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

Reserved on: 29 May 2025
Pronounced on: 9 October 2025

\+ FAO(OS) (COMM) 43/2025, CM APPL. 17608/2025, CM APPL. 17609/2025, CM APPL. 17610/2025, CM APPL. 17611/2025, CM APPL. 17612/2025, CM APPL. 17613/2025 & CM APPL. 17614/2025

F. HOFFMANN-LA ROCHE AG & ANR. .....Appellants

Through: Mr. Sandeep Sethi, Sr. Adv. with Mr. Pravin Anand, Ms. Archana Shanker, Mr. Shrawan Chopra, Ms. Prachi Agarwal, Mr. Devinder Rawat, Mr. Achyut Tewari, Ms. Elisha Sinha, Ms. Krisha Baweja, Mr. Aayush Maheshwari, Mr. N. Mahabir, Ms. Shreya Sethi and Mr. Sumer Seth, Advs.

versus

NATCO PHARMA LIMITED .....Respondent

Through: Mr. J. Sai Deepak, Sr. Adv. with Mr. Afzal B. Khan, Mr. Samik Mukherjee, Mr. Dominic Alvares, Ms. Amrita Majumdar, Mr. Avinash K. Sharma and Mr. Sharad Besoya, Advs.
Mr. Sethi Grover, Sr. Adv. with Mr. Varun Jain and Mr. Rohin Bhatt, Advs. for Intervener
Ms. Rajeshwari H., Ms. Purva Mittal and Mr. Tahir A. J., Advs. for Intervener

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR
HON'BLE MR. JUSTICE AJAY DIGPAUL

JUDGMENT

% 09.10.2025

C. HARI SHANKAR, J.

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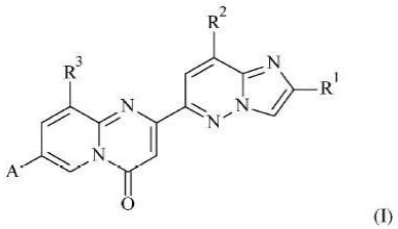
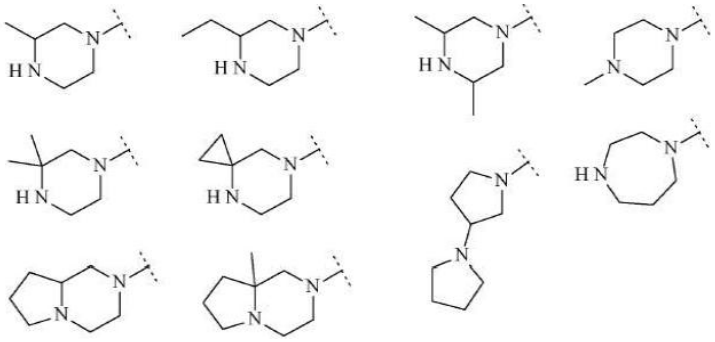
The *lis*

1. The judgment impugned in the present appeal has been passed by a learned Single Judge of this Court in IA 33088/2024 in CS (Comm) 567/2024, in which the present appellants were the plaintiffs and the present respondent was the defendant. By the impugned judgment, the learned Single Judge has dismissed IA 33088/2024, whereby the appellants sought an injunction against the respondent manufacturing and selling the drug Risdiplam, contending that such manufacture and sale infringed Indian Patent IN 334397[1], whereunder "compounds for treating spinal muscular atrophy" stand patented in favour of the appellants. Claim 1 in the suit patent is for the following Markush[2] structure:

> "1. A compound of formula (I)
>
> 
> (I)
>
> wherein
> R^1 is C_{1-7}-alkyl;
> R^2 is hydrogen or C_{1-7}-alkyl;
> R^3 is hydrogen or C_{1-7}-alkyl;
>
> A is selected from the group of:

[1] Hereinafter "IN'397" or "the suit patent"

[2] "Markush claims", or claims covering "Markush structures", which are common in patents for chemical entities, whether agricultural or pharmaceutical, are molecular structures which "cover a group of compounds, which disclose the possibility of individual permutations and combinations that can run into several million (if not more) structurally diverse compounds." [as defined in ***Astrazeneca AB v Intas Pharmaceuticals*, (2020) 84 PTC 326 (Del)**]

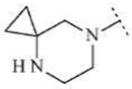


and pharmaceutically acceptable salts thereof."

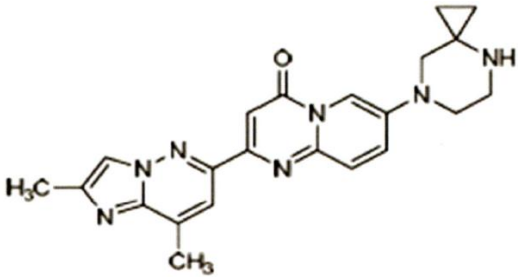
By substituting

(i) the methyl (-CH_3) radical for R^1 and R^2,

(ii) the hydrogen atom (-H) for R^3, and

(iii) the  moiety for A,

one arrived at



which is Risdiplam, and is exemplified as Compound 20 in the suit patent. Risdiplam, therefore, has a molecular formula $C_{22}H_{23}N_7O$, and the chemical name 7-(4,7-diazaspiro [2.5] octan-7-yl)-2-(2,8-dimethylimidazo [1,2-b] pyridazine-6-yl)-4H-pyrido [1,2-a] pyrimidin-4-one.

2. Risdiplam is admittedly manufactured and marketed by the appellants in various countries, including India, under the brand name "'EVRYSDI®". Risdiplam is an oral prescription medicine used for

the treatment of Spinal Muscular Atrophy[3].

