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

CS(COMM) 607/2024 & I.A. 34151/2024

FMC CORPORATION & ORS. .....Plaintiffs

Through: Mr. Sandeep Sethi, Mr. Adarsh Ramanujan, Ms. Bitika Sharma, Ms. Aadya Chawla, Mr. George Vithayathil, Ms. S. L. Soujanya Ms. Ahaana Singh Rana, Ms. Mrinalini Goyat and Mr. Parth Singh, Advs.
Mob: 8449336373
Email: ahaana@singhandsingh.com

versus

NATCO PHARMA LIMITED .....Defendant

Through: Mr. J. Sai Deepak, Sr. Adv. with Mr. Sidhant Goel, Mr. Mohit Goel, Mr. Aditya Goel, Mr. Deepankar Mishra, Mr. Kartikeya Tandon and Mr. Avinash K. Sharma, Advs.
Mob: 9716746496
Email: deepankar@simandsan.com

CORAM:
HON'BLE MS. JUSTICE MINI PUSHKARNA

JUDGEMENT

% 17.11.2025

I.A. 34151/2024 in CS(COMM) 607/2024

INTRODUCTION

1. By way of the present judgement, this Court shall decide the application being *I.A. 34151/2024*, filed by the plaintiffs under Order XXXIX Rules 1 & 2 read with Section 151 of the Civil Procedure Code, 1908 ("**CPC**"), seeking an interim injunction for restraining the infringement of the plaintiffs' patented Compound of Formula 3 as claimed in Claim 12 of the Indian Patent No. 298645 ("**IN'645 / suit patent**"), titled as "*Method For Preparing N-*

Phenylpyrazole-1-Carboxamides".

2. The suit has been filed by the plaintiffs as a *quia timet* action under Section 48 read with Section 108 of the Patents Act, 1970 ("**the Act**"), seeking permanent injunction, restraining the defendant from manufacturing/preparing the product, 'Cyantraniliprole 10.26% OD (Oil Dispersion)' ("**infringing/impugned product**") and/or other admixture, combination, formulation products containing Cyantraniliprole using the Compound of Formula 3 as claimed in Claim 12 of the suit patent as a specific intermediate, as the same allegedly infringes upon the plaintiffs' Claim 12 of the suit patent.

3. This Court notes that *vide* order dated 01st August, 2025, it was brought forth that the defendant has launched its product. Upon the submissions of the defendant that they had already *'cleared the way'* and the statement thereof, this Court issued directions to the defendant to file details of the stock manufactured and launched, in relation to its product, before this Court. The relevant portion of the order dated 01st August, 2025, is reproduced as under:

> *"xxx xxx xxx*
>
> ***2. During the course of hearing, learned Senior Counsel appearing for the plaintiffs has brought forth that the defendant has already launched the product.***
>
> ***3. Learned Senior Counsel appearing for the defendant does not dispute the same. He submits that the defendant has already cleared the way, which is disputed by learned Senior Counsel appearing for the plaintiffs.***
>
> ***4. Learned Senior Counsel appearing for the defendant submits that in view of the fact that the defendant has already launched the product, the defendant shall file all the details of the stock manufactured, as well as launched by the defendant. Further, the defendant shall also file the details of all the revenue earned by the defendant, in a tabular form.***
>
> ***5. He further submits that the defendant shall also clearly state in the affidavit as regards the various approvals obtained by the defendant for the purposes of marketing the product.***
>
> *6. The aforesaid statement is taken note of.*
>
> *7. Let the needful be done by the defendant before the next date of*

hearing.
xxx xxx xxx"

(Emphasis Supplied)

4. Pursuant to the aforesaid order, the defendant has filed its affidavit dated 14th August, 2025, detailing the stocks manufactured, sold and revenue earned by the defendant from the sale of its product up to 31st July, 2025.

FACTUAL MATRIX

5. Facts as relevant to the present case are as follows:

About the parties:

5.1 The plaintiffs in the present case are a group of companies under the FMC group. Plaintiff no. 1 – FMC Corporation, is a company incorporated under the laws of the State of Delaware, United States of America, and is a co-patentee to the suit patent. Plaintiff no. 2 – FMC IP Technology GmbH is a company registered under the laws of Switzerland and is a subsidiary of plaintiff no. 1 corporation. Plaintiff no. 3 – FMC India Private Limited and Cheminova India Ltd., are the local entities through which plaintiff nos. 1 and 2 conduct their agrochemical business in India.

5.2 The plaintiff no. 1 along with its subsidiary, i.e., FMC Agro Singapore Pte. Ltd. were initially the co-patentees to the suit patent. The plaintiffs' group of companies acquired the crop protection business of E.I. DU Pont De Nemours and Company, *inter alia*, including the suit patent. By virtue of Assignment Agreement dated 01st May, 2018, with effective date of 01st November, 2017, all rights, title and interest in the suit patent was transferred to plaintiff no. 1 and its Singaporean subsidiary. Subsequently, the subsidiary of plaintiff no. 1, FMC Agro Singapore Pte. Ltd., by way of Patent Assignment Agreement dated 01st May, 2014, transferred its right as co-patentee in the suit patent to plaintiff no. 2. Therefore, plaintiff no. 1 and plaintiff no. 2 are currently the co-patentees to the suit patent.

5.3 The defendant – Natco Pharma Limited, in the present case is a company incorporated under the Companies Act, 1956, and is involved in the business of pharmaceuticals and agro-chemical solutions. Further, the defendant manufactures crop protection chemicals such as pesticides, insecticides and herbicides. The defendant is alleged to have infringed plaintiffs' patented Compound of Formula 3 as claimed in Claim 12 of the suit patent, by way of its impugned product, 'Cyantraniliprole 10.26% OD', which is an insecticidal composition.

Prior/Existing Lis and Applications:

5.4 Initially, the plaintiffs had filed the suit, i.e., *C.S. (COMM) 611/2019*, titled as *"FMC Corporation & Anr. Versus Natco Pharma Limited"*, seeking to restrain the defendant from infringing another set of plaintiffs' patents bearing nos. IN 201307 ("**IN'307**") and IN 213332 ("**IN'332**").

5.5 Thereafter, the defendant on 06th May, 2022, filed a declaratory suit before this Court bearing no. *C.S. (COMM) 295/2022*, titled as *"Natco Pharma Ltd. Versus FMC Agro Singapore Pte. Ltd. & Ors."* under Section 105 of the Act, seeking a prayer for declaration of non-infringement in respect of Claims 1 to 11 of the suit patent, relating to manufacture of another product, i.e., 'Chlorantraniliprole'.

5.6 Pursuant to the declaratory suit, the plaintiffs on 20th May, 2022, filed a suit for infringement, i.e., *C.S. (COMM) 349/2022*, titled as *"FMC Corporation & Others Versus Natco Pharma Limited"*, seeking injunction against the defendant with respect to infringement of Claims 1, 5 to 8 and 11 of the suit patent. In the said suit, the Co-ordinate Bench of this Court passed a judgement dated 19th September, 2022, dismissing the application filed by the plaintiffs seeking interim injunction against the defendant.

5.7 Subsequently, an appeal, i.e., *FAO (OS)(COMM) 301/2022*, was filed

against the judgement dated 19th September, 2022, wherein, the Division Bench of this Court by way of order dated 05th December, 2022, dismissed the appeal and affirmed the judgement dated 19th September, 2022.

5.8 The defendant in October, 2023, filed another suit for declaration, i.e., *C.S. (COMM) 787/2023*, titled as *"Natco Pharma Limited Versus FMC Agro Singapore Pte. Ltd. & Ors."*, seeking declaration of non-infringement in relation to another one of plaintiffs' patent, i.e., IN 277358 ("**IN'358**") regarding the present impugned product, i.e., 'Cyantraniliprole 10.26% OD'.

5.9 The defendant thereafter filed a revocation petition, i.e., *C.O. (COMM-IPD-PAT) 7/2023*. The defendant also filed an application for registration of insecticides under Section 9(3) of the Insecticides Act, 1968, with the *Central Insecticide Board & Registration Committee, Directorate of Plant Protection Quarantine and Storage*, on 28th July, 2023, for manufacturing and commercialising the insecticidal composition, 'Cyantraniliprole 10.26% OD', which is the impugned product in the present case. Further, the defendant has obtained regulatory approval for technical indigenous manufacture of Cyantraniliprole technical 93% as per the Minutes of the 453rd Central Insecticides Board & Registration Committee ("**CIBRC**") meeting held on 16th January, 2024.

5.10 Pursuant to the same, the plaintiffs filed three other suits, i.e., *C.S. 11/2023, C.S. 2/2024* and *C.S. 3/2024*, against the defendant herein before the District Court (Commercial) Chandigarh seeking to restrain the defendant from infringing Claim 12 of the suit patent in relation to defendant's impugned products therein, i.e., 'NATGEN', 'NATLIGO' and 'NATVOL'. The said suits have been transferred to this Court by the Supreme Court by way of order dated 09th April, 2024, in *Transfer Petition (Civil) Nos. 504, 488* and *513 of 2024*. The said suits were then renumbered as *C.S. (COMM) 410/2024, 409/2024* and

408/2024 respectively, and are currently pending in this Court.

5.11 The defendant has also filed two patent applications, i.e., PCT/IN2019/050321, which shows the process of manufacturing of Cyantraniliprole, and PCT/IN2023/051094, published on 06th June 2024, as WO/2024/116197 A1, which claims to show an improved process for the preparation of intermediate of Cyantraniliprole.

Suit Patent:

5.12 The suit patent was granted to plaintiffs' predecessor-in-interest, E.I. DU Pont De Nemours and Company, a US-based company on 09th July, 2018, under Section 43 of the Act. As noted above, the plaintiff nos. 1 and 2 are the current co-patentees and the successors-in-interest to the suit patent, by way of the aforementioned Assignment Agreements.

5.13 The suit patent, IN'645 is set to expire on 06th December, 2025.

5.14 The plaintiffs have filed corresponding claims in the suit patent which are patented by the plaintiffs in more than 20 countries/jurisdiction, other than India, including, jurisdictions such as Europe, United States of America, Japan and Republic of Korea. It has been disclosed by the plaintiffs that some of the claims of the corresponding patent to the suit patent, have been invalidated in China.

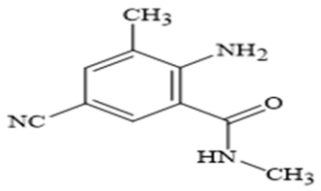
5.15 The plaintiffs in India have been granted four patents in relation to the compound, 'Cyantraniliprole', including the suit patent.

5.16 The suit patent, IN'645 is granted, valid and subsisting in the Register of Patents, whereby, a total of 12 claims have been granted in the suit patent. The suit patent claims a process for the preparation of 'Cyantraniliprole' in Claims 1 to 11 and Claim 12 is for a Compound of Formula 3, which is an intermediate used in the said process.

5.17 As per the plaintiffs, the Compound of Formula 3 is qualified by provisos

(a) to (d), of which the proviso (d) of Claim 12 states '*when R^1 is CH_3 and R^2 is CN, then R^3 is other than H'*.Therefore, as per proviso (d) of Claim 12 of the suit patent, where R^1 is CH_3 and R^2 is CN, then R^3 in the Compound of Formula 3 can be any of C_1-C_4 alkyl groups as limited by Claim 12. Further, when R^3 is C_1 alkyl, i.e., CH_3, the Compound of Formula 3 becomes *2-amino-5-cyano-N, 3-dimethylbenzamide,* which is the intermediate compound in question.The said intermediate compound has also been specifically disclosed as 'Example 6' in the complete specification of the suit patent.

5.18 The intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide*, which is culled out of the proviso (d) of Claim 12 under the suit patent, and is used to manufacture 'Cyantraniliprole', is alleged to have been infringed by the defendant, as the same is covered under the suit patent. The depiction of *2-amino-5-cyano-N, 3-dimethylbenzamide*, is as under:



5.19 As per the plaintiffs, Claim 12 of the suit patent is used for manufacturing and launching a product of 'Cyantraniliprole', which is manufactured using the intermediaries claimed in Claim 12 of the suit patent.

5.20 Thus, the present suit has been filed by the plaintiffs seeking reliefs against the defendant's usage of the intermediate compound in question in the manufacturing of the impugned product, as the intermediate compound in question is protected under Claim 12 of the suit patent. Therefore, the application in question before this Court, seeks an interim injunction against the defendant's usage of the intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide,* which is protected by Claim 12 of the suit patent.

SUBMISSIONS OF PARTIES

Plaintiffs' Submissions:

6. On behalf of the plaintiffs, the following submissions are made:

6.1 The plaintiffs have been granted exclusive rights to prevent third parties from making Compounds which are claimed under Claim 12 of the suit patent. The defendant in their reply to the present application has admitted that they are making and using the intermediate compound in question, *2-amino-5-cyano-N, 3-dimethylbenzamide,* to make 'Cyantraniliprole 10.26% OD'. Therefore, by virtue of the admission by the defendant, and the said intermediate compound in question being protected under Claim 12 of the suit patent, the defendant's use of the intermediate compound in question, amounts to infringement.

6.2 The defendant has admitted to using the intermediate compound in question, and the only defence raised is the alleged invalidity of the suit patent. The said admission has been made by the defendant in their reply to the present application, wherein, they have categorically admitted to manufacturing and using the intermediate compound under Claim 12 of the suit patent. Therefore, based on the said admission, a *prima facie* case is made out for grant of interim injunction.

6.3 The suit is not barred by Order II Rule 2 of the CPC, as the prior suit, i.e., *C.S. (COMM) 349/2022*, filed by the plaintiffs against the defendant was to enforce the process patent covered by Claims 1, 5 to 8 and 11 of the suit patent, and not for asserting rights under Claim 12 of the suit patent. Thus, the cause of action of the present suit is distinct from the cause of action of the aforesaid suit.

6.4 The revocation of the counterpart of the suit patent in China has been on grounds other than prior claiming and novelty, which are the grounds invoked by the defendant in the present case. Further, the grounds of

invalidity/patentability are different in China in comparison to India.

6.5 The onus is upon the defendant to establish invalidity of Claim 12 of the suit patent, and mere filing of a revocation petition by itself, cannot amount to a *'credible challenge'* nor will it amount to *'clearing the way'*.

6.6 The claim of the defendant that the plaintiffs are *'serial litigants'* and have developed their group of patents around two products, i.e., 'Cyantraniliprole' and 'Chlorantraniliprole', in order to evergreen or re-monopolise its products, is an attempt to prejudice and mislead the Court. The formulation, molecule and the process to arrive at 'Cyantraniliprole' and the intermediates used in the said process are all separate inventions, meriting their distinct patents. The intermediates to reach 'Cyantraniliprole' are protected by Claim 12 of the suit patent, and each of the claims/patents independently qualify the patenting standards, even if they are not the final product, but because they all have some commercial viability.

6.7 In contrast, the defendant is a *'habitual infringer'*, which is indicated by the table of injunction orders granted against the defendant in various intellectual property suits.

6.8 The plaintiffs have a patent portfolio of approximately 700 global patents that cover several aspects of their business. Moreover, the plaintiffs continuously improve manufacturing processes and existing active ingredients of the product portfolio through inventions.

6.9 The claim of the defendant that another one of plaintiffs' patent, i.e., IN 269104 ("**IN'104**"), is a prior art and anticipates the suit patent, therefore, the suit patent is not novel, is meritless. To assess anticipation by prior publication under Section 64 (1)(e) of the Act, the test is to see whether the prior art is published before the priority date. In the present case, IN'104 was published on 15th August, 2008, which is much later to the priority date of the suit patent, i.e.,

07th December, 2004, therefore, IN'104 cannot be a prior art with respect to the suit patent. Furthermore, Section 11 (8) of the Act prohibits use of any document published later to attack the novelty and inventive step of a claimed invention.

6.10 The contention of the defendant that it is the position of the plaintiffs that the priority date of IN'104 has shifted owing to its filing in 2008, is incorrect, and IN'104, being published after the priority date of the suit patent, is not a prior art in respect of the suit patent.

6.11 Further, the contention of the defendant that the suit patent is invalid since it is anticipated by the prior publication of WO 03/062226 ("**WO'226**"), which is the international counterpart to IN'104, is incorrect. The defendant, at best, could have contended the aspect of novelty of the suit patent, citing the international publication, WO'226, which was published prior to the suit patent. However, even WO'226 does not anticipate Claim 12 of the suit patent, as it neither discloses nor enables the Compounds claimed under Claim 12 of the suit patent.

