowed under Sections 57 and 59 of the Act.

12.2. That post reserving decision on the Pre-Grant Opposition, Respondent No 1 gave a unilateral hearing to Respondent No. 2 under Section 14 of the Act, without issuing notice or giving an opportunity of hearing

to the Petitioner. The Petitioner did not get an opportunity to object to the Third Amendment.

12.3. The First Amendment was filed under Section 57(1) of the Act. Since the power under Section 57(1) of the Act vests discretion on Respondent No. 1 to allow / disallow the amendment, it is incumbent on Respondent No. 1 to pass an order allowing or rejecting the amendment.

12.4. This also flows from Rule 81(2) of the Patent Rules, 2003 ("**Rules**"), which requires a 'determination' by Respondent No. 1. This is particularly relevant because Section 59 of the Act casts a duty on Respondent No. 1 to not permit certain amendments.

12.5. In ***Ashok Leyland Ltd v. State of T.N. and Anr.***, (2004) 3 SCC 1, it was held that the word 'determination' presupposes application of mind and expression of conclusion as it connotes an official determination, not a mere opinion or finding.

12.6. The Impugned Order passed is also in violation of natural justice since Respondent No. 1 provided the Hearing II to Respondent No. 2 under Section 14 of the Act after the arguments on the Pre-Grant Opposition were reserved. Although the Impugned Order records the submission of the Petitioner regarding violation of Section 59 of the Act, no finding was returned on the said issue.

12.7. The Complete Specification on record does not disclose orally administered dosage form comprising a combination of palonosetron

and netupitant comprising 0.56 mg of palonosetron hydrocholoride and from 200 to 400 mg of netupitant. The Complete Specification enables only 2 types of embodiments: (i) where netupitant + palonosetron are administered where the dosage is outside the range claimed; and (ii) where netupitant + palonosetron is administered with a third substance dexamethasone.

12.8. In ***Allergan Inc. v. The Controller of Patents***, 2023 SCC OnLine Del 295, this Court has that the amendments made to the claims should find support in the complete specification. Thus, amending the originally filed claim to exclude Dexamethasone does not find support in the Complete Specification and is violative of Section 59 of the Act.

12.9. On the aspect of jurisdiction, this Court has jurisdiction under Article 226(2) of the Constitution since the cause of action has arisen within the jurisdiction of this Court *albeit* the Subject Application was filed at the Patent Office, Mumbai, Maharashtra. By virtue of the decision in ***Dr. Reddy's Laboratories Ltd. & Anr. v. The Controller of Patents & Ors.***, 2022 SCC OnLine Del 3747 read with the Full Bench judgment in ***Girdhari Lal Gupta v. K. Gyan Chand Jain & Co.***, AIR 1978 DEL 146, both the static as well as the dynamic effect of the grant confer jurisdiction. The said principle was also applied in the decision of ***Dr. Reddy's Laboratories Ltd. v. Fast Cure Pharma and Anr.***, Neutral Citation: 2023:DHC:6324.

12.10. The decision in ***Rich Products v. The Controller of Patents & Anr.***, 2024 SCC OnLine Del 3144 was cited in the present Petition by the Counsel for Respondent No. 1 during the hearing on 08.04.2024. In ***Rich Products*** (*supra*), this Court had refused to entertain a writ petition emanating from a pre-grant opposition since an alternate efficacious remedy i.e., post-grant was available to the Petitioner. The same argument had been taken by the Respondents in the present Petition as recoded in Paragraph No. 4 of order dated 08.04.2024.

12.11. However, Respondent No. 2 has incorrectly contended that there is an alternate remedy available to the Petitioner in the form of appeal under Section 117A of the Act. A rejection of a pre-grant opposition cannot be appealed under Section 117A of the Act. Further, Section 117A of the Act does not provide a right to appeal for contravention of Section 59 of the Act. Even, if an appeal is permitted against an order under Section 57(1) of the Act, the present Petition is maintainable due to the failure to pass an order under Section 57 of the Act prior to accepting the amendment and, thus, there is no 'decision, order, or direction' under Section 57 of the Act to file an appeal against the same. A violation of natural justice and fundamental right can be challenged through a writ petition as has been held in ***Whirlpool v. Registrar of Trademarks***, (1998) 8 SCC 1.

12.12. The amendment in Claim No. 1 by Respondent No. 2 was to convert the method of treatment claims into pharmaceutical composition claims

as the application for amendment does not state the nature of the amendment or the full particulars of the reasons for which the amendment is made, which is a statutory requirement under Section 57(2) of the Act. The Form 13 merely states that the amendment is being undertaken "*to define the invention more clearly*". Further, the marked-up copy of the amendment clearly shows that the Claim Nos. 1 to 33 have been deleted and Claim No. 34 has been converted into Claim No. 1. The reasons for the said amendment given in the Counter Affidavit dated 30.06.2023 in Paragraph No. 4(i) are an afterthought and also contradicts the position taken in the Form 13, which states that:

> *"i. Claim 1 was created for converting method of treatment claims to pharmaceutical composition claims-by taking the preamble from claim 34 and taking support from claim 27, 28 and 29 (i.e., Claim 11. 1 was created by incorporation of the subject-matter of Claims 28 and 29 into Claim 27). The said amended Claim was well within the scope of the specification and the scope of the originally filed claims."*

12.13. In ***Natco Pharma Limited v. Union of India & Ors***., Neutral Citation: 2022:DHC:2632, it was held that a short and brief order should be passed in respect of the amendments, which should be uploaded on the website of the Patent Office. In the present case, the jurisdictional error arises on account of the fact that the First Amendment is prior to the FER and also prior to the Pre-Grant Opposition. Admittedly, there is no determination by a separate order.

12.14. Further, FER cannot be termed to be the order as required under Rule 81 of the Rules since: (i) there is no determination even in the FER; (ii)

no application of mind is discernible from a plain reading of the FER; and (iii) mere reliance on the list of 'documents on record', listing both the original claims and the pending Form 13 cannot substitute the legal requirement of application of mind and expressing a conclusion through a speaking order.

12.15. The jurisdictional error is also that at the pre-grant stage, when the Petitioner highlighted the breach of Sections 57 and 59 of the Act, Respondent No. 1 failed to give a finding as to how such an amendment could be allowed, after noticing the arguments from both sides.

12.16. It is irrelevant whether the Petitioner has a right under Section 25(1) of the Act to challenge the amendment application. An order granting a patent violating the statutory mandate under Section 57 of the Act read with Rule 81(2) of the Rules, is liable to be quashed, irrespective of whether Section 25(1) of the Act allows this ground.

12.17. It is settled law that where the law requires an act to be done in a particular manner, it must be done in that manner alone, or not at all. The learned Counsel for the Petitioner relied on the decisions in ***State of UP v. Singhara Singh***, 1963 AIR SC 358 and ***Municipal Corporation of Greater Mumbai v. Abhilash Lal & Ors.***, (2020) 13 SCC 234 in support of this submission.

12.18. Accordingly, the Impugned Order is liable to be set aside.

SUBMISSIONS ON BEHALF OF RESPONDENT NO. 1

13. The learned Counsel for Respondent No. 1 made the following submissions:

13.1. It is an admitted fact that the entire prosecution of the Subject Patent from the filing of the Subject Application and Pre-Grant Opposition till the grant of the Subject Patent had transpired in the Patent Office situated at Mumbai, Maharashtra.

13.2. Under the Rules, the definition of "Appropriate Office" of the Patent Office is the governing factor qua the territorial jurisdiction in all proceedings pertaining to the Subject Patent and as per Rule 4(2) of the Rules, it cannot ordinarily be changed. Therefore, the appropriate office is the Patent Office at Mumbai, Maharashtra. In the decisions in ***Filo Edtech Inc. v. Union of India and Anr.***, 2023 SCC OnLine Del 7304 and ***Dr. Reddy's Laboratories Ltd. & Anr.*** (*supra*), it held that the situs of the High Court, which would hear the appeal under Section 117A(2) of the Act, would be determined by the location of the "Appropriate Office".

13.3. As the Patent Office at Delhi had no role to play in the Subject Application, the doctrine of *forum conveniens* be invoked and the present Petition be dismissed.

13.4. A Pre-grant Opposition under Section 25(1) of the Act is a part of the examination process to aid Respondent No. 1 in considering an application for the grant of a patent. In case of failure of pre-grant

opposition, the opponent being a "person interested" has effective mechanisms for assailing the grant of a patent. In ***Novartis AG v. Natco Pharma Ltd.***, 2024 SCC OnLine Del 152, this Court has held that the "person interested" may, after the rejection of the pre-grant opposition (i) file a post-grant opposition under Section 25(2) of the Act; and (ii) file a revocation under Section 64 of the Act. ***Rich Products*** (*supra*) reiterated and summarized the correct position of law as set out in ***Novartis AG*** (*supra*), which has clarified that there is no complete embargo to entertain a writ petition against a pre-grant opposition, however there must be some manifest or jurisdictional error.