3. Inasmuch as the challenge is to an order passed by the learned Single Judge on an application filed by the appellants under Order XXXIX Rules 1 and 2 of the Code of Civil Procedure 1908[4], our jurisdiction is circumscribed by the following exposition of the law in ***Wander Ltd v Antox India (P) Ltd***[5]:

> "14. The appeals before the Division Bench were against the exercise of discretion by the Single Judge. *In such appeals, the appellate court will not interfere with the exercise of discretion of the court of first instance and substitute its own discretion except where the discretion has been shown to have been exercised arbitrarily, or capriciously or perversely or where the court had ignored the settled principles of law regulating grant or refusal of interlocutory injunctions. An appeal against exercise of discretion is said to be an appeal on principle. Appellate court will not reassess the material and seek to reach a conclusion different from the one reached by the court below if the one reached by that court was reasonably possible on the material. The appellate court would normally not be justified in interfering with the exercise of discretion under appeal solely on the ground that if it had considered the matter at the trial stage it would have come to a contrary conclusion. If the discretion has been exercised by the trial court reasonably and in a judicial manner the fact that the appellate court would have taken a different view may not justify interference with the trial court's exercise of discretion.* After referring to these principles Gajendragadkar, J. in ***Printers (Mysore) Private Ltd. v Pothan Joseph***[6]:
>
> > "... These principles are well established, but as has been observed by Viscount Simon in ***Charles Osenton & Co. v Jhanaton***[7] '...the law as to the reversal by a court of appeal of an order made by a judge below in the exercise of his discretion is well established, and any difficulty that arises is due only to the application of well settled principles in an individual case'."

[3] "SMA" hereinafter
[4] "CPC" hereinafter
[5] **1990 Supp SCC 727**
[6] **AIR 1960 SC 1156**
[7] **1942 AC 130**

The ***Wander*** dictum has been recently reiterated, by the Supreme Court, in ***Pernod Ricard India (P) Ltd v Karanveer Singh Chhabra***[8].

4. We, therefore, while exercising appellate jurisdiction in the present appeal, would not revisit the decision of the learned Single Judge on facts. We are essentially concerned with whether the learned Single Judge has applied the principles of law correctly. If the learned Single Judge has applied the correct principles, then, even if we are of the opinion that an alternative conclusion could more preferably be arrived at, that would not make out a ground for interference.

The Statutory Conspectus

5. "Infringement", strangely, is not defined in the Patents Act.[9] Section 48(a)[10] of the Patents Act, however, confers, on the patentee of a granted product patent, the exclusive right to prevent third parties to, without the consent of the patentee, make, use, offer for sale, sell or import, for any of these purposes, the patented product in India. The Sections which succeed Section 48 makes it clear that any such act, if committed by such third party, amounts to "infringement".

6. Section 64(1) of the Patents Act delineates, in its various clauses, the circumstances in which a granted patent can be revoked. Section 107 makes available every ground on which a granted patent

[8] **2025 SCC OnLine SC 1701**

[9] This appears to be a legislative lacuna, which the legislature would do well to remedy.

[10] **48.** **Rights of patentees**.—Subject to the other provisions contained in this Act and the conditions specified in Section 47, a patent granted under this Act shall confer upon the patentee—

(*a*) where the subject-matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;

may be revoked under Section 64, as a ground of defence against a suit alleging infringement of the said patent.

7. Among the circumstances in which a patent can be revoked under Section 64(1) are those envisaged by clauses (e) and (f)[11].

8. Section 64(1)(e) makes the patent liable to be revoked if the patent is not new. Novelty of the patent has to be decided on the basis of whether the patented invention was publicly known or publicly used in India before the priority date of the claim in the patent, which claims the invention. Under Section 11(6), the priority date of a claim in a patent is ordinarily the date of filing of the complete specification of the said patent.

9. Section 64(1)(f) renders a patent liable to revocation if the claimed invention is obvious, or does not involve any inventive step over what was publicly known or publicly used in India, or published in India or elsewhere before the priority date of the claim. A claimed invention is "obvious" if, from the disclosure contained in any earlier patent or other document, commonly known as "prior art", along with common general knowledge on the priority date of the later patent, a

[11] **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,—
*****
(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,
(f) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;

person skilled in the art would be able to arrive at the claimed invention in the later patent. Though the Patents Act does not specifically define the expression "obvious", Section 2(1)(ja) defines "inventive step" as meaning "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance of both and that makes the invention not obvious to a person skilled in the art". If, therefore, the disclosures, along with the teaching contained in earlier prior art, whether in the form of a patent document or otherwise, along with common general knowledge existing on or before the priority date of a claim in a later patent, a person skilled in the art would be able to create the invention claimed in the later patent, that invention would be "obvious" and "lacking in inventive step", vis-à-vis the disclosure in the prior art and would, therefore, be liable to be revoked, if already patented.

10. This constitutes the statutory backdrop in which the dispute before us revolves.

Facts and the Controversy

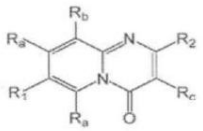
11. We may now turn to the facts.

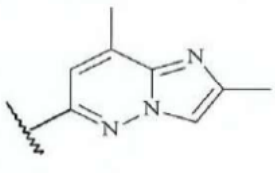
12. The factum of infringement is not in dispute. The suit patent is alive and subsisting as on date, and is scheduled to expire only on 11 May 2035. The respondent is admittedly manufacturing and selling Risdiplam. As such, infringement of the suit patent, within the meaning of Section 48(a) of the Patents Act, has clearly taken place.

13. The respondent, however, pleads the defence available under Section 107(1)[12] of the Patents Act, read with Section 64(1)(e) and (f) of the Patents Act.

14. The learned Single Judge, in a judgment crafted with clinical precision, has upheld the defence raised by the respondent, predicated on Section 64(1)(e) and (f) of the Patents Act.

15. WO'916 and US'955, we may note, were also patents for "Compounds for treating spinal muscular atrophy". The claim in para [00959] of WO'916 was the following Markush structure:

<table>
<tr><td colspan="2">[00959] An embodiment of the use of the compound of Formula (Ha) is the use of the compound of Formula (IIaI):
 
(IIa1)</td></tr>
<tr><td>R_1 is heterocyclyl, wherein, heterocyclyl is optionally substituted with one, two or three R_3 substituents and optionally, with one additional R_4 substituent or, wherein heterocyclyl is optionally, substituted with one, two or three or four R_3 substituents;</td><td></td></tr>
<tr><td>R_2 is heteroaryl wherein, heteroaryl is optionally substituted with one, two or three R_6 substituents and optionally, with one additional R_7 substituent;

<u>Reference: Page No: 37 and</u></td><td>  </td></tr>
</table>

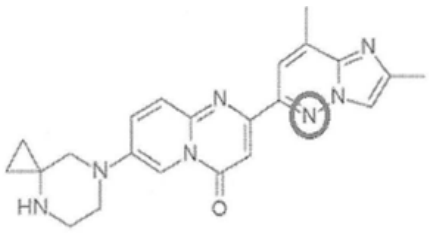
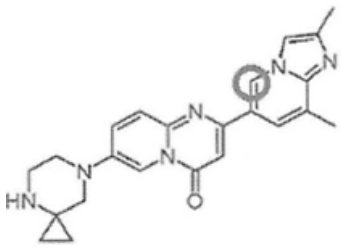
[12] **107. Defences, etc. in suits for infringement**.—
(1) In any suit for infringement of a patent, every ground on which it may be revoked under Section 64 shall be available as a ground for defence.