6.12 The defendant has argued that 'Formula 6' as claimed in WO'226, discloses the Claim 12 of the suit patent. However, WO'226 does not specifically disclose or give an individualised description of the Compounds protected by Claim 12 in proviso (d) or make any specific reference to the intermediates protected by Claim 12 of the suit patent.

6.13 The claim of the defendant that three of the substituent combinations in WO'226, are the same as Claim 12 of the suit patent, is completely misleading and misplaced as 'Formula I' is an entirely different molecule, and is not an intermediary, but rather an end product contemplated in WO'226. Therefore, the defendant cannot break down the end product and assert that the Compounds constitute intermediaries, when the end products of WO'226 and

the suit patent are distinct from one another. The defendant's claim is unfounded and only seeks to cherry-pick one end-product out of the 2700 end products that are suggested in WO'226, reverse engineer the intermediary and then come to a conclusion that Compounds in WO'226, constitute intermediaries in the suit patent.

6.14 The defendant could not overcome the onus that a *'Person Skilled in the Art',* by reading WO'226, can reach the Compounds as claimed in Claim 12 of the suit patent. Furthermore, WO'226 does not have an enabling disclosure to arrive at the intermediate compound in question protected under proviso (d) of Claim 12 of the suit patent, without undue experimentation, which is a matter of trial, and the defendant has not led *prima facie* expert evidence to explain the said disclosure. Moreover, WO'226 being cited by the International Search Authority as a category 'A' prior art means that it is only 'general background art' and therefore, does not destroy the novelty/inventive step of the suit patent.

6.15 The Venn Diagram used by the defendant to try and show anticipation of the suit patent by WO'226, is a hindsight approach and used to mislead the Court, as the size of the circles in the diagram are misleading, since the number of compounds possible in Formula 6 of WO'226 are massive, i.e., 115 billion compounds, while possible compounds in Claim 12 of the suit patent are relatively only a few, i.e., 40 compounds. Furthermore, the Venn Diagram does not show the point in time for each disclosure, as the claims of IN'104, did not exist at the time Claim 12 of the suit patent was filed. Even if there was an overlap of one of the compounds, Claim 12 of the suit patent is a distinct invention as compared to Claim 1 of IN'104 because the molecules of Claim 12 of the suit patent have a technical effect of resulting in a higher yield when used as an intermediate, a property, which was unknown in IN'104.

6.16 The defendant cannot use WO'226 to contend that the suit patent is prior

claimed by IN'104, as in a challenge under Section 64 (1)(a) of the Act, one can only use a granted Indian patent, and WO'226, not being an Indian patent, cannot be used for the purposes of a challenge under Section 64 (1)(a) of the Act. Furthermore, the defendant in its claim of invalidity based upon IN'104, has only done a verbal comparison of the claims with the suit patent, in order to assert the anticipation by prior claiming. However, it is settled law that an invention has to be seen in totality of the claims read with the specifications, and in a case of the present nature, the defendant has to show that IN'104 discloses the special advantages as mentioned in the suit patent, which the defendant has failed to do.

6.17 The contention of the defendant that the plaintiffs' predecessor-in-interest has allegedly admitted that the intermediate compound in question, patented in Claim 12 of the suit patent, was already disclosed in IN'104, is completely misplaced. If indeed the alleged admission was made, the same would only be relevant if IN'104 was a prior art. However, the same being published much after the priority date of the suit patent, cannot be a prior art. Moreover, the complete specifications of IN'104 and the suit patent are directed to different inventions in substance, and the suit patent has a distinct lineage from IN'104. Thus, any statements made in the prosecution of IN'104 form extrinsic evidence, and are therefore of lesser significance in comparison to the intrinsic evidence and should not be considered.

6.18 There are no admissions by the plaintiffs in the rejoinder to the interim application, as usage of the words *"overlap"* and *"discloses"* does not imply admission. Further, disclosure of 'Formula 6' does not amount to admission of disclosure of the specific substance of Claim 12 of the suit patent.

6.19 The suit patent is not liable to be revoked under Section 64 (1)(h) of the Act, as the suit patent sufficiently and fairly describes the invention and its

operation, along with the best method by which it is to be performed. Further, the plaintiffs have been granted corresponding patents in various foreign jurisdictions, based on the same specifications/descriptions as the present suit patent.

6.20 The suit patent is not liable to be revoked under Section 64 (1)(j) of the Act, as the patent application for IN'104 was filed 3.5 years after the priority date of the suit patent. Further, the patent application WO'226 was cited in the International Search Report, therefore, the complete specification contained in WO'226 was never concealed or suppressed from the Patent Office.

6.21 The argument of the defendant that the present case is a case of *reverse genus v. species* or 'prior species' and 'later genus', is misguided, as the said concept is purely hypothetical. Even so, no *species-genus* relationship exists between IN'104 and the suit patent, as there is no common lineage between the said patents, and there exists no hierarchy to enable one to learn the teachings from the other. Furthermore, the scope and purpose of IN'104 and the suit patent are different, as IN'104 is directed to the discovery of a class of new compounds, whereas, the suit patent is directed to a novel chemical process to make specific compounds and certain novel chemical intermediates for that process.

6.22 The defendant has wrongly argued that IN'104 came about as an amendment and hence Section 59 of the Act would apply. However, IN'104 was filed as a divisional application to IN 232417 ("**IN'417**"), therefore, the same is not an amendment, and Section 59 of the Act would not apply.

6.23 The inventors in both patents are entirely different. Therefore, the concept of *'Person in the Know'* is also defeated. Moreover, as there is no enablement/disclosure in IN'104 for the suit patent, a *'Person Skilled in the Art'*, cannot use disclosures contained in IN'104 to arrive at the Compounds

claimed in Claim 12 of the suit patent or *vice versa*, without any undue experimentations, and the same is without prejudice to the argument that IN'104 is published after the suit patent.

6.24 No examination reports by the Patent Office for the suit patent have cited IN'104 or its parent application, i.e., IN'417, as a prior art in India or abroad.

6.25 The book cited by the defendant to show automatic anticipation in *species-genus* cases is incorrect, as there exists no disclosure in WO'226 of the species in question, nor any enabling disclosure. Therefore, when there is no disclosure, the proposition of automatic anticipation does not apply.

6.26 The defendant has not successfully made out a case for *Gillette Defence*, as there is no disclosure/enablement of any process to manufacture the intermediate under the suit patent, in WO'226. Further, the said defence does not apply in the case of IN'104, as the defence only applies to prior art, which IN'104, being published much after the suit patent, cannot be.

6.27 The contention of the defendant that the plaintiffs have not revealed the prosecution history of IN'104 is false. The plaintiffs have clearly stated that they rely on their reply filed in the revocation petition, which adequately deals with the objections in relation to IN'104.

6.28 The case of the defendant that the plaintiffs have not responded to the case set up by the defendant on science, is incorrect. The plaintiffs have demonstrated their case with the science and law involved in respect of novelty, prior claiming and validity of the suit patent. In contrast, the defendant has failed to show as to how the complete specifications of WO'226 demonstrates any lack of novelty or inventive step in the suit patent or the same is anticipated by WO'226.

6.29 The plaintiffs seek a narrow scope for interim injunction as the only issue is with regards to the defendant using the intermediate compound in question to

manufacture ‘Cyantraniliprole 10.26% OD’, and if the same is not used, the defendant is free to manufacture ‘Cyantraniliprole 10.26% OD’.

6.30 The suit patent expires on 06th December, 2025. Thus, considering the limited time left before patent expiry, this case falls under the category of ‘bridgehead’, wherein, balance of convenience is in favour of the plaintiffs. Moreover, the suit patent stood the test of time as it was granted without any pre or post-grant opposition, and only in its 18th year, it was challenged by way of the revocation petition filed by the defendant, therefore, effect must be given to the statutory grant. Further, irreparable harm will be caused to the plaintiffs if the defendant is allowed to frustrate the plaintiffs’ suit patent before its term expires.

6.31 There exists a public interest in protecting patents, especially, when the same is not even a pharmaceutical patent, where there are overriding public concerns. Moreover, the defendant has *malafidely* launched the impugned product during the course of argument of the present application, which is an inequitable conduct and has impacted the balance of convenience, even more in favour of the plaintiffs.

6.32 There is no delay in filing of the present suit as it is the admitted case of the defendant that they are awaiting the regulatory approval for its infringing formulation. Further, in the declaratory suit, i.e., *C.S. (COMM) 787/2023*, the defendant only disclosed the process of making a formulation but not the process of making the active ingredient, Cyantraniliprole. Therefore, there was no indication that the defendant will be using the intermediate compound in question claimed under Claim 12 of the suit patent.

6.33 The judgement of the Division Bench in the case of *F. Hoffman La-Roche AG Versus Natco Pharma, FAO (OS)(COMM) 43/2025*, relates to a *genus-species* relationship, which does not exist in the present matter.

Defendant's Submissions:

7. On behalf of the defendant, the following submissions are made:

7.1 Prior to the filing of the present suit by the plaintiffs, the defendant had filed the revocation petition, i.e., *C.O. (COMM.IPD-PAT) 7/2023*, wherein, the defendant had raised a substantial credible challenge to the validity of Claim 12 of the suit patent. Thus, if the defendant at the present *prima facie* stage demonstrates a credible challenge, the interim injunction ought not to be granted. Furthermore, the defendant has already *'cleared the way'* by filing the revocation petition.

7.2 The defendant filed a suit for non-infringement, being *C.S. (COMM) 295/2022*, titled as *"Natco Pharma Limited Versus FMC Agro Singapore Pte Ltd. & Ors."* on 06th May, 2022, seeking a declaration that the defendant's process for manufacturing 'Chlorantraniliprole' did not infringe the suit patent. In response, the plaintiffs filed the suit being *C.S. (COMM) 349/2022*, titled as *"FMC Corporation & Ors. Versus Natco Pharma Limited"*, for infringement of the suit patent, and also sought *ad-interim* injunction with respect to claims 1, 5 to 8, and 11 of the suit patent against the defendant. *Vide* judgment dated 19th September, 2022, this Court dismissed the plaintiff's application for interim injunction on the ground that the defendant's process did not infringe Claims 1 to 11 of the suit patent. The appeal filed against the said judgment dated 19th September, 2022, was dismissed with costs, *vide* judgement dated 05th December, 2022, in *FAO (OS)(COMM) 301/2022*.

7.3 The plaintiffs claimed the *ad-interim* injunction against the defendant only with respect to Claims 1, 5 to 8, and 11 of the suit patent, and therefore, relinquished the relief of injunction with respect to Claim 12 of the suit patent under Order II Rule 2 of the CPC.

7.4 In the alternative, even if it is assumed that the suit being *C.S. (COMM)*

349/2022, was filed only with respect to Claims 1 to 11 of the suit patent, and not Claim 12 of the suit patent, then also the plaintiffs are barred from claiming relief with respect to Claim 12 by way of a subsequent suit under Order II Rule 2 read with Rule 3 of the CPC.

7.5 The defendant had filed the revocation petition, i.e., *C.O. (COMM.IPD – PAT) 7/2023*, for revocation of Claim 12 of the suit patent. Despite this, the plaintiffs instituted three more suits namely, *C.S. 11/2023 (renumbered as C.S. (COMM) 410/2024)*, titled as *"FMC Corporation and Ors. Versus Natco Pharma Limited", C.S. 2/2024 (renumbered as C.S. (COMM) 409/2024)* titled as *"FMC Corporation Versus Natco Pharma Limited"* and *C.S. 3/2024 (renumbered as C.S. (COMM) 408/2024*) titled as *"FMC Corporation Versus Natco Pharma Limited",* before the District Court, Chandigarh, seeking relief in respect of infringement of Claim 12 of the suit patent. The plaintiffs have, therefore, filed multiple proceedings before the Court with respect to the suit patent, and therefore, the present suit is an abuse of the process of the Court.

7.6 The plaintiffs have a strategy of using a thicket of more than 40 patents to prevent third parties, such as the defendant, from launching the product 'Chlorantraniliprole' or products analogous thereto. The plaintiffs had filed the suit being *C.S. (COMM) 662/2022*, titled as "*FMC Corporation and Ors. Versus GSP Crop Science Private Limited"* for infringement of the suit patent by a third party. By way of the judgment dated 14th November, 2022, this Court observed that the long list of patents filed by the plaintiffs in respect of 'Chlorantraniliprole' and its various components points to an attempt for evergreening 'Chlorantraniliprole', even though the product patent for the same has expired and therefore, fallen into the public domain.

7.7 The Claim 12 of the suit patent is liable to be revoked under Section 64 (1)(a) of the Act on the ground of anticipation by prior claiming, as IN'104

retains its priority date of 22nd January, 2002, despite publication of its amended form in the year 2008. In the present case, Claim 12 of the suit patent falls within the scope of IN'104.

7.8 The argument of the plaintiffs is that the Claim in IN'104 were amended and published in their current form only in the year 2008, however, the said argument is incorrect. For the purpose of Section 64 (1)(a) of the Act in relation to the present case, the relevant date for determining whether IN'104 is a prior art with respect to the suit patent, would be the priority date of IN'104 and not the date of publication. Furthermore, as per Section 13 (1)(b) of the Act, for establishing prior claiming, only the priority date of the prior art is relevant, and the date of publication of the prior art being after the priority date of the impugned patent, would be immaterial.

7.9 The prior art, IN'104 retains the priority date, i.e., 22nd January, 2002, of the United States patent application being US 60/350,632. Therefore, the amended claims of IN'104 would be relevant for the ground of prior claiming of Claim 12 of the suit patent.

7.10 The argument of the plaintiffs that the priority date of IN'104 is pushed to 2008 due to the amendment of IN'104, is not tenable. This is because the priority date of IN'104 from the records of the Indian Patent Office remains 22nd January, 2002. The plaintiffs in their reply dated 07th November, 2013, to the examination report by way of amendments, stated that the amendments made to the patent were within the scope of the original specifications. Therefore, it is not open to the plaintiffs to now contend that the priority date of IN'104 is in 2008 under Section 59 of the Act, and the principle of prosecution history estoppel. Additionally, IN'104 being a divisional application retains the priority date of the parent application, as the subject matter of IN'104 stood disclosed in the parent application.

7.11 The Claim 1 of IN'104 discloses three compounds, and all these three embodiments have also been claimed in Claim 12 of the suit patent. The intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide* under Claim 12 of the suit patent stands prior claimed, when R^3 is methyl in Claim 1 of IN'104. Thus, the specific compound for which the plaintiffs assert their right, i.e., the intermediate compound in question, is specifically claimed in IN'104.

7.12 In relation to proviso (d) of Claim 12 of the suit patent, the same stands prior claimed on another aspect such as when R^3 is isopropyl in Claim 1 of IN'104. Further, proviso (b) of Claim 12 of the suit patent also stands prior claimed when R^3 is H in Claim 1 of IN'104. Therefore, as all three compounds as claimed in Claim 12 of the suit patent are prior claimed in IN'104, it would result in anticipation by prior claiming of Claim 12 in its entirety. Thus, the suit patent is liable to revoked under Section 64 (1)(a) of the Act.

7.13 For the purposes of prior claiming, it is not essential that the claims are identical or that the prior claim be an enabling document.

7.14 In the present case, the patent IN'104 is a species patent, and the suit patent is a genus patent. The Formula 6 of Claim 1 of IN'104, being the species patent, covers the broadly known Formula 3 of Claim 12 of the suit patent. A generic claim cannot be allowed to the plaintiffs if the prior art discloses a species falling within the subsequently claimed genus patent. Thus, the suit patent, being a genus patent, is prior claimed by the species patent.

7.15 The plaintiffs have already enjoyed monopoly rights in the compounds of Claim 1 of IN'104 and are attempting to re-monopolize/evergreen the same compounds through the suit patent.

7.16 The test of *'person in the know'* is applicable to the present matter given the presence of common applicant between IN'104 and the suit patent.

7.17 Alternatively, Claim 1 of IN'104 covers the subject matter of the suit patent, and such coverage is sufficient to prove anticipation of Claim 12 of the suit patent by prior claiming.

7.18 The Claim 12 of the suit patent lacks novelty. The patent IN'104 was filed as a national phase application corresponding to PCT application dated 16th January, 2003 for WO'226, which was published on 31st July, 2003, which is prior to the priority date of the suit patent. Further, the Claims as granted in IN'104 were incorporated by way of an amendment from the original complete specification filed in India, which is identical to WO'226, and the same could have only been done, if the amended claims in IN'104 were within the scope of WO'226. Therefore, any statement to the contrary would statutorily nullify the priority claim in respect of IN'104, as IN'104 cannot extend beyond the claims made in the priority corresponding application WO'226 and any amendments made cannot be inconsistent with the earlier claims, and should fall within the scope of the earlier claims.

