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2025:DHC:10820

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

Reserved on: 15th September, 2025
Date of Decision:02nd December, 2025

\+ CS(COMM) 565/2025 & CRL.M.A. 21608/2025 I.A. 14076/2025 I.A. 17699/2025 I.A. 17802/2025 I.A. 18374/2025 I.A. 19205/2025 I.A. 19361/2025

NOVO NORDISK AS. .....Plaintiff

Through: Mr. Hemant Singh, Ms. Mamta Jha, Mr. Siddhant Sharma, Mr. Rishabh Paliwal, Mr. Abhay Tandon and Mr. Shreyansh Gupta, Advs.

versus

DR. REDDYS LABORATORIES LIMITED & ANR.

.....Defendant

Through: Mr. Gopal Subramanium, Sr. Adv. and Mr. J. Sai Deepak, Sr. Adv. with Mr. Mohit Goel, Mr. Sidhant Goel, Mr. Aditya Goel, Mr. Deepankar Mishra, Mr. Kartikeya Tandon, Mr. Pavan Bhushan and Mr. Avinash K. Sharma, Advs.

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CORAM:
HON'BLE MS. JUSTICE MANMEET PRITAM SINGH ARORA

J U D G M E N T

MANMEET PRITAM SINGH ARORA, J:

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I.A. 14076/2025 (UNDER ORDER XXXIX RULES 1 AND 2 OF CPC)

I. FACTUAL MATRIX

1. By way of the present judgment, this Court shall decide the above-captioned application filed on behalf of the Plaintiff under Order XXXIX, Rules 1 and 2 of the Code of Civil Procedure, 1908 ['CPC'].

2. The present suit has been filed alleging infringement of Patent No. 262697 ['Suit Patent/IN'697'] by the Plaintiff/Novo Nordisk A/S, who is a global healthcare company with more than a hundred [I00] years of innovation and leadership in treatment for diabetes and other rare diseases.

3. By way of the present application, the Plaintiff is seeking an interim injunction to restrain the infringement of the Suit Patent/IN'697, which is titled 'ACYLATED GLP-1 ANALOGS COMPRISING NON-

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PROTEOGENIC AMINO ACID RESIDUE'.

4. The Suit Patent/IN'697 relates to the field of therapeutic peptides, i.e., new protracted GLP-1[1] analogues for the treatment of diseases such as Type 2 Diabetes and Obesity. The Suit Patent/IN'697 is registered in the name of the Plaintiff. The bibliographic details of the Suit Patent/IN'697 are as under:

APPLICATION NUMBER	5107/DELNP/2007
PATENT NO.	262697
APPLICANT NAME	NOVO NORDISK A/S
PRIORITY APPLICATION NUMBER	EP 05102171.5 dated 18.03.2005
PCT INTERNATIONAL APPLICATION NUMBER	PCT/EP2006/060855 dated 20.03.2006
PCT INTERNATIONAL FILING DATE	20/03/2006
DATE OF FILING	02/07/2007
TITLE OF INVENTION	"ACYLATED GLP-1 ANALOGS COMPRISING NONPROTEOGENIC AMINO ACID RESIDUE"
PUBLICATION DATE (U/S 11A)	17/08/2007
REQUEST FOR EXAMINATION	16/03/2009
DATE OF FIRST EXAMINATION REPORT	16/04/2013
DATE OF RESPONSE TO FIRST EXAMINATION REPORT	10/10/2023
DATE OF GRANT	05/09/2014

5. The Suit Patent/IN'697 has a term of twenty [20] years from 20th March 2006, which expires on 20th March 2026 and has not been subjected to either pre-grant opposition and/or post-grant opposition.

6. The Suit Patent/IN'697 claims inter alia, a compound with an International Non-Proprietary Name ['INN'], i.e., 'Semaglutide', as assigned by the World Health Organisation ['WHO']. Semaglutide is a breakthrough drug, as it is the only GLP-1 analogue administered subcutaneously once a week, compared to earlier known GLP-1 analogues

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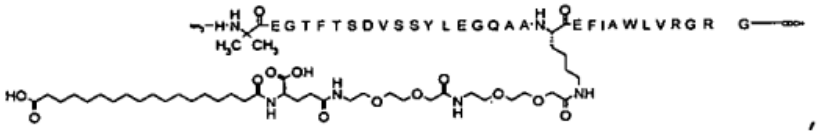
such as Exenatide and Liraglutide, which are administered twice a day and once a day, respectively. The chemical structure of the Semaglutide compound is depicted as under:



N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib^{8},Arg^{34}]GLP-1-(7-37)peptide,

7. Semaglutide is the Active Pharmaceutical Ingredient ['API'] in the Plaintiff's commercial product ['Semaglutide compound'], which is marketed under the brand names Ozempic, Wegovy and Rybelsus worldwide and under the brand names Wegovy and Rybelsus in India.

8. It is stated in the plaint that through due diligence, in October 2024, the Plaintiff discovered that certain Indian pharmaceutical companies might be infringing the Suit Patent/IN'697 by importing or dealing in Semaglutide compound and related products.

9. Thereafter, an independent investigator's report in December 2024 confirmed that Defendant No. 1/Dr. Reddy's Laboratories Limited, who is an Indian Pharmaceutical company with products and services in the field of API, generics, branded generics, biosimilars and over-the-counter pharmaceutical products and Defendant No.2/ OneSource Specialty Pharma Limited, who is a specialty pharmaceutical contract development and manufacturing organization focused on selling drug device combinations, complex injectables, biologics and soft-gelatin capsules [hereinafter collectively referred to as 'the Defendants'], have been importing and exporting Semaglutide compound ['impugned drug'] in significant

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quantities, suggesting commercial rather than research use.

Despite initial uncertainty about whether these activities were protected under Section 107A of the Patents Act, 1970 ['the Patents Act'], the Plaintiff's continued monitoring in early 2025 revealed increasing volumes of impugned drug, indicative of infringement. Consequently, the Plaintiff issued a cease-and-desist notice on 5th May 2025, to Defendant No. 2, who, instead, along with Defendant No. 1, filed a revocation petition bearing [C.O. (COMM.-IPD-PAT) No. 9/2025] against the Suit Patent/IN'697.

10. In these facts, the present suit was filed on 26th May 2025 and listed before the Court on 29th May 2025. On the same day, learned senior counsel appearing on behalf of the Defendants made the following submissions:

i. The Defendants have a licence to manufacture the impugned drug, which was granted in December 2024, and have begun manufacturing the same in April 2025.

ii. Since the Defendants do not have a licence to sell the impugned drug in India till date; therefore, the Defendants shall not sell the impugned drug in India. However, the Defendants reserve their right to export the impugned drug in countries where the Plaintiff has not been granted a patent yet.

11. The Court, vide order dated 29th May 2025, bound the Defendants to the statement that they will not sell the impugned drug in India; however, the Defendants were not restrained from carrying on exports of the said drug to other countries from India.

12. Aggrieved by the said order, the Plaintiff instituted an appeal [bearing FAO(OS) (COMM) 115/2025] under Section 13 of the Commercial Courts Act, 2015, thereby challenging the order dated 29th May, 2025. Subsequently, the Division Bench of this court, vide order dated 23rd July

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2025, directed the Single Judge to decide the captioned application.

13. Thereafter, hearings for this application were advanced on 31.07.2025, 01.08.2025, 08.08.2025, 22.08.2025, 27.08.2025, 08.09.2025, and 09.09.2025, and finally, the judgment was reserved on 15.09.2025.

II. SUBMISSIONS ON BEHALF OF THE PLAINTIFF

14. Mr. Hemant Singh, learned counsel for the Plaintiff, has set up the Plaintiff's case as under: -

SEMAGLUTIDE IS AN INVENTIVE COMPOUND UNDER SECTION 64(1)(f) OF THE PATENTS ACT

14.1. The Semaglutide compound covered in the Suit Patent/IN'697 is a novel and inventive compound. It has also surprisingly demonstrated significantly high therapeutic efficacy for the treatment of Type 2 Diabetes, while preserving safety, potency, and tolerability.

14.2. None of the compounds cited in the prior art document, i.e., IN275964 ['Genus Patent/IN'964'], has shown more than forty-three [43] hours of half-life in minipigs [Example 54 of Genus Patent/IN'964] and thirty-five [35] hours of half-life in minipigs [Example 61 of Genus Patent/IN'964]. None of the compounds of Genus Patent/IN'964 has been developed and approved as a drug for the treatment of Type 2 Diabetes or Obesity.

Even prior to the Genus Patent/IN'964, the earlier known GLP-1 analogue approved drug Exenatide has a dosage of once/twice a day, and Liraglutide has a dosage of once a day.

In contrast, Semaglutide compound covered in the Suit Patent/IN'697, demonstrated a half-life of sixty-nine [69] hours in preclinical minipigs and one hundred and sixty-five [165] hours in clinical trials in humans. Semaglutide compound has a dosage of once a week when administered

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subcutaneously. Hence, the Semaglutide compound has demonstrated exceptionally higher efficacy compared to prior known compounds, and therefore, it fulfils a long-felt need. The Division Bench of this Court in **F. Hoffmann-La Roche v. Cipla Ltd.**[2] has held that if a novel invention fulfils a long-felt need, it is a relevant factor to establish inventive step in the said invention under Section 64(1)(f) of the Act.

14.3. Moreover, the Suit Patent/IN'697 cannot be obvious/non-inventive under the test as laid down by this Court in **F. Hoffmann-La Roche v. Cipla Ltd.**[3] since Genus Patent/IN'964 in any case is not a relevant prior art for purposes of Section 64(1)(f) of the Act, as the same was published on 30th March, 2005 after the priority date of the Suit Patent/IN'697.

14.4. The Defendants' reliance on the International Search Report dated 22nd November 2006 to allege a lack of inventive step in the Suit Patent/IN'697 under Section 64(1)(f) of the Act is misleading. The cited prior art [D1] in the Report refers to the 'Knudsen' article on GLP-1 analogues, such as Exenatide and Liraglutide, not Genus Patent/IN'964, which was not prior art. Similar objections were already raised and satisfactorily addressed before the Indian Patent Office in response to the First Examination Report ['FER'] dated 10th October 2013, leading to the grant of the patent. Hence, the argument of lack of inventive step is unfounded and untenable.

PRIOR CLAIMING UNDER SECTION 64(1)(a) OF THE PATENTS ACT

14.5. The argument of prior claiming under Section 64(1)(a) of the Act based on Genus Patent/IN'964 has no merit since this Court has repeatedly held that for establishing a ground of anticipation by prior claiming or prior publication, it is essential for the Defendants to establish that the same

[2] 2015 SCC OnLine Del 13619
[3] 2015 SCC OnLine Del 13619

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invention as a whole and not its individual constituents or components, was known and has been disclosed in an earlier claim of earlier priority or earlier date of publication.

Hence, the Defendants need to establish that a compound having all the combination of substituents, which, when combined, leads to the synthesis of the Semaglutide compound, was known. The Defendants have failed to do so. In this regard, reliance is being placed on the following judgments: -

a. **Kudos Pharmaceuticals Limited and Others v. Natco Pharma Limited**[4]
b. **FMC Corporation and Another v. Best Crop Science LLP and Another**[5]
c. **Farbewerke Hoechst v. Unichem Laboratories**[6]
d. **The General Tire & Rubber Company Vs. The Firestone Tyre**[7]

14.6. The entire plea of the Defendants is based on 'hindsight reconstruction' of the Semaglutide compound, which is only known from the Suit Patent/IN'697 and not otherwise. The Defendants have examined the prior arts, including Genus Patent/IN'964, for a similarly structured compound and then sought to argue that if 'Ala' at the 8th position of Example 61 is substituted with 'Aib', it would lead to the Semaglutide compound.

14.7. However, there is no teaching in Genus Patent/IN'964 as to why Example 61 should be selected out of 66 examples. Further, there is no teaching as to why GLP-1 (7-37) analogues should be selected out of multiple GLP-1 analogues disclosed in Genus Patent/IN'964 and further

[4] 2024 SCC OnLine Del 1439 [Paragraph Nos. 54 to 63]
[5] 2021 SCC OnLine Del 3647 [Paragraph Nos. 12-13]
[6] 1968 SCC OnLine Bom 118 [Paragraph No. 15]
[7] [1972] R.P.C. [Lines 5 to 30 on pg. 486]

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why one of such GLP-1 (7-37) analogue should be substituted with non-proteogenic amino acid 'Aib' in place of proteogenic amino acid 'Ala', why at the 8th position 'Aib' is to be substituted with Alanine and further why it should be combined with Lysine ['Lys'] at 26th position acylated with two [2] acidic group out of which one [1] is attached terminally with Arginine ['Arg'] at 34th position.