38, paragraph [00215] of WO '916 (D1). R_2 is heteroaryl selected from thienyl, IH- pyrazolyl, IH-imidazolyl, 1,3-thiazolyl, 1,2,4-oxadiazolyl, 1,3,4-oxadiazolyl, pyridinyl, pyrimidinyl, IH-indolyl, 2H- indolyl, IH-indazolyl, 2H-indazolyl, indolizinyl, benzofuranyl, benzothienyl, 1H-benzimidazolyl, 1,3-benzothiazolyl, 1,3-benzoxazolyl, 9H-purinyl, furo [3,2- b] pyridinyl, furo [3,2-c] pyridinyl, furo [2,3 - c] pyridinyl, thieno [3,2-c] pyridinyl, thieno [2,3-d] pyrimidinyl, 1H-pyrrolo [2,3-4] pyridinyl, 1H-pyrrolo [2,3-c] pyridinyl, pyrrolo [1,2- a] pyrimidinyl, pyrrolo [1,2-a] pyrazinyl, pyrrolo [1,2-b]pyridazinyl, pyrazolo [1,5-a]pyridinyl, pyrazolo [1,5-a]pyrazinyl, imidazo [1,2-a]pyridinyl, imidazo [1,2-a]pyrimidiny 1, imidazo [1,2-c]pyrimidinyl, imidazo [1,2-b]pyridazinyl, imidazo [1,2-a]pyrazinyl, imidazo [2, 1-b] [1,3]thiazolyl, imidazo [2,1-£][1,3,4]thiadiazolyl, [1,3] oxazolo [4,5-£]pyridinyl or quinoxalinyl; wherein, each instance of heteroaryl is optionally substituted with R_6 and R_7 substituents.	
R_6 is, in each instance, independently selected from halogen, hydroxy, cyano, nitro, C_{1-8}alkyl, C_{2-8}alkenyl, halo-C_{1-8}alkyl, hydroxy-C_{1-8}alkyl, C_{1-8}alkoxy, halo-C_{1-8}alkoxy, C_{1-8}alkoxy-C_{1-8}alkyl, amino, C_{1-8}alkyl-amino, $(C_{1-8}alkyl)_2$-amino or C_{1-8}alkyl-thio;	C_{1-8}alkyl

R_a is, in each instance, independently selected from hydrogen, halogen or C_{1-8}alkyl	Hydrogen
R_b is hydrogen	Hydrogen
R_c is hydrogen, halogen or C_{1-8}alkyl	Hydrogen

The learned Single Judge has, in the impugned judgment, accepted the respondent's contention that Risdiplam stood disclosed in the above Markush formulation.

16. Additionally, the learned Single Judge has found Claim 1 in the suit patent, which claimed Risdiplam, to be obvious vis-à-vis prior art in the form of Compound 809 of PCT[13] application WO 2013/119916[14], which corresponds to US Patent 9586955[15]. The molecular formulae of Risdiplam and Compound 809 in WO'916/US 955 have been set out, side by side, in para 63 of the impugned judgment, thus:

	
Risdiplam	Compound 809 in WO,916/US,955

As the learned Single Judge has correctly noted, the distinction

[13] Patent Cooperation Treaty
[14] "WO'916" hereinafter
[15] "US'955"hereinafter

between Compound 809 and Risdiplam is only at the circled junction in which, in Compound 809, there is a -CH radical, whereas in Risdiplam, there is a Nitrogen (-N) atom. Otherwise, the two formulae are identical.

17. Our view

17.1 We have our reservations with respect to the issue of whether Risdiplam is vulnerable to invalidity under Section 64(1)(e) of the Patents Act. However, we find no reason to interfere the findings of the learned Single Judge that Risdiplam is vulnerable to invalidity in terms of Section 64(1)(f) of the Patents Act, as being obvious vis-à-vis prior art in the form of the claimed Compound 809 in WO'916/US 955.

17.2 In view of our concurring with the learned Single Judge with respect to her finding in the matter of obviousness of the claim in the suit patent, vis-à-vis Compound 809 in WO'916/US'955, the impugned judgment would be entitled to be upheld on that ground, and the appeal would have to fail.

17.3 We may explain the position thus:

(i) The suit patent would be rendered vulnerable to invalidity under Section 64(1)(e) if the claim in the suit patent, i.e. Risdiplam, is not new, which would require disclosure, of Risdiplam, in prior art. The learned Single Judge has held that, as Risdiplam is one of the myriad compounds which is *covered*

by the broad Markush formulation in WO'916/US'955, it stands *disclosed* therein, and that, therefore, the suit patent, insofar as it claims Risdiplam, is vulnerable to invalidity under Section 64(1)(e). *Prima facie*, we are unable to agree, for reasons which would follow later in this judgment.

(ii) Section 64(1)(f) renders the suit patent vulnerable to invalidity if the claim therein, i.e. Risdiplam in the present case, is *obvious, to a person skilled in the art*, from the teachings in prior art. The learned Single Judge has held that the disclosures in WO'916/US'955, read along with the teachings therein, would enable a person skilled in the art to arrive at Risdiplam and that, therefore, Risdiplam is obvious from WO'916/US'955. The learned Single Judge has given cogent and well-considered reasons for this finding, with which we are unable to discern any cause to interfere.

(iii) As a credible challenge to the validity of the suit patent under *any* of the clauses of Section 64 would suffice to constitute a valid defence to infringement under Section 107, the impugned judgment of the learned Single Judge is entitled to be upheld even on the basis of our concurrence with the learned Single Judge on her findings apropos Section 64(1)(f). Ergo, the appeal would be liable to be dismissed.