7.19 In the present case, it is established that the Claim 12 of the suit patent falls within the scope of the disclosure made in the IN'104 and WO'226. Further, the Claim 12 of the suit patent is enabled by the disclosures made under WO'226. Claim 12 stands anticipated by the disclosures made in WO'226.

7.20 The submission of the plaintiffs that WO'226 only discloses the preparation of Formula 1 is incorrect, as once the preparation and use of Formula 6 is disclosed in enabling detail, Claim 12 of the suit patent will be anticipated by WO'226. Moreover, WO'226 clearly discloses not only the end products of Formula 1, but also the preparation of Formula 6, which are the intermediates that are also claimed in Claim 12 of the suit patent.

7.21 IN'104 explicitly deals with the process of manufacture of Compounds of Formula 6 of Claim 1 of IN'104, which are the class of Compounds that relate

to Formula 3 of Claim 12 of the suit patent. IN'104 and its parent WO'226 disclose the specific process of manufacture of bromo analogue of *2-aminobenzamides*, which is analogous to the Compound in Claim 12 of the suit patent. The prior patent WO'226 also states that by using the said procedure, with methods known in the art, the compounds mentioned in Tables 1-10 can be prepared. The Tables in the said specification provide for the manufacture of the intermediate compound in question under Claim 12 of the suit patent. Thus, IN'104 and WO'226 result in express disclosure of the intermediate compound in question under Claim 12 of the suit patent. Thus, the argument of the plaintiffs that the defendant is slicing the compound in IN'104 is unfounded.

7.22 The plaintiffs admit that there is an overlap between Claim 12 of the suit patent and Claim 1 of IN'104, in the rejoinder to the reply of the present application.

7.23 The plaintiffs have made clear admissions during the prosecution of IN'104, which shows that Claim 12 of the suit patent falls within the scope of WO'226. The plaintiffs in the First Examination Reports dated 18th January, 2013 and 13th December, 2013, Responses dated 07th November, 2013 and 10thJanuary, 2014, to the First Examination Reports, and in their rejoinder to the revocation petition, have made clear admissions to the said aspect. Further, the Controller withdrew the objection under Section 10 (4)(a) of the Act solely on the basis of the submissions that the claimed subject matter of the amended claims of IN'104 was already disclosed in WO'226 and in the originally filed version of IN'104.

7.24 The plaintiffs in their reply to the revocation petition, have admitted to the fact that the Claim 12 of IN'645 is covered by IN'104, and that the Compounds claimed in Claim 12 of IN'645, have been selected from the subject matter of WO'226. Therefore, the admissions made by the plaintiffs in their

reply, disentitles them from taking any defence to the injunction application, at the least at the interim stage.

7.25 The defendant can invoke the *Gillette Defence* as the defendant does not infringe the suit patent since the intermediate compound in question, being *2-amino-5-cyano-N, 3-dimethylbenzamide*, made by the defendant, is both claimed and disclosed by IN'104 and WO'226, which have already expired. Thus, the defendant is practising the prior art already in public domain, and does not infringe the suit patent.

7.26 The *Gillette Defence* also results in the invalidity of the Claim 12 of the suit patent as the same is anticipated by IN'104 by prior claiming, and by WO'226 by prior publication. Additionally, the Compound in Formula 3 of Claim 12 of the suit patent is a known substance, and the same cannot be a valid patent under Section 3 (d) of the Act.

7.27 The Claim 12 of the suit patent lacks inventive step and is liable to be revoked under Section 64 (1)(f) of the Act, as a *'Person Skilled in the Art'* would know the use of alternate halogen, pseudo halogen and bioisosteres, as was done by the plaintiffs in the suit patent in comparison to the prior arts. The same is supported by the statements made by the plaintiffs in their Response to the Examination Reports in IN'104, which shows that a *'Person Skilled in the Art'* would already know Claim 12 of the suit patent.

7.28 The Claim 12 of the suit patent is also liable to be rejected under Section 64 (1)(k) of the Act, as the Compounds claimed in Claim 12 of the suit patent are obvious variant and/or derivative of the already known prior art, and also does not show any significant difference in efficacy between the known Compounds in the prior art and the Compounds claimed in Claim 12 of the suit patent. Further, the burden is on the plaintiffs to show that Claim 12 of the suit patent shows significant efficacy to the prior art Compounds, which they have

failed to do so.

7.29 Claim 12 of the suit patent is also liable to be rejected under Sections 64 (1)(i) and Section 64 (1)(h) of the Act, on account of insufficient description of the invention. Further, the complete specifications of the suit patent are not complete or categorical in defining the best mode of working the invention. Moreover, the plaintiffs have failed to disclose the scope of the said Claim 12 of the suit patent, and use ambiguous terms such as "other than" in all of its proviso, which is ambiguous and suggests that vast number of Compounds can be claimed in Claim 12, which is against the settled principles of patent law.

7.30 Claim 12 of the suit patent is also liable to be rejected under Section 64 (1)(j) of the Act, as the plaintiffs materially suppressed that they were well aware of the existence of IN'104 and other prior art documents, and the plaintiffs were under an obligation to disclose the filing of the same before the Patent Office at the time of prosecuting the suit patent.

7.31 The balance of convenience lies in favour of the defendant and irreparable loss would be caused to the defendant, as the defendant has *prima facie* shown a credible challenge to the validity of Claim 12 of the suit patent, and has already started the commercial production of Cyantraniliprole compound since April, 2025. Therefore, the defendant has invested heavily towards the same. In contrast, the plaintiffs can be compensated by damages in the event they succeed in the suit as any injury that they may suffer would be purely monetary, given that only three months are left for the suit patent to expire.

7.32 The plaintiffs are disentitled to any relief on account of the delay in filing the present suit, as the defendant had filed the revocation petition on 31st October, 2023, and the plaintiffs filed the present suit on 22nd July, 2024. Further, in view of the earlier filed pending litigations between the parties, and

the disclosure made by the defendant in the said proceedings, the plaintiffs have approached this Court with a substantial delay. Therefore, such delay disentitles the plaintiffs from receiving any interim relief.

7.33 The plaintiffs despite there being several litigations between the parties, has been unable to obtain any favourable orders from this Court, particularly, when the defendant has already disclosed the use of the intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide* for the purpose of manufacturing Cyantraniliprole. Therefore, in view of the conduct of the plaintiffs in earlier proceedings, the plaintiffs are not entitled to any equitable/interim relief.

7.34 The patent application, i.e., CN102285899B of the plaintiffs in China, which corresponds to the suit patent, has already been revoked in China on the ground, *inter alia*, of lack of inventive step.

7.35 The judgement of the Division Bench in the case of *F. Hoffman La-Roche AG Versus Natco Pharma, FAO (OS)(COMM) 43/2025*, reaffirms Section 53 (4) of the Act and the test of *'Person in the Know'*. Therefore, the defendant has not infringed the rights of the plaintiffs by using the intermediate compound in question claimed under Claim 12 of the suit patent.

FINDINGS AND ANALYSIS

8. The present suit has been filed by the plaintiffs as a *quia timet* action, on the basis that the plaintiffs had a strong and credible apprehension that the defendant was manufacturing/preparing the product covered by the suit patent, i.e., 'Cyantraniliprole 10.26% OD' and/or other ad-mixture, combination, formulation products containing Cyantraniliprole ("**CNTPR**") using the Compound of Formula 3 as claimed in Claim 12 of the suit patent as a specific intermediate.

9. In the present case, the plaintiffs assert their rights in the suit patent with

respect to Claim 12 of IN'645 for manufacturing and launching a product comprising CNTPR, manufactured using the claimed intermediates. Claim 12 of the suit patent relates to intermediates that can be used in the manufacture of CNTPR, carrying the structure and formula as mentioned in Claim 12.

10. The bibliographical details of the suit patent, IN'645 which is set to expire on 06th December, 2025, are detailed in the table reproduced as under:

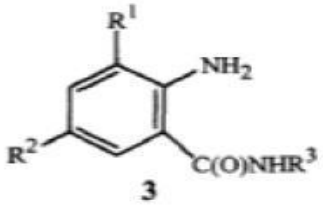
TABLE 1

Indian Patent No.	IN 298645
Patent Application No	3548/DELNP/2007
Title	METHOD FOR PREPARING N-PHENYLPYRAZOLE-1-CARBOXAMIDES
Applicant	E.I. DU PONT DE NEMOURS AND COMPANY
Date of filing in India	11.05.2007
International Application No	PCT/US2005/044131
International filing date	06.12.2005
Priority Date	07.12.2004

WO Publication No	WO 2006/062978 A1 published on 15.06.2006
Section 11A Publication	31.08.2007 - The application was published in the official gazette issued by the Patent Office thereby being open for public to file pre-grant opposition.
Date of grant	09.07.2018
Grantee	E.I. DU PONT DE NEMOURS AND COMPANY
Section 43(2) publication	13.07.2018. Accordingly, the timeline to file post-grant opposition on the suit patent IN' 645 expired on 13.07.2019.
Date of expiry of the patent	06.12.2025
Patentee/Assignee	FMC Corporation FMC Agro Singapore Pte. Ltd. By virtue of confirmatory assignment agreement dated May 1, 2018 with effective date of November 1, 2017 assigning absolute rights in the invention of the suit patent to the Patentees i.e., Plaintiff No. 1 & 2 herein, taken on record by the Indian Patent Office on August 7, 2018. [The Assignment Agreement dated
	May 1, 2024, is yet to be filed and brought on record showing Assignee as FMC IP Technology GmbH.]

11. The suit patent claims a process for the preparation of 'Cyantraniliprole/CNTPR' and a claim for intermediates which are utilised to manufacture CNTPR. The Claim 12 under the suit patent, i.e., the claim in dispute in the present case, is a product claim that claims a Compound of Formula 3. The said Compound of Formula 3 under Claim 12, as per the suit patent, is depicted as under:

12. A compound of Formula 3



3

wherein

R^1 is CH_3 or Cl;
R^2 is Br, Cl, I or CN; and
R^3 is H or C_1-C_4 alkyl;

provided that

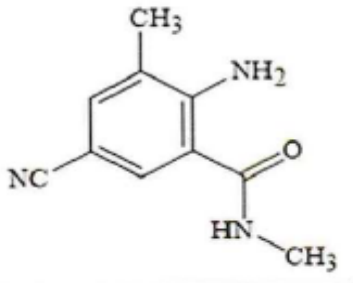
(a) when R^1 and R^2 are Cl, then R^3 is other than H, CH_2CH_3, or $CH(CH_3)CH_2CH_3$;

(b) when R^1 is CH_3 and R^2 is Cl, Br or CN, then R^3 is other than CH_3 or $CH(CH_3)_2$;

(c) when R^1 is Cl and R^2 is Cl or Br, then R^3 is other than CH_3 or $CH(CH_3)_2$; and

(d) when R^1 is CH_3 and R^2 is CN, then R_3 is other than H.

12. The Compound of Formula 3 is qualified by provisos (a) to (d), of which proviso (d) states *"when R^1 is CH_3 and R^2 is CN, then $R^3$is other than H"*. Therefore, as per proviso (d) of Claim 12, where R^1 is CH_3 and R^2 is CN, then R^3 in the Compound of Formula 3 can be any of C_1-C_4 alkyl group as limited by Claim 12. Moreover, when R^3 is C_1 alkyl, i.e., CH_3, the Compound of Formula 3 becomes *2-amino-5-cyano-N, 3-dimethylbenzamide*, which is the intermediate compound in question. The said intermediate compound in question, as depicted in the plaint, is reproduced as under:



13. Thus, the compound named as *2-amino-5-cyano-N, 3-dimethylbenzamide*, i.e., intermediate compound in question, has also been specifically disclosed as

Example 6 in the complete specification of the suit patent, as put forward by the plaintiffs in the plaint.

14. On the basis of the submissions advanced on behalf of the counsels for the parties, it is clear that the defendant's argument of non-infringement is based on the *'Gillette Defence'*, in that the defendant is practicing the prior arts, i.e., IN'104, and WO'226, which have already expired and fallen in public domain, and therefore, the defendant is not infringing Claim 12 of the suit patent.

15. Furthermore, the defendant has challenged the validity of Claim 12 of the suit patent under Section 107(1) of the Act, by raising grounds for revocation of Claim 12 of the suit patent under Section 64 of the Act. From the defences taken by the defendant under Section 64 of the Act, this Court is of the considered opinion that the key questions which arise for consideration before this Court at this stage are, as follows:

a. Whether the suit patent is anticipated by prior claiming by the plaintiffs in IN'104, in terms of Section 64 (1)(a) of the Act.

b. Whether the suit patent lacks novelty as it falls within the scope of WO'226 in terms of Section 64 (1)(e) of the Act.

16. Since the defendant is raising grounds of its non-infringement on the basis of invalidity of Claim 12 of the suit patent, this Court notes that law is well settled that grant of a patent does not guarantee the validity of a patent and there is no presumption of validity. Reference may be made to Section 13 (4) of the Act, which reads as under:

> *"xxx xxx xxx*
>
> ***13. Search for anticipation by previous publication and by prior claim.***
>
> **…….**
>
> *(4) The examination and investigations required under section 12 and*

this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

xxx xxx xxx"

17. Thus, holding that grant of the patent does not guarantee the validity of the patent, which can be challenged on various grounds of revocation, the Supreme Court in the case of ***Bishwanath Prasad Radhey Shyam Versus Hindustan Metal Industries***[1], has held as follows:

"xxx xxx xxx

32. ***It is noteworthy that the grant and sealing of the patent, or the decision rendered by the Controller in the case of opposition, does not guarantee the validity of the patent, which can be challenged before the High Court on various grounds in revocation or infringement proceedings. It is pertinent to note that this position viz. the validity of a patent is not guaranteed by the grant, is now expressly provided in Section 13(4) of the Patents Act. 1970.*** *In the light of this principle, Mr Mehta's argument that there is a presumption in favour of the validity of the patent, cannot be accepted.*

xxx xxx xxx"

(Emphasis Supplied)

18. Similarly, holding that registration of a patent *per se* does not entitle a party to an injunction when a credible challenge has been raised to the patent, and that there is no presumption of a validity of a patent, this Court in the case of ***TenXC Wireless Inc. and Anr. Versus Mobi Antenna Technologies (Shenzhen) Co. Ltd.***[2], has held as follows:

"xxx xxx xxx

7.10 The well settled principles for grant of interim injunction in patent matters laid down by the Courts in the aforesaid judgments are summarized as under:—

7.10.1 The registration of a patent per se does not entitle the plaintiffs to an injunction. The certificate does not establish a conclusive right.

[1] ***(1979) 2 SCC 511***
[2] ***2011 SCC OnLine Del 4648***

7.10.2 There is no presumption of validity of a patent, which is evident from the reading of Section 13(4) as well as Sections 64 and 107 of the Patents Act.

7.10.3 The claimed invention has to be tested and tried in the laboratory of Courts.

7.10.4 The Courts lean against monopolies. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large.

7.10.5 The plaintiff is not entitled to an injunction if the defendant raises a credible challenge to the patent. Credible challenge means a serious question to be tried. The defendant need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage whereas the validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.

7.10.6 At this stage, the Court is not expected to examine the challenge in detail and arrive at a definite finding on the question of validity of the patent. That will have to await at the time of trial. However, the Court has to be satisfied that a substantial, tenable and credible challenge has been made.

xxx xxx xxx"

(Emphasis Supplied)

19. Delving on the aspect of there being no presumption of validity of a patent and that at the interim stage, the defendant is required only to raise a credible challenge to the validity of a patent or show vulnerability to the said patent, the Division Bench of this Court in the case of ***F. Hoffman-LA Roche Ltd. & Anr. Versus Cipla Ltd.***[3], held as follows:

"xxx xxx xxx

53. The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in Biswanath Prasad

[3] ***2009 SCC OnLine Del 1074***

Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444 : PTC (Suppl)(1) 731 (SC), Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd., AIR 2000 Del 23 : 1999 PTC (19) 479 (Del), Bilcare Ltd. v. Amartara Pvt. Ltd., 2007 (34) PTC 419 (Del), Surendra Lal Mahendra v. Jain Glazers, (1979) 11 SCC 511. In Beecham Group Ltd. v. Bristol Laboratories Pty Ltd., (1967-1968) 118 CLR 618 and Australian Broadcasting Corporation v. O'Neill, (2006) 229 ALR 457 it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In Hexal Australai Pty Ltd. v. Roche Therapeutics Inc., 66 IPR 325 it was held that where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S. Court of Appeals for the Federal Circuit 05-1433) the Court of Appeals followed its earlier ruling in Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339 where it was held (at 1359): ***"In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself."*** *(emphasis supplied) In Erico Int'll Corprn v. Vutec Corprn (U.S. Court of Appeals for the Federal Circuit, 2007-1168) it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."*

54. In the present case, the grant of a patent to the plaintiffs for Erlotinib Hydrochloride as a mixture of Polymorphs A and B will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. The use by the learned Single Judge of the expressions "strong credible challenge", "arguable case" or that the defendants claim being not unfounded, cannot be termed as vague and inconsistent since they convey the same meaning in the context of the strength of the defendant's challenge.

