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

Reserved on: 19 January 2026
Pronounced on: 9 March 2026

\+ FAO(OS) (COMM) 204/2025 & CM APPL. 78607/2025

NOVO NORDISK A/S .....Appellant

Through: Mr. Hemant Singh, Ms. Mamta Jha, Mr. Rishabh Paliwal, Mr. Shreyansh Gupta, Mr. Sanchit Sharma, Advs.

versus

DR REDDYS LABORATORIES LIMITED & ANR.
.....Respondents

Through: Mr. Gopal Subramanium, and Mr. J. Sai Deepak, Sr. Advs. with Mr. Mohit Goel, Mr. Sidhant Goel, Mr. Aditya Goel, Mr. Deepankar Mishra, Mr. Kartikeya Tandon, Mr. Pavan Bhushan, Mr. Avinash Sharma, Mr. Raghav Kohli, Mr. Adnan Yousuf and Mr. Ankit Malhotra, Advs.

CORAM:
HON'BLE MR. JUSTICE C. HARI SHANKAR
HON'BLE MR. JUSTICE OM PRAKASH SHUKLA

JUDGMENT

% 09.03.2026

C. HARI SHANKAR, J.

A. Some prefatory thoughts

1. This case makes us ponder, and we have said so in open Court.

2. The dispute relates to a patent held by the appellant for Semaglutide, which is an anti-diabetic. The appellant claims that, in December 2024, it came to learn that the respondents were importing Semaglutide. On the ground that said import infringed the appellant's patent, the suit, from which this appeal emanates, came to be instituted only in 2025. The suit was accompanied, as such suits always are, with an application seeking an interlocutory injunction restraining the respondents from manufacturing or selling Semaglutide in the Indian market. That application was rejected by the learned Single Judge on 2 December 2025, by a detailed and well-reasoned judgment. The appellant is in appeal.

3. Thus far, we have no issue. What perturbs us is the fact that this appeal has been preferred when the suit patent itself is to expire on 20 March 2026. On the date when this appeal was argued before us, and judgment was reserved, a little over two months remained, for the suit patent to expire. It is not the appellant's case that the respondent is manufacturing sub-standard drugs. In any event, after 20 March 2026, the appellant would no longer be able to enforce the suit patent, and it would be open to exploitation by the world at large.

4. What irreparable loss, we ask ourselves, is the appellant suffering, as a result of the impugned judgment? Why, for that matter, should we even spend valuable time of the Court when a mere two months were left for the suit patent to expire? When Courts are inundated with cases, of far greater urgency, which it has no time to decide, should we at all entertain such an appeal? Is the appeal not

liable to be dismissed even on the principles of balance of convenience and irreparable loss, *de hors* the merits of the case?

5. At the highest, even if the appellant were to succeed, it would have, to its credit, only a *prima facie* view in its favour. The opinions we express would have no impact on the adjudication of the *lis* in the suit. Why, then, should we express them at all?

6. This case, at least, relates to drugs. We have, before us, appeals involving patent claims relating to far more pedestrian products, in which interlocutory orders, under Order XXXIX of the CPC[1], are challenged. It is clear, to us, that the case does not involve any issue of urgency, much less pressing urgency. And yet, such appeals are argued for hours at a stretch, holding up, in the process, matters, perhaps relating to the poor and needy, who may be waiting for years without a job or means to fend for themselves and their families, waiting for justice.

7. We wonder - if such persons could access the Court proceedings – as, now, everyone can – and were to notice how Courts hear matters, which are of no serious moment to either party or to the public at large, for hours at a stretch, while they keep waiting, what would they think? We can claim to be abiding by our oath of office only when we can ensure that justice percolates down to the little man and his small family, huddled beneath a torn blanket under the ramshackle railway bridge, in the chilly winter night.

[1] Code of Civil Procedure, 1908

8. We are not, by these observations, seeking to run down commercial or, for that matter, intellectual property litigation. We agree that there may be cases which are of considerable moment. Infringement of a patent relating, for example, of a part which has to go into an aircraft, may be an extremely serious matter, as a duplicate part could endanger the lives of thousands. Equally, for example, trade mark infringement cases involving persons who sell duplicate drugs, imitating the registered trade marks of others, may require expeditious adjudication. For that matter, every person is entitled, in law, to assert his intellectual property rights. Even so, at some stage, however, sifting of the matters is, to our mind, essential.

9. We also understand the importance of ensuring the protection of patent rights, especially in the case of pharmaceutical preparations, and the disincentivisation to invent which may result, if such rights are not safeguarded. A pre-eminent element of public interest also exists in ensuring that scientists must be encouraged to invent.

10. We reiterate that our concern is only with a case such as this, in which only two months were left for the suit patent to expire even when we reserved judgment. No one, therefore, would stand to benefit, even if we were to injunct the respondents for two months. Would the interests of justice, in such a case, be not sufficiently safeguarded by directing the respondents to maintain accounts of the returns from sale of the allegedly infringing drug, for these two months?

11. We sincerely feel that, in such cases, the Court must, apart from addressing itself to the merits of the matter, also consider whether, applying the principles of balance of convenience and irreparable loss, it should interfere. This is especially so as, in ***Wander Ltd v. Antox (India) Pvt Ltd***[2] and ***Pernod Ricard v. Karanveer Singh Chhabra***[3], the Supreme Court has clearly held that such appeals are merely appeals on principle, and that the appellate Court should not disturb the findings of the Commercial Court, unless they err on principle.

12. Nonetheless, we heard these matters, and reserved judgment and are, therefore, duty bound to render judgment as well. We, therefore, proceed to do so. However, we do not intend, in the circumstances, this to be a *de novo* examination of the merits of the appellant's claim for injunction. We will remain strictly within the ***Wander*** confines.