18. We now proceed to deal with the specific findings of the learned Single Judge. We are eschewing the exercise of recounting the rival submissions of learned Counsel for the sake of brevity, but

would address some of the submissions of Mr. Sethi, who appears for the appellant, at the appropriate points in the judgment.

Analysis

19. Re. Section 64(1)(e), the findings of the learned Single Judge, and our view thereon

19.1 For the sake of completion, we propose, briefly, to set out our observations with respect to the finding of the learned Single Judge that Risdiplam, as claimed in the suit patent, is vulnerable to invalidity even under Section 64(1)(e).

19.2 Section 64(1)(e) applies where the claim in the suit patent is not new and has been claimed in prior art. The contention of the respondent, which was upheld by the learned Single Judge, was that though WO'916/US'955 were genus patents which set out Markush formulations, Risdiplam was one of the compounds covered by the Markush formulation disclosed in the genus patent.

19.3 We may note that there is no dispute about the aspect of *coverage* of Risdiplam within the Markush formulation claimed in the genus patent WO'916/US'955. The contention of the appellants was that mere coverage does not amount to disclosure and that a plea of lack of novelty, which is required to be established to sustain a plea of invalidity based on Section 64(1)(e), would require *disclosure*, in the complete specifications of the genus patent, of the claim in the species patent.

19.4 The appellants contended that mere coverage within the Markush formulation claimed in the genus patent WO'916/US'955 would not *ipso facto* amount to disclosure. Several thousands, in fact lakhs, of compounds may fall within the coverage of Markush formulation in the genus patent, and unless there exists sufficient teaching in the complete specification of the genus patent, which would enable a person skilled in the art to make the transition from the genus patent to the claim in the species patent, it cannot be said that the claim in the species patent stands disclosed in, or even that it is obvious from, the genus patent.

19.5 The learned Single Judge has rejected this submission. In doing so, she has relied on para 119 of the judgment of the Supreme Court in ***Novartis AG v Union of India***[16]. The learned Single Judge has also placed reliance on

(i) the Manual of Office Practice and Procedure which applies to the office of Controller General of Patents, Design and Trade Marks[17],

(ii) a suit instituted by the appellants against the respondent in the US,

(iii) a judgment of the Division Bench of this Court in ***Astrazeneca AB v Intas Pharmaceutical Ltd***,

(iv) the fact that four of the lead inventors of the genus and species patents are similar,

(v) the statement made by the appellants for obtaining Patent

[16] **(2013) 6 SCC 1**
[17] "CGPDTM" hereinafter

Term Extensions in the US,

(vi) entries in the US Orange Book,

(vii) a communication from the US Patent & Trade Marks Office[18] to the US Food and Drug Administration[19] dated 9 February 2023,

(viii) a statement made before the Australian Patent Office and

(ix) a representation made by the appellants in the Canada.

19.6 We proceed briefly to deal with each of these aspects, on which the learned Single Judge has relied, to arrive at the finding that Risdiplam, as claimed in the suit patent, stands disclosed in the genus patent WO'916/US'955 and is, therefore, not new.

19.7 Re. aspect of coverage of Risdiplam in the Markush structure claimed in the genus patents WO'916/US'955

19.7.1 On the aspect of whether mere coverage of the claim in the species patent, within the Markush formulation in the genus patent, would amount to disclosure, there are diverse views of this Court. The manner in which the judgment of the Supreme Court in ***Novartis AG*** has been interpreted by different benches of this Court, too, do not exhibit uniformity of thought. One of us (C. Hari Shankar J.), sitting singly, has, in ***FMC Corporation v Best Crop Science LLP***[20], adopted the view that mere coverage of the compound claimed in the species patent within the broad Markush claim in the genus patent would not *ipso facto* amount to disclosure, in the complete specification of the

[18] "USPTO" hereinafter
[19] "USFDA" hereinafter
[20] **2021 (87) PTC 217**

genus patent, of the claim in the species patent, unless the genus patent contains the requisite teaching as would guide a person skilled in the art, and possessed of common general knowledge, to arrive at a claim in the species patent. If such teaching was available in the complete specification of the genus patent, it would, apart from making the claim in the species patent obvious from the claim in the genus patent, additionally render the claim in the species patent vulnerable to invalidity in terms of Section 64(1)(e) of the Patents Act.

19.7.2 The decision in ***Astrazeneca***

19.7.2.1 The judgment of Division Bench of this Court in ***Astrazeneca***, on which the respondent relies, adopted a facially different approach. The appellant Aztra Zeneca AB[21], Sweden, was the holder of Indian patents IN 205147[22] and IN 235625[23]. IN'625 claimed a Markush structure, with suggested permutations and combinations which would cover millions of generally diverse compounds, whereas IN'147 specifically claimed Dapagliflozin[24]. Dapa was, indisputably, one of the millions of diverse compounds which were "covered" by the Markush formulation claimed in IN'625. Astrazeneca filed a number of suits alleging that various third parties were manufacturing and selling Dapa without a license from Astrazeneca and had, therefore, infringed *both the genus IN'625 and the species IN'147 patents* – unlike the present case, in which the appellant alleged infringement, by the respondent, only of IN'397.

[21] "Astrazeneca" hereinafter
[22] "IN'147" hereinafter
[23] "IN'625" hereinafter
[24] "Dapa" hereinafter

19.7.2.2 ***Astrazeneca***, therefore, was a case in which the plaintiff had, in one suit, pleaded infringement, by the defendant, both of the genus patent and the species patent. The Division Bench of this Court held that one compound could be protected only by one patent and that, by alleging infringement, by the defendant, of the genus patent, as well as the species patent, the plaintiff had effectively admitted that Dapa was disclosed both in the genus patent and the species patent. A reading of the decision in ***Astrazeneca*** makes it clear that the decision of the Division Bench is primarily influenced by the fact that the plaintiff before it had sued for infringement both of the genus and the species patents. This single act, according to the Division Bench, disentitled the plaintiff from contending that Dapa was not disclosed in the genus patent.

19.7.2.3 Significantly, however, in the concluding paragraphs of ***Astrazeneca***, the Division Bench notes the reliance, by the plaintiff before it, to the judgment in ***FMC Corporation***. The Division Bench held that it had considered the said decision "in which infringement of one patent was only claimed".

19.7.2.4 The decision in ***Astrazeneca*** was carried to the Supreme Court by way of SLP (C) 15650-15658/2021[25], which was dismissed by the Supreme Court by the following order passed on 19 July 2022:

"O R D E R

IA No. 7628/2022 - The application for intervention is dismissed.