55. ***The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action? During the course of the argument it was suggested by counsel that the challenge had to be both strong and credible. Also, the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue. Without indulging in an exercise in semantics, the Court when faced***

> ***with a prayer for grant of injunction and a corresponding plea of the defendant challenging the validity of the patent itself, must enquire whether the defendant has raised a credible challenge.*** *In other words, that would in the context of pharmaceutical products, invite scrutiny of the order granting patent in the light of Section 3(d) and the grounds set out in Section 64 of the Patents Act 1970.* ***At this stage of course the Court is not expected to examine the challenge in any great detail and arrive at a definite finding on the question of validity. That will have to await the trial. At the present stage of considering the grant of an interim injunction, the defendant has to show that the patent that has been granted is vulnerable to challenge.*** *Consequently, this Court rejects the contentions of the plaintiffs on this issue and affirms the impugned judgment of the learned Single Judge.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

20. It may be noted that prior to the present suit for infringement filed by the plaintiffs, the defendant had filed a revocation petition, wherein, the defendant had challenged the validity of Claim 12 of the suit patent. Thus, in consonance with the principles as laid down in ***F. Hoffman-LA Roche Ltd. & Anr. Versus Cipla Ltd.***[4], at this interim stage, this Court would adjudge whether the defendant has *prima facie* demonstrated a vulnerability of Claim 12 of the suit patent. If a *prima facie* case on invalidity of Claim 12 of the suit patent is demonstrated by the defendant, then this Court would not grant any interim injunction.

Challenge under Section 64 (1)(a) of the Act:

21. It is the case of the defendant that Claim 12 of the suit patent is liable to be revoked under Section 64 (1)(a) of the Act on the ground that the said Claim 12 is prior claimed in IN'104, i.e., another one of plaintiffs' patent, as it claims and discloses the intermediate compounds claimed under Claim 12 of the suit patent, and the priority date of IN'104 is prior to that of the suit patent.

22. Before considering IN'104 on the aspect whether it anticipates Claim 12

[4] ***2009 SCC OnLine Del 1074***

of the suit patent by prior claiming, it would have to be determined as to whether IN'104 can be considered to have a prior claim in relation to the suit patent, i.e., IN'645, in view of the various objections raised by the plaintiffs in this regard. The plaintiffs have averred that considering that IN'104 was published under Section 11A of the Act on 15th August, 2008, much later to the priority date of the suit patent, i.e., 07th December, 2004, the same is not prior art.

Date of Publication or Date of Priority:

23. In the present case, the plaintiffs have relied on the aspect that when ascertaining the claim of invalidity under Section 64 (1)(a) of the Act, it is the *'date of publication'* of the prior patent which has to be considered. In contrast, the defendant propounds that it is the *'priority date'* of the patent, that is to be considered in relation to Section 64 (1)(a) of the Act. Thus, it is for this Court to consider, whether in the present case, it is the *'date of publication'* or *'priority date'* which shall be the relevant date for the purposes of there being any credible challenge raised under Section 64 (1)(a) of the Act.

24. Before adverting to the facts of the present case, it would be apposite to discuss the law in relation to Section 64 (1)(a) of the Act, which lays down factors that are to be considered for determining that an invention is claimed in an earlier claim of the complete specification of another patent granted in India. Section 64 (1)(a) of the Act reads as under:

> *"xxx xxx xxx*
>
> *64. Revocation of patents – (1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government [* * *] or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds, that is to say,—*
>
> ***(a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier***

priority date contained in the complete specification of another patent granted in India*;*

xxx xxx xxx"

(Emphasis Supplied)

25. Anticipation by prior claiming has also been specifically discussed under Section 13 (1)(b) of the Act. According to the said section, for the purpose of ascertaining whether the invention as claimed in any claim of the complete specification is anticipated by prior claiming, the priority date of the prior patent shall be relevant, not the date of publication. Section 13 (1)(b) of the Act, reads as under:

"xxx xxx xxx

13. Search for anticipation by previous publication and by prior claim*.—The examiner to whom an application for a patent is referred under Section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification—*

(a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;

(b) ***is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.***

xxx xxx xxx"

(Emphasis Supplied)

26. Likewise, this Court in the case of ***Boehringer Ingelheim Pharma GMBH & Co. KG Versus Vee Excel Drugs and Pharmaceuticals Private Ltd. and Others***[5], has culled out factors that are to be considered in order for a patent to be revoked under Section 64 (1)(a) of the Act. Thus, it was held as under:

"xxx xxx xxx

54. In order for a patent to be revoked under Section 64(1)(a) of the Patents Act, the following factors have to be established*:*

[5]***2023 SCC OnLine Del 1889***

i. The prior patent has to be the one granted in India.
ii. ***The said prior patent has to have an earlier priority date than the latter patent application.***
iii. The invention claimed in the latter patent was also claimed in the earlier patent application.
iv. ***The date of publication of prior patent is irrelevant.***

55. *In the present case, it is undisputed that the genus patent, IN '719, is an Indian patent having an earlier priority date than the species patent, IN '301. Therefore, what has to be examined is whether what has been claimed in the species patent, has been claimed in the genus patent.* ***The fact that in the present case, the publication date of the genus patent was after the priority date of the species patent, would not be relevant.***

xxx xxx xxx"

(Emphasis Supplied)

27. Thus, it is clear that it is the *'date of priority'*, and not the *'date of publication'* of the prior patent that is relevant for determining whether a patent is a prior art under Section 64 (1)(a) of the Act, and the *'date of publication'* of the prior art is irrelevant. Therefore, the test is to enquire whether subject matter claimed in the patent under dispute has already been claimed in a patent which has an earlier priority date.

28. This Court also notes that IN'104 has been filed as a divisional patent of IN'417, which corresponds to the international counterpart being WO'226.

29. It is settled law that the priority date of a divisional application is the date of filing of that specification in which the matter was first disclosed. Law with regard to division applications is encapsulated in Section 11 and Section 16 of the Act, relevant portions of which are reproduced as under:

"xxx xxx xxx

11. Priority dates of claims of a complete specification*.— (1) There shall be a priority date for each claim of a complete specification.*
……

(4) ***Where the complete specification has been filed in pursuance of a further application made by virtue of sub-section (1) of Section 16 and the claim is fairly based on the matter disclosed in***

any of the earlier specifications, provisional or complete, as the case may be, the priority date of that claim shall be the date of the filing of that specification in which the matter was first disclosed.

xxx xxx xxx

16. Power of Controller to make orders respecting division of application*.—(1) A person who has made an application for a patent under this Act may, at any time before the[grant of the patent], if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.*

(2) ***The further application under sub-section (1) shall be accompanied by a complete specification, but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first mentioned application.***

xxx xxx xxx"

(Emphasis Supplied)

30. In this regard, it would be useful to refer to the Patent Cooperation Treaty ("**PCT**"), wherein, under Article 2, Clause (xi), 'priority date' has been defined as follows:

"xxx xxx xxx

(xi) ***"priority date," for the purposes of computing time limits, means:***

(a) where the international application contains a priority claim under Article 8, the filing date of the application whose priority is so claimed*;*

(b) where the international application contains several priority claims under Article 8, the filing date of the earliest application whose priority is so claimed;

(c) where the international application does not contain any priority claim under Article 8, the international filing date of such application;

xxx xxx xxx"

(Emphasis Supplied)

31. At this stage it would be relevant to note the bibliographic data of IN'104, which is extracted as below:

S. No.	Particulars	Details
1.	Patent's Registration Number	IN269104
2.	Indian Patent Application Number	4361/DELNP/2008
3.	Date of filing in India	22 May 2008
4.	PCT International Application Number and Details	PCT/US2003/01482, dated 16 January 2003;
		Published as WO2003/062226, on 31 July 2003
5.	Priority Details	US60/650,382, dated 22 January 2002
6.	Date of Patent IN269104 (Effective filing date)	16 January 2003
7.	Publication of the Patent Application under Section 11A of the Patents Act, 1970	15 August 2008
8.	Date of issuance of First Examination Report	18 January 2013
9.	Reply to First Examination Report	07 November 2013
10.	Hearing Notice under Section 14 of the Act	N/A
11.	Written submissions pursuant to the hearing under Section 14 of the Act	N/A
12.	Date of Grant of IN269104	30 September 2015
13.	Date of Recordal in Patent Register of IN269104	05 October 2015

14.	Date of publication of Grant of Patent	09 October 2015
15.	Name of Grantee	E.I. Dupont De Nemours and Company
16.	Assignees / Patentees (based on the entry in the E-register)	1. FMC Agro Singapore Pte. Ltd.;
17.	Name of inventors	1. Clark, David Alan; 2. Lahm, George Philip;
18.	Expiry Date of the Patent	16 January 2023
19.	Legal status	Expired

32. This Court notes that as per the bibliographic data of IN'104, the priority date of IN'104 is 22nd January, 2002. Thus, from the documents on record, it can be ascertained that WO'226 has retained the priority date of the US phase application, i.e., US60/350,632 which is 22nd January, 2002.

33. This Court further makes note of the admission on behalf of the plaintiffs in their replication, wherein, it is stated that IN'417 takes priority from WO'226, which in turn takes priority from the US60/350,632. The relevant portion of the replication filed by the plaintiffs is reproduced as under:

> *"xxx xxx xxx*
>
> *25.* ***As mentioned hereinabove, IN'104 is a divisional of patent application 1492/DELNP/2004, which in turn is the national phase application of PCT/US2003/01482 (published as WO 03/062226A1) which in turn takes priority from US60/350632.*** *A reading of the complete specifications of all these patent documents would inform the person skilled in the art that the invention was actually directed to a broad class of insecticides, having Formula I, as depicted hereinbelow.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

34. It is also noted that even the records maintained by the Indian Patent Office for IN'104 on their website reflects the priority date as 22nd January, 2002. The relevant portion of the Indian Patent Office website reflecting details

of IN'104 is reproduced as under:

"xxx xxx xxx

Office of the Controller General of Patents, Designs & Trade Marks
Department for Promotion of Industry and Internal Trade
Ministry of Commerce & Industry,
Government of India

INTELLECTUAL PROPERTY INDIA

Legal Status : Term Expired
Date of Expiry : 16/01/2023

Patent Number	:	269104	Date of Patent	:	16/01/2003
Application Number	:	4361/DELNP/2008	Date of Grant	:	30/09/2015
Type of Application	:	DIVISIONAL PCT NATIONAL PHASE APPLICATION	Date of Recordal	:	05/10/2015
Parent Application Number	:	1492/DELNP/2004	Appropriate Office	:	DELHI
PCT International Application Number	:	PCT/US2003/01482	PCT International Filing Date	:	16/01/2003
Grant Title	:	"QUINAZOLINE(DI) ONES FOR INVERTEBRATE PEST CONTROL"			

Sl No	Name of Grantee	Grantee Type	Grantee Address
1	E.I. DU PONT DE NEMOURS AND COMPANY.	OTHER THAN NATURAL PERSON	1007 MARKET STREET, WILMINGTON, DELAWARE 19898, U.S.A.

Sl No	Name of Patentee	Patentee Type	Address of Patentee
1	FMC Agro Singapore Pte. Ltd.	NA	77 Robinson Road, #13-00 Robinson 77, Singapore 068896, Singapore

Address of Service	:	Remfry & Sagar Attorneys-at-Law Remfry House at the Millennium Plaza, Sector 27, Gurgaon-122 002 National Capital Region India.
Additional Address of Service	:	--
Priority Date	:	22/01/2002

xxx xxx xxx"

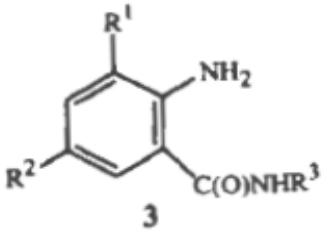
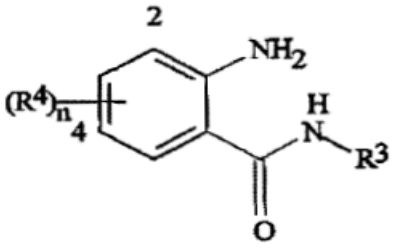
35. Therefore, keeping in view of the aforesaid, the divisional patent, i.e., IN'104 filed by the plaintiffs having retained its priority date, i.e., 22nd January, 2002, from IN'417, will be relevant for the purposes of Section 64 (1)(a) of the Act.

36. Thus, in effect, as the suit patent, IN'645 has its date of priority as 07th December, 2004 and IN'104 which, as noted above, retains date of priority of IN'417, i.e., 22nd January, 2002, will be a prior art to IN'645. Therefore, the contention of the plaintiffs that IN'104, cannot be considered as a prior art for assessing anticipation under Section 64 (1)(a) of the Act, is *prima facie* untenable.

37. Therefore, keeping the above into consideration, if this Court arrives at the conclusion that IN'104 prior claims the Claim 12 of the suit patent, the same would necessarily be vulnerable to invalidity.

Claim to Claim Comparison:

38. Thus, to examine whether Claim 12 of the suit patent is prior claimed in Claim 1 of IN'104, a comparison of Claim 12 of IN'645 and Claim 1 of IN'104, is set out below:

Claim 12 of Suit patent along with Example 6	**Claim 1 of IN'104**
12. A compound of Formula 3  3 wherein R^1 is CH_3 or Cl; R^2 is Br, Cl, l or CN; and R^3 is H or C_1-C_4 alkyl; provided that (a) when R^1 and R^2 are Cl, then R^3 is other than H, CH_2CH_3, or $CH(CH_3)CH_2CH_3$; (b) when R^1 is CH_3 and R^2 is Cl, Br or CN, then R^3 is other than CH_3 or $CH(CH_3)_2$; (c) when R^1 is Cl and R^2 is Cl or Br, then R^3 is other than CH_3 or $CH(CH_3)_2$; and (d) when R^1 is CH_3 and R^2 is CN, then R^3 is other than H.	**1.** 2-aminobenzamides compound of Formula 6:  6 wherein R^3 is H, methyl or isopropyl; n is 2; one R^4 group is attached to the phenyl ring at the 2-position and said R^4 is CH_3; and a second R^4 is attached to the phenyl ring at the 4-position and said R^4 is CN.
Example 6: Preparation of **<u>2-amino-5-cyano-N,3-dimethylbenzamide</u>**	

39. From the aforesaid comparative table, it is manifest that Claim 12 of IN'645, the suit patent, directly claims the intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide.* In this regard, reference may be made to proviso (d) in Claim 12 of IN'645, the suit patent, wherein, R^1 is CH_3, R^2 is CN and R^3 is other than H. The Compound of Formula 3 in IN'645, the suit patent, itself stipulates as follows:

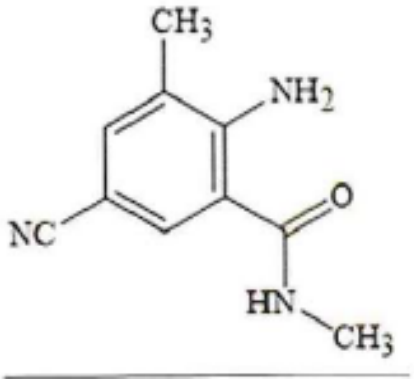
I. R^1 is CH_3 or Cl;

II. R^2 is Br, Cl, 1 or CN; and

III. R^3 is H or C_1-C_4 alkyl

40. Thus, the Compound of Formula 3 in IN'645, the suit patent, itself shows that if R^3 is other than H, then it would be C_1-C_4 alkyl. Thus, in proviso (d), when R^3 is C_1 alkyl group or Methyl, i.e., CH_3, then the said proviso (d) of Claim 12 in IN'645, the suit patent, claims the intermediate compound in question, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide.*

41. The intermediate compound in question as claimed in proviso (d) of Claim 12, and as exemplified in Example 6 is specifically claiming '*2-amino-5-cyano-N, 3-dimethylbenzamide'*. This Compound is structurally represented as below:



42. This compound has a benzene ring with –CONHCH₃ (benzamide with N-methyl) at 1-position, –NH₂ (amino group) at 2-position, –CH₃ (ring methyl) at

3-position and –CN (cyano group) at 5-position.