B. The Statute

13. Though the Patents Act, 1970[4] does not define "infringement", it does refer to it, and it is accepted, in law, that the proscriptions to which Section 48[5] of the Act refers are the acts which, if committed, would amount to infringement.

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[2] **1990 Supp SCC 727**
[3] **2025 SCC OnLine SC 1701**
[4] "the Act" hereinafter
[5] **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;
(b) where the subject-matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using,

14. Section 64 enlists the circumstances in which a granted patent can be revoked. The opening words of Section 64 make it clear that a patent may be revoked on *any* of the grounds enlisted in the clauses which follow, which indicates that each ground, independently, constitutes a ground for revocation. Section 107(1)[6] provides that *every ground* on which a patent may be revoked under Section 64 shall be available as a ground of defence in any infringement suit. It is also settled that, at the Order XXXIX stage, the defendant is only required to set up a credible challenge to the validity of the suit patent, on any one or more of the grounds contained in Section 64, to escape an injunction. The Court is not required to delve deep into the merits of the challenge at that stage, and has only to satisfy itself that the defendant has made out a case of *vulnerability* of the suit patent to revocation under Section 64. This position is classically captured in the following passage from the judgment of the Division Bench of this Court in ***F. Hoffmann-La Roche Ltd v. Cipla Ltd***[7]:

> "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

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offering for sale, selling or importing for those purposes the product obtained directly by that process in India:

[6] **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.

[7] **159 (2009) DLT 243 (DB)**, referred to, hereinafter, as **Roche-I**

> 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."

The standard of responsibility of the defendant who raises a Section 107 defence, and the scope of examination of the merits of the challenge at the Order XXXIX stage, as set out in the above passage from ***Roche-I*** may be said, by now, to have become legally fossilized.

15. We now examine the scope of Sections 64(1)(a), (e) and (f)[8] of the Act, as they alone would be relevant for the conclusion at which we propose to arrive.

16. Section 64(1)(a) is clear in its terms. It applies only where the invention forming subject matter of the suit patent, "so far as claimed in any claim" of the complete specification of the suit patent, has been "claimed in a valid claim" of earlier priority date contained in the complete specification of another patent granted in India. There is no

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[8] **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;
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(*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;

reference to disclosure, or coverage, or obviousness, or "newness" or novelty. The clause uses only the expression "claim" and "claimed". The use is obviously deliberate, and the intention of the legislature in employing the said expression has to be respected. The clause further specifically employs the expression "the invention, so far as claimed in any claim". What matters, therefore, is not the invention per se, but *the extent to which the invention is claimed in the claim of the suit patent*. It is only, therefore, where the claim in the suit patent is claimed in an earlier granted patent that Section 64(1)(a) would apply. *Identity of claims* in the suit patent and the prior art is, therefore, the *sine qua non* for Section 64(1)(a) to apply.

17. This interpretation is fortified by Section 13(1)(b)[9] of the Act. Section 13 sets out the responsibility of the Examiner in the Patent Office, while scrutinising an application for grant of patent, and examining whether it cannot be granted on account of "anticipation by previous publication" or "anticipation by prior claim". Insofar as anticipation by prior claim is concerned, under Section 13(1)(b), the Examiner is required to examine whether the invention, so far as claimed in any claim of the complete specification of the applicant's patent application, is claimed in any claim of earlier priority date. What is, therefore, required is a claim-to-claim comparison.

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[9] **13. Search for anticipation by previous publication and by prior claim**.—
(1) 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—

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(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.

18. The "person skilled in the art" has no role to play, while applying Section 64(1)(a).

19. The distinction between clauses (e) and (f) of Section 64(1) is, however, not so clear. Section 64(1)(e) applies where the invention, so far as claimed in the suit patent is not "new", having regard to prior public knowledge or public usage in India. The scope and ambit of the expression "new" is not disclosed in the Act. The clause, however, covers "anticipation by prior publication", in any document referred to in Section 13. The relevant clauses of Section 13, for the purposes of Section 64(1)(e), would be Section 13(1)(a) and 13(2)[10], which introduce the concept of "anticipation by publication".

20. The Act does not define "anticipation". It is generally accepted, however, that "anticipation" dovetails into the concept of "novelty", and this interpretation also appears to be in sync with the provisions of the Act, as Section 64(1)(e), which uses the expression "new" but does not use the expression "anticipated", requires reference to the documents to which Section 13(1) refers, and Section 13(1), *per contra*, uses the expression "anticipated by publication" but does not use the expression "new". One may, therefore, reasonably understand

[10] **13. Search for anticipation by previous publication and by prior claim**.—
(1) 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;
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(2) The examiner shall, in addition, make such investigation for the 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 sub-section (1) before the date of filing of the applicant's complete specification.

the statutory provisions as envisaging an invention, or a claim, which is "anticipated by publication" not to be "new".

21. The jury is still out, however, on how exactly to determine whether a claim, in a later patent application, is "anticipated by prior publication". Though Courts, in India, have, in several decisions, sought to explain the expression, there is still lack of uniformity among the decisions.

22. It is truly ironical that, while devoting an entire chapter[11] to "anticipation", with the individual Sections titled "Anticipation by previous publication", Anticipation by previous communication to Government", Anticipation by public display, etc", Anticipation by public working" and "Anticipation by use and publication after provisional specification", not one of these provisions actually explains what anticipation, in any of these contexts, means. The provisions only set out circumstances *which would not* amount to anticipation, without explaining the circumstances *which would*.