13.5. Accordingly, the Petition is liable to be dismissed, and the Impugned Order be upheld.

SUBMISSIONS ON BEHALF OF RESPONDENT NO. 2

14. The learned Senior Counsel for Respondent No. 2 made the following submissions:

14.1. The Petitioner has alternate efficacious remedies available to it and, thus, the present Petition is not maintainable as appeals under Section 117A of the Act can be filed against decisions, orders and directions passed by the learned Controller under specific Sections of the Act, including Sections 15 and 57 of the Act.

14.2. The Impugned Order has been passed under Section 15 of the Act read with Rule 55(5) of the Rules and, thus, appealable under Section 117A of the Act. Moreover, decisions of the learned Controller allowing or

refusing amendment of claims in exercise of discretion under Section 57 of the Act, which discretion must be exercised in accordance with Section 59 of the Act, are also appealable under Section 117A of the Act. Thus, the appropriate remedy available to the Petitioner was to file an appeal under Section 117A of the Act.

14.3. The Petitioner could have filed an application for review of the Impugned Order under Section 77(1)(f) of the Act. The Petitioner also had an option to a Revocation Petition under Section 64 of the Act. The main grievance of the Petitioner in the present Petition is that the claim amendments as sought by Respondent No. 2 should not have been allowed by Respondent No. 1. This grievance can only be correctly raised and adjudicated upon under a Revocation Petition Section 64(o) of the Act, which specifically provides for revocation of a patent on the ground that an amendment under Section 57 of the Act was obtained by fraud. Such a ground is conspicuously absent under Section 25(1) of the Act. Hence, the validity of amendment of the claims of the Subject Patent cannot be challenged by way of a Pre-Grant Opposition.

14.4. In the absence of any objection raised by the Petitioner at the stage of the Pre-Grant Opposition regarding the procedural determination of the First Amendment despite the FER having considered the same, the Petitioner cannot be permitted to agitate such objection belatedly in the present Petition.

14.5. In ***UCB Farchim Sa v. Cipla Ltd. & Ors.***, 2010 SCC OnLine Del 523 and ***Rich Products*** (*supra*) it is held that a pre-grant opposition under Section 25(1) of the Act forms part of the patent examination process and assists the learned Controller in deciding the grant of a patent. An order suffering from a jurisdictional error entitles the aggrieved party to invoke the writ jurisdiction of the High Court under Article 226 of the Constitution. The jurisdiction under Article 226 is discretionary and not to be exercised as a matter of course. The existence of an efficacious statutory alternative remedy ordinarily persuades the Court to decline interference. However, the availability of such alternative remedies does not bar the exercise of writ jurisdiction in cases of manifest jurisdictional error. In the absence of a patent jurisdictional infirmity, the aggrieved party must pursue remedies under the Act.

14.6. Further, the Petitioner has already filed a counterclaim in the Respondent No. 2's Suit being CS(COMM) 629/2023 ("**Suit**"), in which the pleadings stand completed.

14.7. A pre-grant opponent cannot take an objection under Section 57 of the Act as regards amendment of claims as Section 25(1) of the Act does not provide this as a ground of opposition at a pre-grant stage. In direct contrast to this, Section 64(1) of the Act specifically has a provision to allow a person interested to challenge the patent on the ground that the leave to amend was undertaken by fraud.

14.8. Section 3(d) of the Act is not applicable as before the priority date of the Subject Patent as there was no prior art, which disclosed a combination of palonosetron and netupitant, and, therefore, there was no 'known substance' or 'known efficacy'. Further, Example 5 of the Subject Patent clearly demonstrates the synergistic effect of the oral dosage combination as claimed in the Subject Patent. Thus, Section 3(e) of the Act is also inapplicable in the facts of the present case.

14.9. Due to the pendency of the present Petition, the application seeking interim injunction for infringement of the Subject Patent filed in the Suit by Respondent No. 2 is not yet heard. Whereas other parties, who have attempted to bring the same infringing products as the Petitioner to the market, have been injuncted by way of *ad-interim* orders passed in respect of the Subject Patent *vide* order dated 30.04.2024 in ***Helsinn Healthcare SA & Anr. v. Hetero Healthcare Ltd.*** in CS(COMM) 347/2024 and *vide* order dated 23.12.2024 in ***Helsinn Healthcare SA & Anr. v AET Laboratories Pvt. Ltd.*** in CS(COMM) 1188/2024.

14.10. There has been no violation of principles of natural justice. The Petitioner was duly heard by Respondent No. 2 in the Pre-Grant Opposition. The Pre-Grant Opposition process and examination of patent are separate proceedings. A pre-grant opponent cannot be countenanced to have a right of hearing in the examination process as held in ***Novartis AG*** (*supra*).

14.11. Accordingly, the present Petition is liable to be dismissed and the Impugned Order be upheld.

ANALYSIS AND FINDINGS

15. The Petitioner has filed the present Writ Petition challenging the Impugned Order of Respondent No. 1 granting the Subject Patent, on account of manifest jurisdictional error because of violation of principles of natural justice by not giving opportunity of hearing and infraction of Sections 57 and 59 of the Act by not determining the amendment of claims sought by Respondent No. 2.

16. In view of the pleading, oral submissions and written submissions by the Parties, the following issues arise for consideration in this Petition:

a. Whether this Court has territorial jurisdiction to decide this Petition as the Subject Patent was granted by the Patent Office not located withing the jurisdiction of this Court?
b. Whether this Petition ought to be entertained in case the Petitioner has alternative efficacious remedy?
c. Whether there is a need to pass separate speaking order determining the amendment sought at pre-FER stage or whether FER can be treated as determination under Sections 57(1) and 59 of the Act read with Rule 81(2) of the Rules?
d. Whether there is violation of principles of natural justice as opportunity of hearing was not granted to the Petitioner at Hearing II pursuant to

the Third Amendment to the Claims after reserving the order in Pre-Grant Opposition at Hearing I?

TERRITORIAL JURISDCTION:

17. In ***Dr. Reddy's Laboratories & Anr.*** (*supra*), it is held that the impact of a patent can be felt wherever a person interested carries on its business and that would confer the jurisdiction to that High Court. It was further held that the commercial interest of the person interested could be affected in various other jurisdictions apart from the jurisdiction where the patent was granted, as under:

> *"82.* ***Section 48*** *of the 1970 Act vests exclusive rights in the patentee for making, using, offering for sale, selling or importing the patented product or any product made using the patented process.* ***The impact of such a patent can be felt wherever a person interested carries on its business*** *including for manufacturing or selling or even packing or distributing the product in respect of which patent has been granted.* ***Thus, the commercial interest of the person interested could be affected in various other jurisdictions apart from the jurisdiction where the patent was granted.*** *Such a person may be aggrieved by the incorrect grant of the patent and may even challenge the validity of the patent.*
>
> *83.* ***Undoubtedly the High Court in whose jurisdiction the patent was granted would be one of the fora which would have jurisdiction as the cause of action consists of a series of events beginning with the grant of the patent.*** *In the opinion of this Court since the dynamic effect of the patent as contemplated in Girdhari Lal Gupta (supra) would also extend to other places where the commercial interest of the person interested may be affected such other High Courts would also have jurisdiction to entertain revocation petitions, under section 64 of the Act. Thus, the expression 'High Court having territorial jurisdiction in that State or Union Territory' in case of revocation petitions would have to be decided on the basis of both the static effect and the dynamic effect of the grant of the patent. The place where the*

commercial interest of the applicant is affected would also be relevant."

[Emphasis added]

18. However, in the case of appeals where challenges against orders of the Patent Office are raised, ***Dr. Reddy's Laboratories & Anr.*** (*supra*) holds that the concept of cause of action cannot be pleaded to vest jurisdiction in other High Courts only the High Court, where the appropriate patent office is located shall have the jurisdiction, as under:

"104. In view of the above legal position. an order passed by the Delhi Patent Office as a part of arrangement put in place by the Office of CGPDTM. though within the territorial limits of this Court. would not vest territorial jurisdiction in the High Court under section 117A of the 1970 Act. In this background. it is clear that even after the enactment of the TRA appeals under Section 117A challenging the order or direction of the Patent Office would lie before the High Court having territorial jurisdiction over the appropriate office from where the patent application originates and which is the situs of the said application. ***In the case of appeals where challenges against orders of the Patent Office are raised the concept of cause of action cannot be pleaded to vest jurisdiction in other High Courts i.e. other than the one in the territorial jurisdiction of which the appropriate office is located.***

105. Suits for infringement have been filed by Boehringer against both the Petitioners herein in the High Court of Himachal Pradesh and interim injunctions have been granted. However, revocation petition before this Court was filed prior to the suits for infringement themselves. Ideally, after the filing of infringement proceedings, the Defendant, if it wishes to seek revocation, ought to prefer the counter claim in the said suit so as to avoid multiplicity of proceedings and possibility of contradictory judgments. However, in the present case, since the revocation petition was filed prior to filing of the suits for infringement and the patent was itself granted by the Delhi Patent Office, and the appropriate office is the Delhi Patent Office. Hence, the present petition is maintainable before this Court. C.O. (COMM.