14.8. The Defendants' argument that prior coverage amounts to prior claiming is equally fallacious and has been rejected by this Court in the following judgments: -

a. **FMC Corporation and Another v. Best Crop Science LLP and Another**[8]
b. **Novartis AG and Another v. Natco Pharma Limited**[9]
c. **Kudos Pharmaceuticals Limited and Others v. Natco Pharma Limited**[10]

14.9. Coverage determines the scope of the right claimed in respect of a patented invention, and such right is violated and infringed by undertaking any of the acts prohibited under Section 48 of the Patents Act, which includes manufacture, sale, offer for sale, etc. Coverage, therefore, is an infringement issue, not a validity issue.

14.10. Every novel and inventive product is a technical advancement on the earlier state of the art. In case the novel and inventive product embodies or is built on the use of an earlier patented invention, it will fall within its coverage and would infringe it. However, such infringement is not a ground of rejection of a Patent. Section 19 of the Patents Act recognises that in case of infringement, the controller will merely incorporate a reference to the earlier patent and still proceed to grant the patent.

[8] 2021 SCC OnLine Del 3647 [Paragraph No. 11.18]
[9] 2023 SCC OnLine Del 106 [Paragraph Nos. 139 and 140]

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14.11. This is also evident from a bare reading of Section 3(d) of the Patents Act, where a new form of a known substance, which could fall within the scope of a patented known substance, can still be patented if it fulfils the condition of enhanced efficacy. Statutory provisions like Section 3(d) and Section 19 of the Patents Act establish that prior coverage is not a ground of rejection of a subsequent novel and inventive product or process.

14.12. The Defendants' claim that foreign Patent Term Extensions ['PTE'] and Supplementary Protection Certificates ['SPC'] for Semaglutide compound prove prior claiming in Genus Patent/IN'964 is misconceived.

Indian patent law has no provision for PTE or SPC, and foreign extensions cannot determine the validity of an Indian patent. Notably, countries that granted such extensions also granted separate species patents for the Semaglutide compound. The European Patent Office upheld the novelty of the Semaglutide compound [EP'839] over the Genus Patent/IN'964 [EP'981], disproving the Defendants' argument. Extensions abroad reflect regulatory or jurisdictional factors, not prior disclosure.

14.13. The Defendants' plea under Section 3(d) of the Patents Act is untenable, as the provision applies only to new forms of known substances, not to new compounds like Semaglutide.

It is contended that Genus Patent/IN'964's compounds were not publicly known before the priority date of the Suit Patent/IN'697 and cannot serve as a reference for Section 3(d) of the Patents Act. Moreover, Semaglutide compound shows significantly enhanced efficacy, enabling once-weekly dosing versus Liraglutide's once-daily regimen with such data included in the original specification, not as post-filing evidence. Accordingly, Semaglutide compound is neither a derivative nor a known form of a prior substance, and the Section 3(d) of the Patents Act objection

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must be rejected.

14.14. Therefore, the Defendants have failed to establish any credible challenge to the validity of the Suit Patent/IN'697. Reliance is placed on the following judgments: -

a. **Mold Tek Packaging Limited v. Pronton Plast Pack Pvt. Ltd.**[11],
b. **FMC Corporation and Another v. Best Crop Science LLP and Another**[12],
c. **Kudos Pharmaceuticals Limited and Others v. Natco Pharma Limited**[13], and
d. **Strix Limited Vs. Maharaja Appliances Limited**[14].

INFRINGEMENT BY THE DEFENDANTS

14.15. The Defendants do not dispute infringement of the Suit Patent/IN'697; hence, the manufacturing of the Semaglutide compound by the Defendants, even if for export and sale, amounts to infringement of the Suit Patent/IN'697, as it violates the statutory right conferred on the Plaintiff under Section 48 of the Patents Act. Reliance is placed on **Merck Sharp & Dohme Corp. and Another Vs. Sanjeev Gupta and Others**[15].

14.16. Damages would not be an adequate remedy in case of infringement of a Patent as recognised by this Court in the judgment of **Merck Sharp and Dohme Corporation & Another Vs. Glenmark Pharmaceuticals**[16]**.**

14.17. The Courts have invariably held that a Patent which has remained unchallenged either by way of a pre-grant or a post-grant opposition or revocation for a period of up to nineteen [19] years, is 'prima facie valid' and any infringement of such Patent thereof must be injuncted. In this

[11] 2025 SCC OnLine Del 4883 [Paragraph Nos. 41 to 44]
[12] 2021 SCC OnLine Del 3647 [Paragraph No. 10.4]
[13] 2024 SCC OnLine Del 1439 [Paragraph Nos. 26 & 27]
[14] 2009 SCC OnLine Del 2825 [Paragraph No. 22]
[15] 2019 SCC OnLine Del 11167 [Paragraph Nos. 13-14]
[16] 2015 SCC OnLine Del 8227 [Paragraph No. 85]

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regard, reliance is placed on the following judgments:

a. **Kudos Pharmaceuticals Limited and Others v. Natco Pharma Limited**[17]

b. **FMC Corporation and Another v. Best Crop Science LLP and Another**[18]

c. **Bristol-Myers Squibb Company and Ors. v. J. D. Joshi and Ors.**[19]

d. **Strix Limited Vs. Maharaja Appliances Limited**[20]

14.18. It is stated that Defendant No. 1 filed an ANDA ['Abbreviated New Drug Application'] with the US-FDA,[21] seeking permission to manufacture and sell Semaglutide injections in the US market. This led to the Plaintiff filing suit for infringement of US Patent Number 8129343 [US'343], among other patents, corresponding to the Suit Patent/IN'697 before the District Court of Delaware in March 2022.

14.19. During the pendency of the said proceedings, the Defendants withdrew their counterclaims and affirmative defences in the litigation, including their plea of invalidity and entered into a settlement agreement dated 08th October 2024 with the Plaintiff; the terms of which are confidential. The same has been acknowledged by the District Court of Delaware, USA, in its order dated 16th October 2024. And, in furtherance of the order dated 01st August 2025 passed by this Court, the terms of the aforesaid settlement agreement have been filed in a sealed cover for perusal by this Court.

14.20. After the prior patent, i.e., Genus Patent/IN'964 expired on 17th September 2024, Defendant No. 1 in December 2024 reached out to the Plaintiff to seek a license to manufacture the Semaglutide compound in

[17] 2024 SCC OnLine Del 1439 [Paragraph No. 77]
[18] 2021 SCC OnLine Del 3647 [Paragraph nos. 12.11 – 12.16]
[19] 2015 SCC OnLine Del 10109 [Paragraph nos. 82-84]
[20] 2009 SCC OnLine Del 2825 [Paragraph No. 22]

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India. Thereafter, vide email dated 25th January 2025, Defendant No. 1 forwarded the 'Draft License Agreement' for the Plaintiff's approval. The 'Draft License Agreement' has also been placed on record in a sealed cover.

14.21. The Defendants' claim that their request for a license for manufacturing Semaglutide compounds in December 2024 and their request for a Term Sheet in January 2025 were made 'without prejudice' is baseless, as no such disclaimer appears in the communications. Their actions of seeking a license after the expiry of Genus Patent/IN'964 and beginning commercial manufacture in April 2025, without challenging the Suit Patent/IN'697, show clear acknowledgement that the Suit Patent/IN'697 covers the Semaglutide compound.

14.22. Moreover, Defendant No.1's 2020 patent application filed before the Indian Patent Office with application no. 202041041229 entitled "A Process for Preparation of Semaglutide and Semapeptide" for the process of manufacturing Semaglutide compound expressly cites the US counterpart of Suit Patent/IN'697 [US8129343B2], confirming prior knowledge. This conduct is inequitable and weighs heavily against them in considering interim relief.

14.23. Despite having given up the plea of invalidity on the Patent for Semaglutide compound in the US and not receiving the consent from the Plaintiff to manufacture the Semaglutide compound in India, Defendant No. 1 commercially commenced manufacturing of the Semaglutide compound from April 2025. The said fact has also been recorded in this Court's order dated 29th May 2025.

14.24. The Defendants had not taken any steps to 'clear the way' by seeking revocation of the Suit Patent/IN'697 before undertaking commercial manufacturing. In this regard, reliance is placed on **Merck Sharp and**

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Dohme Corporation Vs. Glenmark Pharmaceuticals[22] and **E. R. Squibb and Sons, LLC Vs. Zydus Lifesciences Limited**[23]**.**

14.25. In view of the above, the Plaintiff is entitled to an order of interim injunction as prayed in the captioned application.

III. SUBMISSIONS ON BEHALF OF THE DEFENDANTS

15. Mr. Gopal Subramanium and Mr. J. Sai Deepak, learned senior counsel for the Defendants, have set up the Defendants' case as under: -

15.1. The foundation for the grant of a patent under the Patent Law is a Patent Bargain, wherein the inventor gets twenty [20] years of exclusive rights, and in return, the public gets full disclosure of the subject matter covered by the said patent[24].

This bargain ensures that, on expiry, the subject matter covered by the said patent becomes part of the state of the art, and can be freely exploited without any hindrance. The right of the public to use the teaching and knowledge of a patent upon expiry is the foundation for the grant of a patent.

PRIOR COVERAGE/CLAIMING UNDER SECTION 64(1)(a) OF THE PATENTS ACT

15.2. As per the Plaintiff's own admission in the plaint, Semaglutide compound was discovered in the year 2004[25], which coincides with the filing of the PCT[26] Application of the Genus Patent/IN'964 in the year 2004. It is stated that the said PCT Application of the Genus Patent/IN'964 also covered the Semaglutide compound.

15.3. The Semaglutide compound is merely a derivative of Example 61 compound enlisted in the Genus Patent/IN'964 and does not possess any enhanced efficacy over the said compound. Accordingly, it falls within the purview of Section 3(d) of the Act, which expressly provides that the mere

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[22] 2015 SCC OnLine Del 8227 [Paragraph No. 87]
[23] 2025 SCC OnLine Del 4975 [Paragraph Nos. 148-151]
[24] Section 53(4) of the Patents Act, 1970.
[25] At Paragraph no. '27' of the plaint.

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discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance, is not patentable.

As per the Plaintiff itself in the written submissions before the Indian Patent Office for the Genus Patent/IN'964, Example 61 demonstrates a superior half-life [35 hrs] and albumin-binding ratio 170.77, already hitting efficacy targets.

15.4. The Suit Patent/IN'697 and the Genus Patent/IN'964 both pertain to GLP-1 derivatives that comprise amino acids.

15.5. Semaglutide compound's coverage under the Genus Patent/IN'964 has not been denied by any of the Plaintiff's experts[27], who have filed their affidavits. The Plaintiff, in its rejoinder to I.A. 14076/2025, has also failed to deny the fact that the Semaglutide compound is claimed and covered under the Genus Patent/IN'964.

15.6. If the Semaglutide compound is covered under the Genus Patent/IN'964, then the principle enunciated by the Supreme Court in **Novartis AG v. Union of India** [28]**,** will apply the said principle bars a later claim to appropriate the same subject matter already claimed or covered in an earlier patent.

15.7. A comparative analysis of the claims and/or specifications reveals that the Genus Patent/IN'964 and the Suit Patent/IN'697 share an identical chemical structure; the only variation between [Example 61 as claimed in Claim 21 of] the Genus Patent/IN'964 and [Example 4 as claimed in Claim 23 of] the Suit Patent/IN'697 is the substitution of 'Aib' [2-methyl Alanine] in place of 'Ala' at the 8th position. Such substitution was already disclosed and enabled by the Genus Patent/IN'964 itself, and also formed part of the

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[26] Patent Cooperation Treaty

[27] Sam Thompson, Sir Robin Jacob and Professor Gregory L Challis

[28] (2013) 6 SCC 1 [Paragraph Nos. 118, 119 and 134]

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common general knowledge[29] as of the priority date of the Suit Patent/IN'697.

15.8. Admittedly, Example 61, along with Claim 21 of the Genus Patent/IN'964, is essentially a Semaglutide compound except for 'Ala' with 'Aib' substitution at the 8th position, which has already been structurally represented in the Genus Patent/IN'964. The advantages of substituting 'Aib' [2-methylalanine] at the 8th position have been known in the literature[30] since at least the late 1990s, which motivates, suggests, and teaches a 'person skilled in the art' to substitute 'Ala' with 'Aib' at the 8th position in a native GLP-1.

15.9. In the present case, the inventors of both the Genus Patent/IN'964 and the Suit Patent/IN'697 are the same and are therefore 'persons in the know', having complete knowledge of the invention disclosed in the Genus Patent/IN'964. Although the Patents Act does not define the terms 'genus' and 'species' patents, the Genus Patent/IN'964 specifically claims and teaches a 'person skilled in the art' that the substitution of 'Aib' at the 8th position is advantageous, which was also part of the common general knowledge.

Therefore, the real test is whether a 'person skilled in the art', and in this case, such persons in the know with full awareness of the teachings of the Genus Patent/IN'964, could have readily arrived at the Semaglutide compound based on that Genus Patent/IN'964. In this regard, reliance is placed on **F.Hoffman-La Roche AG and Another v. Natco Pharma Limited**[31], and **AstraZeneca AB and Another v. Intas Pharmaceuticals Limited** [32].