43. Now coming to the prior patent, it is seen that IN'104 claims the Compound of Formula 6, i.e., *2-aminobenzamides*. Further, from a reading of Formula 6 of Claim 1 of IN'104 from the point of view of a *Person Skilled in the Art*, the following can be culled out:

i. There are three positions on the chemical structure namely, R^3, first R^4 attached to the phenyl ring at the 2-position, and the second R^4 attached to the phenyl ring at the 4-position.

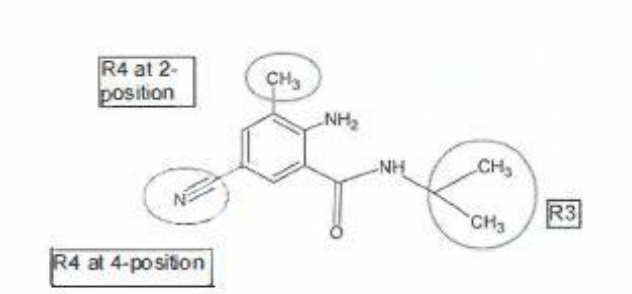
ii. It is claimed that R^4 attached to the phenyl ring at the 2-position is CH_3, and the second R^4 attached to the phenyl ring at the 4-position is CN, which does not vary in all the compounds claimed under Claim 1 of IN'104.

iii. It is claimed that R^3 position in the chemical structure has three variables, namely, H, methyl or isopropyl.

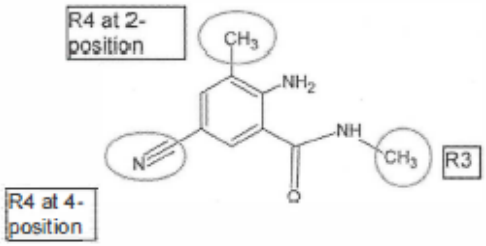
iv. Thus, the only variable is R^3, which has three variants namely H, Methyl, or Isopropyl. All other aspects of Claim 1 of IN'104 are fixed.

44. From the above, *prima facie*, it is seen that there are three compounds claimed in Claim 1 of IN'104, as also asserted by the defendant, which position the plaintiffs have been unable to controvert with any substantial argument. Though the plaintiffs have argued that IN'104 discloses a vast number of compounds, the said argument was not substantiated or addressed in any manner by demonstrating or bringing forth any other compound which could be derived from Claim 1 of IN'104. The three compounds which have been claimed in Claim 1 in IN'104 are as follows:

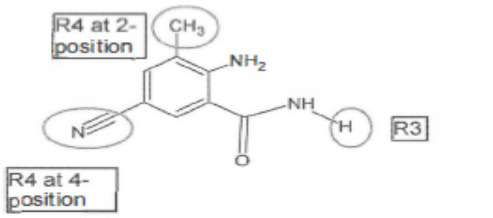
a) When R^3 is Isopropyl, the compound claimed in IN'104 would be chemically represented as follows:



b) When R^3 is Methyl, the compound claimed in IN'104 would be chemically represented as follows:

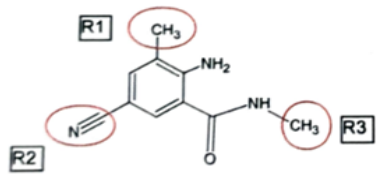
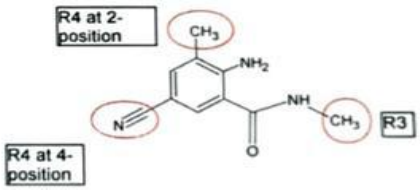


c) When R^3 is Hydrogen, the compound claimed in IN'104 would be chemically represented as follows:



45. Therefore, when comparing Claim 12 along with Example 6 of the suit patent with the three compounds derivable from the Claim 1 of the prior patent, i.e., IN'104, it is to be seen as to whether the intermediate compound in question of Claim 12 of the suit patent is already claimed as one of the compounds in Claim 1 of the prior patent, IN'104. Thus, the Compounds of Formula 6 in Claim 1 of IN'104, i.e., prior art, has to be perused alongside the intermediate compound in question in Claim 12 of the suit patent.

46. This Court notes that when R^3 is methyl, i.e., CH_3 , in Claim 1 of the IN'104, the prior art, the resultant compound is *2-amino-5-cyano-N, 3-dimethylbenzamide*. Thus, in both the compounds of Claim 1 of IN'104, i.e., prior art, and C_1 alkyl group variable in proviso (d) of Claim 12 of IN'645, i.e., suit patent, in the said two patents, the resultant compound, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide,* is the same. This is diagrammatically shown below:

COMPOUND IN PROVISO (D) OF CLAIM 12 OF THE SUIT PATENT, IN'645	**COMPOUND IN CLAIM 1 OF THE PRIOR ART, IN'104 WHEN R^3 IS METHYL (CH_3)**
	

47. From the above, it is manifest that the intermediate compound in question which is being asserted for infringement by the plaintiffs is *2-amino-5-cyano-N, 3-dimethylbenzamide,* which has been specifically claimed in IN'104, the prior art, as well. Thus, it is clear that the intermediate compound in question of Claim 12 of suit patent alongwith Example 6 has already been claimed in Claim 1 of IN'104, the prior art.

48. Even when seen from the perspective of a *Person Skilled in the Art*, wherein, upon following the instructions in Claim 1 of IN'104 without using any inventive ingenuity, the *Person Skilled in the Art* would be able to form the compound in IN'104, the prior art, where R^3 is methyl, and it would be clear that the compound would be *2-amino-5-cyano-N, 3-dimethylbenzamide,* i.e., the intermediate compound in question in the present suit. The *Person Skilled in the Art* would further be guided to reach the other two compounds which are

claimed in Claim 1 of IN'104. Since it has come to the fore that there are only three compounds which can be claimed in Claim 1 of IN'104, the intermediate compound in question being one of them, it cannot be said that *Person Skilled in the Art* would be cherry picking any one specification out of the multifarious options, when only three compounds are claimed in the Claim 1 of prior art, IN'104.

49. In view of the above, it is apparent that the requirement of the intermediate compound in question of Claim 12 of the suit patent, being prior claimed in Claim 1 of IN'104, i.e., prior art, under Section 64 (1)(a) of the Act, stands satisfied.

Species v. Genus:

50. At this stage, this Court notes the submission made on behalf of the defendant that besides the intermediate compound in question, the suit patent claims the other two compounds of the prior art of Claim 1 of IN'104, as well.

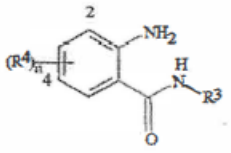
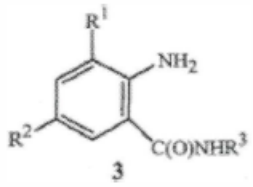
51. It is also the case of the defendant that the prior art, IN'104 is a species patent and the suit patent, IN'645 is the genus patent, therefore, IN'104 anticipates the suit patent, IN'645 and there exists *species-genus* relationship between the said patents. The defendant has further argued that if any embodiment of Claim 12 of the suit patent stands anticipated by IN'104, then it would result in anticipation of the Claim 12 of the suit patent in its entirety. On the other hand, the plaintiffs have argued that no *species-genus* relationship lies between IN'104 and suit patent, as the lineage, scope, purpose and inventors of IN'104 and the suit patent, are completely different. The plaintiffs have further argued that no *Person Skilled in the Art* can use the disclosure in IN'104 to arrive at the impugned compound in question without undue experimentation.

52. In terms of patent law, there is no such definition that is enumerated by the legislature in the Act with regards to a genus or species patent/claim.

However, the concept of genus and specie relationship often occurs, though not necessarily, in cases that are related to chemical patents, wherein, the 'Genus' refers to a larger set or a broader class of compounds, whereas, in the case of 'Specie', the reference is made to a more specific embodiment or a subset therein, which are related to the same core structure.

Core Structure & Common Lineage:

53. At this stage, this Court takes note of the argument of the plaintiffs that there exists no common lineage between IN'104, i.e., the prior patent and IN'645, i.e., the suit patent, and thus, there exists no *species-genus* relationship between the said patents. Hence, in order to adjudicate the issue as regards the *specie-genus* relationship as raised by the defendant, it would be apposite to consider the core structure of Claim 12 of the suit patent with Claim 1 of the prior art. The Claim 12 of the suit patent and Claim 1 of the prior art, are reproduced as follows:

IN269104 (Prior Art of the Patentees)	IN298645 (IN298645 of the Patentees)
Claims priority from US patent application no. 60/350,632, dated 22 January 2002	Claims priority from US patent application no. 60/633,899, dated 07 December 2004
1. 2-aminobenzamides compound of Formula 6:  Wherein R^3 is H, methyl or isopropyl; n is 2; One R^4 group is attached to the phenyl ring at the 2- position and said R^4 is CH_3; and	2. A compound of Formula 3  3 Wherein R^1 is CH_3 or Cl; R^2 is Br, Cl, 1 or CN; and R^3 is H or C_1-C_4 alkyl; provided that

a second R^4 is attached to the phenyl ring at the 4-position and said R^4 is CN	(a) when R^1 and R^2 are Cl, then R^3 is other than H, CH_2CH_3, or $CH(CH_3)CH_2CH_3$; (b) when R^1 is CH_3 and R^2 is Cl, Br or CN, then R^3 is other than CH_3 or $CH(CH_3)_2$; (c) when R^1 is Cl and R^2 is Cl or Br, then R^3 is other than CH_3 or $CH(CH_3)_2$; and (d) when R^1 is CH_3 and R^2 is CN, then R^3 is other than H."

54. A perusal of the Claim 1 of IN'104 and Claim 12 of the IN'645 reveals that both are Markush Structures. In a Markush Structure the compounds exemplified arise from a common core structure. The said compounds may have multiple variations and combinations, however, when exemplified from a Markush, the core structure remains the same. In a case, where even if one of the variations arising from the core structure are known in a prior art, the same would be susceptible to the challenge of not being novel under the Act. Reference in this regard be made to ***Para 2-089 and 2-090, Chapter 2, Pratibha M. Singh on Patent Law***, ***First Edition***, which reads as under:

> *"xxx xxx xxx*
>
> ***MARKUSH PATENTS***
>
> *2-089 In the case of NCEs, it is seen that the general practice that is adopted is to define and* ***disclose a common core structure (a 'pharmacophore') of a class of compounds in the patent specification and to exemplify certain possible compounds based on***

the core structure by carrying out substitutions in the core structure. *Thereafter, if the compound is targeted towards medical use, the possible ailments for which the said compounds can be used are identified.*

2-090 On this basis, ***patents are sought for novel core structures, the plethora of compounds that could be prepared from the core structure, various methods and processes of preparation of the compounds, as also for the different forms in which the compounds could exist. The range of molecules with the various combinations of possible substitutions could run into millions, billions, trillions and even quintillions. Such a structure is described as a Markush formula.*** *The said name is derived from the title of a decision by the USPTO in Ex Parte Markush". For a Markush structure, there are several challenges in establishing novelty.* ***Since the patent covers a broad spectrum of compounds and several forms of the same compound, if even one of the permutations or combinations arising from the core structure is known in prior art, questions challenging novelty can be raised.***

xxx xxx xxx"

(Emphasis Supplied)

55. Comparison of the aforesaid structures of the Claim 12 of the suit patent and Claim 1 of the prior art makes it apparent that both the structures have a common benzene ring having common molecules at position 1 and 2, i.e., C(O)NH and NH_2 respectively, in both the structures, in Claim 1 of the prior art and Claim 12 of the suit patent. Further, it is apparent that Claim 1 of the IN'104, i.e., the prior art claims a *2-Aminobenzamides* compound of Formula 6. Thus, as both Claim 12 of the IN'645, the suit patent, and Claim 1 of IN'104, the prior art, claim compounds of *2-Aminobenzamide*, they have a common core structure, and thus share a significant structural element. Therefore, Claim 1 of IN'104, the prior art and Claim 12 of IN'645, the suit patent, are *prima facie* related to each other, as they share a common core structure of *2-aminobenzamides*.

56. Further, it is also to be noted that the plaintiffs in their written submissions have made a categorical admission towards the possibility of

overlap between the compounds of Claim 12 in IN'645 and Claim 1 in IN'104. The relevant portion of the plaintiffs' written submissions are as under:

"xxx xxx xxx

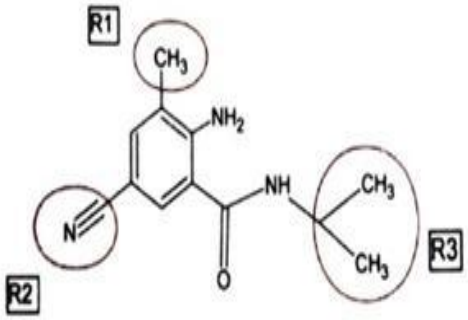
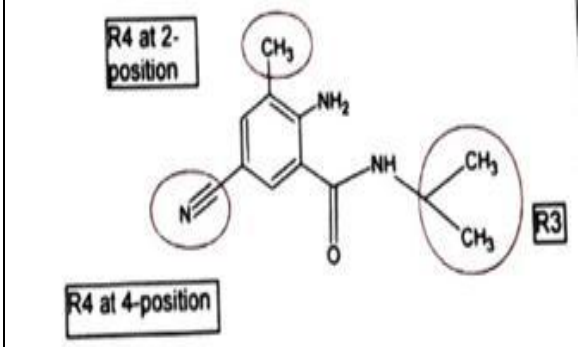
> 33. At best, IN '645 and IN '104 is a case of overlap of one of the compounds, as a matter of chance – identified in the hindsight approach. In the Venn Diagram reproduced above, the Defendant has deliberately and mechanically compared the claims of IN '645 and IN '104 by cherry picking, and without actually perusing the scope of the invention – which has to be read in light of the complete specification of the patents. The same does not establish disclosure/ enablement of the said compound in IN'104 to make out a case for anticipation by prior claiming.

xxx xxx xxx"

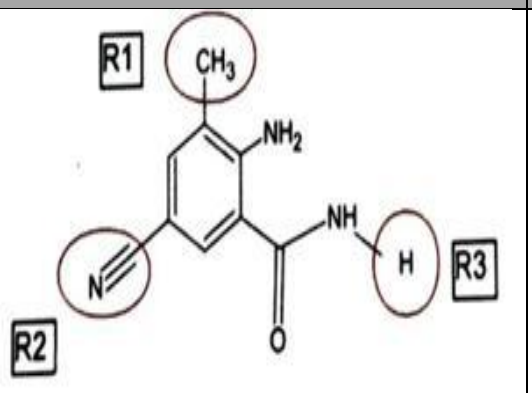
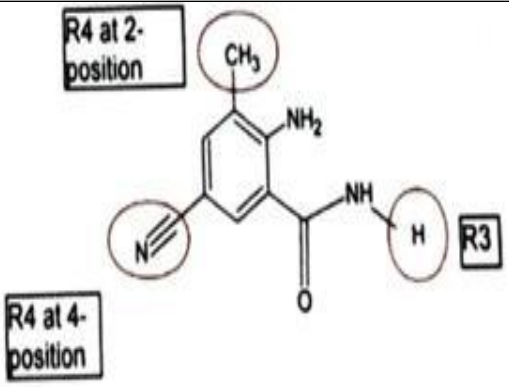
57. Thus, in view of there being a *prima facie* finding of IN'104, prior art and the suit patent, IN'645 having a common core structure, this Court is of the view that there exists a common lineage between the said patents, and thus, the argument of the plaintiffs on this aspect, cannot be accepted.

58. At this stage, it would be pertinent to see whether the other compounds in Claim 12 of the suit patent are prior claimed by the compounds in Claim 1 of IN'104, prior art.