[25] **Astrazeneca Ab v Intas Pharmaceuticals Limited**

> The present Special Leave Petitions are directed against an interim order refusing to grant ad-interim injunction to the petitioners. We are not inclined to interfere with such interim order in the present special leave petition.
>
> The trial will proceed uninfluenced by the findings recorded by the High Court.
>
> We hope that the civil suit(s) filed by the present petitioners shall be decided expeditiously in accordance with law.
>
> The costs imposed by the High Court shall abide the final Judgment and decree to be passed in the suits.
>
> In view of above, the Special Leave Petitions are disposed of.
>
> Pending interlocutory application(s), if any, is/are disposed of."

19.7.2.5 In no manner of law can it be said that, by the afore-extracted order, the Supreme Court has affirmed the position of law enunciated by the Division Bench of this Court in ***Astrazeneca.*** Clearly, the Supreme Court has declined to interfere only because the order under challenge before it was an interim order. In ***Kunhayammed v State of Kerala***[26], the Supreme Court has categorically held that the dismissal of SLP in *limine*, without reasons, does not result in merger of the order under challenge with the decision of the Supreme Court or amount to an affirmation, on merits, of the decision under challenge before the Supreme Court. Still less would any such presumption of affirmation arise where the dismissal of the SLP is solely on the ground that the order under challenge was an interim order.

19.7.2.6 We are of the respectful and considered view that, in

[26] **(2000) 6 SCC 359**

passing the order dated 19 July 2022, the Supreme Court cannot be said to have lent its imprimatur to the correctness of the decision in ***Astrazeneca***.

19.7.2.7 As we have noted, ***Astrazeneca*** primarily proceeds on the premise that, if the product of the defendant is alleged to infringe a genus as well as species patent it would amount to an admission of disclosure, in the genus patent, of the claim in the species patent.

19.7.2.8 With greatest respect to the learned Judges constituting the Division Bench which rendered ***Astrazeneca***, we have our doubts as to whether this principle is correct in law. To our mind, infringement is predicted on coverage, whereas invalidity is predicated on disclosure. This distinction, to our mind, the decision in ***Astrazeneca*** overlooks.

19.7.3 Any manufacture or sale, by a defendant, of a compound, which falls within the broad coverage of the Markush formulation in the genus patent would by itself entitle the holder of the genus patent to sue for infringement. Thus, if the compound falls within the broad coverage of the Markush formulation in the genus patent, and is specifically claimed in a species patent, a valid claim for infringement may, to our mind, lie against a defendant who markets and sells the said product without a license from the holder of the genus and species patents, of both the genus and the species patent.

19.7.4 Section 64(1)(e) is, however, predicated on *prior claiming*. This would, in its turn, entail *prior disclosure*. It is only if the claim in

the species patent is *disclosed* in the genus patent, that Section 64(1)(e) would apply.

19.7.5 Disclosure, it is settled, has to be enabling in nature. It must be such as would enable a person skilled in the art to synthesize the product claimed in the species patent. In other words, it is only if the product claimed in the species patent is specifically *so* disclosed or exemplified in the genus patent, that it can be said that the claim in the species patent is disclosed in the genus patent.

19.7.6 The decision rendered in ***FMC Corporation*** sets out in detail why, the decision in ***Novartis***, of the Supreme Court, cannot be so read as to equate coverage with disclosure. We merely make a passing reference thereto, as, for the purposes of deciding the present appeal, it is not necessary for us to enter into this thicket. We, nonetheless, deem it appropriate to observe that the issue of whether coverage of a product in a broad Markush formulation in a genus patent would *ipso facto* amount to disclosure of the product in the genus patent may require further consideration.

19.7.7 The learned Single Judge has noted the fact that, in the suit instituted by the appellants in the US, it had alleged that Risdiplam infringed both the genus patent US'955 as well as the species patent US 9969754[27]. If the law laid down in ***Astrazeneca*** is to be treated as correct, this would undoubtedly justify the finding of the learned Single Judge that a credible challenge to the vulnerability of the claim in the species patent to invalidity under Section 64(1)(e) may be made

[27] "US'754" hereinafter

out.

19.7.8 However, if it is to be held, as we feel, that infringement requires only coverage whereas invalidity requires disclosure, and coverage by itself does not necessarily imply disclosure, then the filing of the suit in the US by the appellants would not by itself render the claim in the species patent vulnerable to invalidity on the ground of disclosure in genus patent WO'916/US'955.

19.7.9 The decision in ***Astrazeneca*** bound the learned Single Judge. Given the fact that, in the US, the appellant had sued the respondent, alleging Risdiplam to be infringing both the genus US'955 and species patent US'754, the learned Single Judge cannot be faulted in having relied on this fact to hold, *prima facie* that Risdiplam was disclosed in both the genus and species patents.

19.8 Re. disclosures in US PTE Application

19.8.1 Insofar as the disclosures by the appellants in the PTE application filed in the US, and the recitals in the US Orange Book are concerned, they, too, cannot, to our mind, make out a *prima facie* case of vulnerability of the suit patent to invalidity under Section 64(1)(e).

19.8.2 As the learned Single Judge has held, in para 46 of the impugned judgment, the appellant, in the PTE application filed in the US, contended that Risdiplam was *covered* and *claimed* in the genus patent. As we have already held, mere coverage and claiming would not *ipso facto* result in disclosure, which is the *sine qua non* for

Section 64(1)(e) to apply.

19.9 Re. the US Orange Book

Insofar as the US Orange Book is concerned, it contained a specific disclaimer, which reads thus:

> "Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner."

The learned Single Judge, to our mind, did not notice the aforesaid disclaimer entered in the Orange Book itself, which would considerably dilute its reliability as an indicator of vulnerability of the suit patent to invalidity under Section 64(1)(e).

19.10 Re. communication dated 9 February 2023 from USPTO to the FDA

The communication dated 9 February 2023 from the US PTO to the FDA also merely stated that Risdiplam was *covered* by US'955. The appellant does not dispute the coverage of Risdiplam within the broad Markush claim in US'955. That may not, however, amount to justify a *prima facie* finding of invalidity on the ground of prior claiming.