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[29] Deacon et al. (1998), Knudsen et al. (2004)
[30] ibid
[31] 2025 SCC OnLine Del 1826
[32] 2021 SCC OnLine Del 3746

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15.10. In the post-hearing written submissions[33] filed before the Patent Office for the Genus Patent/IN'964, Plaintiff has expressly admitted that the examples therein are not limited and merely illustrative.

15.11. Particularly, the Semaglutide compound is already claimed in Claim 1 of the Genus Patent/IN'964. Therefore, Defendants claim that the Suit Patent/IN'697 is not novel, as it is anticipated and previously claimed in the Genus Patent/IN'964, thereby attracting revocation under Section 64(1)(a) of the Patents Act.

15.12. Additionally, as per **F.Hoffman-La Roche AG and Anr. v. Natco Pharma Limited**[34], and **AstraZeneca AB and Another v. Intas Pharmaceuticals Limited**[35], grant of a patent does not guarantee validity, and there is no presumption of validity as per section 13(4) of the Act.

LACK OF NOVELTY AND INVENTIVE STEP UNDER SECTION 64(1)(e) AND 64(1)(f) OF THE PATENTS ACT

15.13. The Opposition Division of the European Patent Office held that in view of the wide-ranging amendments made by the Plaintiff to the PCT Application corresponding to the Suit Patent/IN'697, the priority date of Claim 1 of the European Union Species Patent corresponding to the Suit Patent/IN'697 is 20th March 2006, i.e., the date of filing the PCT Application, and not 18th March 2005.

15.14. Given that the Plaintiff itself relies on, and claims priority with the corresponding EU Patent, such a changed priority date from 18th March 2005 to 20th March 2006 will also apply to the Suit Patent/IN'697. Since Claim 23 of the Suit Patent/IN'697 is dependent on Claim 1, the shift in priority date of Claim 1 will also apply vis-à-vis Claim 23.

15.15. With this priority, the Genus Patent/IN'964 qualifies as relevant prior

[33] Dated 22nd October 2014 filed by the Plaintiff in the proceedings qua prosecution of Genus Patent.
[34] 2025 SCC OnLine Del 1826 [Paragraph Nos. 33, 36 to 43]

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art under Sections 64(1)(e) and 64(1)(f) of the Patents Act.

15.16. Once the Genus Patent/IN'964 is shown to be the relevant prior art for grounds of lack of novelty and lack of inventive step, it becomes apparent that the Suit Patent/IN'697 is invalid.

15.17. International Search Report issued by the World Intellectual Property Organisation ['WIPO'] in the PCT Application corresponding to the Suit Patent/IN'697 itself referred to the Genus Patent/IN'964 as a category "X" document, which shows that the Genus Patent/IN'964 is sufficient by itself to destroy the novelty or inventive step of the Suit Patent/IN'697. Reliance is being placed upon the judgment of a Coordinate Bench of this Court in **Boehringer Ingelheim Pharma GMBH & Co. KG v. Vee Excel Drugs and Pharmaceuticals Pvt. Ltd & Ors.**[36].

PLAINTIFF'S ADMISSION ON THE GENUS PATENT'S SCOPE IN FOREIGN JURISDICTIONS FOR SECTION 64(1)(a) OF THE PATENTS ACT

15.18. Plaintiff has claimed, and been granted PTEs, in several jurisdictions, for the Semaglutide compound in respect of patents corresponding to both the Suit Patent/IN'697 and Genus Patent/IN'964.

15.19. The Plaintiff has, across multiple jurisdictions [Australia, Japan, Korea], sought and obtained PTEs and SPCs [Bulgaria, Slovakia, Slovenia and Romania] for the Genus Patent/IN '964 in respect of Semaglutide compound. This is an admission that the Semaglutide compound falls within the scope of the claims of the Genus Patent/IN'964. Plaintiff has not only obtained PTEs for the Genus Patents/IN'964 but has also secured extensions for the species patents for the Semaglutide compound.

15.20. Furthermore, it is a settled principle of law that disclosure can be implicit/ inherent, and there is no stringent rule that it ought to be explicit in

[35] 2021 SCC OnLine Del 3746 [Paragraph No. 30]
[36] 2025 SCC OnLine Del 1889 [Paragraph Nos. 37 and 38]

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nature. Thus, if from the prior art, it can be inferred that there is disclosure, though implicit/inherent, that would be a valid ground for challenging the validity of a patent. **F. Hoffmann-La Roche AG & Anr. V. Natco Pharma Limited**[37].

15.21. The Supreme Court, as well as this Court, have relied on such admissions made by patentees in foreign jurisdictions to show vulnerability of a patent. Reliance is being placed upon the following judgments:

a. **Novartis AG v. Union of India**[38],

b. **F. Hoffmann-La Roche AG & Anr. V. Natco Pharma Limited**[39], and

c. **Bayer Healthcare LLC v. NATCO Pharma Limited**[40].

15.22. If the Semaglutide compound was treated by the Plaintiff as covered and disclosed by the Genus Patent/IN'964 in foreign jurisdictions, the Plaintiff cannot now claim that it is not covered or enabled under the same Genus Patent/IN'964. This is an incorrect and inconsistent position.

15.23. The Plaintiff has filed a single Form 27 covering both the Suit Patent/IN'697 and the Genus Patent/IN'964 in India. This practice was followed by the Plaintiff successively for three [3] years, from 2020-21 to 2022-23.

Semaglutide compound is the 'only' GLP-1 analogue, covered in Genus Patent/IN'964 and Suit Patent/IN'697, for which the Plaintiff holds an import licence in India. By clubbing both patents in a single Form 27 for the Semaglutide compound, the Plaintiff has admitted that Semaglutide is covered under both the Genus Patent/IN'964 and the Suit Patent/IN'697, which demonstrates that the Plaintiff has commercially worked both the

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[37] 2025 SCC OnLine Del 1826 [Paragraph Nos. 34 to 37]
[38] (2013) 6 SCC 1 [Paragraph Nos. 101, 102, 105, 118 and 134]
[39] 2025 SCC OnLine Del 1826 [Paragraph Nos. 44 to 58]
[40] 2025 SCC OnLine Del 3921 [Paragraph Nos. 73 and 81]

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patents in India solely through the import of the Semaglutide compound.

This conduct constitutes a clear admission and directly supports the Defendants' case that the Genus Patent/IN'964 already covers the Semaglutide compound, rendering the Suit Patent/IN'697 liable to revocation under Section 64(1)(a) of the Patents Act. In furtherance of this argument, reliance is placed on the judgment of the Coordinate Bench of this Court in **Boehringer Ingelheim Pharma GMBH & Co.KG v. Vee Excel Drugs and Pharmaceuticals Pvt. Ltd.**[41].

15.24. The Plaintiff has misrepresented the ANDA proceedings both in the Pleadings and during oral submissions.

15.25. It is stated that the Plaintiff has breached confidentiality by filing US settlement agreements and has misrepresented their legal effect, as confirmed by an Affidavit dated 06th August 2025, filed by Ms. Elaine Herrmann Blais. The Plaintiff's portrayal of the US ANDA proceedings is inaccurate; the Delaware litigation was dismissed 'without prejudice', preserving Defendant No.1's right to challenge validity elsewhere, and the settlement concerned only US patents and territory, not Indian Suit Patent/ IN'697.

15.26. Further, the Plaintiff has incorrectly presented the Draft Term Sheet as a post-settlement license request, whereas discussions began earlier and the draft was shared 'without prejudice' solely for exploratory purposes, with no admission of patent validity or enforceability.

15.27. The Plaintiff has falsely represented that it manufactures Rybelsus in India, whereas the record shows that it only holds an import licence [Form CT-18] and not the requisite manufacturing licence [Form CT-21]. This amounts to a deliberate suppression of material facts and regulatory misrepresentation in the Statement of Truth, attracting consequences under

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Section 246 of the Bharatiya Nyaya Sanhita, 2023.

15.28. The Plaintiff has not amended the incorrect pleadings, rendering the leave sought in the rejoinder to the present application meaningless. Moreover, the non-working of the patent in India must weigh against the grant of an interim injunction, as held in **Boehringer Ingelheim Pharma GmbH & Co. KG v. Vee Excel Drugs and Pharmaceuticals Pvt. Ltd**[42].

15.29. The Plaintiff has suppressed and failed to disclose material facts and documents, including the Genus Patent/IN'964, prosecution histories, International Search Report, Form 27 filings, PTEs abroad, and CDSCO approvals for Rybelsus and Wegovy, while also misrepresenting key facts. Such non-disclosure violates Rules 3 and 4 of the Delhi High Court Patent Suits Rules, 2022, and Order XI Rule 1 CPC, as has been affirmed in the following judgments:

a. **Freebit AS v. Exotic Mile Pvt. Ltd.**[43]**,**

b. **Satish Khosla v. Eli Lilly Ranbaxy Ltd and Ors.**[44], and

c. **Kishore Samrite v. State of U. P. and Ors.**[45]

In view of this suppression and settled law, the Plaintiff is disentitled to any interim or ad interim injunction.

15.30. The Defendants' product, based on the Semaglutide compound, addresses the widely prevalent condition of Type 2 Diabetes, and its lower pricing enhances public access to treatment. It was only after the Genus Patent/IN'964 expired on 17th September 2024 that the Defendants began commercial activities, such as manufacturing and preparing for the export of the Semaglutide compound. Any activities done by the Defendants before

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[41] 2023 SCC OnLine Del 1889 [Paragraph No. 56]
[42] ibid
[43] 2023 SCC OnLine Del 8213 [Paragraph Nos. 29, 30, 31, 34, 36 to 42]; 2024 SCC OnLine Del 5361 [Paragraph Nos. 7 to 9, 20, and 21]
[44] 1997 SCC OnLine Del 935 [Paragraph Nos. 15 and 16]
[45] (2013) 2 SCC 398 [Paragraph Nos. 32, 36, and 38]

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the expiry of the Genus Patent/IN'964 were done as permitted under Section 107A of the Patents Act.

15.31. Manufacturing commenced with substantial investments exceeding Rs. 1,000 crores and ongoing export activities to non-patent jurisdictions pursuant to court-recorded undertakings.

By contrast, the Plaintiff does not manufacture in India and relies solely on imports. With barely seven [7] months left until expiry of the Suit Patent/IN'697, restraining the Defendants would cause disproportionate hardship and irreparable injury, particularly if the patent is later invalidated, while any potential injury to the Plaintiff is compensable in monetary terms. Accordingly, the balance of convenience and equity strongly favours the Defendants, and an injunction would unjustly penalise lawful conduct.

15.32. It is stated that the Semaglutide compound is covered by the expired Genus Patent/IN'964, invoking the 'Gillette Defence' to argue non-infringement and prior claiming under Section 64(1)(a) of the Patents Act, as well as revocation under Sections 64(1)(f) and (k) of the Patents Act, noting common inventors and a changed priority date. The Plaintiff admitted coverage in foreign PTEs, confirming prior claiming, while reliance on post-prosecution efficacy data and EU SPCs is misplaced. Defendants disclosed all PTEs and SPCs, and even correcting an inadvertent misquote of [D1], the Suit Patent/IN'697 provides no experimental proof of technical advantage over prior art.

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IV. FINDINGS AND ANALYSIS

16. This Court has heard the learned counsels for the parties and perused the record.

17. At the outset, it is noted that on 29th May 2025, when the suit was first listed, for the purposes of the captioned interim injunction application, the Defendants made a statement that though they are manufacturing the impugned drug, and they will not sell the same in India. The Defendants further made a statement that they will sell the impugned drug through export only to countries where the Plaintiff does not hold a patent for the Semaglutide compound.

Mr. Gopal Subramanium, learned senior counsel appearing on behalf of the Defendants, has, in the conclusion of his submissions on 27th August 2025, made a statement that the Defendants will continue to abide by the statement made on 29th May 2025, and not sell the impugned drug in India. The Defendants have also filed an affidavit to this effect on 29th October 2025.

18. However, the Plaintiff has argued that the manufacturing of the impugned drug in India for exporting itself amounts to infringement of the Suit Patent/IN'697.

19. Therefore, in view of the aforesaid submission of the parties, the limited issue arising for consideration in this application is whether the Defendants should be restrained from manufacturing the impugned drug in India until the expiry of the Suit Patent/IN'697 on 26th March 2026.

20. After hearing both sides, it is clear to this Court that the factum of infringement of the Suit Patent/IN'697 is not in dispute. However, the Defendants have contended that they are not infringing the Suit

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Patent/IN'697 and are relying upon the 'Gillette Defence'[46] based on their submission that the Semaglutide compound is covered, disclosed, claimed and/or enabled in the Genus Patent/IN'964. To this effect, Defendants have raised their defence under Section 107(1)[47] of the Patents Act, challenging the validity of the Suit Patent/IN'697 primarily on the following grounds of Section 64 of the Patents Act:

i. Section 64(1)(a) of the Act
ii. Section 64(1)(e) of the Act
iii. Section 64(1)(d) of the Act
iv. Section 64(1)(f) of the Act
v. Section 64(1)(h) of the Act
vi. Section 64(1)(i) of the Act
vii. Section 64(1)(j) of the Act
viii. Section 64(1)(k) of the Act

21. However, in this application, the Defendants have only addressed arguments on the aspect of invalidity of the Suit Patent/IN'697 on the grounds under Section 64(1)(a), (e), (f) and (k) of the Patents Act.