59. Thus, it is seen that the compound formed when R^3 is isopropyl under Claim 1 of IN'104, the prior art, is the exact same compound which is claimed under proviso (d) of Claim 12 of IN'645, the suit patent, when R^3 is C_3 alkyl group, i.e, isopropyl. This is diagrammatically shown below:

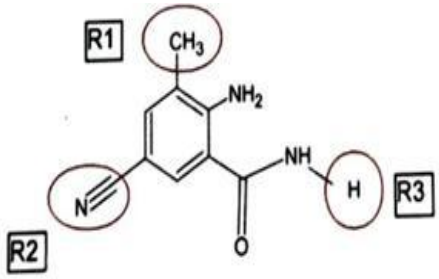
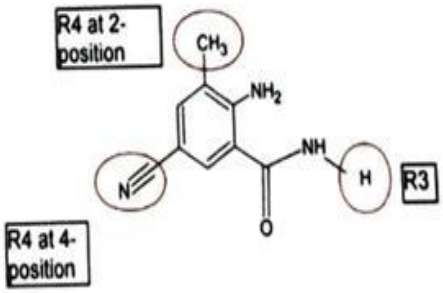
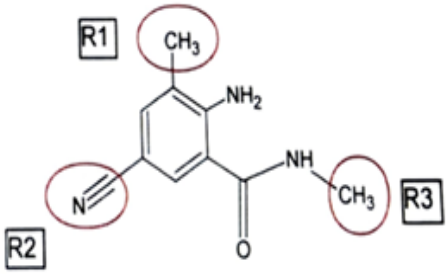
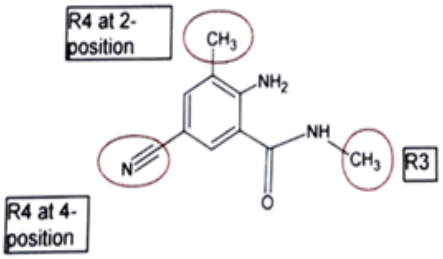
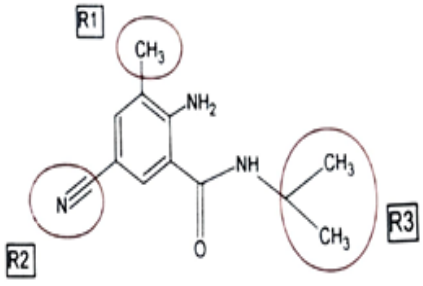
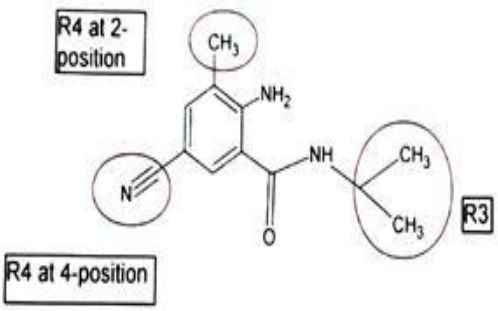
COMPOUND IN PROVISO (D) OF CLAIM 12 OF THE SUIT PATENT, IN'645	COMPOUND IN CLAIM 1 OF THE PRIOR ART, IN'104 WHEN R^3 IS ISOPROPYL (C_3 ALKYL GROUP)
	

60. Similarly, it is seen that the compound formed when R^3 is H in Claim 1 of IN'104, and the other non-variables, i.e., R_4 at 2-position and R_4 at 4-position, are CH_3 and CN, is the exact same compound which is claimed under proviso (b) of Claim 12 of IN'645, the suit patent, when R^3 is H, R^1 is CH_3 and R^2 is CN. This is diagrammatically shown below:

COMPOUND IN PROVISO (B) OF CLAIM 12 OF THE SUIT PATENT, IN'645	COMPOUND IN CLAIM 1 OF THE PRIOR ART, IN'104 WHEN R^3 IS HYDROGEN (H)
	

61. A cumulative table comparing the compounds claimed in Claim 1 of IN'104, the prior art and Claim 12 of IN'645, the suit patent, is reproduced as

below:

COMPOUNDS CLAIMED UNDER CLAIM 12 OF IN'645	COMPOUNDS CLAIMED UNDER CLAIM 1 OF IN'104
 When R^3 is Hydrogen (H) (Proviso (b) of Claim 12)	 When R^3 is Hydrogen (H)
 When R^3 is Methyl (CH_3) (Proviso (d) of Claim 12)	 When R^3 is Methyl (CH_3)
 When R^3 is Isopropyl (Proviso (d) of Claim 12)	 When R^3 is Isopropyl

62. Thus, all three compounds as claimed in Formula 6 of Claim 1 of IN'104 are claimed exactly in Formula 3 in provisos (b) and (d) of Claim 12 of the suit patent, i.e., IN'645. Therefore, as all compounds of Claim 1 of IN'104 are found in Claim 12 of IN'645, it becomes apparent that Claim 1 of IN'104 is the specie claim in relation to Claim 12 of IN'645, which is the genus claim that has encompassed all the three claimed compounds of Claim 1 of IN'104.

63. Furthermore, the compounds resulting from the claims as discussed above, when placed in a side-to-side comparison, also show that the positioning of the variable and non-variable molecules in Claim 12 of the suit patent and Claim 1 of IN'104 are the same, *albeit* with different terminology being used to depict and describe the compound structure.

64. It is also noted that during the course of prosecution for IN'104, the *predecessor-in-interest* of the plaintiffs in their response dated 10th January, 2014 before the Indian Patent Office, has made a categorical admission that the disclosures in Claim 1 of IN'104 presents a general method for the synthesis of compounds of Formula 6 and the procedures disclosed will enable a *Person Skilled in the Art* to use the claimed compounds in Formula 6 of IN'104. Thus, when this Court has already held that the said compounds in IN'104 are claimed in IN'645, the plaintiffs cannot argue that a *Person Skilled in the Art* will require undue experimentation to come to the compounds as claimed in Claim 12 of IN'645, using the disclosures made in IN'104. The relevant portion of the response dated 10th January, 2014, is reproduced as under:

"xxx xxx xxx

Regarding paragraph 1, the applicant resists and reiterates that claim 1 has been revised to incorporate a broad chemical name of the compound in the preamble of claim 1. Further, the learned Controller's contention that the claimed compound is not well defined in terms of the definition of substituents and support of compound in question,\ in the working examples, is resisted.

In this regard, we invite the attention of the learned Controller to page Nos. 22 and 23 of the specification and to scheme Nos. 3 and 4 wherein process for preparing compound of formula 6 and its use is fully described. The compounds of Formula 6 require a methyl group in the 2-position and a cyano group in the 4-position of the phenyl ring. Synthesis Example 1 provides experimental details (see Steps E-H) for the synthesis and use of the 4-bromo analog of the claimed compounds of Formula 6, and synthesis Example 2 provides experimental details (see Steps A and B) for the use of the 4-H analog of the claimed compounds of Formula 6. Both Examples 1 and 2 ultimately prepare compounds of Formula 1. Finally, Table 8 on page 56 of the PCT published application contains 18 examples of final products of Formula 1 (see lines 21-26) wherein R4b is cyano.

The disclosure therefore presents (a) a general method for the synthesis of compounds of Formula 6, (b) two experimental procedures for the preparation and use of close analogs of the compounds of Formula 6, and (c) 18 examples of compounds of Formula 1 that can clearly be prepared from the intermediates of Formula 6. One skilled in the art would thus have no trouble in following these procedures to use the claimed compounds of Formula 6.

xxx xxx xxx"

65. Moreover, the plaintiffs in their replication have reiterated the aspect of the compounds in Formula 6 in Claim 1 of IN'104 being disclosed in the complete specification of IN'104. Therefore, the disclosure itself would enable a *Person Skilled in the Art* to arrive at the compounds in Claim 1 of IN'104, which are also the subject matter of compounds in Claim 12 of IN'645, including the impugned intermediate in question. The relevant portion of the plaintiffs' replication is reproduced as under:

"xxx xxx xxx

21. Without prejudice, ***the complete specification of IN' 104, which was filed as a divisional application by E.I. DuPont's Crop Protection to the parent application bearing 1492/DELNP/2004, also filed by E.I. DuPont's Crop Protection, merely discloses the said Formula 6, on pages 22 and 23 of the complete specification, as an intermediate used in the process of preparing certain variations of Formula I therein****. It is submitted that the complete specification of TN' 104 neither discloses, teaches, instructs nor enables the technical effect of using the intermediate depicted as Formula 6, nor the advantages of using certain compounds of Formula 6.*

xxx xxx xxx"

(Emphasis Supplied)

66. At this stage, it would be appropriate to refer to the case of ***Boehringer Ingelheim Pharma GMBH & Co. KG Versus Vee Excel Drugs and***

Pharmaceuticals Private Ltd. and Others[6], wherein, while holding that reliance can be placed on the admissions made by the plaintiff in their pleadings, the Court noted as follows:

> *"xxx xxx xxx*
>
> ***66.*** *The principles of law that emerge from the judgment of the Division Bench are as follows:—*
>
> *i. Once a patentee claims infringement of an earlier genus patent in respect of a product, it necessarily follows that the said product was the subject matter of the earlier genus patent.*
>
> *ii. Only one patent can be granted in respect of one inventive concept. Therefore, a patentee cannot claim infringement of the two patents in respect of the same inventive concept.*
>
> *iii. The term of a patent is twenty years in terms of the Patents Act and it cannot be granted successive protection by means of separate patents.*
>
> *iv. The Indian law permits grant of a Markush patent. However, if one of the combinations in the Markush patent includes the product in question, it would form part of the inventive concept of the earlier patent and cannot again be claimed as an inventive concept of a subsequent patent.*
>
> ***v. The pleadings made on behalf of the plaintiff in the suit can be considered by the Court to determine the stand of the plaintiff vis-à-vis the genus patent and the species patent.***
>
> *xxx xxx xxx*
>
> ***100.*** *It has been vehemently contended on behalf of the plaintiffs that no reliance can be placed on any post grant admissions made by the plaintiffs after the priority date of the suit patent. However, in the judgments of the Supreme Court in Novartis (supra) as well as the judgment of the Division Bench in Astra Zeneca (supra), the Court has placed reliance on admissions made by the plaintiffs in the pleadings that were filed much after the grant of the suit patent.* ***Therefore, there is no merit in the submission of the plaintiffs that reliance cannot be placed on any admissions made by the plaintiffs after the priority date or after the grant of the suit patent.***
>
> *xxx xxx xxx*
>
> ***102.*** ***The pleadings/admissions made by the plaintiffs in the present***

[6] ***2023 SCC OnLine Del 1889***

> ***case, when examined in light of the scheme of the Patents Act and the principles of law laid down by the judgments above, leads me to a prima facie view that Linagliptin was "disclosed", "claimed" and "covered" under the genus patent, IN '719 as well as the suit patent, IN '301.*** *Had Linagliptin not been disclosed or claimed in the genus patent, the plaintiffs could not have made a claim for infringement of the genus patent in CS(COMM) 239/2019 and CS(COMM) 240/2019. Therefore, at an interlocutory stage at least, the requirements with regard to prior claiming under Section 64(1)(a) of the Patents Act are satisfied in the present case.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

67. Thus, in view of the aforesaid detailed discussion, it is apparent that while Claim 1 of IN'104 is the prior species claim, the Claim 12 of the suit patent is a subsequent genus claim. Thus, *prima facie* it is seen that there exists a *species-genus* relationship between the said two patents, which in consequence would lead to automatic anticipation of the genus by the species.

68. Thus, holding that a generic claim cannot be allowed to an applicant, if the prior art disclosed is a species falling within the claimed genus, the United States Court of Customs and Patent Appeals in the case of ***IN Re Slayter***[7], has held as follows:

> *"xxx xxx xxx*
>
> *Appellant seems to place great reliance on the contention that he has a broad inventive concept involving the use of two classes of materials, which concept is lacking in Smith. Assuming that to be true, it would not justify allowance of claims which are readable on Smith's disclosure, which we think is the case here.* ***It is well settled that a generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus; in other words, whatever would infringe if subsequent will anticipate if prior****. Peters v. Active Manufacturing Co., 129 U.S. 530, 537, 9 S.Ct. 389, 32 L.Ed. 738; Knapp v. Morss, 150 U.S. 221, 14 S.Ct. 81, 37 L.Ed. 1059; Faries Mfg. Co. v. S. W. Farber Mfg. Co., 2 Cir., 47 F.2d 571, and cases there cited.*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

[7] ***276 F.2d 408***

69. Likewise, holding that a later genus claim is not patentably distinct from being anticipated by the earlier species claims and therefore, defeats the novelty of a subsequent claim to the genus, US Court of Appeals, Federal Circuit, in the case of ***Eli Lilly & Co. Versus Barr Laboratories***[8], has held as follows:

> *"xxx xxx xxx*
>
> *The only other difference between claim 1 of the '213 patent and claim 7 of the '549 patent is that the former is directed to humans while the latter is directed to animals. Humans are a species of the animal genus.* ***Our case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.*** *In re Berg, 140 F.3d at 1437, 46 USPQ2d at 1233 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 1053, 29 USPQ2d 2010, 2016 (Fed. Cir. 1993); In re Gosteli, 872 F.2d 1008, 1010, 10 USPQ2d 1614, 1616 (Fed. Cir. 1989); Titanium Metals Corp. v. Banner, 778 F.2d 775, 782, 227 USPQ 773, 779 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d at 944, 214 USPQ at 767 (C.C.P.A. 1982).*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

70. Further, Chapter 9 of the ***Manual of Patent Office Practice and Procedure***, dated 26th November, 2019, published by the Office of Controller General of Patents, Designs & Trademarks, states that while a generic disclosure in the prior may not necessarily take away the novelty of a specific disclosure, a specific disclosure in the prior art takes away the novelty of a generic disclosure, in the following manner:

> *"xxx xxx xxx*

[8] ***251 F.3d 955***

9. A specific disclosure in the prior art takes away the novelty of a generic disclosure. For instance, a copper spring takes away the novelty of a metal spring.

10. In a case where a prior art is cited as an anticipation in the Examination Report, the onus of proving that the same is not to be an anticipation by reason of Section 29-34, lies on the applicant.

xxx xxx xxx"

71. Likewise, the ***Manual of Patent Examining Procedure (MPEP), Ninth Edition, Revision 01.2024***, issued by the United States Patent and Trademark Office, under ***Section 2131.02*** states that a species will anticipate a claim to a genus, in the following manner:

"xxx xxx xxx

2131.02 Genus-Species Situations [R-07.2022]

I. A SPECIES WILL ANTICIPATE A CLAIM TO A GENUS

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gosteli claimed a genus of 21 specific chemical species of bicyclic thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

xxx xxx xxx"

72. The rationale behind a species automatically anticipating a genus, can be understood by way of an analogy. If a patent is granted over a specific claim, the same would enjoy a monopoly for 20 years. A subsequent patent sought for

the broader genus, would necessarily encompass the earlier specific species within it, thereby granting another 20-year protection to the genus patent, which would then mean, granting an extension beyond the term of 20 years to the earlier specific species therein, leading to double patenting and re-monopolization of the specific species.

73. Holding that patent with respect to the same invention cannot be granted more than once successively in time, as the same will negate the legislative intent of limiting the life of the patent, Division Bench of this Court in the case of ***Astrazenca AB and Another Versus Intas Pharmaceuticals Ltd.***[9], held as follows:

> *"xxx xxx xxx*
>
> ***31.*** *The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open for all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee.* ***If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefor.***
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

74. Thus, in view of the above, the argument of the plaintiffs that there exists no common lineage between Claim 1 of IN'104 and Claim 12 of IN'645 and

[9] ***2021 SCC OnLine Del 3746***

there being no *species-genus* relationship between the said claims, cannot be accepted.

75. For the purposes of the present interim application, and in view of the discussion made as above, the defendant has been able to *prima facie* establish its case that Formula 6 of Claim 1 of the IN'104 claims the intermediate in question known as *2-amino-5-cyano-N, 3-dimethylbenzamide,* which is the subject of Formula 3 of Claim 12 of the suit patent. The said intermediate in question is *prima facie* one of the three intermediate compounds claimed in Claim 1 of IN'104, prior art, belonging to the plaintiffs, which has already expired on 16th January, 2023. Moreover, it is further apparent that the other two compounds under Claim 1 of IN'104, the prior art, are also claimed in Claim 12 of the suit patent. Therefore, Claim 1 of IN'104 is a species, while Claim 12 of the IN'645, the suit patent, is the genus. Consequently, a *prima facie* credible challenge is made to the validity of Claim 12 of the suit patent, on this ground.