IPDPAT) 3/2021 is held to be maintainable before this Court. The application under Section 10 CPC would, however, be decided on its own merits"

[Emphasis added]

19. Pertinently, ***Dr. Reddy's Laboratories & Anr.*** (*supra*) has not examined the aspect of which High Court would have jurisdiction to decide the Writ Petition under Article 226 of the Constitution as the said matter involved jurisdiction for Revocation Petition under Section 64 of the Act and Appeals under Section 117A of the Act.

20. The concept of dynamic effect of the patent where the commercial interest of the person interested may be affected to entertain revocation petitions under Section 64 of the Act would not extend to the Writ Petitions under Article 226 of the Constitution. ***Dr. Reddy's Laboratories & Anr.*** (*supra*) was decided in a case of Revocation Petitions under Section 64 of the Act based on both the static effect and the dynamic effect of the grant of the Patent and the place where the commercial interest of the applicant was affected was held to be relevant. However. ***Dr. Reddy's Laboratories & Anr.*** (*supra*) has clarified that in the case of Appeals under the Act where challenges against orders of the Patent Office are raised, the concept of cause of action cannot be pleaded to vest jurisdiction in other High Courts and only the High Court where the 'appropriate patent office' is located shall have the jurisdiction.

21. As the Writ Petition under Article 226 of the Constitution to examine manifest jurisdictional error committed by the learned Controller is akin to an

Appeal under the Act, the observation in ***Dr. Reddy's Laboratories & Anr.*** (*supra*) as applicable to the appeals under the Act would be applicable to the Writ Petitions under Article 226 of the Constitution as well. The dynamic effect principle applicable to the Revocation Petitions under Section 64 of the Act would not be applicable to the Petitions under Article 226 of the Constitution. Accordingly, the Petitioner's submission that since the dynamic effect of the grant of the patent / the effect of the registration is felt under the jurisdiction of this Court, this Petition under Article 226 of the Constitution is maintainable is rejected.

22. In view of the above, it is held that as the relevant Patent Office is not located within the jurisdiction of this Court, the present Petition is not maintainable due to lack of territorial jurisdiction, and this Court cannot entertain and decide the present Petition.

ALTERNATIVE EFFICACIOUS REMEDY:

23. Respondent No. 1 argued that it is settled law that the role of a pre-grant opponent and the nature of the proceeding in the pre-grant opposition is very different. According to Respondent No. 2, in case of failure of pre-grant opposition, the opponent as the Petitioner herein being a "person interested" has effective mechanisms for assailing the grant of a patent. Relying upon the decision in ***Novartis AG*** (*supra*), Respondent No. 2 submitted that the "person interested" may after the rejection of the pre-grant opposition can: (i) file a post-grant opposition under Section 25(2) of the Act; and (ii) file a revocation under Section 64 of the Act.

24. In ***Glochem Industries Ltd. v. Cadila Healthcare Ltd. & Ors***., 2009 SCC OnLine Bom 1701, while rejecting the petition stating that the petitioner had an equally efficacious remedy against rejection of its pre-grant opposition in the given facts of that case, it was held that:

> *"12. Having considered the rival submissions, we would deal with the last objection first.* ***Although the Petitioners may have remedy of post grant opposition or of seeking suo moto revocation as well as filing of a counter claim as is suggested by the Respondents that by itself can be no basis to non-suit the Petitioners, if the Petitioners were right in their grievance that the authority has committed manifest or jurisdictional error while considering the representation by way of opposition or for that matter decided the objections on palpable misreading and misapplication of the relevant provisions of law****. This is so because the law provides for remedy of pre-grant opposition by virtue of Section 25(1) of the Act. If such a remedy is provided, the authority is obliged to consider the representation by way of pre-grant opposition under Section 25(1) keeping in mind the parameters of law by observing principles of natural justice. It is not necessary for us to examine the argument of the Petitioners that the remedy of pre-grant opposition is qualitatively different than the remedy of post-grant opposition. According to the Petitioners, in the pre-grant opposition, the onus is on the patent applicant to show that the alleged invention would result in enhancement of the known efficacy of the stated substance; whereas in the post-grant opposition, the onus will be on the objector to show that the alleged invention does not result in enhancement of the known efficacy of the stated substance.* ***Suffice it to observe that the preliminary objection raised by the Respondent No. 1 does not mean that this Court has no jurisdiction to entertain writ petition under Article 226 of the Constitution of India against the decision of the authority on the opposition under Section 25(1) of the Act. It is a matter of prudence and discretion as to whether the Court should entertain the writ petition or not. In the facts of the present case, we think that it would not be proper to non-suit the Petitioners at the threshold on this count.****"* [Emphasis added]

25. In ***UCB Farchim Sa*** (*supra*), this Court held that the Court should decline to entertain the writ petition not because it has no jurisdiction, but because the petitioner has an efficacious alternative statutory remedy to exhaust, as under:

> "*16.* ***The law is well settled that notwithstanding that a High Court has the power and the jurisdiction under Article 226 of the Constitution to interfere with the orders of any statutory authority which is of a quasi-judicial nature, it will decline to exercise such jurisdiction where there is an efficacious alternative statutory remedy available to the aggrieved person.***
>
> *17. Counsel for the parties have drawn the attention of this Court to a recent decision of the Division Bench of the Bombay High Court in Glochem Industries Ltd. v. Cadila Healthcare Ltd., (its decision dated 6th November, 2009 in Writ Petition No. 1605 of 2009). Although in that case the petitioner whose pre-grant opposition had been rejected was obviously a person interested, the High Court overruled the objections as to maintainability since it took the view that the Controller's order in that case suffered from obvious jurisdictional errors. The Bombay High Court nevertheless noted that "it is a matter of prudence and discretion as to whether this Court should entertain the writ petition or not" and that in the facts and circumstances of that case it was "not proper to non-suit the petitioners at the threshold on this count."* ***To this Court it appears that the settled law as explained in several decisions of the Supreme Court (which incidentally have not been adverted to by the Bombay High Court in Glochem) makes it clear that this Court should not entertain the writ petition, not because it does not have the power or jurisdiction, but because the petitioner has an efficacious alternative statutory remedy to exhaust.***"
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> [Emphasis added]

26. In ***Rich Products*** (*supra*), the Division Bench of this Court relying upon ***Glochem Industries*** (*supra*) and ***UCB Farchim Sa*** (*supra*) held that if the order passed by the authority suffers from jurisdictional errors, the aggrieved person can invoke the extraordinary jurisdiction under Article 226 of the Constitution as under:

> "*10. It is well settled that a pre-grant opposition under Section 25(1) of the Act is a part of the examination process and is to aid the Controller in considering an application for the grant of a patent.* ***Undisputedly, if an authority passes an order which suffers from jurisdictional errors, the person aggrieved would have a recourse to invoke the extraordinary jurisdiction of this Court under Article 226 of the Constitution of India.*** *Ho wever, it is necessary to note that the remedy under Article 226 of the Constitution of India is a discretionary remedy and the Court can decline to exercise the same if there is an efficacious, alternate and statutory remedy.*"
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> ***** ***** *****
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> "*16. There is no cavil that in case where it is apparent the Controller has committed a jurisdictional error; the Court may entertain a petition under the Article 226 of the Constitution of India.*"

27. Hence, the aggrieved party would have a recourse to invoke the extraordinary jurisdiction of this Court under Article 226 of the Constitution, but it is a discretionary remedy, and the Court can decline to exercise the same in cases where the petitioner is not able to establish manifest jurisdictional error irrespective alternative remedy of filing a post-grant opposition under Section 25(2) of the Act and / or filing a Revocation Petition under Section 64 of the Act.

NEED TO PASS SEPARATE SPEAKING ORDER DETERMINING THE PRE-FER AMENDMENTS:

28. The Subject Application was filed by Respondent No. 2 through Patent Cooperation Treaty ("**PCT**") route. The PCT claims were entered into the Indian National Phase on 20.07.2013. Thereafter, Respondent No. 2 made the First Amendment. Respondent No. 2 again amended *vide* Second Amendment.

29. After that, the Petitioner filed its Pre-Grant Opposition, and raised an objection to the amendment of claims, apart from the objections taken on merits. The said objection was taken during Hearing I and in the Written Submissions filed by the Petitioner.