22. At this juncture, it is also relevant to address the argument of the Plaintiff that it has been nineteen [19] years since the Suit Patent/IN'697 was granted, and the Defendants failed to file a pre-grant opposition, post-grant opposition or revocation petition in the intervening period until the Plaintiff served a cease-and-desist notice; and therefore, the Suit Patent/IN'697 is prima facie valid and any infringement thereof must be injuncted.

23. The Defendants have rebutted this argument by relying on Section

[46] Gillette Safety Razor Co. v. Anglo-American Trading Co. (1913) 30 RPC 465 at 481.

[47] 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.

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13(4)[48] of the Patents Act, which unambiguously states that there is no presumption of validity for a granted patent in India, and any challenge raised by the Defendants under Section 107(1) of the Patents Act would have to be considered by the Court even at the interim injunction stage.

24. This Court finds merit in the submissions of the Defendants. In view of Section 13(4) of the Patents Act, there is no guarantee to the validity of the patent and in case, the defendant raises a Section 107(1) defence, the Court has to examine whether the defendant has raised a credible challenge of vulnerability of the suit patent to revocation on one or more grounds envisaged in Section 64 of the Patents Act. A reference can be made in this regard to the decision by the Supreme Court in **Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries**[49]. The relevant paragraph reads as follows:

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

25. It is also a trite law that, in a patent infringement suit, where the defendant raises defences under Section 107(1) of the Patents Act, the burden is on the defendant to establish that it has successfully raised a

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[48] 13. Search for anticipation by previous publication and by prior claim.:
xxx
(4) The examination and investigations required under Section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

[49] (1979) 2 SCC 511

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credible challenge to the validity of the patent in question. In this aspect, a reference could be made to a recent decision by the Division Bench of this Court in **Mold Tek Packaging Limited v. Pronton Plast Pack Pvt. Ltd**[50]**.** The relevant paragraph is here as under:

> "44. Thus, every court which is seized with a patent infringement action has ordinarily two aspects to consider. The first aspect is whether the defendant's product does, or does not, infringe the suit patent. In case the defendant raises a Section 107 defence, the second aspect that the Court has to consider is whether the defendant has raised a credible challenge of vulnerability of the suit patent to revocation on one or more of the grounds envisaged in Section 64 of the Patents Act. The "credibility" of the challenge has to be tested on the anvil of the decisions cited *supra*."

26. In this background, now, this Court will examine each relevant ground of defence raised by the Defendants in the present case, challenging the validity of the Suit Patent/IN'697 under Section 64 of the Patents Act to examine whether the Defendants have raised a credible challenge to the validity of the Suit Patent/ IN'697.

A. <u>ISSUE OF ANTICIPATION BY PRIOR CLAIMING UNDER SECTION 64(1)(a) OF THE PATENTS ACT</u>

27. Under Section 64(1)(a) of the Patents Act, if an invention claimed in any claim of a Complete Specification has already been claimed in a valid claim of an earlier patent granted in India having an earlier priority date, the subsequently granted patent is liable to be revoked. Thus, this section essentially prevents the granting of a patent for the same subject matter twice. This position of law is also clear from the plain reading of Section 53(4)[51] of the Patents Act, which stipulates that the subject matter covered

[50] 2025 SCC OnLine Del 4883

[51] 53. Term of patent.— …
(4) Notwithstanding anything contained in any other law for the time being in force, on cessation of the patent right due to non-payment of renewal fee or on expiry of the term of the patent, the subject matter

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by the prior patent shall not be entitled to any protection on the expiry of the term of the prior patent. This embargo against double patenting is also deliberated by the Division Bench of this Court in **AstraZeneca AB and Another v. Intas Pharmaceuticals Limited**[52], while similarly adjudicating on a claim of infringement by the patentee with respect to a species patent. The Court observed that the same pharmaceutical product, i.e., DAPA, cannot be protected under two [2] patents with separate validity periods, as it would be against public interest. The relevant paragraphs of the said judgment read as under: -

> "31. The Patents Act, though protects the rights and interests of inventors, but for a limited period, whereafter the monopoly of the patentee ceases and comes to an end and the invention with respect to which patent was granted, falls in public domain i.e. open for all to practice and reap benefit of. A patent, vide Section 48 of the Act, confers a right on the patentee of a product patent, as DAPA is, to, during the life of the patent, prevent others from making, using, offering for sale, selling or importing, the new product with respect whereto patent is granted. **The life of a patent is limited, whereafter, notwithstanding the new product having been invented by the patentee, patentee no longer has exclusive right to make, use or offer for sale the same and anyone else interested can also make, use or offer for sale the said new product invented by the patentee, without any interference from the patentee. If patents with respect to the same invention can be granted more than once, successively in time, the same will negate the legislative intent of limiting the life of the patent and enable the patentee to prevent others from making, using or offering for sale, the new product invented by the patentee, till the time patentee successively keeps on obtaining patent therefo**r.
>
> .....
>
> 46. In our opinion, a single formulation as DAPA, is incapable of protection under two separate patents having separate validity period.

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covered by the said patent shall not be entitled to any protection.

[52] 2021 SCC OnLine Del 3746

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> The appellants/plaintiffs, in their pleadings, are not found to have pleaded the difference, save for pleading that DAPA was discovered by further research. From the field of the invention subject matter of the two patents being verbatim same, at this stage, it also appears that there is no enhancement of the known efficacy, within the meaning of Section 3(d) of the Act, between the product subject matter of IN 147 and the product subject matter of IN 625."
>
> [emphasis supplied]

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**[53], 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.

29. In response, the Plaintiff has contended that there is no valid claim of the Semaglutide compound in the Genus Patent/IN'964, as there is no enabling disclosure of the Semaglutide compound in the Genus

[53] (2013) 6 SCC 1[Paragraph No 118, 119 and 134]

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Patent/IN'964.

30. The factors for assessing anticipation by prior claiming under Section 64(1)(a) of the Patents Act have been listed by the Coordinate Bench of this Court in **Boehringer Ingelheim Pharma v. Vee Excel Drugs**[54] at paragraph '54'. The said factors are as follows: -

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

31. The prior patent in question is the Genus Patent/IN'964, which admittedly has an earlier priority date of 19th September 2003, vis-à-vis the Suit Patent/IN'697. Thus, there is no dispute that aforenoted factors [i] and [ii] are satisfied in the present case; however, the issue arising for consideration is as to whether the invention, i.e., Semaglutide compound claimed in the Suit Patent/IN'697, was also claimed in the Genus Patent/IN'964.

32. To appreciate the rival submissions of the parties and to determine whether the Plaintiff has claimed the Semaglutide compound in the Genus Patent/IN'964 or not, this Court deems it appropriate to take into account the following facts: -

(a) Comparison of the relevant claims made in the Genus Patent/IN'964 and the Suit Patent/IN'697.

(b) Disclosures made by the Plaintiff before the Indian Patent Office in Statutory Form 27.

(c) Disclosures made by the Plaintiff in the foreign jurisdiction for the corresponding Genus Patent/IN'964.

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COMPARISON OF THE CLAIMS IN THE GENUS PATENT/IN'964 AND THE SUIT PATENT/IN'697

33. The Plaintiff has relied upon the judgment of the Coordinate Benches of this Court in **Novartis AG and Another v. Natco Pharma Limited**[55], **Kudos Pharmaceuticals Limited and Others v. Natco Pharma Limited**[56] and **FMC Corporation and Another v. Best Crop Science LLP and Another**[57] to contend that the challenge on the basis of prior claiming under Section 64(1)(a) of the Patents Act can only be upheld if there is an enabling disclosure in the genus patent. The Plaintiff has contended that specific compounds have been enlisted under Claim 18 and Claim 21 of the Genus Patent/IN'964, and it is these compounds alone that have been claimed under the Genus Patent/IN'964. The Plaintiff contends that since the Semaglutide compound is not listed as a specific compound under Claim 18 and Claim 21, the Semaglutide compound was not claimed in the Genus Patent/IN'964. The Plaintiff contends that the Defendants must demonstrate that the Semaglutide compound with the same properties was disclosed in the Genus Patent/IN'964 to succeed in setting up a credible challenge on the ground of anticipation by prior claiming under Section 64(1)(a) of the Patents Act. Since the Plaintiff has cited the aforesaid judgments for the same legal proposition, this Court deems it appropriate to refer to paragraphs '137' to '140' of **Novartis AG and Another v. Natco Pharma Limited**[58], as it sets out the proposition relied upon by the Plaintiff succinctly: -

> "137. Mr. Sai Deepak, for Natco, submitted, relying on the judgment of the Supreme Court in ***Novartis-I***, that there is no conceptual difference between "coverage" and "disclosure" and that, once

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[54] 2023 SCC OnLine Del 1889
[55] 2023 SCC OnLine Del 106 [Paragraph Nos. 137 to 141 and 153 to 156]
[56] 2024 SCC OnLine 1439 [Paragraph Nos. 47 to 49 and 57 to 63]
[57] 2021 SCC OnLine Del 3647 [Paragraph Nos. 11.15 to 11.19, particularly, para nos. 11.18.6 to 11.18.10 & 11.19, also 12.15-12.21]
[58] 2023 SCC OnLine Del 106

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Novartis had admitted coverage of the claims in the suit patent by the cited prior art, *ipso facto* the claims also stood disclosed thereby. Disclosure of the claims in prior art, he submits, renders the claims vulnerable to revocation on the ground anticipation by prior claiming as well as anticipation by prior disclosure.

138. I have already noted that Claim 1 and Claims 4 and 5 (Ceritinib) in the suit patent have not been claimed in any prior art. Sans a bare submission to that effect, no substantial material has been cited, by Natco, to indicate to the contrary.

139. The submission that the Supreme Court has, in ***Novartis-I***, equated "coverage" and "disclosure" has been addressed, at length, by this Court, in its decisions in ***Novartis-II*** and in F.*M.C. Corporation*. *Novartis-I* does not equate "coverage" with "disclosure". It merely holds that a "wide gap" between coverage of a patent, and what is disclosed therein, was not to be encourage, as it would enable circumnavigation of prior art, artfully handled. **What matters, at all times, is disclosure. If the claim in a specie patent is disclosed in the genus patent, the specie patent stands invalidated thereby. Disclosure must be enabling; it must enable a person skilled in the art to reach the invention claimed in the specie patent *from the teachings in the genus patent.*** I venture to state that, where this end is achieved before the publication of the specie patent, and before the invention claimed in the specie patent is made known to the public, it would be a far easier task for the claimant contesting the validity of the specie patent to so assert. Where, however, the claim to invalidity is made *after* the claim in the specie patent has been made known to the public, the challenger becomes a person armed with foreknowledge of the specie patent, so that the task of establishing that the derivation of the claim in the specie patent, from the claim in the genus patent, is actually guided by the teachings in the genus patent, and not by hindsight analysis and cherry-picking of substituents from the suggestion in the genus patent, becomes far more arduous. Where the genus patent is a Markush moiety, the difficulty of the task multiplies manifold. Thus does the "disclosure" in the genus patent attain significance.

140. Mr. Hemant Singh has not contested the "coverage", of Claim 1

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> in the suit patent, of indeed even of Ceritinib, by the cited prior art. In doing so, he submits that every molecule of the millions which, theoretically, would result, by effecting the substitutions suggested in the Markush prior art at the suggested sites in the Markush moiety, are "covered" thereby. Theoretically, the synthesis of any such molecule, and its dissemination, without a license from the holder of the prior art patent, would infringe prior art. That the claim in the suit patent, thus empirically seen, stands "covered" by and, in that sense, even infringes, prior art, he submits, does not indicate that it is *disclosed* in prior art. No person skilled in the art can, without hindsight analysis and cherry-picking of suggested substitutions, reach the suit patent from the cited prior art. Ergo, he submits, the prior art does not contain the requisite *teaching*, or *disclosure*, as would *enable* the person skilled in the art to reach the specie patent. The specie patent, i.e. the suit patent in the present case, is not, therefore, anticipated, or obvious, from the cited prior art."
>
> [emphasis supplied]

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.

35. The Plaintiff herein has raised identical arguments as were raised in the aforesaid judgment of **Novartis AG and Another v. Natco Pharma Limited**[59]. The Plaintiff, at paragraph '16' of its rejoinder to I.A. 14076/2025, has pleaded that the number of compound structures possible within the Markush Claim 1 of Genus Patent/IN'964 herein runs into several billions of compounds. It is stated that Genus Patent/IN'964 provided

[59] Ibid.