76. Thus, in view of the discussion hereinabove, the defendant has *prima facie* raised a credible challenge under Section 64 (1)(a) of the Act in relation to Claim 12 of the suit patent.

Challenge under Section 64 (1)(e) of the Act:

77. In relation to Section 64 (1)(e) of the Act, it is the case of the defendant that Claim 12 of IN'645, i.e., suit patent, stands anticipated by various disclosures in WO'226, in light of which , the defendant has raised a challenge to the validity of Claim 12 of the suit patent under Section 64 (1)(e) as well.

78. *Per contra*, it is the case of the plaintiffs that WO'226 does not disclose, nor enable the group of compounds of Formula 3 under Claim 12 of the suit patent, therefore, the challenge raised under Section 64 (1)(e) is not cogent.

79. It is to be noted that WO'226 is the international counterpart of IN'417 under which the division patent, i.e., IN'104, the prior art in question for the

argument under Section 64 (1)(a), was granted. The defendant has asserted that compounds of Formula 6 in Claim 1 of IN'104 is disclosed in WO'226, therefore, in effect, WO'226 will also disclose and thereby anticipate Claim 12 of IN'645.

80. At this stage it would be pertinent to make reference to Section 64 (1)(e) of the Act. The same is reproduced as under:

> *"xxx xxx xxx*
>
> ***64. Revocation of patents**.—(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, [be revoked on a petition of any person interested or of the Central Government [* * *] or on a counter-claim in a suit for infringement of the patent by the High Court] on any of the following grounds, that is to say,—*
>
> *xxx xxx xxx*
>
> *(e) **that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;***
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

81. From the above it can be culled out that the prior art under the ambit of Section 64 (1)(e) of the Act can be any document, i.e., patent or non-patent document, which was publicly known or used anywhere in the world before the priority date of the patent under question. Therefore, WO'226 despite being an international patent, having its national phase patent, i.e., IN'417 granted in India, with divisional application, IN'104, will be relevant for the purposes of Section 64 (1)(e) of the Act, as it falls within the ambit of what was *"published in India or elsewhere"*.

82. Further, under the said section for a prior art to anticipate a patent, it should have been published prior to the priority date of the said patent. In the

present case, the date of publication of WO'226 is 31st July, 2003, which is prior to the priority date of the suit patent, IN'645, i.e., 07th December, 2004. Therefore, if this Court comes to the conclusion that WO'226 anticipates the intermediate compound in question in Claim 12 of IN'645, i.e., the suit patent, it would lead to a *prima facie* credible challenge being laid by the defendant to the validity of Claim 12 of the suit patent under Section 64 (1)(e) of the Act.

83. The parameters for the assessment of novelty under the Act have been elaborated under ***Section 09.03.02 of Manual of Patent Office Practice and Procedure***, dated 26th November 2019, published by the Indian Patent Office, in the following manner:

> *"xxx xxx xxx*
>
> *Novelty*
>
> *1.* ***An invention is considered as new(novel), if it is not anticipated by prior publication in patent and non-patent literature, i.e., an invention is novel if it has not been disclosed in the prior art, where the prior art means everything that has been published, presented or otherwise disclosed to the public before the date of filing/priority date of complete specification.***
>
> ***2. An invention is considered as novel, if it has not been anticipated by prior use or prior public knowledge in India.***
>
> *3. For the purpose of determining novelty, an application for patent filed at the Indian Patent Office before the date of filing of complete specification of a later filed application, but published after the same, is considered for the purposes of prior claiming.*
>
> *4. While ascertaining novelty, the Examiner takes into consideration, inter alia, the following documents:*
>
> *-* ***which have been published before the date of filing of the application in any of the specifications filed in pursuance of application for patent in India on or after 1st January, 1912****.*
>
> *- such Indian Patent Applications which have been filed before the date of filing of complete specification and published on or after the date of filing of the complete specification, but claims the same subject matter.*
>
> *5. The examiner shall make such investigation for purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in*

India or elsewhere in any document other than those mentioned in section 13(1) before date of filing of the applicant's complete specification.

6. A prior art is considered as anticipating novelty if all the features of the invention under examination are present in the cited prior art document.

7. The prior art should disclose the invention either in explicit or implicit manner. Mosaicing of prior art documents is not allowed in determination of novelty.

xxx xxx xxx"

(Emphasis Supplied)

84. The test for determining anticipation under Section 64 (1)(e) of the Act has been consolidated by the Court in the case of ***LAVA International Limited Versus Telefonaktiebolaget LM Ericsson***[10]**,** in the following manner:

"xxx xxx xxx

83. *In my opinion, the seminal guidance on determination of novelty has been provided in the decision of the House of Lords in Hills v. Evans, wherein it has been concluded that* ***the test of novelty evaluates whether an invention is truly new by assessing if it was previously disclosed in a manner that would allow a person skilled in the art to reproduce the invention without additional research or experimentation.*** *The relevant extracts from the said decision are set out below:*

"I have therefore to consider, and to give my opinion upon, the question that has been argued, namely, whether there be or be not ***anything in these specifications which has rendered the Plaintiff's invention matter of public knowledge, and therefore matter of public property, anterior to the granting of the patent…*** *With regard to the specification of a prior patent it is not to be distinguished in principle from any other publication. The only peculiarity attending the specification of a prior patent is this, that it must of necessity be considered as a publication. There has been some doubt with regard to books and documents under particular circumstances, whether they can be considered as amounting to a publication. With regard to a specification there can be no doubt, because the specification is that which the patentee gives to the public and makes a matter publici juris in return for the privilege which he receives. But upon all principle a specification is not to be distinguished from any prior publication contained in a book*

[10] ***2024 SCC OnLine Del 2497***

published in the ordinary manner. The question then is, what must be the nature of the antecedent statement? I apprehend that the principle is correctly thus expressed-the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand, and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent. By the words of the statute of James, ***it is necessary for the validity of a patent that the invention should not have been known or used at the time.*** *These words are held to mean "not publicly known or publicly used." What amounts to public knowledge or public user is still to be ascertained. One of the means of imparting knowledge to the public is the publication of a book, or the recording of a specification of a patent. If, therefore, in disproving that an allegation which is involved in every patent, that the invention was not previously known, appeal be made to an antecedently published book or specification, the question is, what is the nature and extent of the information thus acquired which is necessary to disprove the novelty of the subsequent patent? There is not, I think, any other general answer that can be given to this question than this:* ***that the information as to the alleged invention given by the prior publication must, for the purposes of practical utility, be equal to that given by the subsequent patent****. The invention must be shown to have been before made known. Whatever, therefore, is essential to the invention must be read out of the prior publication. If specific details are necessary for the practical working and real utility of the alleged invention, they must be found substantially in the prior publication.*

Apparent generality, or a proposition not true to its full extent, will not prejudice a subsequent statement which is limited and accurate, and gives a specific rule of practical application*.*

The reason is manifest, because much further information, and therefore much further discovery, are required before the real truth can be extricated and embodied in a form to serve the use of mankind. It is the difference between the ore and the refined and pure metal which is extracted from it.

Again, it is not, in my opinion, true in these cases to say, that knowledge, and the means of obtaining knowledge, are the same. There is a great difference between them. To carry me to the place at which I wish to arrive is very different from merely putting me on the road that leads to it. There may be a latent truth in the words of a former writer, not known even to the writer himself, and it would be unreasonable to say that there is no merit in discovering and unfolding it to the world.

Upon principle, therefore, I conclude that the ***prior knowledge of an invention to avoid a patent must be knowledge equal to that required to be given by a specification, namely, such knowledge as will enable the public to perceive the very discovery, and to carry the invention into practical use.****"*

(Emphasis supplied)

84. *In addition, in General Tires & Rubber Co. v. Firestone Tyre & Rubber Co. Ltd., it has been held that even if not all details are present in the earlier document cited as novelty destroying prior art, it is possible that the prior art document and the patent in question essentially convey the same message but in different terms. The key question to resolve in such instances is* ***whether the prior art document provides clear and unmistakable instructions that, if followed, would inevitably lead to a result that falls within the scope of the patent's claims or inventive concept.*** *The relevant extract from the said decision is set out below:*

*"As to novelty, one must consider in relation to each of the documents cited whether all the specific details are disclosed and if not, whether the reader would assume from his ordinary knowledge that he should carry out the steps in question and if so how. One must also instruct oneself with the surrounding circumstances as they exist; Hills v. Evans (supra)****. If one cannot find all the details in the early document, it may still be possible that the prior document and the patent-in-suit were really saying the same thing in different words.*** ***The question to be answered in such a case is; does the prior document give clear and unmistakeable directions which when carried out will inevitably result in something coming within the claims of the patent?****"*

(Emphasis supplied)

85. *The aforesaid decisions lay down* ***the legal framework for assessing the novelty of an invention, emphasising that for an invention to be considered novel, it must not have been previously disclosed in a manner that would enable a skilled person to reproduce the invention without further experimentation. It has also been specified that for prior knowledge or disclosure to challenge the novelty of an invention, it must offer practical utility equivalent to the invention. In addition, it has also been clarified that if disclosures from prior art inevitably led to the invention, even without explicit details, it can be said the novelty of an invention is compromised.***

xxx xxx xxx

88. When assessing the novelty of an invention, a Judge or even a patent examiner ought to follow a systematic approach to ensure a thorough and unbiased analysis of the invention claimed and the

prior art cited. Another important aspect of the test for assessment of novelty in an invention is to maintain a distinction between the test of novelty and test for inventive step or lack of obviousness. I am of the view that the following steps, which may be referred to as the 'Seven Stambhas Approach' serve as guiding principles and provide a clear framework for assessing novelty, reflecting the distinction between novelty and non-obviousness:

(i) Understanding of the Claims of the Invention

• The determination of lack of novelty should begin with the understanding of the Claims of the invention as it is the Claims that define the boundaries of the invention and what the applicant considers as their novel contribution.

(ii) Identify Relevant Prior Art

• Collecting the prior art, including any public disclosure, publication, patent, or patent application that predates the filing date of the patent application which is relevant to the Claims of the patent.

(iii) Analyse the Prior Art

• Conducting a detailed analysis of the identified prior art to ascertain its relevance to the Claims of the invention. This step involves searching and documenting both the similarities and the differences, if any, between the Claims of the invention and the text of the prior art. This step requires comparing the technical details and features of the prior art against those claimed in the invention.

(iv) Determine Explicit and Implicit Disclosures

• Examining whether the prior art explicitly or implicitly discloses the same invention. Explicit disclosure means the prior art directly describes the invention claimed. Implicit disclosure refers to whether the prior art describes elements or aspects so similar to the claimed invention that a direct link can be drawn.

(v) Assessment material differences while considering the entire scope of the Claims

• Identifying the material differences between the claimed invention and the prior art, if any, such that a material difference would indicate that the claimed invention has not been disclosed in the prior art and, therefore, the invention, is novel.

(vi) Verifying Novelty in light of Comprehensive Scope and Specific Combination of Claimed Elements

• Evaluation of novelty of the invention is carried out in light of the comprehensive scope of its claims, not just individual elements.

• The invention is novel only if the combination of claimed elements as a whole has not been previously disclosed.

(vi) Documentation of the Analysis and Novelty Determination

• Specify the finding of the examination of novelty, while providing a clear rationale for the said determination. The specific documentation must include references to specific sections of the prior art examined and a reasoning as to how the section affects the novelty of the claims and the inventive concept of the invention.

• Based on the analysis, issue a formal decision, if the invention or any of its claimed elements is found in the prior art, the invention is not novel. Conversely, if the invention is not disclosed by the prior art, it is considered novel.

xxx xxx xxx"

(Emphasis Supplied)

85. It is the case of the defendant that the intermediate in question under Claim 12 of the suit patent is already claimed and disclosed in IN'104, therefore, it will automatically be disclosed under WO'226, as IN'104 is the divisional patent to the national phase patent, i.e., IN'417, which relates to the international counterpart, WO'226.

86. As noted above, IN'104 was a divisional patent of IN'417 which is the national phase patent for WO'226. Therefore, the disclosure in the complete specification of IN'104, regardless, cannot be inconsistent or beyond the scope of the disclosures made in the complete specification of the original application granted as IN'417, and in consequence with the international counterpart being WO'226. Thus, the disclosures made in the complete specification of IN'104 would necessarily fall within the scope of the disclosures made in WO'226.

87. It is noted that a divisional patent, IN'104 cannot disclose anything which is not in substance already disclosed under the original application, which in the present case would be for the granted patent, IN'417, i.e., national phase application. The national phase application, IN'417, takes its lineage from its international counterpart, WO'226. In effect, as per the operation of law, the disclosure made under IN'104, cannot extend beyond what has been in substance disclosed under the complete specification of WO'226. In this regard, reference is made to Section 16 of the Act, which is reproduced as under:

"xxx xxx xxx

16. Power of Controller to make orders respecting division of application*.—(1) A person who has made an application for a patent under this Act may, at any time before the [grant of the patent], if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.*

(2) ***The further application under sub-section (1) shall be accompanied by a complete specification, but such complete specification shall not include any matter not in substance disclosed in the complete specification filed in pursuance of the first mentioned application.***

(3) The Controller may require such amendment of the complete specification filed in pursuance of either the original or the further application as may be necessary to ensure that neither of the said complete specifications includes a claim for any matter claimed in the other.

Explanation.—For the purposes of this Act, the further application and the complete specification accompanying it shall be deemed to have been filed on the date on which the first mentioned application had been filed, and the further application shall be proceeded with as a substantive application and be examined when the request for examination is filed within the prescribed period.

xxx xxx xxx"

(Emphasis Supplied)

88. Reading of the aforesaid section makes it clear that a division application shall not include any matter which is not in substance disclosed in the complete specification filed in pursuance to the original application.

89. A reference in this regard, may be made to the decision of this Court in the case of ***Novartis AG Versus Controller of Patents & Designs***[11], wherein, the Court held as follows:

"xxx xxx xxx

22. Thus, there are twin conditions under Section 16 of the Act for filing of divisional application:

[11] ***2022 SCC OnLine Del 2532***

1. ***The divisional application has to be in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.***
2. *There cannot be duplication of claims in the two specifications i.e. the parent specification and the divisional specification.*

23. ***Therefore, as per Section 16 of the Act, the claims of the divisional cannot be outside the scope of the claims of the parent specification*** *and at the same time there cannot be duplication of claims. In the present case, it is not in dispute that the compound being claimed in the divisional application is within the scope of the parent application. The matter forming part of the divisional application is also disclosed in the original parent specification as well. The objection of the patent office is that the compound being claimed in the divisional application is already covered by the granted claims of the parent application and hence, there is duplication of claims. The crux of the argument of the learned CGSC is that there can only be one patent for one invention.*

xxx xxx xxx"

(Emphasis Supplied)

90. Further, the aforesaid aspect has been clarified by the Division Bench of this Court in the case of ***Syngenta Limited Versus Controller of Patents and Designs***[12], wherein, it has categorically been held that any further application filed in respect of an invention under Section 16 (1) of the Act, must be disclosed in the specifications contained in the earlier application. The relevant portion of the said judgement is reproduced as under:

"xxx xxx xxx

18. ***We note that Section 16(1) in unambiguous terms enables the filing of a further application in respect of an invention, provided it is disclosed in the provisional or complete specification already filed.*** *As the learned Judge rightly observes there appears to be no justification to restrict the filing of a Divisional Application only to a situation where the plurality of inventions is found in the claims.* ***The significance of the provision using the expression "disclosed in the provisional or complete specification" can neither be ignored nor discarded. While it would have been open for the Legislature to restrict the amplitude of that provision by stipulating that plural inventions must be embodied or be identifiable from the claims as originally filed, it has in unequivocal terms provisioned for the same being discernible from the provisional or complete specification. The***

[12] ***2023 SCC OnLine Del 6392***

> ***provision as structured neither leaves any space of ambiguity nor does the language of the text warrant any doubt being harbored in respect of the clear intent of the provision.*** *We thus find ourselves unable to concur with the interpretation placed upon that provision in Boehringer Ingelheim.*
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

91. Thus, as this Court has already come to a finding that the intermediate compound in question under Claim 12 of the suit patent is claimed and disclosed under IN'104, and further this Court has noted that the disclosure made under IN'104 would in substance be already disclosed under WO'226 as per Section 16 of the Act, it would follow that the intermediate compound in question under Claim 12 of the suit patent is also disclosed under WO'226.