30. After Hearing I, the order was reserved. Subsequently, Respondent No. 1 issued a Hearing Notice under Section 14 of the Act only to Respondent No 2. In view of the objections raised in the Hearing Notice, Respondent No. 2 made another amendment *vide* Third Amendment and hearing was given to Respondent No. 2 at Hearing II. However, no opportunity of a hearing was provided to the Petitioner. Thereafter, the Impugned Order was passed by Respondent No. 1, whereby the Pre-Grant Opposition of the Petitioner was rejected, and the Subject Patent was granted. The Impugned Order accepted the voluntary amendments made by Respondent No.1, however no finding was returned as to how the said amendments did not violate Section 59 of the Act.

31. Table for the originally filed Claims and Amended Claims is as under:

Originally Filed Claims	Proposed Amended Claims
34) An orally administered dosage form comprising a combination of palonosetron and an NK I antagonist, or a pharmaceutically acceptable salt or prodrug thereof, comprising: *a) an outer shell;* *b) one or more NKI antagonist units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt or prodrug thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said or pharmaceutically acceptable ester or prodrug thereof and one or more pharmaceutically acceptable excipients;* *wherein said dosage form comprises (3S)-3-[(3aS)-l-oxo-2,3,3a,4,S,6-hexahydro-l Hbenzo[de]isoquinoline-2-yl]-1-azoniabicyclo[2.2.2]octane-1-olate in an amount that does not exceed 3 wt%.*	*1) An orally administered dosage form comprising a combination of palonosetron and an NKI antagonist, or a pharmaceutically acceptable salt or prodrug thereof, comprising: about 0.56 mg. of palonosetron hydrochloride and from about 200 to about 400 mg of netupitant or a pharmaceutically acceptable salt thereof.* *2) The dosage form of claim 1 comprising about 300 mg of netupitant or a pharmaceutically acceptable salt thereof.* *3) The dosage form of claim 1, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.* *4) Use of a therapeutically effective amount of netupitant or a pharmaceutically acceptable salt thereof and a therapeutically effective amount pf palonosetron or a pharmaceutically acceptable salt thereof in the manufacture of a combination medicament for the treatment of nausea and vomiting for five consecutive davs through a single administration in a patient in need thereof.* *5) The use of claim I wherein:*

	a) the therapeutically effective amount of netupitant or pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases of emesis, and which enters the systemic circulation, crosses the blood brain barrier and occupies at least 70% of NK, receptors jn the striatum seventy-two hours after said administration: and *b) the therapeutically effective amount of palonosetron or a, pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases, delayed phases,* *6) The use of claim 1 wherein said therapeutically effective amount of netpitant comprises from about 200 to about 400 mg. of netpitant or a pharmaceutically acceptable salt thereof, and said therapeutically effective amount of palonosetron comprises from about 0.25 to about 0. 75 mg. of palonosetron or a pharmaceutically acceptable salt thereof.* *7) The use of claim 1 wherein said therapeutically effective amount of netupitant comprises about 300 mg. of netupitant as a free base and said about 0.56 mg. of palonosetron hydrochloride, corresponding to about 0,5 mg of palonosetron as a free base,*

	8) The use of claim I wherein said medicament is an oral medicament. *9) The use of Claim I wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.* *10) An orally administered dosage form comprising a combination of palonosetron and an NKI antagonist, or a pharmaceutically acceptable salt thereof, comprising;* *a) an outer shell;* *b) one or more NKl antagonist netupitant units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt-or prodrug thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said palonosetron or pharmaceutically acceptable ester or prodrug thereof and one or more pharmaceutically acceptable excipients:*
35) *The dosage form of claim 34, comprising about 0.56 mg. of palonosetron hydrochloride and from about l00 to about 500 mg, or from about 200 to about 400 mg, or about 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*	11) *The dosage form of claim 7, comprising about 0.56 mg. of palonosetron hydrochloride and from about JOO to about 500 mg, or from about 200 to about 400 mg, or about 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*

36) The dosage *form of claim 34 or 35, wherein said one or more NK I antagonist units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.*	12) *The dosage form of claim 7, wherein said one or more netupitant units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.*
37) *The dosage form of any one of claims 34 to 36, wherein each of said tablets comprise from about 50 to about 200 mg, or from about 100 to about 150 mg, or about 100 mg of netupitant.*	13) *The dosage form of claim 7, wherein each of said tablets comprises from about 50 to about 200 mg, or from about 100 to about 150 mg, or about 100 mg of netupitant.*
38) *The capsule of any one of claims 34 to 37, wherein said outer shell of said capsule has an oxygen permeability of less than 1.0 x 10' m!cm/(cm·24 hr. atm).*	14) *The dosage form of claim 7, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.*

32. In the FER, Respondent No. 1 has raised objections on the grounds of lack of inventive step under Section 2(1)(ja) of the Act, non-patentability under Section 2(1)(j) of the Act. Additionally, Respondent No. 1 also raised objections on the ground of sufficiency of disclosure, clarity and conciseness and other requirements.

33. Respondent No. 2 while replying to the FER, again amended its claims to overcome / address the objections raised in order to satisfy Respondent No. 1 as under:

Amended Claims submitted before FER	Amended Claims submitted in Reply to the FER
1) An orally administered dosage form comprising a combination of palonosetron and an NKI antagonist, or a pharmaceutically acceptable salt or prodrug thereof, comprising: about 0.56 mg. of palonosetron hydrochloride and from about 200 to about 400 mg of netupitant or a pharmaceutically acceptable salt thereof.	*I) An orally administered dosage form comprising a combination of palonosetron and ~~an NKI antagonistnetupitant,~~ or a pharmaceutically acceptable salt ~~or prodrug~~ thereof, comprising ~~about~~ 0.56 mg. of palonosetron hydrochloride and from ~~about~~ 200 to ~~about~~ 400 mg of netupitant or a pharmaceutically acceptable salt thereof.*
2) The dosage form of claim 1 comprising about 300 mg of netupitant or a pharmaceutically acceptable salt thereof.	*2) The dosage form as claimed in~~of~~ claim I comprising ~~aboot~~ 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*
3) The dosage form of claim L, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.	*3) The dosage form as claimed in~~of~~ claim I, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.*
4) Use of a therapeutically effective amount of netupitant or a pharmaceutically acceptable salt thereof and a therapeutically effective amount pf palonosetron or a pharmaceutically acceptable salt thereof in the manufacture of a combination medicament for the treatment of nausea and vomiting for five consecutive davs through a single administration in a patient in need thereof.	*~~4) Use of a therapeutically effective amount of netupitant or a pharmaceutically acceptable salt thereof and a therapeutically effective amount pf palonosetron or a pharmaceutically acceptable salt thereof in the manufacture of a combination medicament for the treatment of nausea and vomiting for five consecutive davs through a single administration in a patient in need thereof.~~*
5) The use of claim I wherein:	*~~5) The use of claim I wherein:~~*

a) the therapeutically effective amount of netupitant or pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases of emesis, and which enters the systemic circulation, crosses the blood brain barrier and occupies at least 70% of NK, receptors jn the striatum seventy-two hours after said administration: and *b) the therapeutically effective amount of palonosetron or a, pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases, delayed phases,*	~~*a) the therapeutically effective amount of netupitant or pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases of emesis, and which enters the systemic circulation, crosses the blood brain barrier and occupies at least 70% of NK, receptors jn the striatum seventy-two hours after said administration: and*~~ ~~*b) the therapeutically effective amount of palonosetron or a, pharmaceutically acceptable salt thereof is effective to treat nausea and vomiting during the acute and delayed phases, delayed phases,*~~
6) The use of claim 1 wherein said therapeutically effective amount of netpitant comprises from about 200 to about 400 mg. of netpitant or a pharmaceutically acceptable salt thereof, and said therapeutically effective amount of palonosetron comprises from about 0.25 to about 0. 75 mg. of palonosetron or a pharmaceutically acceptable salt thereof.	*4) The* ~~*use of*~~ *orally administered dosage form as claimed in claim I, wherein* ~~*said therapeutically effective amount of*~~ *netupitant comprises from* ~~*about*~~ *200 to* ~~*about*~~ *400 mg of netupitant or a pharmaceutically acceptable salt thereof, and said* ~~*therapeutically effective amount*~~ *of palonosetron comprises from* ~~*about*~~ *0.25 to* ~~*about*~~ *0. 75 mg of palonosetron or a pharmaceutically acceptable salt thereof.*
7) The use of claim 1 wherein said therapeutically effective amount of netupitant comprises about 300 mg. of netupitant as a free base and said about 0.56 mg. of palonosetron hydrochloride, corresponding to	*5) The* ~~*use of*~~ *orally administered dosage form as claimed in claim I, wherein said* ~~*therapeutically effective amount of*~~ *netupitant comprises about 300 mg of netupitant as a free base, and said palonosetron comprises* ~~*about*~~ *0.56*