23. Perhaps, we would have to await an authoritative Apical exposition on this issue.

24. We do not, however, propose to devote more time on Section 64(1)(e), as the findings of the learned Single Judge, with which we agree, make out a clear prima facie case of vulnerability of the suit patent to invalidity in terms of Section 64(1)(f).

[11] Chapter VI

25. Section 64(1)(f) invalidates the invention, so far as it is claimed in any claim of the complete specification in the suit patent, which "is obvious or does not involve any inventive step", having regard to prior public knowledge.

26. Unlike "anticipation" or "anticipation by prior publication", the Act does not even purport to define "obviousness". The jury, however, is *not* out on this one, and the legal position, in this regard, is somewhat settled. "Obviousness" is to be decided by examining whether a "person skilled in the art" would, from the teachings in prior art, in conjunction with his existing prior knowledge, be able to arrive at the invention claimed in the later patent. If he can, the claim in the later patent is "obvious" from prior art, and would, therefore, not be patentable. The presumption of obviousness can be dispelled by establishing that, in transitioning from the teachings in prior art to the claim in the later patent, an inventive step is involved. "Inventive step" is defined, in Section 2(ja), as meaning "a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".

27. ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd.***[12]**,** postulates the following five inquisitorial steps which a Court must follow to decide whether a later patent is "obvious" from prior art:

> "120. From the decisions noted above to determine obviousness/lack of inventive steps the following inquires are required to be conducted:

[12] **(2016) 65 PTC 1 (DB),** referred to, hereinafter, as **Roche-II**

> Step No. 1 To identify an ordinary person skilled in the art,
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> Step No. 2 To identify the inventive concept embodied in the patent,
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> Step No. 3 To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date.
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> Step No. 4 To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications,
>
> Step No. 5 To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hideside approach."

The Division Bench in ***Roche-II*** identified these five steps after a careful study of authoritative prior pronouncements, largely from judicial authorities overseas, on the issue. We have no doubt that the aforesaid five steps could constitute a litmus test to arrive at a final conclusion on obviousness of a later patent vis-à-vis prior art.

28. We, however, have our doubts as to the employability of these steps by a Court which is examining an application for interlocutory injunction under Order XXXIX of the CPC. The Supreme Court has, inter alia in its decision in ***Brihan Karan Sugar Syndicate (P) Ltd. v. Yashwantrao Mohite Krushna Sahakari Sakhar Karkhana***[13], cautioned against Courts building deep into complicated factual and legal issues while adjudicating on interlocutory applications. A *prima facie* view is all that is justified at that stage. In arriving at such a

[13] **(2024) 2 SCC 577**

prima facie view, it is our respectful opinion that strict adherence to the aforesaid five steps, postulated by the Division Bench in ***Roche-II***, would be both impractical and unnecessary.

29. This is apparent when one refers to the precedents to which ***Roche-II*** adverted, and which have guided the Court to formulate the above five steps. The first step, as per ***Roche-II***, is identification of the "person skilled in the art". In this regard, the Division Bench takes a leaf from the following exposition, in the judgment of the United States Supreme Court in ***William T. Graham et al v. John Deere Company of Kansas City et al***[14]:

> "In determining the level of ordinary skill in the art, you should first determine whether there was a number of people who regularly worked to solve the type of problem that the invention solved, and, if so, determine the level of ordinary skill of such people at the time the invention was made. You must consider the level of skill as to the time the invention was made. Among the factors that may be considered in your determination are:
>
> (1) The various ways that others sought to solve the problems existing;
> (2) The types of problems encountered;
> (3) The rapidity with which new inventions are made in this art;
> (4) The sophistication of the technology involved; and
> (5) The educational background of those actively working in the field."

These tests, though undoubtedly of great pith and moment in a final ascertainment of obviousness, if employed by the Court at the Order XXXIX stage, would unquestionably result in the Court embarking on a mini trial, which is what the judgment of the Supreme Court in ***Brihan Karan Sugar Syndicate*** specifically proscribes.

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[14] **383 US 1 (1966)**

30. With greatest respect to the eminent authors of the ***Roche-II*** judgment, we are of the opinion that the detailed examination which that decision advocates undertaking, in order to arrive at a conclusion on the aspect of obviousness of the claims in a suit patent *vis-à-vis* prior art would be more relevant at the stage of final adjudication of the suit, after evidence is led, and the necessary material, on the basis of which the five steps postulated in the decision may be meaningfully applied, is available. At the Order XXXIX stage, the Court is only required to satisfy itself, *prima facie*, that a credible challenge to the validity of the claims in the suit patent, as obvious from the disclosures contained in prior art, is made out. For this, the judge may permissibly himself don the mantle of the "person skilled in the art", and examine the issue from such a perspective. For that matter, even if the judge were, by an intricate exercise, able to fashion a "person skilled in the art" for the purposes of the controversy before him, the aspect of obviousness would, in the ultimate eventuate, be invariably decided by the judge himself.

31. Though the learned Single Judge has, in the impugned judgment, faithfully followed the five steps envisioned in ***Roche-II***, she has independently found Semaglutide to be obvious, to a person skilled in the art, from the teachings in prior art, particularly IN 275964[15]. We are in entire agreement with her findings in that regard, and find no scope for interference therewith, within the limited peripheries of appellate jurisdiction being presently exercised by us.

[15] "IN'964", hereinafter

32. We, therefore, would be limiting the present judgment to this aspect of the matter as, even on this single score, the impugned judgment deserves to be upheld.