19.11 Statement before the Australian Patent Office

Similarly, before the Australian Patent Office, the appellants' statement was that Risdiplam was, "in substance generally disclosed

in Australian Patent'870". Mr. Sethi, learned Counsel for the appellants submits that the reference to "in substance general disclosure" was because of the applicable laws in Australia. In any event, such a statement cannot amount to an admission of specific disclosure of Risdiplam in the genus patent.

19.12 The sequitur

19.12.1 For all these reasons, we are not, *prima facie*, inclined to hold that a credible challenge to the vulnerability of the Risdiplam, as claimed in the suit patent, stands made out on the basis of the claims/disclosures contained in the genus patent documents WO'916/US'955, as is required by Section 64(1)(e) of the Patents Act.

19.12.2 That said, we also agree with Mr. Sai Deepak, learned Senior Counsel for the respondent, that the reasoning of the learned Single Judge is *prima facie* in sync with the declaration of the law by the Division Bench in ***Astrazeneca***, essentially because the appellant, in the US, alleged infringement, by the manufacture and sale of Risdiplam by third parties, of both the US genus US'955 and species US'754 patents. To that extent, the learned Single Judge is correct.

19.12.3 Whether ***Astrazeneca*** is, or is not, correctly decided, we feel, may have to be examined in another, more appropriate, case. We do not deem it necessary to dwell further on this aspect, as the impugned judgment of the learned Single Judge, we feel, is liable to be upheld even on the basis of the findings, therein, with respect to

Section 64(1)(f) of the Patents Act which, to our mind, are unexceptionable.

20. Re. obviousness of claim in suit patent vis-à-vis US'955/WO'916 and resultant vulnerability to invalidation under Section 64(1)(f)

20.1 On the aspect of obviousness and vulnerability of the claim in the suit patent to invalidity under Section 64(1)(f) of the Patents Act, however, we do not find any reason to interfere with the decision of the learned Single Judge, within the limited parameters of ***Wander***.

20.2 Obviousness has to be decided by examining whether a person skilled in the art would, from the teachings contained in the genus patent and common general knowledge, be able to arrive at the claim in the species patent. If he would be able to do so, the claim in the species patent would be obvious from the disclosures and teachings in the genus patent.

20.3 The "person in the know" test

20.3.1 In ***Astrazeneca,*** the Division Bench of this Court devised a new test, where the inventors of the genus patent and species patent were the same. The Division Bench held that the aspect of obviousness would, in such a case, have to be assessed from the perspective of the inventor, who would be a person conscious of the specifics of the invention and would, therefore, be a "person in the know". The mythical "person skilled in the art" from whose perspective, a plea of obviousness has normally to be examined would, therefore, according

to the Division Bench in ***Astrazeneca,*** have to cede place to a "person in the know", where the inventors of the genus and species patent are the same or are common.

20.3.2 While, at first glance, such a proposition may appear to be a bold extrapolation of the law, there is sturdy logic behind it. The aspect of obviousness has to be examined from the point of view of whether, from the disclosures and teachings in the prior art genus patent, it would be possible to arrive at the claim in the species patent. While, normally, this assessment is to be made from the point of view of a person skilled in the art, where the inventors of the genus and species patent are the same, the paradigm shifts. The inventor of the genus patent would obviously be conversant with its specifics and would also be in a position to more easily appreciate the manner in which the Markush formulations in the genus patent, or the compounds exemplified in the genus patent, would have to be modified in order to arrive at formulation or product which achieves the objectives that the species patent aspires to achieve. Something which is "obvious" to a person skilled in the art would, therefore, be "more obvious" to the inventor of the genus patent, who would be "in the know" of things, and of all the angularities and peculiarities of the genus patent.

20.3.3 The aspect of obviousness, therefore, becomes easier to establish where the inventors of the genus and species patent are the same. This aspect may be easily understood when one compares Risdiplam with Compound 809 in the genus patent WO'916. As the two formulae, as reproduced in para 16 *supra* clearly disclose, the

difference between the two is merely of a Nitrogen (-N) atom in the case of Risdiplam and a -CH radical at the same junction in Compound 809.

20.3.4 Where the species patent, which claims Risdiplam, is invented by the same inventors, who were the creators of the genus patent, there is obviously more motivation to select the –N substitute at the place, where, in Compound 809 in WO'916, –CH is present. Expressed otherwise, if the inventors of the Compound 809 in the genus patent wanted to arrive at a product having the properties of Risdiplam, they would, as the inventors of Compound 809 itself, be in a position to select the correct substituent, i.e. -N, in place of -CH, as would enable the transition from Compound 809 to Risdiplam. They would also be in a position to identify Compound 809 as the appropriate starting point, from which to proceed towards the Risdiplam destination. The "obviousness" of Risdiplam, *vis-à-vis* Compound 809 in the genus patent would, therefore, be enhanced, when seen from the perspective of the inventors of Compound 809.

20.3.5 The learned Single Judge has appreciated this aspect of the matter and we are in entire agreement with her.

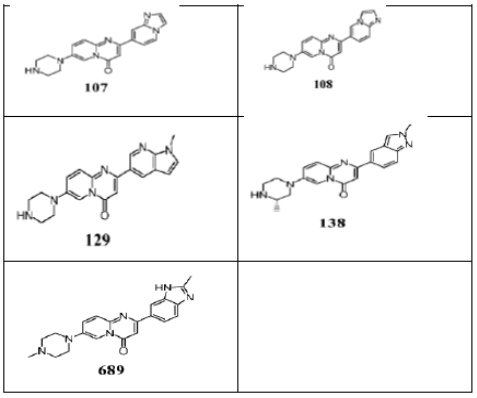
20.4 Findings of obviousness in the impugned judgment based on the teachings in the genus patent

20.4.1 The learned Single Judge has also proceeded to hold that the teachings in the genus patent WO'916/US'955 were sufficient to enable a person skilled in the art to arrive at the claim in the species patent. She has explained this in the following manner:

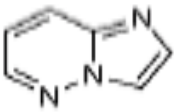
"64. As highlighted during the course of arguments, the primary distinction between the *Compound 809* in the International Genus Patent and Risdiplam in the Suit Patent, is the presence of Nitrogen (N) in Risdiplam, whereas, the compound of the International Genus Patent features a Carbon-Hydrogen ("CH") group at the even position.