about 0,5 mg of palonosetron as a free base	*mg of palonosetron hydrochloride, corresponding to ~~about~~ 0.5 mg of palonosetron as a free base.*
8) The use of claim I wherein said medicament is an oral medicament.	*6) The ~~use of~~ orally administered dosage form as claimed in claim I, wherein said medicament is an oral medicament.*
9) The use of Claim I wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.	*~~9) The use of Claim I wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.~~*
10) An orally administered dosage form comprising a combination of palonosetron and an NKI antagonist, or a pharmaceutically acceptable salt thereof, comprising; *a) an outer shell;* *b) one or more NKl antagonistnetupitant units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt-or prodrug thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said palonosetron or pharmaceutically acceptable ester or prodrug thereof and one or more pharmaceutically acceptable excipients.*	*7) An orally administered dosage form comprising a combination of palonosetron and ~~an~~ netupitant,~~NK1 antagonist~~ or a pharmaceutically acceptable salt thereof, comprising:* *a) an outer shell;* *b) one or more netupitant units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said palonosetron ~~or pharmaceutically acceptable ester or prodrug~~ thereof or more pharmaceutically acceptable excipients.*
11) *The dosage form of claim 7, comprising about 0.56 mg. of*	8) *The dosage form as claimed in~~of~~ claim 7, comprising ~~about~~ 0.56 mg*

palonosetron hydrochloride and from about 100 to about 500 mg, or from about 200 to about 400 mg, or about 300 mg of netupitant or a pharmaceutically acceptable salt thereof.	*of palonosetron hydrochloride and from ~~about~~ 100 to ~~about~~ 500 mg, or from about 200 to ~~about~~ 400 mg, or ~~about~~ 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*
12) The dosage form of claim 7, wherein said one or more netupitant units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.	*9) The dosage form as claimed in~~of~~ claim 7, wherein said one or more netupitant units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.*
13) The dosage form of claim 7, wherein each of said tablets comprises from about 50 to about 200 mg, or from about 100 to about 150 mg, or about 100 mg of netupitant.	*10) The dosage form as claimed in~~of~~ claim 7, wherein each of said tablets comprises from ~~about~~ 50 to about 200 mg, or from ~~about~~ 100 to ~~about~~ 150 mg, or ~~about~~ 100 mg of netupitant.*
14) The dosage form of claim 7, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt are synergistically effective for the treatment of nausea and vomiting.	*11) The dosage form as claimed in~~of~~ claim 7, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt thereof are synergistically effective for the treatment of nausea and vomiting.*

34. According to the Petitioner, the First Amendment enlarged the scope of the independent Claim 1, since the limitations in the claim were deleted, resulting in broadening of the scope thereof. The Petitioner further submitted that the amendments were undertaken on the already enlarged set of claims and, therefore, the incorrect enlargement of the scope of the claims percolated from the First Amendment to the Second Amendment.

35. The Petitioner submitted that it is a settled position of law that the scope of the claims cannot be enlarged through amendments and thus, the First Amendment was impressible in law. It was also submitted by the Petitioner that Respondent No. 1 did not return any finding on whether the First Amendment was accepted and issued the FER. The Petitioner argued that the following 3 limitations have been deleted:

> *"i. "an outer shell";*
> *ii. "palonosetron units housed within said outer shell"; and*
> *iii. the impurity "(3S)-3-[(3aS)- l-oxo- 2,3,3a,4,5,6-hexahydro- l H-benzo[de] isoquinoline-2-yl]-lazoniabicyclo[2.2.2]octan- l-olate in an amount that does not exceed 3 wt.%"*

36. Regarding the First Amendment, the Petitioner has submitted that the Complete Specification of the Subject Application enables only 2 types of embodiments: one where netupitant + palonosetron are administered, where the dosage is outside the range claimed; and the other where netupitant + palonosetron is administered with a third substance dexamethasone. The Petitioner relied on the decision in ***Allergan Inc***. (*supra*) to argue that that the amendments made to the claims should find support in the Complete Specification. Therefore, according to the Petitioner, amending the originally filed claim to exclude dexamethasone does not find support in the Complete Specification and is violative of Section 59 of the Act.

37. According to the Petitioner, Respondent No. 2 claimed that the dosage form to be their inventive step and because the administration of netupitant + palonosetron with a third substance, dexamethasone is bound to have an impact on the effect of the drug, this limitation could not have been omitted

from the claims. Therefore, according to the Petitioner, amending the originally filed claim to exclude dexamethasone does not find support in the Complete Specification of the Subject Application and is violative of Section 59 of the Act.

38. *Per contra*, Respondent No. 2 submitted that claims amended *vide* First Amendment were within the scope of the originally filed claims and the amended Claim No. 1 was created by taking the preamble from Claim No. 34 and taking support from Claim Nos. 27 to 29. Therefore, according to Respondent No. 2, the amended Claim No. 1 was within the scope of the originally filed Claim Nos. 27 to 29. Respondent No. 2 further submitted that by way of the First Amendment, Respondent No. 2 only sought to convert "method of treatment" claims to "pharmaceutical composition" claims.

39. In view of the above rival contentions, this Court is of the view that the First Amendment was made prior to FER and, therefore, there was no requirement for separate 'determination' by Respondent No. 1 as regards the amendment by passing an order prior to issuance of the FER. The FER mentions the amended claims, which indicates that Respondent No. 1 has applied its mind to the amended claims while issuing FER. As the First Amendment was duly considered by Respondent No. 1 in FER, the Act and Rules do not contemplate the two-step procedure for issuance of a formal order in cases where the applicant has made amendments voluntarily prior to the issuance of FER. Respondent No. 1 is entitled to duly consider the un-amended and amended claims in a consolidated manner in FER as

examination phase is a continuous process.

40. The Petitioner has not raised the above objection regarding the procedural step of determination regarding allowing or rejecting the First Amendment prior to issuance of FER in the Pre-Grant Opposition as FER already considered the First Amendment. Hence, it is not open for the Petitioner to raise the same belated by way of this Petition.

41. Hence, the objection by the Petitioner regarding non-passing of a formal order after the First Amendment and before the FER to determining either to accept or reject the First Amendment by Respondent No. 1 is hereby rejected as there is no jurisdictional error by examining the amendments sought prior to FER in the FER itself as there is no requirement under the Act or the Rules to pass a separate order determining the pre-FER amendment by way of separate order and FER itself is the determination of the pre-FER amendments.

REVIEW ON MERITS IN ABSENCE OF MANIFEST JURISDICTIONAL ERROR IN A WRIT PETITION:

42. As regards the objection of the Petitioner that the First Amendment was beyond the Complete Specification and contrary to Section 59 of the Act, this Court held that such objection cannot be entertained in the present Petition under Article 226 of the Constitution as the review of the decision of Respondent No. 1 on merit is not permissible in absence of manifest jurisdictional error as held in ***Rich Products*** (*supra*), the Division Bench of this Court, as under:

> *"20. The appellant, in effect, seeks a merit's review of the decision of the Controller. In the given facts, we concur with the conclusion of the learned Single Judge that it would not be apposite to entertain the petition filed by RPC challenging the rejection of its post-grant opposition. This is not because the Court does not have the jurisdiction to entertain petition against an order of the Controller rejecting the pregrant opposition but for the reason that we find no manifest or jurisdictional error warranting exercise of jurisdiction under Article 226 of the Constitution of India. As noted above, the Controller has examined the objections raised by RPC on merits and it would not be apposite to undertake a merits review in a proceeding under Article 226 of the Constitution of India. Thus, RPC must be relegated to availing of its other remedies as provided under the Patents Act, 1970, if so advised."*

43. The above finding also applies to the grounds raised by the Petitioner that the Subject Patent is *ultra vires* Sections 3(d) and 3(e) of the Act. The Petitioner has already filed a counterclaim in Respondent No. 2's Suit before this Court, in which the pleadings of the Suit are complete. As the Petitioner has already availed an alternative remedy, it would not be apposite to enter into disputed questions of merits under the writ jurisdiction to avoid any conflicting decisions due to complete overlap between the grounds raised in the present Petition as well as the counterclaim filed by the Petitioner in the Suit filed by Respondent No. 2, which is pending before this Court.

44. A review of the Impugned Order on merits is not permissible while exercising the writ jurisdiction in absence of any jurisdictional error committed by Respondent No. 1 while passing the Impugned Order to warrant any interference by this Court in the present Petition.