C. Scope of interference in appeal – the *Wander* standard

33. Before proceeding to deal with the reasoning of the learned Single Judge, and the relevant statutory provisions, we may reproduce the following note of caution, entered by the Supreme Court in its judgment in ***Wander,*** with respect to the nature of the jurisdiction that an appellate Court exercises while dealing with appeals against interlocutory orders passed in intellectual property matters:

> "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***[16]:
>
> > "... These principles are well established, but as has been observed by Viscount Simon in ***Charles Osenton &***

[16] **AIR 1960 SC 1156**

> ***Co. v. Jhanaton***[17] '...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'."

34. The Supreme Court has, in ***Pernod Ricard,*** reiterated the aforesaid principle in the following words:

> 19.8. In ***Wander Ltd.***, this Court elaborated the principles governing the grant or refusal of interim injunctions in trademark infringement and passing off actions. It was underscored that appellate courts ought to be circumspect in interfering with the discretionary orders of lower courts in such matters. Interference is warranted only where the discretion has been exercised arbitrarily, capriciously, perversely, or in disregard of settled legal principles."

D. Facts

35. The appellant, as the plaintiff before the learned Single Judge, asserted Indian Patent 262697[18] for an invention titled "ACYLATED GLP-1 ANALOGS COMPRISING NON-PROTEOGENIC AMINO ACID RESIDUE". The priority date of the suit patent is 18 March 2005. The suit specifically relates to Semaglutide, which is specifically claimed as Claim 23 in the suit patent, which is an anti-diabetic drug, and is sold by the appellant in India under the brand names Wegovy and Rybelsus.

36. The appellant alleged that it had come to learn, in December 2024, that the respondents were importing and exporting Semaglutide, which resulted in infringement of the suit patent. The appellant,

[17] **1942 AC 130**

[18] "IN'697", hereinafter referred to as the suit patent

therefore, addressed a notice to the respondents on 5 May 2025, calling on the respondents to cease and desist from any further dealing in Semaglutide. No response having been received from the respondents. As the respondents did not oblige, the appellant proceeded to institute CS (Comm) 565/2025, from which the present appeal emanates, before the Intellectual Property Division of this Court on 26 May 2025.

37. By order dated 29 May 2025, a learned Single Judge of this Court bound the respondents to their statement that they would not sell Semaglutide in India. That undertaking remains in effect till date.

38. The respondents did not dispute the fact that they were in fact importing and exporting Semaglutide and that, therefore, *stricto sensu,* they were infringing the suit patent. They, however, invoked Section 107(1) of the Patents Act, 1970[19], by contesting the validity of the suit patent. Their defence was that the suit patent was vulnerable to invalidity in terms of clauses (a), (e), (f) and (k) of Section 64(1) of the Act.

39. The learned Single Judge has considered, seriatim, the plea of *prima facie* invalidity of the suit patent under Section 64(1)(a), (e) and (f) and found that the respondents have setup a credible challenge to its validity.

[19] "the Act", hereinafter

40. Thus, we are examining this appeal solely with a view to ascertaining whether the learned Single Judge has so erred in principle as to justify interference by us in appeal.

E. Our view, disclosed

41. We are not in agreement with the learned Single Judge that a credible challenge to the validity of the suit patent had been set up by the respondents under Section 64(1)(a), but we do agree that a credible challenge under Section 64(1)(e) and (f), particularly under Section 64(1)(f) was clearly made out.

42. To our mind, Semaglutide is obvious to a person skilled in the art from the complete specifications, and the teachings contained therein, in IN 275964[20]. The learned Single Judge has also held so, and we agree with her findings. The only point on which we differ with the learned Single Judge is in her finding that these facts would make out a credible challenge, *under Section 64(1)(a)*, to the validity of the suit patent. It appears, to us, that though a credible challenge to the validity of the suit patent *is* thereby made out, the challenge would be relatable, not to Section 64(1)(a), but to Section 64(1)(e) and (f).

43. As a credible challenge under *any* of the clauses of Section 64(1) would suffice to set up a successful defence, under Section 107(1), to an infringement action, we concur in the final decision of the learned Single Judge that the respondents have been able to make

[20] "IN'964", hereinafter

out a credible challenge to the validity of the suit patent. Ergo our observation that no case for interference is made out.

F. The impugned judgment

44. We now proceed to set out the reasoning of the learned Single Judge, to the extent it is necessary for our findings in the matter.

I. Re. Section 64(1)(a) – Anticipation by prior claiming

45. The respondents contended, before the learned Single Judge, that Semaglutide stood claimed in IN'964, which was a granted patent of earlier priority date, and was, therefore, vulnerable to invalidity on the ground of anticipation by prior claiming. The learned Single Judge has, in this context, recorded the stand of the respondents thus, in para 28 of the impugned judgment:

> "28. The Defendants have contended that the Semaglutide compound falling under the Suit Patent/IN'697 is not novel since the same compound is claimed/disclosed under the Genus Patent/IN'964, and therefore, applying the principle of ***Novartis AG v. Union of India***[21], the Plaintiff is barred from appropriating the same subject matter claimed in the Genus Patent/IN'964 again in the subsequent Suit Patent/IN'697. Therefore, the Suit Patent/IN'697 is vulnerable to invalidity under Section 64(1)(a) of the Patents Act. It is contended that claims in the Suit Patent/IN'697 are not novel as they are anticipated by the claims of the Genus Patent/IN'964 and therefore, liable for revocation. It is further contended that the teaching in the Genus Patent/IN'964 sufficiently enables the Semaglutide compound. The Defendants also rely upon the admissions made by the Plaintiff on the scope of the claims in Genus Patent/IN'964 in corresponding patent across various foreign jurisdictions, as well as in Plaintiff's filings before

[21] **(2013) 6 SCC 1**

> the Indian Patent Office, wherein the Plaintiff has claimed that the Semaglutide compound is the only commercial product that has resulted from both the Genus Patent/IN'964 and the Suit Patent/IN'697."