92. Further, this Court notes that the disclosure in the complete specification of WO'226 would necessarily have to be an enabling disclosure. The same is obligatory to fulfil the tenor of Section 10 (1) and 10 (4) of the Act, which reads as under:

> *"xxx xxx xxx*
> *10. Contents of specifications.—(1**) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates.***
> *xxx xxx xxx*
> ***(4) Every complete specification** shall—*
> *(a) **fully and particularly describe the invention and its operation or use and the method by which it is to be performed**;*
> *(b) **disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection**; and*
> *(c) end with a claim or claims defining the scope of the invention for which protection is claimed.*
> *(d) be accompanied by an abstract to provide technical information on the invention:*
>
> *Provided that—*
>
> *(i) the Controller may amend the abstract for providing better information to third parties; and*

(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as the satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an [international depository authority under the Budapest Treaty] and by fulfilling the following conditions, namely:—

[(A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;]

(B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;

(C) access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of the priority;

(D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.]

xxx xxx xxx"

(Emphasis Supplied)

93. Perusal of the above brings forth that any invention filed in India should sufficiently and fairly describe the invention as per Section 10 (4) of the Act, and the complete specification of a patent application should have a proper description of the invention, which would enable a *Person Skilled in the Art* to perform the invention.

94. Further, this Court notes that the international patent, WO'226 has entered India as a national phase application which was granted as an Indian patent, i.e., IN'417, which was later divided into two patents according to Section 16 of the Act, one of which is IN'104 and the other being IN'417.

95. It is noted that any patent that enters into India, will be obligated to sufficiently and fairly describe the invention as per Section 10 (4) of the Act, and the complete specification of the same should have proper description of the invention, which would enable a *Person Skilled in the Art* to understand and work the invention. Thus, any international patent, when filed in national phase under the contours of Section 10 (4) of the Act, would necessarily also be

required to provide disclosure which enables a *Person Skilled in the Art*, to practice the invention without undue experimentation. Accordingly, as this Court has already held that the intermediate compound in question under Claim 12 of IN'645 is also claimed and disclosed in Claim 1 of IN'104, therefore, at *prima facie* stage for the purposes of deciding the present application, this Court is of the considered view that WO'226, which is the international counterpart would also necessarily have an enabling disclosure to allow a *Person Skilled in the Art* to come to the intermediate compound in question as claimed in Claim 12 of IN'645.

96. Thus, this Court is of the *prima facie* view that the intermediate compound in question under Claim 12 of the suit patent, IN'645 will be anticipated by WO'226, and therefore, would be vulnerable to challenge on the ground of Section 64 (1)(e) of the Act.

Gillette Defence:

97. The defendant has raised the *'Gillette Defence'* of non-infringement, i.e., that the defendant does not infringe the suit patent since it is practicing the teachings of the earlier patent IN'104. *'Gillette Defence'* is premised on the principle that if the defendant's product or process is nothing more than what was already disclosed in the prior art, then there can be no infringement of the suit patent. In such a case, the defendant does not need to challenge the validity of the suit patent itself. It is sufficient to demonstrate that its activities fall entirely within the scope of prior disclosures, thereby avoiding infringement. Thus, as per the case put forward by the defendant, since the specific compound being practiced by the defendant, i.e., *2-amino-5-cyano-N, 3-dimethylbenzamide,* is also claimed and disclosed in IN'104 and WO'226, the defendant has a right to practice this compound, once the period of protection of IN'104 has expired.

98. The *'Gillette Defence'*, as raised by the defendant has its origin from the decision of the House of Lords in the case of ***Gillette Safety Razor Versus Anglo-American Trading***[13]. The aspect of *'Gillette Defence'* has been elucidated in ***Para 12-176, Chapter 12, Pratibha M. Singh on Patent Law***, ***First Edition***, in the following manner:

> *"xxx xxx xxx*
> ***GILLETTE DEFENCE***
> *12-176* ***Another defence which can be raised by the defendant is that it is manufacturing its product as per the teachings in the prior art to the plaintiff's patent.*** *While raising such a defence, the defendant argues that the plaintiff's patent is invalid due to lack of novelty and in addition, is also not infringing the plaintiff's patent.* ***This defence is known as the Gillette defence having its origin from the decision of the House of Lord. As per this defence, the defendant can rely upon a prior art document that may also destroy the novelty of the plaintiff's patent, and argue that the product or process being manufactured or followed by the defendant is in line with the disclosure made in the said prior art document. When the defendant raises such a defence and relies on a specific prior art or a publication, the Court would only consider the narrow issue raised by the defendant and thus need not go into other issues of infringement/invalidity. Such a defence has been recognised by Indian courts***.
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

99. This Court has made a categorical finding that the intermediate compound in question in Claim 12 of IN'645, suit patent is prior claimed by Claim 1 of IN'104, prior art. Therefore, since IN'104 has already expired on 16th January, 2023, this Court is of the considered view that in the present case, the defence as raised by the defendant on the aspect of *'Gillette Defence'* is *prima facie* tenable.

100. Considering the pleadings/admissions made by the plaintiffs in the present case and the detailed discussion hereinabove, this Court is of the view that the defendant has, at this interim stage, set out a credible challenge to the

[13] ***(1913) 30 RPC 465***

validity of Claim 12 of IN'645, by showing that Claim 12 of IN'645, the suit patent, is *prima facie* vulnerable to challenge. The requirements with regard to prior claiming under Section 64 (1)(a) and Section 64 (1)(e) of the Act are satisfied in the present case at the interlocutory stage. Thus, an interim injunction cannot be granted in favour of the plaintiffs.

101. In view of the aforesaid findings, it would not be necessary to consider the other grounds of revocation of the patent and dismissal of the suit, as raised by the defendant, which shall be considered at the stage of the trial.

Balance of Convenience and Irreparable Harm:

102. This Court notes that during the course of pendency of the present suit, the defendant has already launched the product. Thus, *vide* order dated 01st August, 2025, it was noted and directed as follows:

> *"**I.A. 34151/2024 in CS(COMM) 607/2024***
>
> *1. Learned Senior Counsel appearing for the plaintiffs has commenced his rejoinder arguments*
>
> *2. During the course of hearing, learned Senior Counsel appearing for the plaintiffs has brought forth that the defendant has already launched the product.*
>
> *3. Learned Senior Counsel appearing for the defendant does not dispute the same. He submits that the defendant has already cleared the way, which is disputed by learned Senior Counsel appearing for the plaintiffs.*
>
> *4. Learned Senior Counsel appearing for the defendant submits that in view of the fact that the defendant has already launched the product, the defendant shall file all the details of the stock manufactured, as well as launched by the defendant. Further, the defendant shall also file the details of all the revenue earned by the defendant, in a tabular form.*
>
> *5. He further submits that the defendant shall also clearly state in the affidavit as regards the various approvals obtained by the defendant for the purposes of marketing the product.*
>
> *6. The aforesaid statement is taken note of.*
>
> *7. Let the needful be done by the defendant before the next date of hearing.*
>
> *8. Re-notify for hearing on 18th and 19th August, 2025 at 2:30 PM"*

103. As per the plea raised by the defendant, the defendant has already

'cleared the way', before the commencement of the production and marketing of the impugned product.

104. As per ***Terrell on the Law of Patents***[14], the defendant can avoid an interlocutory injunction in situations where litigation is bound to ensue if the defendant introduces his product, provided he *clears the way* first. This can be achieved by using the procedures for revocation and declaration of non-infringement.

105. The whole concept is resting on the aspect that the Courts shall avoid multiplicity of litigation. If a party clears the way first, thereafter, the said party need not face the rigors of an interim injunction. Furthermore, the legal mechanism provides for direct approaches to *'clear the way'*, for instance by filing a suit for non-infringement.

106. The Single Bench in the case of ***Merck Sharp and Dohme Corporation Versus Glenmark Pharmaceuticals***[15], while discussing the principle of the *'clearing the way'* held that it would be a relevant factor, if a party with knowledge of forthcoming proceedings between the parties would launch its product without filing a revocation petition. Further, the Division Bench relied on the ***Smithkline Beecham Cases*** which first developed the concept of 'clearing the way', wherein it was observed that non-infringement and revocation cases are the procedures to follow for *'clearing the way'*. The relevant portion of the judgement reads as under:

> *"xxx xxx xxx*
>
> *87. A related concern that this Court heeds - the fourth principle operative in this case - is that of the chronology of events and Glenmark's decision to release Zita without first challenging Januvia or Janumet. Undoubtedly, the Act creates a right to oppose patents even after grant.* ***There is no obligation to only utilize the pre or post***

[14]***See Terrell on the Law of Patents (19th ed) at paragraphs 19-245, 19-246***
[15]***2015 SCC OnLine Del 8227***

grant opposition mechanisms. Neither does a patent benefit from a presumption of validity if it is challenged in the course of an infringement suit. However, if a defendant is aware that there may be a possible challenge to its product, but still chooses to release the drug without first invoking revocation proceedings or attempting to negotiate, that is surely a relevant factor. *The defendant's legal right to challenge the patent at any point in time is intact, but that does not mean that this factor cannot determine the interim arrangement. This is more so where Glenmark today argues that MSD ought to have disclosed international patent applications for SPM and Sitagliptin plus Metformin since they were the "same or substantially the same" as the suit patent under Section 8. That is Glenmark's stated position. Such being the state of things, it is surely reasonable for Glenmark to detect the possibility to challenge, when a US patent application for SPM filed by it was opposed by MSD.* ***Despite this, Glenmark released the drug without initiating revocation proceedings under the Act, which is also a right vested in Glenmark that would have obviated the need for the interim arrangement we are today considering.*** *This does not mean that Glenmark's right to question the validity of the patent in an infringement is affected, but the manner of challenge is a relevant factor against it at the interim stage.* ***As Justice Jacob noted in both Smithkline Beecham cases (supra):***

> ***"I remain of the same opinion that I was in the Generics case. Where litigation is bound to ensue if the defendant introduces his product he can avoid all the problems of an interlocutory, injunction if he clears the way first. That is what the procedures for revocation and declaration of non-infringement are for."***

Similarly, in the Australian decision of Pharmacia Italia S.p.A. v. Interpharma Pty Ltd., [2005] FCA 1675, the Court noted the fact that Inter-pharma had acted in full knowledge of Pharmacia's patent and the possible consequences flowing from that. This consideration that the patentee is already in the market and has been operating the patent has found favour in Indian Courts as well. In K. Ramu v. Adayar Ananda Bhavan and Muthulakshmi Bhavan, (2007) 34 PTC 689 (Mad), Bajaj Auto Ltd. v. TVS Motor Company Ltd., (2008) 36 PTC 417 (Mad) and National Research Development Corporation of India v. The Delhi Cloth and General Mills Co. Ltd., AIR 1980 Del 132 : (1950-2000) Supp 22(1) PTC 95 (Del), the fact that the patentee was already dealing in the market on the basis of the patent weighed in as a factor in granting the interim injunction."
xxx xxx xxx"

(Emphasis Supplied)

107. In the facts of the present case the defendant had filed a revocation petition seeking invalidity of Claim 12 of the suit patent on 31st October, 2023.

Further, the defendant had first disclosed the impugned product, i.e., Cyantraniliprole 10.26% OD, in the suit for non-infringement filed by the defendant on 30th October, 2023, with respect to another patent of the plaintiffs, i.e., IN'358.

108. This Court notes that the defendant has already commenced commercial production of the impugned product using the intermediate compound in question, and has been continuously marketing and selling the said product since April, 2025. As noted above, the defendant has at this interim stage, *prima facie* set out a credible challenge to the validity of Claim 12 of IN'645 by showing that the same is *prima facie* vulnerable to challenge. Thus, a credible defence to the infringement action has been set up by the defendant. Thus, the balance of convenience lies in favour of the defendant and against the plaintiffs.

109. This Court notes the submission made on behalf of the defendant that the defendant has invested heavily in infrastructure, regulatory compliance and commercial arrangements, with investments in its manufacturing facilities amounting to several crores. Given that the patent is about to expire in less than two months, any injury that may be caused to the plaintiffs are purely monetary in nature and can be adequately compensated by damages. In this regard, reference may be made to the judgment in the case of ***Astrazeneca AB and Another Versus Intas Pharmaceutical Ltd.***[16], wherein, it has been held as follows:

> *"xxx xxx xxx*
>
> *130. Having considered the case from the point of view of facets involving balance of convenience and irreparable harm, it has to be stated that the fact that a challenge has been laid at the stage when the plaintiffs seek to enforce their rights under the patents would not propel the Court [as indicated above] to grant an injunction if the challenge is credible.*

[16]***2020 SCC OnLine Del 2765***

131. The provisions of the Act do not provide any shield of inviolability. This principle is true not only in India but jurisdictions across the world. In no country, a mere grant of a patent by the patent offices' guarantees their validity. It is important to remember that grant of monopoly to the inventor, which is necessary for her/him to recoup investments and/or derive profits from her/his inventions, comes with a quid pro quo as noticed in paragraph 38 of Report on the Revision of the Patents Law by Shri Justice N. Rajagopala Ayyangar (September, 1959). Paragraph 38 reads thus:

> *"38.* ***I have already set out the considerations which are said to constitute the quid pro quo for the grant of the patent monopoly, namely; (1) the working of the invention within the country so as to result in the establishment in the country of a new industry or an improvement of an existing industry which would profitably employ the labour and capital of the country and thus increase the national wealth, and (2) disclosure to the public of the invention and the manner of its working so that on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other.*** *Where the patentee has no intention of working the invention in this country either because he considers that this is not profitable or because he prefers to expand the production in his home country so as to achieve there greater efficiency and more production or is otherwise not interested in working the invention in India, the grant of the Indian patent might tend to improve the economy of the patentee's home country but offers little advantage to us.* ***Unless therefore the law provides for measures to be taken to compel the patentees to work the invention within the country, and these measures are effective to achieve their purpose, the social cost involved in the grant of the patent is not offset by any benefit to the community****. As regards the possible advantage which might result by disclosure it should be noted that most of the inventions patented by foreigners in this country are also patented abroad and the theory therefore that but for patent protection the invention would have been worked in secret and that the public would have been deprived of the knowledge of the invention has no relevance in the case of the large majority of patents granted in India. As neither of the above considerations seems to be present in the case of patents granted to foreign nationals which are not worked in this country the cost to the community by the grant of the patents is unrelieved by any positive advantage by way of an increase of technical skill or of national wealth."*
>
> *[Emphasis is mine]*

xxx xxx xxx

> *135.* ***What persuades me to decline injunction, in addition to what I have stated above, is also the fact that in this case damages if proved at trial, appear to be compensable.*** *The defendants have averred that the plaintiffs have, possibly, licensed their rights under the suit patents to two entities i.e. Sun and Abbott. The packaging of the products of the drug sold through these entities is indicative of this aspect. The plaintiffs, however, for reasons best known to them have not placed on record the agreements arrived at with these entities in support of their plea. Therefore, it has to be inferred that the said entities are licensees.*
>
> *136. Besides this, the plaintiffs also aver that they are importing their drug into the country. Therefore, the plaintiffs seek to monetize their invention.* ***Thus, at the end of the trial, if they were to succeed, they could be granted damages, if proved, under the law. Thus, as long as a mechanism can be put in place for securing the recovery of damages by the plaintiffs, it would, at this stage balance the interest of the parties.*** *[See: Dynamic Manufacturing, Inc. v. David A. Craze, and Miller Industries, Inc., 1998 WL 241201]*
>
> *xxx xxx xxx"*
>
> *(Emphasis Supplied)*

110. Accordingly, the plaintiffs have failed to make out a *prima facie* case for grant of interim injunction. Thus, considering the discussion as above with respect to the balance of convenience and irreparable harm as well *prima facie* case, this Court is not inclined to grant an injunction to the plaintiffs. If the plaintiffs were to succeed at the end of the trial, they could be granted damages, if proved, under the law.

111. Considering the fact that the defendant has already commenced commercial manufacturing and marketing of the product in question, the defendant shall place on record the details, quantum and value of the product manufactured and sold.

112. It is clarified that the observations made hereinabove are only *prima facie* in nature for the purpose of deciding the application for interim injunction, on the basis of submissions made before this Court and facts brought forth at the time of hearing. Nothing contained herein shall be construed as an expression

on the merits of the case, which shall be decided after trial, independent of any observations made herein.

113. Accordingly, the present application for grant of injunction is dismissed.

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114. List before the Roster Bench for directions on 24th November, 2025.

MINI PUSHKARNA
(JUDGE)

NOVEMBER 17, 2025/au/kr