VIOLATION OF PRINCIPLES OF NATURAL JUSTICE:

45. Respondent No. 1 through the Hearing Notice under Section 14 of the Act further raised objections. Considering such objections, Respondent No. 2 amended its claims for the third time by way of the Third Amendment as under:

Amended claims submitted in Reply to the FER	**Amended claims submitted after the Hearing II**
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.	*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.*
2) The dosage form as claimed in claim 1, comprising 300 mg of netupitant or a pharmaceutically acceptable salt thereof.	*2) The dosage form as claimed in claim 1, comprising 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*
3) The dosage form as claimed in claim I, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt thereof are synergistically effective for the treatment of nausea and vomiting.	~~*3) The dosage form as claimed in claim I, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt thereof are synergistically effective for the treatment of nausea and vomiting.*~~
4) The orally administered dosage form as claimed in claim I, wherein said netupitant comprises from 200 to 400 mg of netupitant or a pharmaceutically acceptable salt	~~*4) The orally administered dosage form as claimed in claim I, wherein said netupitant comprises from 200 to 400 mg of netupitant or a pharmaceutically acceptable salt*~~

thereof, and said palonosetron comprises from 0.25 to 0. 75 mg of palonosetron or a pharmaceutically acceptable salt thereof.	~~*thereof, and said palonosetron comprises from 0.25 to 0. 75 mg of palonosetron or a pharmaceutically acceptable salt thereof.*~~
5) The orally administered dosage form as claimed in claim I, wherein said netupitant comprises 300 mg of netupitant as a free base, and said palonosetron comprises 0.56 mg of palonosetron hydrochloride, corresponding to 0.5 mg of palonosetron as a free base.	*3) The orally administered dosage form as claimed in claim I, wherein said netupitant comprises 300 mg of netupitant as a free base, and said palonosetron comprises 0.56 mg of palonosetron hydrochloride, corresponding to 0.5 mg of palonosetron as a free base.*
6) The orally administered dosage form as claimed in claim I, wherein said medicament is an oral medicament.	*4) The orally administered dosage form as claimed in claim I, wherein said medicament is an oral medicament.*
7) An orally administered dosage form comprising a combination of palonosetron and netupitant, or a pharmaceutically acceptable salt thereof, comprising: *a) an outer shell;* *b) one or more netupitant units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said palonosetron and one or more pharmaceutically acceptable excipients.*	*5) ~~An~~ The orally administered dosage form comprising a combination of palonosetron and netupitant, or a pharmaceutically acceptable salt thereof as claimed in claim 1, comprising:* *a) an outer shell;* *b) one or more netupitant units housed within said outer shell, each comprising said netupitant or pharmaceutically acceptable salt thereof and one or more pharmaceutically acceptable excipients; and* *c) one or more palonosetron units housed within said outer shell, each comprising said palonosetron and one or more pharmaceutically acceptable excipients.*

8) The dosage form as claimed in claim 7, comprising 0.56 mg of palonosetron hydrochloride and from 100 to 500 mg, or from 200 to 400 mg, or 300 mg of netupitant or a pharmaceutically acceptable salt thereof.	~~*8) The dosage form as claimed in claim 7, comprising 0.56 mg of palonosetron hydrochloride and from 100 to 500 mg, or from 200 to 400 mg, or 300 mg of netupitant or a pharmaceutically acceptable salt thereof.*~~
9) The dosage form as claimed in claim 7, wherein said one or more netupitant units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.	*6) The dosage form as claimed in claim ~~7~~ 5, wherein said one or more netupitant units are in the form of one or more orally administered tablets, and said palonosetron units are in the form of one or more orally administered soft-gel capsules.*
10) The dosage form as claimed in claim 7, wherein each of said tablets comprises from 50 to 200 mg, or from 100 to 150 mg, or 100 mg of netupitant.	~~*10) The dosage form as claimed in claim 7, wherein each of said tablets comprises from 50 to 200 mg, or from 100 to 150 mg, or 100 mg of netupitant.*~~
11) The dosage form as claimed in claim 7, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt thereof are synergistically effective for the treatment of nausea and vomiting.	~~*11) The dosage form as claimed in claim 7, wherein said netupitant or pharmaceutically acceptable salt thereof and palonosetron or pharmaceutically acceptable salt thereof are synergistically effective for the treatment of nausea and vomiting.*~~

46. The Petitioner has submitted that no opportunity of hearing was given to the Petitioner pursuant to the Third Amendment made by Respondent No. 2. The Petitioner submitted as under:

> *"F. ABSENCE OF THE PETITIONER IN THE HEARING CONDUCTED UNDER SECTION 14 OF THE ACT AMOUNTS TO VIOLATION OF PRINCIPLES OF NATURAL JUSTICE*

> *8. The Respondent No. 2 has contended that the Opponent was not required to be heard in a hearing under Section 14 of the Act incorrectly alleging that powers under Section 14 are discretionary and there is no obligation to issue a notice to the pre-grant opponent. It is respectfully submitted that the said contention is incorrect since a pre-grant opposition is a proceeding which is quasi-judicial in nature and thus, has the trappings of court proceedings. Therefore, a pre-grant opponent cannot be kept in the dark about the hearings that are undertaken by the learned Controller once a pre-grant opponent has entered the fray. It is respectfully submitted that this Hon'ble Court in Natco Vs. Assistant Controller of Patents and Designs & Ors. (2023/DHC/000268) has already returned the finding that a pre-grant opponent is required to be served a notice under Section 14 and a hearing conducted in the absence of the pre-grant opponent would result in violation of the principles of natural justice. It is correct that a Division Bench of this Hon'ble Court is presently hearing the matter, however, the stay order has been passed only in view of the fact that there appeared to be contradictory views with regard to requirement of notice to be given to the pre-grant opponent under Section 14. It is relevant to note that the stay order does not hold that the view taken by the learned Single Judge is incorrect."*

47. Section 25(1) of the Act provides for grounds for opposition at the pre-grant stage and ends with "but no other ground". Accordingly, the grounds mentioned in Section 25 (1) of the Act are exhaustive and if any particular ground is not mentioned therein, it would not be permissible for Respondent No. 1 to consider any such ground for objection during the pre-grant opposition phase. Section 25(1) of the Act does not specify the ground of amendment of the claim and, therefore, it is not open for the Petitioner to raise that ground in the Pre-Grant Opposition. As there is no jurisdictional error by not considering any such ground by Respondent No. 2, the Petitioner is not entitled to raise any such ground in the present Petition as well.

48. In the decision of ***Novartis AG*** (*supra*), it is held that the pre-grant opposition proceeding and examination of patent are two separate proceedings and a pre-grant opponent cannot be countenanced to have a right of hearing in the examination process. As the Third Amendment was made pursuant to the Hearing Notice for Hearing II under Section 14 of the Act, it was during the examination process independent of Pre-Grant Opposition under Section 25 of the Act.

49. Hence, there was no requirement to give opportunity of hearing to the Petitioner second time after the Third Amended was submitted by Respondent No. 2 whereby only the Claim Nos. 3, 4, 8, 10 and 11 were deleted and the Claim No. 7 was made dependent on Claim No. 1 and was re-numbered as Claim No. 5 while there were no changes made to Claim No. 1.

50. In any event, Respondent No. 1 had uploaded the Hearing Notice on the website of Respondent No. 1 on the 17.02.2023. Respondent No. 1 also uploaded the Written Submissions filed thereafter by Respondent No. 2 on the 08.03.2023. The printout of Respondent No. 1's website showing the dates on which various documents were uploaded in respect of the Subject Patent is as under:

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Office of the Controller General of Patents, Designs & Trade Marks
Department of Industrial Policy & Promotion,
Ministry of Commerce & Industry,
Government of India

(http://ipindia.nic.in/index.htm)

(http://ipindia.nic.in/index.htm)

Document Name	*Created Date/Uploaded Date
1009-MUMNP-2012-ASSIGNMENT WITH VERIFIED COPY [13-06-2023(online)].pdf	13/06/2023
1009-MUMNP-2012-FORM-16 [13-06-2023(online)].pdf	13/06/2023
1009-MUMNP-2012-POWER OF AUTHORITY [13-06-2023(online)].pdf	13/06/2023
1009-MUMNP-2012-IntimationOfGrant23-03-2023.pdf	23/03/2023
1009-MUMNP-2012-PatentCertificate23-03-2023.pdf	23/03/2023
1009-MUMNP-2012-FORM 3 [08-03-2023(online)].pdf	08/03/2023
1009-MUMNP-2012-PETITION UNDER RULE 137 [08-03-2023(online)].pdf	08/03/2023
1009-MUMNP-2012-Written submissions and relevant documents [08-03-2023(online)].pdf	08/03/2023
1009-MUMNP-2012-Correspondence to notify the Controller [01-03-2023(online)].pdf	01/03/2023
1009-MUMNP-2012-US(14)-HearingNotice-(HearingDate-03-03-2023).pdf	17/02/2023
1009-MUMNP-2012-Annexure [04-07-2022(online)].pdf	04/07/2022
1009-MUMNP-2012-Written submissions and relevant documents [04-07-2022(online)]-1.pdf	04/07/2022
1009-MUMNP-2012-Written submissions and relevant documents [04-07-2022(online)].pdf	04/07/2022
1009-MUMNP-2012-PETITION UNDER RULE 138 [04-06-2022(online)].pdf	04/06/2022
1009-MUMNP-2012-PETITION UNDER RULE 138 [03-06-2022(online)].pdf	03/06/2022
1009-MUMNP-2012-RELEVANT DOCUMENTS [03-06-2022(online)].pdf	03/06/2022
1009-MUMNP-2012-Written submissions and relevant documents [24-05-2022(online)].pdf	24/05/2022
1009-MUMNP-2012-Correspondence to notify the Controller [19-05-2022(online)].pdf	19/05/2022
1009-mumnp-2012-Response to office action [19-05-2022(online)].pdf	19/05/2022
1009-MUMNP-2012-Correspondence to notify the Controller [16-05-2022(online)].pdf	16/05/2022
1009-MUMNP-2012-PETITION UNDER RULE 138 [26-04-2022(online)].pdf	26/04/2022
1009-MUMNP-2012-PreGrant-ExtendedHearingNotice-(HearingDate-20-05-2022).pdf	25/04/2022
1009-MUMNP-2012-Correspondence to notify the Controller [26-04-2022(online)].pdf	22/04/2022
1009-MUMNP-2012-REQUEST FOR ADJOURNMENT OF HEARING UNDER RULE 129A [22-04-2022(online)].pdf	22/04/2022
1009-MUMNP-2012-PreGrant-ExtendedHearingNotice-(HearingDate-28-04-2022).pdf	12/04/2022