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specific exemplification of 66 compounds only. It is stated that the Semaglutide compound is neither exemplified nor disclosed in Genus Patent/IN'964.

36. The Defendants have contended that Genus Patent/IN'964 contains claims which enable a 'person skilled in the art' to reach the invention of the Semaglutide compound claimed in the Suit Patent/IN'697. The Defendants have set out their pleadings in this regard at paragraphs '23' to '30' of their reply to the captioned application. The Defendants have referred to the teachings in Claim(s) 1, 16, 18 and 21 along with the examples enlisted therein of the Genus Patent/IN'964 and more specifically Example 61 compound to contend that there is a direct enablement for 'person skilled in the art' to reach the invention of the Semaglutide compound claimed in the Suit Patent/IN'697.

37. It is relevant to note here that the Plaintiff, in its rejoinder, has extensively relied upon a research article by Lau [2015][60]. In this article, the compound listed as Example 61[61] of the Genus Patent/IN'964 has been referred to as the Alanine [Ala] version of the Semaglutide compound, or Ala Semaglutide compound. As discussed later, the Plaintiff has admitted that the only difference between the said compound at Example 61[62] of the Genus Patent/IN'964, with the Semaglutide compound of the Suit Patent/IN'697 is 'Aib' in place of 'Ala' at the 8th position.

The reference to the Example 61 compound as the Ala Semaglutide compound in the research article by Lau [2015] evidences the similarity of the chemical structure of the Example 61 compound with the Semaglutide compound of Suit Patent/IN 697. For the purpose of discussion under this

[60] Lau, J et al. Discovery of the Once-Weekly Glucagon-Like Peptide-1 (GLP-1) analogue semaglutide. Journal of Medicinal Chemistry, 58(18), 7370-7380.
[61] As claimed in claim 21
[62] As claimed in claim 21

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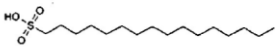
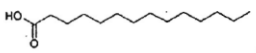
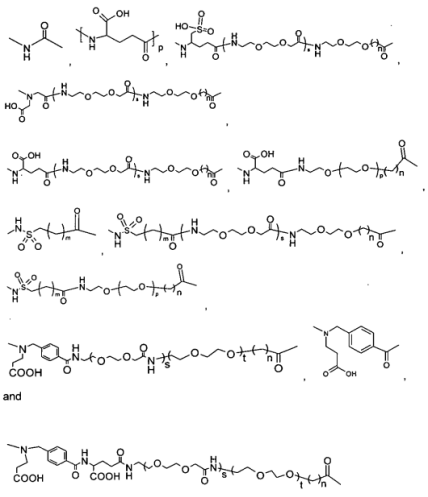
section of the judgment, Example 61 compound of Genus Patent/IN'964 will be referred to as '**Ala Semaglutide compound/Example 61**'.

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. For this purpose, a claim-to-claim comparison is given below:

Relevant Claims of Genus Patent/IN'964	**Relevant Claims of Suit Patent/IN'697 (species patent)**
We claim: 1. A compound which has the formula (I): A—W—B—Y—therapeutic polypeptide (I) wherein: the therapeutic polypeptide is a GLP-1 peptide comprising the amino acid sequence of formula (V): Xaa_7-Xaa_8-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Xaa_{18}-Tyr-Leu-Glu-Xaa_{22}-Xaa_{23}-Ala-Ala-Xaa_{26}-Glu-Phe-Ile-Xaa_{30}-Trp-Leu-Val-Xaa_{34}-Xaa_{35}-Xaa_{36}-Xaa_{37}-Xaa_{38} Formula (V) (SEQ ID No: 3) wherein Xaa_7 is L-histidine, D-histidine, desamino-histidine, 2-amino-histidine, β-hydroxy-histidine, homohistidine, N^{α}-acetyl-histidine, α-fluoromethyl-histidine, α-methyl-histidine, 3-pyridylalanine, 2-pyridylalanine or 4-pyridylalanine; Xaa_8 is Ala, Gly, Val, Leu, Ile, Lys, Aib, (1-aminocyclopropyl) carboxylic acid, (1-aminocyclobutyl) carboxylic acid, (1-aminocyclopentyl) carboxylic acid, (1-aminocyclohexyl) carboxylic acid, (1-aminocycloheptyl) carboxylic acid, or (1-aminocyclooctyl) carboxylic acid; Xaa_{18} is Ser, Lys or Arg; Xaa_{22} is Gly, Glu or Aib; Xaa_{23} is Gln, Glu, Lys or Arg; Xaa_{26} is Lys, Glu or Arg; Xaa_{30} is Ala, Glu or Arg; Xaa_{34} is Lys, Glu or Arg; Xaa_{35} is Gly or Aib; Xaa_{36} is Arg or Lys; Xaa_{37} is Gly, Ala, Glu or Lys; Xaa_{38} is Lys, amide or is absent; A is an albumin binding residue selected from the group consisting of:  	1. A GLP-1 analog having at least one non-proteogenic amino acid residue in positions 7 and/or 8 relative to the sequence GLP-1(7-37), which is acylated with a moiety B-U' to the lysine residue in position 26, wherein (i) B-U' comprises at least two acidic groups one of which is attached terminally; (ii) U' is selected from  and Wherein: m is 0, 1, 2, 3, 4, 5, or 6, n is 1, 2, or 3, s is 0, 1, 2, or 3, t is 0, 1, 2, 3, or 4, p is 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17,18, 19, 20, 21, 22, or 23; and (iii) B is an acidic group selected from

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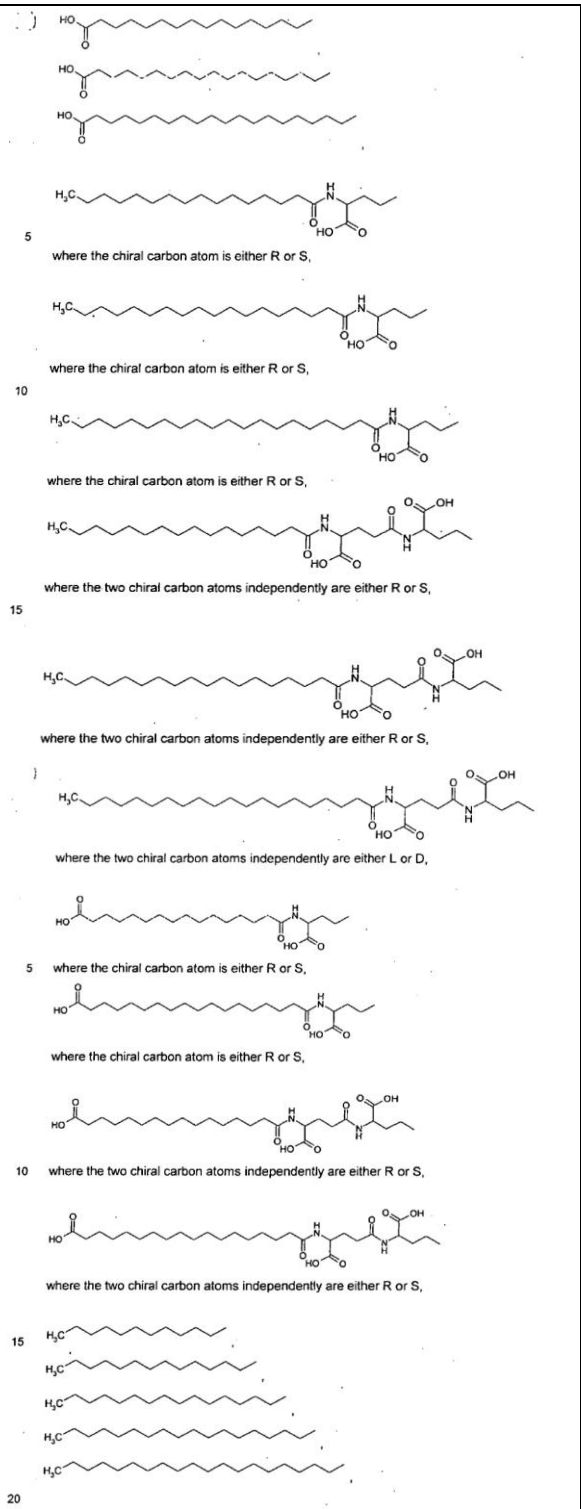


where the chiral carbon atom is either R or S,

where the chiral carbon atom is either R or S,

where the chiral carbon atom is either R or S,

where the two chiral carbon atoms independently are either R or S,

where the two chiral carbon atoms independently are either R or S,

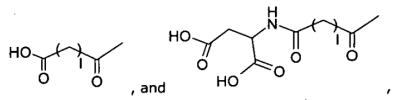
where the two chiral carbon atoms independently are either L or D,

where the chiral carbon atom is either R or S,

where the chiral carbon atom is either R or S,

where the two chiral carbon atoms independently are either R or S,

where the two chiral carbon atoms independently are either R or S,



wherein I is 12, 13, 14, 15, 16, 17, 18, 19, or 20.

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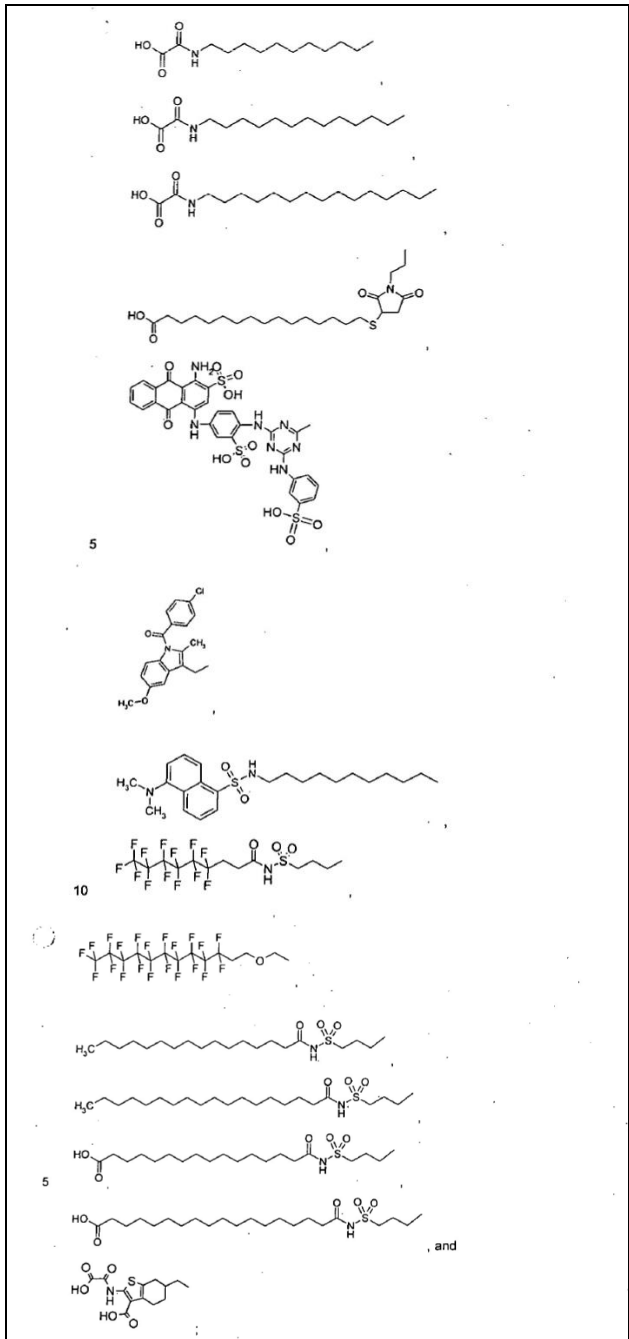

B is -(CH$_2$)$_r$-O-[(CH$_2$)$_n$-O]$_m$-(CH$_2$)$_o$-[C(O)NH-(CH$_2$)$_r$-O-[(CH$_2$)$_n$-O]$_m$-(CH$_2$)$_p$]$_q$-,
where l, m, n, and p independently are 1-5, and q is 0-5,

Y is a chemical group linking B and the therapeutic polypeptide, selected from the group consisting of -C(O)NH-, -NHC(O)-, -C(O)NHCH$_2$-, -CH$_2$NHC(O)-, -OC(O)NH -, -NHC(O)O-, -C(O)NHCH$_2$-, CH$_2$NHC(O)-, -C(O)CH$_2$-, -CH$_2$C(O)-, -C(O)CH=CH-, -CH=CHC(O)-, -(CH$_2$)$_s$-, -C(O)-, -C(O)O-, -OC(O)-, -NHC(O)- and –C(O)NH-, wherein s is 0 or 1, and

W is a chemical group linking A and B, selected from the group consisting of -C(O)NH-, -NHC(O)-, -C(O)NHCH$_2$-, -CH$_2$NHC(O)-, -OC(O)NH -, -NHC(O)O-, -C(O)CH$_2$-, -CH$_2$C(O)-, -C(O)CH=CH-, -CH=CHC(O)-, -(CH$_2$)$_s$-, -C(O)-, -C(O)O-, -OC(O)-, -NHC(O)- and –C(O)NH-, wherein s is 0 or 1;

or a pharmaceutically acceptable salt or prodrug thereof.