46. In response, the appellant contended, before the learned Single Judge, that there was neither any valid claim, nor any enabling disclosure in respect of Semaglutide in IN'964. It was contended by the appellant that there were only two compounds specifically claimed in IN'964 which were in Claims 18 and 21 thereof, and neither of them was Semaglutide. As such, the appellant asserted that Semaglutide could not be treated as invalid on the ground of anticipation by prior claiming.

47. Having recorded these rival submissions, the learned Single Judge has thus identified the issue arising before her for consideration:

> "34. This aforesaid judgment lays down the legal proposition that after the publication of a species patent, the defendant who challenges the validity of the species patent on the ground of anticipation by prior claiming in the genus patent has to establish that the derivation of the claim in the species patent, from the claim in the genus patent, is actually guided by the teachings in the genus patent itself. It further holds that where a genus patent is a Markush structure, the existence of enabling disclosure in the genus patent attains significance."

48. Proceeding thereafter to examine the merits of the respondents' challenge, the learned Single Judge initially refers to a research article, 'Discovery of the Once-Weekly Glucagon-Like Peptide-I (GLP-1) Semaglutide, Journal of Medicinal Chemistry', by Lau, J *et al*. This research article, she notes, refers to the compound at Serial No.61 of the Genus Patent /IN'964 as the 'Alanine' version of the semaglutide or alternatively as 'Ala Semaglutide'. The appellant also admitted that

the only difference between the compound exemplified at Example 61 in Claim 21 of the Genus Patent/IN'964, and Semaglutide, was the presence of the α-aminoisobutyric acid (Aib) amino acid in place of Alanine (Ala) at the 8th position.

49. The learned Single Judge thereafter proceeds to observe as under, in para 38 of the impugned judgment:

> "Thus, to assess whether the Suit Patent/lN'697, i.e.. Semaglutide compound, is claimed in the Genus Patent/lN '964, this Court will examine whether there is a disclosure of each feature or sufficient teachings in the claims of the Genus Patent/IN '964 enabling a 'person skilled in the art regarding the features of the Suit Patent/IN' 697, i.e., the Semaglutide compound."

The learned Single Judge thereafter proceeds to undertake a claim-to-claim comparison between the claims in the Genus Patent/IN'964 and the claims in the Suit Patent.

50. Following this, the learned Single Judge has extracted para 10 of the rejoinder filed by the appellant before her, which read as under :

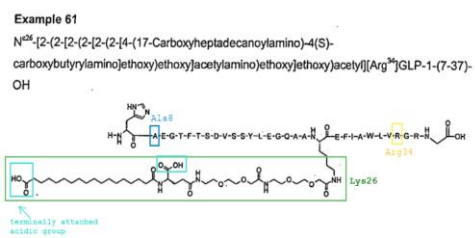
> "10. The first of the compounds in claim 23 of IN 697 is the compound now known as Semaglutide. **The novel and inventive compound Semaglutide, comprises the native GLP-1(7-37) peptide sequence with the following modifications**:
>
> **10.1 substitution of the amino acid alanine (Ala) at position 8 with a-aminoisobutyric acid (Aib), a nonproteogenic amino acid;**
>
> **10.2 substitution of the amino acid lysine (Lvs) with arginine (Arg) at position 34; and**
>
> **10.3 Lvs at position 26 acvlated on its side chain with a moiety that comprises two "**OEG**" groups, a y-Glu group, and a C18 fatty diacid, The specific OEG groups are "AEEA"**

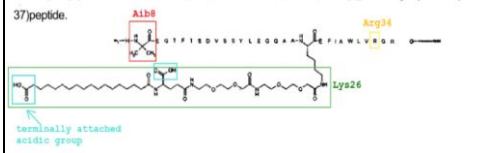
groups - AEEA is short for 2-(2-(2-Aminoethoxy)ethoxy)acetic acid. (Said moiety comprises at least two acidic groups, wherein one acidic group is attached terminally)."

(Emphasis contained in the original)

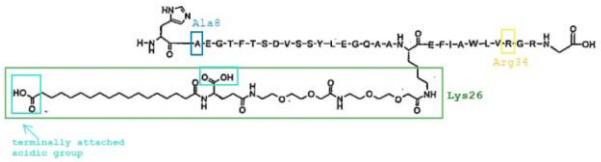
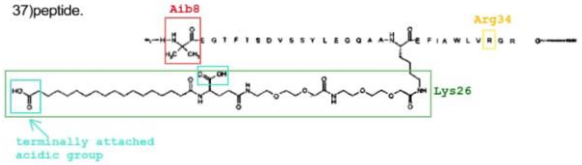
51. The learned Single Judge thereafter proceeds, on the plea of anticipation by prior claiming, to hold as under:

> "40. The Defendants have contended that these features enlisted by the Plaintiff are already exemplified in the Ala Semaglutide compound/Example 61. The Plaintiff has also compared the structure of the Semaglutide compound, as claimed in Claim 23 of the Suit Patent/IN'697, with the Ala Semaglutide compound/Example 61 of the Genus Patent/IN'964. The comparison is set out below:

Name of Compound	**Structural Similarities**	**Difference between the Semaglutide compound and the Ala Semaglutide compound**
Ala Semaglutide compound		- Aib at the 8th position instead of Ala

Semaglutide compound	Example 4 N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib8,Arg34]GLP-1-(7-37)peptide.  	