https://ipsearch.ipindia.gov.in/PatentSearch/PatentSearch/ViewDocuments 1/3

51. Therefore, Respondent No. 1 has followed the procedure i.e., uploading Hearing Notice for Hearing II as well as the Written Submissions filed by Respondent No. 2 post-Hearing II. Therefore, the Petitioner had ample opportunity to file a Miscellaneous Petition before Respondent No. 1, seeking liberty to make further submissions, which the Petitioner did not avail.

52. In ***Dr. Snehlata C. Gupte v. Union of India***, 2010 SCC OnLine Del 2374, this Court has held that various representations may be submitted at the pre-grant opposition stage and there is the need to strike a balance between

the right of opponent and the imperatives of a patent application being disposed of as expeditiously as possible in light of the statutory command of Section 43(1) of the Act.

53. Section 57(4) of the Act reiterates the right of the person filing opposition. However, Section 57(3) of the Act also requires only those amendments proposed by the applicant to be advertised, which were substantive in the opinion of the learned Controller. Therefore, if the learned Controller believes that the proposed amendment is not substantive, he may refrain from advertising the same. ***Novartis AG*** (*supra*) also holds as under:

> *"73. Section 57(4) as it existed in its original form obliged the Controller to afford an opportunity to any person interested to oppose the amendment and thus envisaged the Controller holding a hearing in which both the applicant as well as the opponent may be heard.* ***While Section 57(4) principally retains the procedure that was originally intended, it appears to have been amended structurally so as to lend clarity to the extent and scope of the proceedings. It essentially reinforced and reiterated the right of any person interested to submit an opposition to any amendment that may have come to be published. This, of course, would have to be appreciated bearing in mind the fact that Section 57(3) as it came to exist in the legislation post its amendment in 2002 required only those proposed amendments to be advertised which were, in the opinion of the Controller, substantive.*** *Post the 2005 amendments, the aforenoted Rule if literally read would appear to suggest a shift towards a regime where only amendments claimed after the grant of a patent came to be made. However, and as would be evident from the discussion which follows, a mere facial or literal construct may not be the correct the view to take.*
>
> *74. Section 57(4) restricts the right of opposition to a person interested. This is in sync with Section 25(2) which deals with oppositions submitted post the grant of the application. Of equal significance is Section 57(6) and the various amendments made*

thereto in terms of the provisions of the 2002 and 2005 Amending Acts. It becomes pertinent to note that Section 57(6) as it stood in its unamended avatar prescribed that its provisions would be without prejudice to the right of an applicant to amend the specification in compliance with a directive issued by the Controller either before the acceptance of the complete specification or during proceedings in opposition to the grant of a patent. ***Section 57(6) was retained substantially by the Amending Act, 2002 except to the extent of extending its coverage further to amendments in any document relating to the specification.*** *However, sub-section (6) of Section 57 and its exclusionary march remained the same and extended right up to any amendments and directives issued by the Controller either before the acceptance of the complete specification or during the continuance of the PGO proceedings.* ***Sub-section (6) thereafter came to be restructured by the Amending Act, 2005 and now provides that its provisions would operate without prejudice to the right of the applicant to either amend the specification or any document related thereto to comply with the directions of the Controller issued before the grant of a patent.*** *It is also pertinent to note that Section 57(1) has always remained static and deals with amendments that may have been sought by the patent applicant itself."*

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"T. An amendment proposed by the applicant in order to comply with a directive of the Controller is placed on a pedestal distinct from any voluntary amendment that the applicant may choose to introduce. Section 57(6) thus not only liberates the applicant from the rigours of contestation which follows amendments proposed at its discretion, it additionally highlights the intent of the statute to draw a clear line of distinction between amendments traceable to Section 57(1) and those covered by sub-section (6). The hearing and the adjudicatory process envisaged in Section 57 (4) of the Act would thus be limited to amendments proposed by the applicant of its own volition as opposed to amendments stimulated by a directive of the Controller.

U. Our finding that an amendment based upon the directions of the Controller would not fall within the ambit of Section 57(6) lends

additional credence to our conclusion that the examination process is one which is separate and independent of proceedings of opposition. As observed hereinabove, the representation for opposition merely constitutes input and material which the Controller may take into consideration while evaluating the patent application. Those representations do not absolve the Controller from examining the application and being satisfied that the patent is liable to be granted. That function is to be performed and the statutory duty discharged by the Controller irrespective of the merits or otherwise of the objection or even in a case where no objections may have been preferred."

[Emphasis added]

54. Therefore, Section 57(6) of the Act provides that its provisions are applicable without prejudice to the right of the applicant to amend the specification / any document to comply with the directions / overcome the objection raised by the learned Controller issued before the grant of a patent.

55. ***Novartis AG*** (*supra*) further holds that:

"85. We are thus of the firm opinion that notwithstanding the invitation of objections, the Controller has to be independently satisfied that the application merits acceptance. This independence is vital to uphold the credibility of the patent system ensuring that decisions are made impartially, based on the merits of the application rather than external and interested influences. *The Court thus finds itself unable to sustain the theory of merger as advocated on behalf of the respondents and which found favour with the learned Single Judge. Both the Act as well as the Rules clearly envisage a dichotomy between the examination process and opposition process.* ***While in the course of examination, the Controller may hypothetically draw sustenance from any opposition that may have been filed, it would be wholly incorrect to accept that such eventuality would also warrant the objector being accorded participation in the examination process****."*

[Emphasis added]

56. Additionally, Rule 55(3)(ii) of the Rules requires the learned Controller to pass an order within one month from the date of hearing, after giving the opponent an opportunity of being heard. The learned Controller has to independently undertake the examination process, and the provisions of the Rule 55 of the Rules cannot be interpreted as either extending to or regulating the examination process. Rule 55 of the Rules is also interpreted in the decision of ***Novartis AG*** (*supra*) as under:

> *"86. We also bear in mind the provisions of Rule 55 and which speaks of representations for opposition that may be received.* ***It is on a consideration of such a representation and on the basis of which the Controller may come to form the opinion that the application for patent should be refused or the complete specification amended that it would proceed to place the applicant upon notice. The consideration under Rule 55(3) is thus confined to the contents of the representation and which in turn would be restricted to the grounds of opposition which are available to be raised in terms of clauses (a) to (k) of Section 25(1) of the Act.*** *This would also be evident from a reading of Rule 55(4) and in terms of which the applicant is afforded an opportunity to file its statement and evidence in response to the opposition. The proceedings which are thus envisaged in sub-rules (1) to (4) of Rule 55 are confined to the grounds of opposition that may be raised by way of a representation.* ***Those provisions cannot be interpreted as either extending to or regulating the examination process which the Controller has to, and in any case, independently undertake.*** *We also note that the prescription of the applicant being placed on notice by virtue of sub - rules (3) and (4) of Rule 55 is also confined to the applicant and the opponent. The expressions "submissions made by the parties" and "after hearing the parties" must consequentially draw meaning from the above.* ***Rule 55(5) thus cannot possibly be stretched or be interpreted as intended to regulate the examination process. The said provision also cannot possibly be construed as embodying a legislative intent to confer a participative right upon the opponent***

in the examination process. The right of hearing envisaged in that provision stands confined to a consideration of issues raised by the representation alone.