65. It is noted that in the International Genus Patent, 835 compounds have been disclosed, of which, Pyrimidine is a constituent in almost all the compounds, including, *Compound 809*. Further, it is seen that Pyridine is also a constituent in most of the compounds. As per the scientific definition, Pyridine has just one Nitrogen atom, whereas, Pyrimidine, has two Nitrogen atoms. As such, it is clear that the common component in most of the compounds, as disclosed in the International Genus Patent, is with respect to the Nitrogen atom, which could be either Pyridine or Pyrimidine.

66. At this stage, it would be fruitful to refer to the reply of the defendant to the interim injunction application, i.e., *IA 33088/2024*, wherein, it has been stated in categorical terms that the International Genus Patent discloses different chemical structures with Nitrogen placed at different positions. Relevant portion of the reply, is extracted as follows:

> "52. WO '916 further provides that various fused-ring heterocycles with nitrogen placed at different positions in the same ring could be used. The compounds are reproduced below:
>
> 
>
>
> 53. Therefore, it is submitted that using the same kind of ring varying the number of nitrogen atom and position is obvious for a person skilled in the art.
>
> 54. Further, Imidazo[1,2-b]pyridazinyl is one of the

substituents for R2 specifically disclosed in WO '916 (Page No: 37 and 38, paragraph [00215] of D1).



"

67. Therefore, on account of myriads of occurrences of the 'Nitrogen' atom in the various compounds, it is *prima facie* established that it would have been obvious to a person skilled in the Art/person in the know that Nitrogen is a dominant component of most of the compounds as disclosed in the International Genus Patent. Therefore, such person skilled in the Art/ person in the know would have easily been motivated to use the Nitrogen atom instead of the Carbon atom, while looking at *Compound 809* in the International Genus Patent. The defendant has *prima facie* established that the compounds claimed in the Suit Patent represent routine optimization of compounds disclosed in the prior art. Further, this Court notes the submission of the defendant that, it is common practice in the field of pharmaceuticals to make iterative modifications to chemical structures in order to improve properties such as potency, selectivity or metabolic stability.

68. There is another aspect that needs to be considered. As noted above, the difference between the two compounds, i.e., Risdiplam and *Compound 809* of WO'916, is the replacement of the CH group by Nitrogen (N). It is to be noted that in Chemistry, the table under the '*Grimm's Hyride Displacement Law'*, clearly places Nitrogen (N) and CH in the same group. According to Grimm, each vertical column of the table represents a group of isosteres. Isosterism has been defined as compounds or groups of atoms having the same number of electrons. Bioisosteres have been defined as atoms or molecules that fit the broadest definition for isosteres and have the same type of biological activity. The Table 2 of '*Grimm's Hyride Displacement Law*', representing a group of isosteres, is reproduced as under:

Table 2. Grimm's Hydride Displacement Law

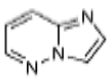
C	N CH	O NH CH_2	F OH NH_2 CH_3	Ne FH OH_2 NH_3 CH_4	Na – FH_2^+ OH_3^+ NH_4^+

69. Thus, it is evident that Nitrogen (N) and CH groups are often considered Bioisosteres. Therefore, substitution of a CH group with a Nitrogen (N) atom which are Bioisosteres, would be

> obvious to a person skilled in the Art of medicinal chemistry, or to *'a person in the know'*, in the facts and circumstances of the present case. Given the aforesaid fact, it would be obvious for a person skilled in the art of medicinal chemistry/person in the know, to consider/explore replacing or substituting the CH group with a Nitrogen atom, in order to explore its effects on the compound's biological activity and furthermore, on account of the considerable occurrences of Nitrogen atom in the compounds exemplified from the International Genus Patent.
>
> 70. Moreover, it is to be noted that the comparative data showing the values of compounds, reflected as Effective Concentration of a drug for measuring the dosage of a drug for achieving the desired biological response, i.e., $EC_{1.5x}$, shown by the plaintiffs for proving technical advancement or therapeutic efficacy, has been heavily contested by the defendant. Hence, the analysis of this data requires further examination and expert testimony, which can only be addressed during the trial.
>
> 71. Therefore, this Court is of the *prima facie* view that the Suit Patent is vulnerable on the grounds of obviousness on account of compounds, as disclosed in the Genus Patents."

20.4.2 In arriving at her findings, therefore, the learned Single Judge has kept two factors in mind, apart from the fact that four of the lead inventors of the genus patent WO'916/US'955 and of the species patent were common.

20.4.3 The first factor that the learned Single Judge has taken into consideration is the fact that, in several of the chemical structures exemplified in the genus patent, Nitrogen figured at different positions. The substitution of -N in place of -CH would, therefore, be obvious to a person skilled in the art. The learned Single Judge has also noted, in this context, the fact that Imidazo[1,2-b]pyridazinyl

() is one of the substituents specifically disclosed in WO '916 for the radical R2.

20.4.4 Thus, there was a clear pointer, even in the disclosures in WO'916, as would enable a person skilled in the art, and even more easily enabled the inventors of WO'916 themselves, to make the necessary substitution of -CH with -N, in the exemplified Compound 809, as would enable them to arrive at Risdiplam.

20.4.5 The second factor which the learned Single Judge has taken into consideration is based on the table in Grimm's Hyride Displacement Law. The learned Single Judge has noted that, in the same vertical column in the table in Grimm's Hyride Displacement Law, N and CH figured. N and CH are, therefore, bioisosteres, which represent atoms having the same number of electrons and the same biological activities. Inasmuch as they are reflected as bioisosteres, figuring in the same vertical column in the table in Grimm's Hyride Displacement Law, the learned Single Judge has arrived at a *prima facie* finding that a person in the know, who is aware of the intricacies of medicinal chemistry, would be readily motivated to substitute – CH with -N, which would result in the synthesis of Risdiplam, from Compound 809 in the genus patent.

20.5 Re. non-exemplification of Risdiplam in the genus patent

Mr. Sethi contends that Risdiplam is not among the 835 exemplified compounds in the genus patent and could, not, therefore, be regarded as "obvious" from the teachings in the genus patent. We are unable to agree. For making out a *prima facie* case of obviousness, all that is to be seen is whether, from the disclosures which exist in the prior art, in

the form of exemplified compounds or the teachings contained therein, a person skilled in the art would be able to reach the claim in the suit patent. Specific exemplification of the claim in the suit patent, in the complete specifications of the prior art document, is by no means necessary.