16. A compound as claimed in any one of the previous claims, wherein said GLP-1 peptide comprises an Aib residue in position 8.	16. A GLP-1 analogue according to claim 15, wherein said GLP-1 analogue comprises Aib^{8}.

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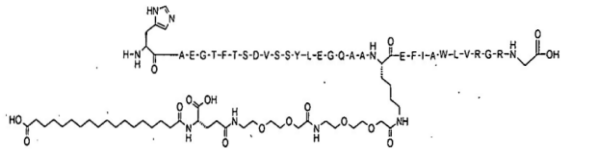
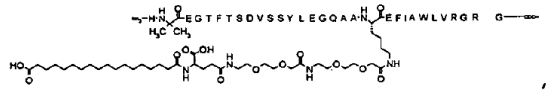
21. A compound as claimed in any one of the previous claims, wherein said compound is selected from the group consisting of: [multiple GLP-1 analogues are specifically claimed here, for brevity, only the relevant compound (corresponding to **Example 61**) is listed here]  $N^{\varepsilon 26}$-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Arg^{34}]GLP-1-(7-37)-OH	23. A compound according to any one of the preceding claims, which is selected from [multiple GLP-1 analogues are specifically claimed here, for brevity, only the relevant compound corresponding to **Example 4** i.e., Semaglutide is listed here]  N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib^{8},Arg^{34}]GLP-1-(7-37)peptide,

39. According to the Plaintiff, the novel features of the Suit Patent/IN'697, i.e., the Semaglutide compound, which distinguishes the said compound from the known compounds and more specifically the Ala Semaglutide compound/Example 61 disclosed in the Genus Patent/IN'964, as pleaded in its rejoinder, are as follows:

> "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 α-aminoisobutyric acid (Aib), a nonproteogenic amino acid;**
>
> **10.2. substitution of the amino acid lysine (Lys) with arginine (Arg) at position 34; and**
>
> **10.3. Lys at position 26 acylated on its side chain with a moiety that comprises two "OEG" groups, a γ-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 supplied]

40. The Defendants have contended that these features enlisted by the Plaintiff are already exemplified in the Ala Semaglutide compound/Example

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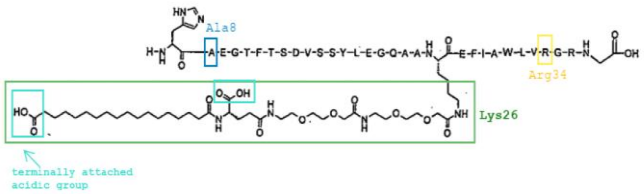
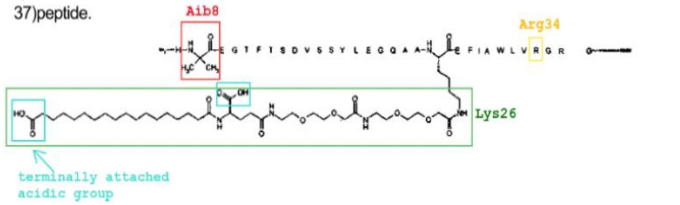
61. The Plaintiff has also compared the structure of the Semaglutide compound, as claimed in Claim 23 of the Suit Patent/IN'697, with the Ala Semaglutide compound/Example 61 of the Genus Patent/IN'964. The comparison is set out below:

Name of Compound	**Structural Similarities**	**Difference between the Semaglutide compound and the Ala Semaglutide compound**
Ala Semaglutide compound	**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  	- 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:

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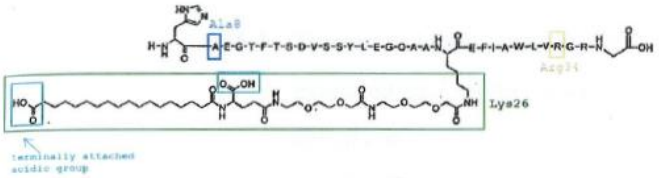
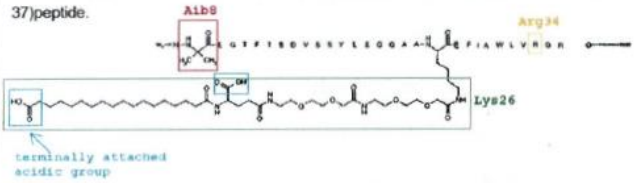
Example 61 of IN '964	Difference between Example 61 of IN '964 and Example 4 of IN '697 (Semaglutide):
Example 61 $N^{\varepsilon 26}$-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Arg^{34}]GLP-1-(7-37)-OH  	Semaglutide contains 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 the resulting compound. Any such change can also raise the risk of 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.
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.  	

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

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Plaintiff had already claimed a compound[63] 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 [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

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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

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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.

DISCLOSURES MADE BY THE PLAINTIFF BEFORE THE INDIAN PATENT OFFICE IN STATUTORY FORM 27

47. Now, a reference may be made to Form 27 filed by the Plaintiff before the Indian Patent Office. This form is filed by a patentee in terms of Section 146 of the Patents Act, read with Rule 131 of the Patent Rules, 2003. In these forms, the patentee provides periodical statements demonstrating that the patented invention has worked commercially in India.

48. The Defendants have submitted that the Plaintiff herein has filed a common Form 27 with the Indian Patent Office for the Suit Patent/IN'697 and the Genus Patent/IN'964 for the years 2020-2023. In this regard, the Defendants have also placed on record the copies of Form 27 filed by the Plaintiff for the years 2014 to 2023 and contended that the filing of a common Form 27 illustrates the understanding of the Plaintiff that the Semaglutide compound is claimed in the Suit Patent/IN'697 and the Genus Patent/IN'964.

49. The Plaintiff has not disputed the filing of the common Form 27 for the years 2020-23. It has, however, been stated that filing of a common Form 27 is permissible for related patents. Therefore, the common Form 27 filed for both Genus Patent/IN'964 and the Suit Patent/IN'697 for the identical product is permissible and does not amount to admission of the said compound being disclosed in the Genus Patent/IN'964.

50. This Court deems it appropriate to reproduce the specimen of the statutory Form 27 as well as illustratively the Form 27 filed by the Plaintiff for the year 2023 and a tabular representation of the declarations made by the Plaintiff to the Indian Patent Office in the Form 27 for the Genus Patent/IN'964 and the Suit Patent/IN'697. The statutory Form 27, as well as

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the Form 27 filed by the Plaintiff for the year 2021-22 and tabular representation for the period 2015-2023 are as under: -

(i) SPECIMEN STATUTORY FORM 27

FORM 27
THE PATENTS ACT, 1970
(39 of 1970)
AND
THE PATENTS RULES, 2003
No Fee
STATEMENT REGARDING THE WORKING OF PATENTED INVENTION(S) ON A COMMERCIALSCALE IN INDIA
[*See* section 146(2) and rule 131(1)]

1. Insert name, address, nationality, patent number(s).	I/ We, the Patentee(s)/ Licensee ....., in respect of patent number(s)....., furnish this statement, (Explanation: One form may be filed in respect of multiple patents, provided all of them are related patents and are granted to the same patentee(s)).
2. State the financial year to which the statement relates.	in respect of the financial year .....
3. Worked / not worked. Please state whether each patent in respect of which this form is being filed is worked or not worked.	Patent Number(s) | Worked [Tick (✓) if applicable] | Not worked [Tick (✓) if applicable] | | | | | |
4. If not worked, please tick the appropriate reasons	☐ Patented Invention is under development/ commercial trial ☐ Patented Invention is under Review/approval with Regulatory authorities ☐ Exploring commercial licensing ☐ Any other, may specify:
5. Whether the patent is available for licensing	☐ YES ☐ NO In case of YES, would you be interested in receiving communications from any person interested in seeking a license. If so, kindly provide contact details as below: Email address: ..... Contact Number: .....
	The facts and matters stated above are true to the best of my/ our knowledge, information and belief. Dated this ..... day of ..... 20.....
6. To be signed by Patentee(s) / Licensee / Authorised Agent furnishing the statement.	Signature(s) ..... To The Controller of Patents, The Patent Office, at .....

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(ii) FORM 27 FILED BY THE PLAINTIFF FOR THE YEAR 2021-2023

FORM 27
THE PATENTS ACT, 1970 (39 of 1970)
AND
THE PATENTS RULES, 2003

STATEMENT REGARDING THE WORKING OF PATENTED INVENTION(S) ON A COMMERCIAL SCALE IN INDIA
[*See* section 146(2) and rule 131(1)]

<table>
<tr><td>1. Insert name, address, nationality, patent number(s).</td><td colspan="3">~~I~~/We, the Patentee(s)~~/Licensee~~ Novo Nordisk A/S, a corporation organized and existing under the Laws of Denmark, of Novo Allé, DK-2880, Bagsværd, Denmark, in respect of patent number(s) 275964, 262697, 299408, 338268, 338308, 332406, 325669 furnish this statement,</td></tr>
<tr><td>2. State the financial year to which the statement relates.</td><td colspan="3">in respect of the financial year 2021-2022</td></tr>
<tr><td rowspan="8">3. Worked/not worked.
Please state whether each patent in respect of which this form is being filed is worked or not worked.</td><td>Patent Number(s)</td><td>Worked [Tick (✓) if applicable]</td><td>Not worked [Tick (✓) if applicable]</td></tr>
<tr><td>275964</td><td>✓</td><td></td></tr>
<tr><td>262697</td><td>✓</td><td></td></tr>
<tr><td>299408</td><td>✓</td><td></td></tr>
<tr><td>338268</td><td>✓</td><td></td></tr>
<tr><td>338308</td><td>✓</td><td></td></tr>
<tr><td>332406</td><td>✓</td><td></td></tr>
<tr><td>325669</td><td>✓</td><td></td></tr>
<tr><td rowspan="2">4. If worked.</td><td colspan="3">(a) Approximate revenue/value accrued in India to the patentee(s)/licensee furnishing the statement from patent number(s) where the working is through:</td></tr>
<tr><td colspan="2">(1) Manufacturing in India - NA</td><td>(2) Importing into India - Approx. 36 Crores (INR)</td></tr>
<tr><td></td><td colspan="3">(b) Brief in respect of (a) above - NA</td></tr>
</table>

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FORM 27
THE PATENTS ACT, 1970 (39 of 1970)
AND
THE PATENTS RULES, 2003

STATEMENT REGARDING THE WORKING OF PATENTED INVENTION(S) ON A COMMERCIAL SCALE IN INDIA
[See section 146(2) and rule 131(1)]

1. Insert name, address, nationality, patent number(s).	~~I~~/We, the Patentee(s)/~~Licensee~~ Novo Nordisk A/S a corporation organized and existing under the Laws of Denmark, of Novo Alle 1, 2880, Bagsvaerd, Denmark , in respect of patent number(s) **275964, 262697, 299408, 338268, 424195, 338308, 332406, 325669** furnish this statement,		
2. State the financial year to which the statement relates.	in respect of the financial year **2022-2023**		
3. Worked/not worked. Please state whether each patent in respect of which this form is being filed is worked or not worked.	Patent Number(s)	Worked [Tick (✓) if applicable]	Not worked [Tick (✓) if applicable]
	275964		
	262697		
	299408		
	338268		
	424195		
	338308		
	332406		
	325669		
4. If worked.	(a) Approximate revenue/value accrued in India to the patentee(s)/licensee furnishing the statement from patent number(s) where the working is through:		
	(1) Manufacturing in India ..... (INR) -	(2) Importing into India **Approx. 147 Crores (INR)**	
	(b) Brief in respect of (a) above- **NA**		

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(iii) TABULAR REPRESENTATION OF THE DECLARATION MADE BY THE PLAINTIFF IN FORM 27

Date	IN 262697 [Suit Patent]	IN 275964 [Prior Art/Genus Patent], IN 262697 [Suit Patent]	IN 275964 [Prior Art/Genus Patent]
25.03.2015	Studies with semaglutide are underway, and marketing will be taken up in due course. For the time being, the patentee expects to be able to market semaglutide in India as of 2020.		
28.02.2017	Studies with the new drug are underway, and marketing will be taken up in due course. For the time being, the patentee expects to be able to market in India as of 2019.		
21.03.2017			**Studies with the new drug are underway, and marketing will be taken up in due course. For the time being, the patentee expects to be able to market in India as of 2019.**
19.03.2018	Drug has not yet received an approval from drug regulatory authority in India.		