87. The opposition process as envisaged under the Act has a specific and a targeted purpose. Its primary objective is to provide a platform for any person to express objections and concerns regarding a patent application. *The objections received during the opposition process play a crucial role in enabling the Controller to have the benefit of diverse views on the question of grant including whether the application should be rejected or amendments to the complete specifications be warranted. The opposition process therefore serves the avowed purpose of allowing external inputs to be placed for the consideration of the Controller enabling it to make a well-informed decision regarding the grant of the patent application.*

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95. The other significant amendment to Rule 55 is evident from a reading of sub-rule (5) and which now obliges the Controller to simultaneously dispose of the representations of opposition and the patent application. However, and as observed in the preceding parts of this decision, the "hearing" that is contemplated clearly appears to be confined to the representation alone, a position which clearly emerges upon a conjoint reading of sub-rules (3), (4) and (5). It is pertinent to note that sub-rule (3) visualizes the applicant being placed on notice if the Controller "on consideration of the representation" be "of the opinion" that the application for patent should either be refused or the complete specification amended. The process of a hearing thus gets triggered upon the Controller on a consideration of the representation being of the opinion that the opponent has raised issues which either warrant the patent application being rejected or the specification being amended. Once the Controller is satisfied that the representation raises questions worthy of consideration, it would proceed to place the applicant on notice enabling it to file its statement and evidence. However, these proceedings are unconcerned with issues that the Controller may have flagged in the course of the examination process. Thus, the right

to oppose and to be heard is indelibly pivoted to the representation for opposition as distinct from questions that may arise from the FER or those that the Controller may identify as germane and material in the examination process.

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97. It is thus apparent that the right of hearing that is contemplated in Rule 55(5) is one which is concerned solely with the adjudication and disposal of the representation for opposition. The opponent cannot be countenanced to have a right of hearing in the examination process merely because the statute confers such an opportunity at the stage where the Controller is considering the representation. While the pre grant opposition indisputably facilitates the decision-making function of the Controller, we find ourselves unable to accept the contention that the opponent must consequentially be recognised to have the right of participation or audience in the examination process."

[Emphasis added]

57. Therefore, the legislative intent of the Rule 55(5) of the Rules is not to confer a participative right upon the opponent in the examination process. Therefore, the right of hearing of the opponent under Rule 55 of the Rules is confined to a consideration of issues raised in the Pre-Grant Opposition. The two processes are separate from each other as the examination process demands a focused evaluation of the application while the opposition process is to address the concerns of external stakeholders. ***Novartis AG*** (*supra*) has interpreted the Rules 55 of the Rules as under:

"88. This separation helps in striking a balance between the need for a rigorous examination and the task of including various perspectives in the decision-making process. The examination process demands a focused evaluation of the patent application against set legal standards wherein the Controller is tasked with the

duty to ensure that only deserving inventions are granted patent protection. On the other hand, the opposition process serves as a forum for external stakeholders or any person to voice concerns and provide valuable insights thus contributing to a more comprehensive evaluation of the patent application.

89. To merge the process would be to compromise the rigors of examination, since external inputs, though valuable, are best considered within the distinct and specific framework of the opposition. ***Merging these distinct processes would render the entire system unwieldy and counterproductive quite apart from negatively impacting the legislative policy of expeditious consideration. The separation, thus, subserves the legislative intent and allows for a more structured and organized approach where objections from various sources are factored in without disrupting the streamlined process of examination of the patent application."***

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"J. The "hearing" that is contemplated in Rule 55 clearly appears to be confined to the representation alone, a position which clearly emerges upon a conjoint reading of sub-rules (3), (4) and (5). It is pertinent to note that sub-rule (3) visualizes the applicant being placed on notice if the Controller "on consideration of the representation" be "of the opinion" that the application for patent should either be refused or the complete specification amended. The process of a hearing thus gets triggered upon the Controller on a consideration of the representation being of the opinion that the opponent has raised issues which either warrant the patent application being rejected or the specification being amended. Once the Controller is satisfied that the representation raises questions worthy of consideration, it would proceed to place the applicant on notice enabling it to file its statement and evidence. K. However, these proceedings are unconcerned with issues that the Controller may have flagged in the course of the examination process. Thus, the right to oppose and to be heard is indelibly pivoted to the representation for opposition as distinct from questions that may

arise from the FER or those that the Controller may identify as germane and material in the examination process."

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L. It is also relevant to note that the opponent can claim a right of hearing only if the Controller is satisfied and is of the opinion that the representation merits consideration. A mere filing of a representation would not prompt or precipitate issuance of notice under Rule 55(4). The matter becomes contentious only once the Controller takes cognizance of the representation and issues notice to the applicant. It is at that stage and for the aforesaid reasons that the principles of natural justice become applicable.

M. It is thus apparent that the right of hearing that is contemplated in Rule 55(5) is one which is concerned solely with the adjudication and disposal of the representation for opposition. The opponent cannot be countenanced to have a right of hearing in the examination process merely because the statute confers such an opportunity at the stage where the Controller is considering the representation. While the pre grant opposition indisputably facilitates the decision-making function of the Controller, we find ourselves unable to accept the contention that the opponent must consequentially be recognised to have the right of participation or audience in the examination process."

[Emphasis added]

58. Therefore, merging the two distinct processes would delay the application process and, therefore, go against the legislative policy of expeditious consideration as held in ***Novartis AG*** (*supra*) as under:

"The opposition process as envisaged under the Act has a specific and a targeted purpose*. Its primary objective is to provide a platform for any person to express objections and concerns regarding a patent application. The objections received during the opposition process play a crucial role enabling the Controller to have the benefit of diverse views on the question of grant including whether the*

application should be rejected or if amendments to the complete specifications are warranted. The opposition process therefore serves the avowed purpose of allowing external inputs to be placed for the consideration of the Controller enabling it to make a well-informed decision regarding the grant of the patent application.

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F. However, the opposition by itself is not the sole determinative of whether the patent is liable to be granted. *This since the mere rejection of the opposition would not inevitably result in the grant of a patent. The rejection of an opposition would not, ipso facto, lead to the grant of the patent or compel and bind the Controller to allow the patent application.* ***Notwithstanding the rejection of an opposition, the Controller is legally as well as statutorily bound to independently examine the patent application based on the FER as well as on its enquiry on whether the patent is liable to be granted in law.***

G. The examination process serves a wider and significant objective. This stage involves an in-depth assessment of the patent application, ensuring it complies with the statutory requirements for patent approval and facilitates a thorough and independent evaluation of the application by the examiner and the Controller. ***Maintaining a clear distinction between the examination and the opposition process is essential to not only fulfil the underlying objectives sought to be achieved but are also fundamental in ensuring that the sanctity and efficacy of each stage is maintained.***

To merge the process would be to compromise the rigors of examination since external inputs, though valuable, are best considered within the distinct and specific framework of the opposition. ***Merging these distinct processes would render the entire system unwieldy and counterproductive quite apart from negatively impacting the legislative policy of expeditious consideration. The separation, thus, subserves the legislative intent and allows for a more structured and organized approach where objections from various sources are factored in without disrupting the streamlined process of examination of the patent application****."*

[Emphasis added]

59. Since the grounds of opposition in the Pre-Grant Opposition filed by the Petitioner were considered at Hearing I and the order was reserved, and the Hearing Notice and Written Submissions filed by Respondent No. 2 pursuant to Hearing II were uploaded on the website by Respondent No. 1, there is no jurisdictional error by Respondent No. 1 by not giving opportunity of hearing to the Petitioner at Hearing II requiring this Court to exercise the jurisdiction under Article 226 of the Constitution. As the examination process is entirely different and independent of the opposition process, there is no requirement to issue notice and give opportunity of hearing to the opponent so long as opportunity of hearing is given for any of the grounds specified in Section 25(1) of the Act to oppose the grant of patent in the pre-grant opposition phase.

CONCLUSION

60. In view of the above analysis, it is concluded that:

a. If the relevant Patent Office is not located within the jurisdiction of the High Court, the Writ Petition under Article 226 of the Constitution is not maintainable due to lack of territorial jurisdiction. As the Patent Office is not located in Delhi, this Court cannot entertain and decide the present Petition.

b. Irrespective of the alternative remedy, an aggrieved party would have a recourse to invoke the extraordinary jurisdiction of this Court under Article 226 of the Constitution, and it is the discretion of the High Court to exercise the jurisdiction if it is found that there is manifest

jurisdictional error committed by the learned Controller while deciding the pre-grant opposition.

c. There is no requirement under the Act or the Rules to pass a separate order determining the voluntary amendments sought prior to First Examination Report issued by the learned Controller and the same can be considered and determined in the First Examination Report itself.

d. A review on merits involving disputed questions of fact is not permissible while exercising the writ jurisdiction under Article 226 of the Constitution in absence of any jurisdictional error committed by the learned Controller.

e. As the pre-grant opposition and examination of patent are two separate proceedings, a pre-grant opponent cannot be countenanced to have a right of hearing in the examination process. There was no violation of principles of natural justice as there was no requirement to give opportunity of hearing for a second time, if any further amendments to claim are made after the hearing of pre-grant opposition is given such opposition is not contemplated under Section 25(1) of the Act.

61. In view of the above discussion, the present Writ Petition is dismissed.

TEJAS KARIA, J

DECEMBER 24, 2025
'KC' / 'N'