20.6 Re. plea of "non obviousness" of Compound 809 to the person skilled in the art

20.6.1 This also answers a submission, advanced by Mr. Sethi, that there is no rationale for selecting Compound 809 out of the 835 exemplified compounds in the genus patent. It is here that the importance of the inventors in the genus and species patent being the same, becomes significant. The whole *raison d' etre*, behind providing for obviousness from prior art as a defence against infringement, is to prevent the inventor from evergreening the invention, by making obvious modifications, inventing what is facially a "new" invention, and obtaining a fresh patent lease of life for 20 years. Where the inventor of both patents is the same, that fact has necessarily to inform the Court, or other authority, seized with the task of determining whether the later patent is obvious from the earlier. A person who patents one invention is entitled to exclusivity, over the patented invention, only for a period of 20 years. Thereafter, the patented invention falls into the public domain, and is available for the public to exploit. In the case of drugs and pharmaceutical products, this principle acquires a superadded and predominant element of public interest. If patents relating to essential and life saving drugs are permitted to be evergreened, the drug may forever remain outside the public domain and available only for the original inventor to exploit,

which could result in calamitous and incalculable public harm. *By no means can an inventor be permitted, by making changes to an invented pharmaceutical preparation, which is essential or life-saving in nature, to keep the invention out of the public domain beyond the period of life of the patent, by making modifications which, perceptibly, would be obvious to the inventor – as the "person in the know" – and, by claiming the modified invention to be "new", seek a fresh lease of patent life. Needless to say, however, if the later invention is, to the perception of the Court or authority, not "obvious" from the earlier patented invention, even to the inventors themselves, and actually manifests a non-obvious inventive step, the Court or authority has to sedulously safeguard the right of the inventor, who has expended his intellectual faculties and possibly considerable expense in conceptualizing and creating the invention, to exclusive rights to exploit the patent during its life, and to be protected against its infringement. The balance is delicate, and it is for the Court, or authority seized with the task, to match up to the task.*

20.6.2 Thus, where four of the inventors of the genus WO'916/US'955 were also inventors of the suit species patent, there is legitimate basis to presume, at least *prima facie*, that they would be possessed of the requisite degree of knowledge to select Compound 809, from the exemplified compounds in the genus patent, as the compound to be worked upon, or modified, to arrive at Risdiplam. The choice of Compound 809 from the exemplified compounds in the genus patent, which may not be obvious to another person, even if he is "skilled in the art", would conceivably be obvious to the inventors of the genus patent.

20.6.3 The submission that it was Compound 774, from the exemplified compounds in the genus patent, which was selected for clinical trials is not, therefore, of significance.

20.7 Applying ***Wander***

20.7.1 We reiterate, here, that we are examining the merits of this appeal within the boundaries of the law enunciated in ***Wander***. We are not, in that process, to re-examine, as though we were the Court hearing the suit, the entire aspect of obviousness and all the myriad submissions raised in that regard *ad nauseam*. We have to satisfy ourselves that the learned Single Judge has applied the correct principles. Many of the submissions of Mr. Sethi, such as the "non-obviousness" of the choice of making a substitution within the ring atom, or substituting at the 5th and not the 7th position, are pleas which essentially lie within the domain of the Commercial Court exercising original jurisdiction over the Order XXXIX application of the plaintiff. We cannot reverse the decision of the learned Single Judge, which has clearly been passed in entirely wholesome exercise of the discretion which vested in her, by re-examining all these issues.

20.7.2 The defendant, in a patent infringement suit, who pleads a Section 107 defence, has only to set up a *credible challenge* to the validity of the suit patent[28], and to expose it as vulnerable to invalidity for one or more of the reasons envisaged in Section 64. He is not

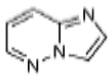
[28] Refer **F. Hoffmann La Roche Ltd v Cipla Ltd, 2009 (110) DRJ 452 (Del-DB), Intex Technologies (India) Ltd v Telefonaktiebolaget L.M. Ericsson, 2023 SCC OnLine Del 1845, Mold Tek Packaging Ltd v Pronton Plast Pack Pvt Ltd, 2025 SCC OnLine Del 4883**

required to make out a cast iron case. So long as the learned Single Judge has found that such a credible challenge has been made out by the defendant, unless the challenge is *not credible*, or the learned Single Judge has applied incorrect principles or ignored the applicable principles, we would be loath to interfere. ***Wander*** tells us, in no uncertain terms, to step back in such a case.

20.7.3 Within the parameters of our jurisdiction as circumscribed by ***Wander***, we do not feel that a case has been successfully made out by the appellants, as would justify our interference with the *prima facie* findings of the learned Single Judge on the aspect of obviousness of Risdiplam, as claimed in the suit species patent, *vis-à-vis* the disclosures and teachings contained in the genus patent WO'916/US'955. The four aspects on which the learned Single Judge has held the Risdiplam, as claimed in the species patent, to be obvious from the teachings in the genus patents, viz.

(i) the fact that four of the lead inventors of both the patents are common,

(ii) the fact that the genus patent WO'916 provided for use of various fused-ring heterocycles with Nitrogen placed at different positions in the same ring,

(iii) one of the specifically disclosed substitutions, in this regard, was the Imidazo [1,2-b] pyridazinyl (), and

(iv) N and CH figured in the same vertical column in Grimm's Hyride Displacement Law,

to our mind, have been correctly held by the learned Single Judge to

make out a *prima facie* case of obviousness of Risdiplam as claimed in the suit species patent, *vis-à-vis* the disclosures and teachings contained in the genus patent WO'916/US'955.

20.7.4 At any rate, no case for interference with the said decision, within the parameters of ***Wander***, can be said to have been made out.

21. Once we have found the judgment of the learned Single Judge, that the respondent had succeeded in set up a credible challenge to the validity of the suit patent, within the meaning of Section 107 read with Section 64 of the Patents Act, worthy of acceptance, we are not required to enter into other aspect of the matter.

Conclusion

22. We, therefore, do not deem this to be a fit case for interference with the impugned judgment of the learned Single Judge.

23. The appeal is, accordingly, dismissed.

C. HARI SHANKAR, J.

AJAY DIGPAUL, J.

OCTOBER 9, 2025*/dsn/*ar