Further, Plaintiff has also made a comparison of Ala Semaglutide compound/Example 61 of Genus Patent/IN'964 with Semaglutide compound of the Suit Patent/IN'697 in the expert affidavit of Gregory L Challis dated 11th July 2025. The extract of the comparison is set out below:

Example 61 of IN'964 Example 61 N$^{\varepsilon 26}$-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Arg^{34}]GLP-1-(7-37)-OH  	**Difference between Example 61 of IN '964 and Example 4 of IN '697 (Semaglutide)**: Semaglutide contains Aib (which is a non-proteogenic amino acid) at position 8. Example 61 contains Ala at position 8 which is a proteogenic amino acid. Any change in peptide sequence can alter the physical, chemical and pharmacological properties of
Example 4 of IN'697 (Semaglutide) Example 4 N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib8,Arg34]GLP-1-(7-37)peptide.  	

	the resulting compound. Any such change can also raise the risk immunogenicity. In some settings there were fears that non-proteogenic amino acids could exacerbate this risk (non-proteogenic amino acids are amino acids which do not occur in nature in proteins). This risk could be particularly pronounced for medicines taken chronically (such as treatments for type 2 diabetes) as this provides a long time for immunogenicity to develop.

41. The aforesaid comparisons filed by the Plaintiff acknowledges that the sole/only difference in the Semaglutide compound claimed in Claim 23 as exemplified in Example 4 of the Suit Patent/IN'697 from the Ala Semaglutide compound/Example 61 of the Genus Patent/IN'964, is in the insertion of 'Aib', i.e., a non-proteogenic amino acid, at the 8th position.

42. The tables above show that there is no dispute as to the effect that the Plaintiff had already claimed a compound[22] in Claim 21 of the Genus Patent/IN'964, which has the GLP-1 (7-37) sequence with modification of Arg at the 34th position and Lys at the 26th position with at least two [2] acidic groups, wherein one

[22] Example 61

[1] acidic group is attached terminally. Thus, the differences set out by the Plaintiff at paragraphs '10', '10.2' and '10.3' of its rejoinder [as noted above] have already been claimed in the identical positions of the Ala Semaglutide compound/Example 61.

It would also be relevant to note that substitution of the amino acid Lys with Arg at position 34 has been specifically claimed at Claim 18 of the GLP-1 (7-37) analogue. So also, the preference for GLP-1 (7-37) analogue is also apparent in the dependent claims of the GLP-1 (7-37) analogue.

43. In the aforenoted admissions of the Plaintiff, the issue that arises for consideration is whether a 'person skilled in the art' will be enabled by following the specific instructions of the claims of the Genus Patent/IN'964 to substitute 'Ala' with 'Aib' residue at the 8th position of the Ala Semaglutide compound/Example 61.

44. Upon perusal of the claims of the Genus Patent/IN'964, it is apparent that the independent Claim 1 of the Genus Patent/IN'964 claims a GLP-1 analogue that comprises an amino acid sequence, i.e., formula [V], where an unspecified amino acid at the 8th position [Xaa$_8$] could be selected from a broader group containing '**Ala'**, Gly, Val, Leu, lle, Lys, '**Aib'**, etc.

Later, in the dependent Claim 16 of the Genus Patent/IN'964, the patentee has specifically claimed that the amino acid at the 8th position of GLP-1 analogue claimed in Claim 1 of the Genus Patent/IN'964 is 'Aib', thereby asserting that 'Aib' is the preferred amino acid for the substitution at the 8th position.

Therefore, for a 'person skilled in the art', upon perusal of the Ala Semaglutide compound/Example 61 or any compounds claimed in Claim 21 of the Genus Patent/IN'964, he/she will be enabled to make a substitution at the 8th position with 'Aib', in light of specific Claim 16 of the Genus Patent/IN'964.

With Claim 16 of the Genus Patent/IN'964, it is evident that the sole novel feature of the Suit Patent, i.e., 'Aib' at the 8th position, was already claimed in the Genus Patent/IN'964.

45. Now, upon considering the independent Claim 1 of the Suit Patent/IN'697, the Plaintiff/Patentee has claimed that the GLP-1 analogue has at least one [1] non-proteogenic amino acid residue at position seven [7] and/or eight [8]. Thereafter, in the dependent Claim 16 of the Suit Patent/IN'697, the patentee has specified that at the 8th position of the GLP-1 analogue, it is nothing but 'Aib'; however, GLP-1 (7-37) analogue with 'Aib' at the 8th position was already claimed in Claims 1, 11 and 16 of the Genus

Patent/IN'964.

> 46. Therefore, from the Claims 1 and 21 [Example 61 compound therein], read with explicit disclosure of non-proteogenic amino acid, i.e., 'Aib' at the 8th position in Claim 16 of the Genus Patent/IN'964 as the most preferred non-proteogenic amino acid of the inventor, a 'person skilled in the art' will be enabled to make the substitution at the 8th position of the Ala Semaglutide compound/Example 61. With this substitution, the 'person skilled in the art' will undoubtedly reach the Semaglutide compound as claimed in Claim 23 [Example 4] of the Suit Patent/IN'697. In view of Claim 21 [Ala Semaglutide compound/Example 61] and Claim 16 of the Genus Patent/IN'964, it is evident that all the features of the Semaglutide compound enlisted by the Plaintiff in its rejoinder at paragraphs '10', '10.1', '10.2' and '10.3' already stand claimed in the Genus Patent/IN'964, with an explicit instruction to combine these features. Thus, based on the analysis above, it could be concluded that the Semaglutide compound, as claimed in the Suit Patent/IN'697, was prior claimed in the Genus Patent/IN'964."