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20.03.2018			**Drug has not yet received an approval from drug regulatory authority in India.**
08.03.2019	Drug has not yet received an approval from the drug regulatory authority in India		**Drug has not yet received an approval from the drug regulatory authority in India**
18.03.2020	Drug has not yet received a regulatory approval from the regulatory authorities in India.		**Drug has not yet received a regulatory approval from the regulatory authorities in India.**
	w.e.f. 2021-22, the Plaintiff started filing common Form-27 for both the Genus Patent IN'964 and the Suit Patent IN'697 and it made the following declaration for the information to the filed with respect to row no. 4 of Form 27.		
16.09.2021		Patentee is in the process of assessing the commercial viability of patented product in India.	
06.09.2022		Worked (importing to India for **Approx. 36 Crores (INR))**	
14.09.2023		Importing into India **Approx. 147 Crores (INR)**	

51. It is not in dispute that the declaration under Form 27 filed by the Plaintiff for the period 2021-22 and 2022-23 with respect to imports pertains

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solely to the drugs containing the Semaglutide compound.

52. The Plaintiff, at paragraph '36' of its rejoinder to the captioned application, has categorically asserted that the compounds exemplified in Genus Patent/IN'964 were never developed as a therapeutic drug. In its written submissions, at paragraph '2.1', the Plaintiff has stated that none of the compounds of Genus Patent/IN'964 have been developed and approved as a drug for the treatment of Type 2 Diabetes or Obesity.

53. However, a perusal of Form 27 for the year 2021-22 shows that the Plaintiff has categorically declared to the Indian Patent Office that Genus Patent/IN'964 has been commercially worked in India and that a turnover of INR 36 crores has been achieved from the sale of drugs. Also, for Form 27 filed for the year 2022-23, the Plaintiff has declared that Genus Patent/IN'964 has worked out in India and that it has a turnover of INR 147 crores from the drugs sold.

54. The Plaintiff has not disputed that the declaration filed in Form 27 pertains only to the pharmaceutical product containing the Semaglutide compound. The Plaintiff, at paragraph '25.4' of its rejoinder, has stated that, since Form 27 allows the patentees to file a single working statement for related patents, the filing of a common Form 27 cannot lead to any adverse inference.

55. In the considered opinion of this Court, the pleading of the Plaintiff at paragraph '25.4' of the rejoinder fails to explain the basis of the declaration made in Form 27 vis-à-vis the Genus Patent/IN'964 as per Section 146 of the Patents Act. The said Forms for the years 2021-22 and 2022-23 repeatedly make a declaration to the Indian Patent Office that the Genus Patent/IN'964 has been 'commercially worked' in India, and the pharmaceutical product based on which declaration has been made is admittedly the compound of Semaglutide. In the considered opinion of this

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Court, this filing of Form 27 is an acknowledgement by the Plaintiff that the Semaglutide compound is claimed and disclosed in the Genus Patent/IN'964 as it is also evident from the claim-to-claim comparison above.

56. Pertinently, it is noted that in the Form 27 for the preceding years 2017, 2018, 2019 and 2020 for the Genus Patent/IN'964, the Plaintiff at serial [1][a] declared that the drug has not received approval from the Drug Regulatory Authority in India and offered this as a justification for the non-working of the Genus Patent/IN'964.

57. The Plaintiff thus continuously, from 2016 to 2021, represented to the Indian Patent Office that the invention, Genus Patent/IN'964, was being worked and never disclosed, and/or asserted that no drug was developed for commercial use from the compounds disclosed therein. Further, the Plaintiff subsequently, for the years 2021-22 and 2022-23, categorically represented to the Indian Patent Office that the Genus Patent/IN'964 has indeed worked and also made a declaration of the commercial revenues from the Genus Patent/IN'964. The Plaintiff is bound by the said disclosures made before the Indian Patent Office. At this prima facie stage, this Court is of the considered opinion that the stand taken by the Plaintiff in its rejoinder is a mere afterthought.

58. A Coordinate Bench of this Court in **Boehringer Ingelheim Pharma v. Vee Excel Drugs**[64] has held that the declaration of commercial working of the invention made by the patentee in Form 27 before the Indian Patent Office is binding on the said patentee as an admission that the compound is claimed/covered by the patent in which the form has been filed.

59. The Plaintiff's stand in the rejoinder that no pharmaceutical product came out from the invention claimed in the Genus Patent/IN'964 is, however, not the stand taken before the Indian Patent Office in Genus

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Patent/IN'964 in the Form 27, and it is noted above that the representation is to the contrary by positive assertion. For instance, in the standalone Form 27 filed for the Genus Patent/IN'964 for the years 2018 to 2020, it was specifically declared that the drug has not received regulatory approval from the authority in India. This was preceded by Form 27 filed in 2017, which stated that studies for the new drug are underway and are expected to be launched in India in 2019. The subsequent Form 27 filed for the years 2021, 2022 and 2023 have to be read in the aforesaid context. Thus, the Plaintiff repeatedly represented to the Indian Patent Office that the Genus Patent/IN'964 had been worked and that a pharmaceutical drug had resulted therefrom.

The submission of the Plaintiff that the Genus Patent/IN'964 and the Suit Patent/IN'697 are 'related patents' and therefore, a common Form 27 was filed as permissible under the Rules is also misleading. The Plaintiff in Form 27 for the years 2021-22 at row nos. 3 and 4, which requires the patentee to declare if the patent has worked or not, has categorically declared and represented vis-à-vis Genus Patent/IN'964 that the said patent has worked. These declarations filed by the Plaintiff before the Indian Patent Office, therefore, reflect its own understanding that the Semaglutide compound is disclosed in the Genus Patent/IN'964.

DECLARATIONS MADE BY THE PLAINTIFF IN FOREIGN JURISDICTIONS FOR THE CORRESPONDING GENUS PATENT/IN'964

60. The Defendants have placed on record the PTEs applied by the Plaintiff for the corresponding Genus Patent/IN'964 in the countries Australia, Japan and South Korea. The Defendants have also placed on record the SPCs applied for by the Plaintiff in Bulgaria, Slovakia, Slovenia

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and Romania for the EU Genus Patent/IN'964. The Defendants have contended that in the PTE applications filed by the Plaintiff in all the aforesaid countries for the Genus Patent, the Plaintiffs have sought the extension with specific reference to the pharmaceutical product containing the Semaglutide compound. The Defendants have contended that the claims in the Genus Patent in each of the aforesaid countries are identical in all material aspects to the Genus Patent/IN'964 granted in India. It is stated that the aforesaid facts constitute an admission of the Plaintiff that the Semaglutide compound falls within the scope of the claims of the Genus Patent/IN'964.

61. The Defendants have relied upon the judgment of the Supreme Court in **Novartis AG v. Union of India**[65], which reads as under: -

> **"**101. After the grant of drug approval for Gleevec, on 3-7-2001, the appellant made a patent term extension application for the Zimmermann Patent (US Patent No. 5,521,184) under 35 U.S.C. § 156(*g*)(1)(B), for extending the term of the patent for the time taken in the regulatory review for Gleevec. This application leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for drug approval as covered by the Zimmermann Patent. In Column 4 of the application, it was stated that the sole active ingredient in Gleevec is Imatinib Mesylate. Further, it was stated that Imatinib, or any salt thereof, including Imatinib Mesylate, had not previously been approved for commercial marketing under the Federal Food, Drug and Cosmetic Act prior to the approval of NDA # 21-235. In Column 9 of the application, it was stated as under:
>
> > *"(9) Statement showing how the claims of the patent for which extension is sought cover the approved product:*
> >
> > The operative claims in question are Claims 1-5, 10-13, and 21-23. Each of Claims 1-5, 10-13 and 23 claim a compound or compounds which include the approved product, *Imatinib Mesylate*. Claim 21 claims a composition containing a compound or compounds which include the approved product, *Imatinib Mesylate*. Claim 22 claims a method of treating tumors in warm-blooded animals with a compound

[65] (2013) 6 SCC 1[Paragraph Nos. 101, 102, 105]

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> or compounds which include the approved product, *Imatinib Mesylate*."
>
> (emphasis supplied)
>
> 102. The application was accepted and the term of the patent, which was due to expire on 28-5-2013, was extended for the period of 586 days.
>
> .....
>
> 105. From the above discussion it would be clear that the drug Gleevec directly emanates from the Zimmermann Patent and comes to the market for commercial sale. Since the grant of the Zimmermann Patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann Patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann Patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in UK on the basis of the Zimmermann Patent. Not only the appellant but the US Board of Patent Appeals, in its judgment granting patent for beta crystalline form of Imatinib Mesylate, proceeded on the basis that though the beta crystalline form might not have been covered by the Zimmermann Patent, the Zimmermann Patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological compositions for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the US Board of Patent Appeals, in the case of the appellant itself, on the very same issue that is now under consideration. The appellant is, therefore, fully bound by the finding and cannot be heard to take any contrary plea."

62. The Defendants have also relied upon the judgment of the Coordinate Bench of this Court in **Bayer Healthcare LLC v. NATCO Pharma Limited**[66], wherein the plaintiff in the said suit had similarly made admissions in its PTE applications with respect to the coverage of the pharmaceutical product in the genus patent before the foreign authorities and the Court held that the said admissions were relevant for determining

[66] 2023 SCC OnLine Del 3921 [Paragraph Nos. 73 to 81]

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credible challenge at the interlocutory stage.

63. The Defendants herein have asserted that the claims in the Genus Patent in Australia, Japan, Korea and Europe are identical to the Genus Patent/IN'964. The Defendants have asserted that Plaintiff, in its claims for PTEs and SPCs vis-à-vis the Genus Patent/IN'964, respectively, in these foreign jurisdictions, has asserted that the pharmaceutical drug made from the invention [which is a subject matter of the said Genus Patent/IN'964, is/contains Semaglutide compound]. The Defendants have placed on record the relevant documents which substantiate this plea, and the same have not been disputed by the Plaintiff.

64. The Plaintiff, at paragraphs '25.1', '25.2' and '25.3' of its rejoinder to the captioned application, has stated that the PTE applications in Australia, Japan and South Korea, as well as SPCs in Europe, are not an admission that the Genus Patent/IN'964 discloses the Semaglutide compound. The Plaintiff has contended that the Patent laws in India differ from those in the said countries and that there are no provisions for the grant of PTE or SPC in India; therefore, the jurisprudence governing the grant of PTE or SPC in foreign jurisdictions is distinct.

65. The Plaintiff contended that it has been granted patent protection for the species patent containing the Semaglutide compound in Australia, South Korea and Japan. It also contended that the correct interpretation of these PTEs and SPCs is that they are granted on account of prior coverage or other country-specific requirements, but these extensions do not amount to prior claiming in the Genus Patent/IN'964.

66. As noted above, the Plaintiff does not dispute the submission of the Defendants that the claims in the corresponding Genus Patent granted in Australia, Japan, South Korea and the EU are identical with the Genus Patent/IN'964. It further does not dispute that Plaintiff has sought PTE and

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SPC respectively in the aforesaid countries by declaring that the pharmaceutical product worked under the said invention is the Semaglutide compound. The aforesaid statement of fact made by the Plaintiff in those foreign jurisdictions corroborates the stand already taken by the Plaintiff in the Form 27 filed by it before the Indian Patent Office. The Plaintiff has thus consistently taken the stand in all jurisdictions that the pharmaceutical product commercially worked from the Genus Patent/IN'964 is Semaglutide compound.

67. The submission of the Plaintiff that laws governing the grant of PTE and SPC in these jurisdictions are distinct from India, in the considered opinion of this Court, has no effect on the statement of fact made by the Plaintiff vis-à-vis the Semaglutide compound being an invention derived from the Genus Patent/IN'964 in the foreign jurisdictions.

68. The aforesaid declaration made by the Plaintiff in Form 27 before the Indian Patent Office and patent offices in foreign jurisdictions, therefore, is evidence of the fact acknowledged by the Plaintiff that the Semaglutide compound is the invention claimed in the Genus Patent/IN'964. The Plaintiff is bound by its declarations made to patent offices in India and abroad in light of the law settled in **Novartis AG v. Union of India**[67].

69. Thus, in view of the aforesaid findings on the enabling disclosure of the Semaglutide compound in the claims of Genus Patent/IN'964 as well as the declarations made by the Plaintiff admitting this fact before the patent offices in India and abroad, this Court is of the considered opinion that the Defendants have set up a credible challenge to the Suit Patent/IN'697 under Section 64(1)(a) of the Patents Act.

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[67] (2013) 6 SCC 1

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B. PRIORITY DATE OF THE SUIT PATENT AND THE RELEVANCE OF THE DECISION BY THE EUROPEAN OPPOSITION DIVISION DATED 25TH JANUARY 2013.

70. Before addressing the remaining grounds of invalidity raised by the Defendants, it is pertinent to first consider the Plaintiff's argument that the identified prior art, i.e., the Genus Patent/IN'964, cannot be relied upon for the purposes of assessing challenge on the grounds of anticipation by prior publication under Section 64(1)(e) of the Patents Act and/or lack of inventive step or obviousness under Section 64(1)(f) of the Patents Act as the publication date of the Genus Patent/IN'964 is subsequent to the priority date of the Suit Patent/IN'697.

It is stated by the Plaintiff that the priority date of the Suit Patent/IN'697 is 18th March, 2005, and the publication date of the Genus Patent/IN'964 is 31st March, 2005. On this plea, as per the Plaintiff, the Genus Patent/IN'964 cannot be considered as a prior art for the challenge raised under Section 64(1)(e) and Section 64(1)(f) of the Patents Act.