52. Thus, in the afore-extracted paragraphs 40 to 46 of the impugned judgment, the learned Single Judge essentially holds thus:

(i) The novel features of Semaglutide over prior art, as identified by the appellant itself, in para 10 of the rejoinder filed before the learned Single Judge were

(a) substitution of the amino acid alanine (Ala) with α-aminoisobutyric acid (Aib) at position 8,

(b) substitution of the amino acid lysine (Lys) with arginine (Arg) at position 34 and

(c) activation of lysine at position 26 on its side chain with a moiety comprising at least two acidic groups in which one acidic group is attached terminally.

(ii) The defendants' contention, *per contra*, was that these features already stood disclosed in the exemplified Compound 61 in Claim 21 in the Genus Patent IN'964.

(iii) The appellant had itself undertaken a comparison of Semaglutide, as Claim 23 in the Suit Patent, with Compound 61 in Claim 21 in the Genus Patent IN'964 and had also filed an affidavit of an expert in that regard. The appellant clearly admitted, at both points, that the only difference between the exemplified Compound 61 in Claim 21 of the Genus Patent IN'964 and Semaglutide as Claim 23 of the Suit Patent was the replacement of 'Ala' at the 8th position, in the Genus Patent with 'Aib' in Semaglutide.

(iv) Claim 21 in IN'964 already claimed a GLP-1 sequence which was modified with arginine at the 34th position and lysine at the 26th position with two acidic groups, one of which was attached terminally. In other words, the purportedly novel features of semaglutide, as contained in paras 10.2 and 10.3 of the rejoinder filed by the appellant, before the learned Single Judge, already stood claimed in Claim 21 of IN'964.

(v) The only issue to be considered, therefore, was whether a person skilled in the art would be enabled, by the teachings in the claims of IN'964, to substitute 'Ala' with 'Aib' at the 8th position in Compound 61 in Claim 21 of IN'964.

(vi) Claim 1 of the genus patent IN'964 claimed a GLP-1 analogue with an amino acid sequence in which the amino acid at position 8 could be selected from a group which included 'Ala' and 'Aib'.

(vii) Dependant Claim 16 below Claim 1 in IN'964 specifically claimed an amino acid formed by substituting Aib at position 8 of Claim 1. Thus, it was disclosed, in the genus patent IN'964 that Aib was the preferred amino acid for substitution at position 8 in claim 1 of IN'964.

(viii) A person skilled in the art would, therefore, be guided by the teachings in the Genus Patent IN'964 to substitute Aib at position 8 in claim 1 in the said Genus patent instead of Ala.

(ix) Thus, claim 1 and Example 61 in claim 21 of IN'964, read with the disclosure of Aib at position 8 in claim 16 of IN'964, was sufficient to enable a person skilled in the art to substitute Aib at position 8 in the exemplified compound 61 in Claim 21 of the Genus Patent IN'964. This substitution would result in Semaglutide.

(x) As all other features of Semaglutide were already claimed in IN'964, with the explicit instruction to combine them, the learned Single Judge holds that semaglutide was anticipated by prior claiming in the Genus Patent/ IN'964.

II. <u>Section 64(1)(e) – Anticipation by prior publication</u>

53. To support their challenge to the validity of the suit patent under Section 64(1)(e), the respondents again relied on IN'964 as the applicable prior art. The learned Single Judge disposes of this challenge by holding, in paras 83 and 84 of the impugned judgment, that the findings returned in respect of the challenge under Section 64(1)(a) would apply *mutatis mutandis* to the challenge under Section 64(1)(e):

> "83. In the present case, Defendants have identified Genus Patent/IN'964, as the relevant prior art for challenging the validity of the Suit Patent/IN'697 under Section 64(1)(e) of the Patents Act. The priority date of the Suit Patent/IN'697 has already been decided in the previous section as after the publication of the Genus Patent/IN'964.
>
> 84. The analysis under Section 64(1)(a) of the Patents Act is relevant in the fact of this case under Section 64(1)(e) of the Patents Act and applies mutatis mutandis since the prior patent referred to in the deliberations under Section 64(1)(a) and the prior art referred to under Section 64(1)(e) in the facts of this case is the same document i.e., Genus Patent/IN'964. In the considered view of this Court, when Example 61 compound of Genus Patent/IN'964 is read in conjunction with the specific Claim 16 therein, the Genus Patent/IN'964 specifically discloses the Suit Patent/IN'697, i.e., Semaglutide compound for a 'person skilled in the art' to reproduce it without undue experimentation. Therefore, the Suit Patent/IN'697 is anticipated by the Genus Patent/IN'964, which was published before the priority date of the Suit Patent/IN'697.

III. Section 64(1)(f) – Obviousness

54. With respect to the challenge under Section 64(1)(f), the respondents relied on three prior arts i.e. Genus Patent / IN'964 and the teachings of Deacon et al [1998] and Knudsen et al [2004]. The learned Single Judge, thereafter, proceeds on an intricate analysis of

the facts before her, in compliance with the "5-step test" postulated by the Division Bench in ***Roche-II***.

G. Analysis

55. The exercise, as undertaken, is detailed and thorough, and deserves commendation. However, we do not deem it necessary to examine the findings of the learned Single Judge with respect to Section 64(1)(f), as we are of the view that her findings, with respect to Section 64(1)(a), as noted *supra*, make out a clear case of obviousness of Semaglutide, as claimed in the suit patent, *vis-à-vis* the claims and complete specification in prior art in the form of IN'964.

56. We feel, in fact, here, that the learned Single Judge has erred, albeit to a slight degree, in conflating the concept of obviousness, which is relevant for Section 64(1)(f), and anticipation by prior claiming, which pertains to Section 64(1)(a). The findings returned by the learned Single Judge, for holding a *prima facie* case to have been made out under Section 64(1)(a), in fact make out a *prima facie* credible challenge to the validity of the suit patent under Section 64(1)(f).

57. The following paragraphs from the impugned judgment would make this apparent:

> "28. The Defendants have contended that the Semaglutide compound falling under the Suit Patent/IN'697 is not novel since the same compound is claimed/disclosed under the Genus Patent/IN'964, and therefore, applying the principle of ***Novartis AG v. Union of India***, the Plaintiff is barred from appropriating the same subject matter claimed in the Genus Patent/IN'964 again in

the subsequent Suit Patent/IN'697. Therefore, the Suit Patent/IN'697 is vulnerable to invalidity under Section 64(1)(a) of the Patents Act. It is contended that claims in the Suit Patent/IN'697 are not novel as they are anticipated by the claims of the Genus Patent/IN'964 and therefore, liable for revocation. *It is further contended that the teaching in the Genus Patent/IN'964 sufficiently enables the Semaglutide compound. The Defendants also rely upon the admissions made by the Plaintiff on the scope of the claims in Genus Patent/IN'964 in corresponding patent across various foreign jurisdictions, as well as in Plaintiff's filings before the Indian Patent Office, wherein the Plaintiff has claimed that the Semaglutide compound is the only commercial product that has resulted from both the Genus Patent/IN'964 and the Suit Patent/IN'697.*

*****

34. This aforesaid judgment[23] lays down the legal proposition that after the publication of a species patent, the defendant who challenges the validity of the species patent on the ground of anticipation by prior claiming in the genus patent *has to establish that the derivation of the claim in the species patent, from the claim in the genus patent, is actually guided by the teachings in the genus patent itself. It further holds that where a genus patent is a Markush structure, the existence of enabling disclosure in the genus patent attains significance*.

*****

38. Thus, to assess whether the Suit Patent IN'697, i.e., Semaglutide compound, is claimed in the Genus Patent/IN'964, this Court will examine *whether there is a disclosure of each feature or sufficient teachings in the claims of the Genus Patent/IN'964 enabling a 'person skilled in the art' regarding the features of the Suit Patent/IN'697, i.e., the Semaglutide compound.*"

(Emphasis supplied)

The italicized parts of the above paragraphs from the impugned judgment pertain, not to the realm of anticipation by prior claiming under Section 64(1)(a), but obviousness to a person skilled in the art, under Section 64(1)(f). To this limited extent, we are unable to agree

[23] **Novartis AG v. Natco Pharma Ltd, 2023 SCC OnLine Del 106**, authored by the author of this judgment, sitting singly

with the learned Single Judge that a *prima facie* credible challenge to the validity of the suit patent had been laid by the respondents, *under Section 64(1)(a),* which requires *congruence of claims*, and nothing less.

58. The person skilled in the art, in fact, has no real part to pay in Section 64(1)(a). His perspective is relevant to Section 64(1)(f) and, to a lesser degree, to Section 64(1)(e).

59. However, the exercise undertaken by the learned Single Judge, following these findings, though undertaken in the context of Section 64(1)(a), make out a clear case under Section 64(1)(f).

60. We have already extracted, earlier, the findings of the learned Single Judge in that regard, and also paraphrased them in our own words, and do not deem it necessary to reiterate them. Suffice it to state that the learned Single Judge has held, in essence, that

(i) of the novel and inventive features of Semaglutide, as identified by the appellant itself in para 10 of the rejoinder filed before the learned Single Judge, the features in paras 10.2 and 10.3 were already claimed in Claim 21 of IN'964,

(ii) the appellant had itself acknowledged that the only distinguishing feature between Compound 61 in Claim 21 of the Genus Patent IN'964 and Semaglutide was the amino acid 'Aib' at the 8th position in place of 'Ala',

(iii) Claim 1 read with dependent Claim 16 in the Genus Patent IN'964 teach that 'Aib' was a preferred amino acid for substitution at position 8,

(iv) the combined effect of these teachings would lead a person skilled in the art to substitute, in Example 61 in Claim 21 of the Genus Patent IN'964, the 'Aib' amino acid in place of 'Ala', which would result in Semaglutide.

61. Five of the inventors were common to the Genus Patent IN'964 and the suit patent. Where the inventors are common, the Division Bench of this Court has, in ***AstraZeneca AB v. Intas Pharmaceuticals Ltd.***[24], held that the aspect of obviousness would have to be viewed from the perspective of a "person in the know", rather than a "person skilled in the art". This Bench has, in ***F Hoffmann-La Roche AG v. Natco Pharma Limited***[25], approved and followed the said test. Special Leave Petitions, preferred against both these decisions, stand dismissed by the Supreme Court. The "person in the know" test may, therefore, be regarded as having been accorded Apical affirmation.

62. Viewed from the perspective of a person in the know, it is *prima facie* clear that Semaglutide would be obvious from the teachings contained in the Genius Patent IN'964 and that, therefore, a credible challenge to the validity of the suit patent, under Section 64(1)(f), is made out.

63. Even on this sole ground, as the impugned judgment is liable to be affirmed, we do not deem it necessary to enter into any other aspect of the matter.

[24] **2021 SCC OnLine Del 3746**
[25] **2025 SCC OnLine Del 6390**

64. We also do not deem it necessary to reproduce the submissions of learned Counsel for the appellant in this regard, as, on the aspect of obviousness of Semaglutide from the teachings contained in the Genus Patent IN'964, there is no substantial traversal.

Conclusion

65. We, therefore, see no reason to disturb the impugned judgment of the learned Single Judge.

66. The appeal is dismissed.

67. Observations contained in this judgment, needless to say, are only *prima facie*, and would not influence the learned Single Judge while adjudicating the suit on merits.

C. HARI SHANKAR, J.

OM PRAKASH SHUKLA, J.

MARCH 09, 2026*/aky/yg*