71. The Plaintiff has averred that from the bibliographic details, it is clear that the Suit Patent/IN'697 claims priority from European Patent Application No. EP 05102171.5 dated 18th March, 2005 ['EP Application'].

However, the Defendants have referred to the decision by the European Opposition Division ['EOD'] dated 25th January 2013, concerning the priority date of the EP Application. It is the argument of the Defendants that the European Opposition Division in its decision has postdated the priority of Claim 1 of the EP Application, which is the only independent claim of the Suit Patent/IN'697 to a later date, i.e., 20th March 2006. The said decision of the EOD has been filed and relied upon by the Plaintiff itself in these proceedings.

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72. According to Section 11(1)[68] of the Patents Act and Article 88[69] of the European Patent Convention, 1973 ['EPC'], each claim of a Complete Specification shall have a priority date. The determination of the priority date of a patent or a claim is a question of fact.

73. Upon perusal of the EOD decision, it is clear that the priority date of the EP Application, which is the priority application of the Suit Patent/IN'697, has been determined and held to be after the publication date of the Genus Patent/IN'964 [D9:WO2005/027978[70]]. The relevant paragraphs of the EOD decision are as follows: -

> "4.3 **The OD decided that at least claim 1 was not entitled to the priority date**. All particular moieties disclosed in D2 are indeed linked to Formula I wherein claim 1 is not restricted to any particular sequence. In addition, U' 1-4 and 10-12 have no basis in D2, U' 5-6 and 8-9 are only similar, but not identical to U1, 2, 4 and 5 in D2, the difference being that n might be 1, 2, or 3 in claim 1 wherein the moieties in D2 do not provide basis for different options for n. No basis at all could likewise be found for B 2 in D2. Likewise, the undefined orientation of U in D2 with regard to the carbonyl group as well as B results in new combinations in claim 1 due to the different presentation of U, U' and B. Therefore, in view of the clear structural differences, it can even not be agreed to the P's argument that the invention is similarly defined in the application as filed and in its priority document. Even if similarity could be acknowledged, for

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

[69] Article 88, Claiming priority:
(1) An applicant desiring to take advantage of the priority of a previous application shall file a declaration of priority and any other document required, in accordance with the Implementing Regulations.
(2) Multiple priorities may be claimed in respect of a European patent application, notwithstanding the fact that they originated in different countries. Where appropriate, multiple priorities may be claimed for any one claim. Where multiple priorities are claimed, time limits which run from the date of priority shall run from the earliest date of priority.
(3) If one or more priorities are claimed in respect of a European patent application, the right of priority shall cover only those elements of the European patent application which are included in the application or applications whose priority is claimed.
(4) If certain elements of the invention for which priority is claimed do not appear among the claims formulated in the previous application, priority may nonetheless be granted, provided that the documents of the previous application as a whole specifically disclose such elements.

[70] This is the publication number of the PCT application of the Genus Patent/IN' 964.

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assessing priority there should be an if not literal, but at least with regard to the contents identical and unambiguously derivable disclosure.

4.3.1 **In view of this decision, D9 is relevant under Articles 54(1) and (2) as well as 56 EPC for at least claim 1**"

[emphasis supplied]

74. The Plaintiff, in its plaint at paragraph '57', has claimed a priority date of 18th March, 2005, with reference to the filing date of the EP Application. The aforesaid EOD decision unambiguously holds that the priority date of Claim 1 of the EP Application is after the publication date of the Genus Patent/IN'964 and that the Genus Patent/IN'964 would qualify as a prior art for considering the claims of the opposition for lack of novelty and inventive step. In the considered opinion of this Court, the said finding of fact as regards the determination of the priority date of the EP Application binds the Plaintiff. At this prima facie stage, it is thus held that Genus Patent/IN'964 qualifies as a relevant prior art for evaluating the contentions of the parties under Sections 64(1)(e) and 64(1)(f) of the Patents Act.

75. It is contended by the Plaintiff that since the EOD decision considers the Suit Patent/IN'697 as novel and inventive after considering the Genus Patent/IN'964 as prior art, the same should be considered as proof of prima facie validity of the Suit Patent/IN'697.

76. Thus, insofar as the priority date of the Suit Patent/IN'697 is concerned, this Court is of the view that the Plaintiff is bound by the EOD decision, as the same is an issue of fact. And, it is also pertinent to note that the Plaintiff themselves have relied upon the EP application as their priority patent application for determining the priority date of the Suit Patent/IN'697.

However, insofar as the finding returned in the EOD decision that the Suit Patent/IN'697 is novel and inventive over the Genus Patent/IN'964, is based on the legal parameters followed up by EOD and

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therefore, the same is not binding on this Court. In addition, this Court notes that on a perusal of the EOD's decision, there is no discussion or reference to Claims 11, 14, 15, 16, and 18 of the Genus Patent/IN'964, which, in the opinion of this Court, are integral to the assessment of novelty and inventive steps.

77. It is a trite law that patent validity in a suit proceeding must be assessed in accordance with domestic law, i.e., under Section 64(1) of the Patents Act, and that the tests for each requirement are those approved by decisions of this Court and the Supreme Court. The tests for novelty and inventive step have been developed by the Courts through multiple decisions, setting a threshold for satisfying the requirements under the Patents Act. A reference in this regard may also be made to a decision by this court in **Communication Components Antenna Inc. v. Ace Technologies Corp. And Ors.**[71] The relevant paragraph of the said judgment is reproduced hereunder: -

> "41. The language of the claims in different jurisdictions of the same convention application after it is granted in the various domestic jurisdictions, would usually never be identical. This is due to the subjectivity that exists in the prosecution process of the application, as discussed above. While determining infringement in India, the variation in the language of the claims in different jurisdictions, cannot be examined in a minute fashion. For the purposes of ascertaining infringement of a patent granted in India, the claims of the patent granted in India, need to be seen along with the complete specification. The language of the claims in corresponding foreign patents can be looked at to ensure that broadly the invention is the same and no substantive claims have been either deleted or withdrawn. **International patents relating to the same patent can also be referred to in order to establish '*evergreening*' of an invention. However, the granted claims in foreign jurisdictions cannot be read as though they are etched in stone. Insofar as an**

[71] 2019 SCC OnLine Del 9123

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Indian Court are concerned, while determining the question of validity of a patent, it would be concerned primarily with the claims that have been granted in India. The unique nature of grant of patents in various jurisdictions or the wording of claims in various jurisdictions would only have a broad impact on the Indian claims, and not more."

[emphasis supplied]

78. Accordingly, this Court deems it appropriate to independently assess the question of novelty and inventive step of the Suit Patent/IN'697 in accordance with Indian laws.

C. ISSUE OF ANTICIPATION BY PRIOR-PUBLICATION UNDER SECTION 64(1)(e) OF THE PATENTS ACT

79. A combined reading of Sections 64(1)(e), 13(1)(a)[72], 2(1)(j)[73] and 2(1)(l)[74] of the Patents Act makes it clear that the invention is not novel if the invention has already been disclosed or is anticipated by a 'person skilled in the art' on the basis of the disclosure made in any of the document/s, which have been published before the priority date of the patent under scrutiny.

80. The test for assessing novelty under the Patents Act is set out in section 09.03.02 of The Manual of Patent Office Practice and Procedure, version 3.0, dated 26th November 2019, published by the Indian Patent

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[72] 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;

[73] 2. Definitions and interpretation.—(1) In this Act, unless the context otherwise requires,
…
(j) "invention" means a new product or process involving an inventive step and capable of industrial application;

[74] 2. Definitions and interpretation.—(1) In this Act, unless the context otherwise requires,
…
(l) "new invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art;

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Office. The same is reproduced under:

"Novelty

1. **An invention is considered as new(novel), if it is not anticipated by prior publication in patent and non-patent literature, i.e., an invention is novel if it has not been disclosed in the prior art, where the prior art means everything that has been published, presented or otherwise disclosed to the public before the date of filing/priority date of complete specification.**

2. An invention is considered as novel, if it has not been anticipated by prior use or prior public knowledge in India.

3. For the purpose of determining novelty, an application for patent filed at the Indian Patent Office before the date of filing of complete specification of a later filed application, but published after the same, is considered for the purposes of prior claiming.

4. While ascertaining novelty, the Examiner takes into consideration, inter alia, the following documents:

- which have been published before the date of filing of the application in any of the specifications filed in pursuance of application for patent in India on or after 1st January, 1912.
- such Indian Patent Applications which have been filed before the date of filing of complete specification and published on or after the date of filing of the complete specification, but claims the same subject matter.

5. The examiner shall make such investigation for purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by publication in India or elsewhere in any document other than those mentioned in section 13(1) before date of filing of the applicant's complete specification.

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

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

8**. A generic disclosure in the prior art may not necessarily take away the novelty of a specific disclosure. For instance, a metal spring may not take away the novelty of a copper spring.**

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

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

[emphasis supplied]

81. A Co-ordinate Bench of this Court in **LAVA International Limited v. Telefonaktiebolaget LM Ericsson**[75] has combined the aforesaid parameters into a seven-step test for assessing novelty under Section 64(1)(e) of the Patents Act. The test laid down in the said judgement can be summarised as under: -

(i) Understanding of the Claims of the Invention,
(ii) Identifying Relevant Prior Art,
(iii) Analysing the Prior Art,
(iv) Determination of Explicit and Implicit Disclosures,
(v) Assessment of material differences while considering the entire scope of the claims,
(vi) Verifying Novelty in light of Comprehensive Scope and Specific Combination of Claimed Elements,
(vii) Documentation of the Analysis and Novelty Determination.

82. The prerequisite for determining challenge to the patent on the ground of anticipation by prior publication is the presence of a relevant patent or non-patent literature published before the priority date of the patent under scrutiny.

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

[75] 2024 SCC OnLine Del 2497

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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.

D. ISSUE OF OBVIOUSNESS UNDER SECTION 64(1)(f) OF THE PATENTS ACT

85. Section 64(1)(f) of the Patents Act provides that a patent may be revoked if the invention, as claimed in any claim of the Complete Specification, is obvious or lacks an inventive step having regard to what was publicly known or used or published anywhere before the priority date of the claim.

86. The Defendants have challenged the validity of the Suit Patent/IN'697, which is a species patent, under Section 64(1)(f) of the Patents Act, on the ground of obviousness or lack of inventive step, i.e., the Defendants have alleged that the compound in question i.e., Semaglutide is obvious to a 'person skilled in the art'/'person in the know', on account of the teachings in the relevant prior arts, i.e., Genus Patent/IN'964, Deacon et al. [1998] and Knudsen et al. [2004].

87. The test for assessing the challenge of obviousness/lack of inventive

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step under Section 64(1)(f) of the Patents Act has been formulated by the Division Bench of this Court in **F. Hoffmann-La Roche Ltd. v. Cipla Ltd.**[76] The relevant paragraph of the said judgment is as under:

> "153. From the decisions noted above to determine obviousness/lack of inventive steps the following inquiries (sic) are required to be conducted:
>
> Step No.1 To identify an ordinary person skilled in the art,
>
> Step No.2 To identify the inventive concept embodied in the patent,
>
> 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.
>
> 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 [hindsight] approach."

88. In view of the test of obviousness/lack of inventive step laid down in **F. Hoffmann-La Roche Ltd. v. Cipla Ltd.**[77]**,** this Court will now proceed to analyse the facts and circumstances of the present case.

PERSON SKILLED IN THE ART

89. **Step No.1** requires proper identification of the 'person skilled in the art'. The level of the skill of the hypothetical 'person skilled in the art' is determined based on the nature of the technology that has been dealt within the Suit Patent/IN'697 and the prior arts.

---

[76] 2015 SCC OnLine Del 13619

[77] Ibid.

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90. The Defendants have contended that the presence of the common inventors between Genus Patent/IN'964 and the Suit Patent/IN'697 raises a legitimate presumption that the Plaintiff and the inventors were 'persons in know' and possessed the requisite knowledge of the invention claimed in the Suit Patent/IN'697 even when they applied for the Genus Patent/IN'964, and by filing the Suit Patent/IN'697 they are only seeking to evergreen the invention which is already claimed in the Genus Patent/IN'964.

91. The parameters for defining the skill of the said hypothetical person are referenced in the aforesaid Division Bench judgment of **F. Hoffmann-La Roche Ltd. v. Cipla Ltd**[78]. The relevant paragraph of the said judgment read as under: -

> "148. **The Supreme Court of United States in the decision reported as 383 U.S. 1 (1966) William T. Graham et al. v. John Deere Company of Kansas City et al. analyzed the factual determination of the level of ordinary skill in the art** which analysis was followed with approval in 218 U.S. P.Q. 865 Environmental Designs Ltd. v. Union Oil Company of California, 702 F.2d 1005 Orthopedic Equipment Co. Inc. v. The United States, 864 F.2d 757 Newell Companies, Inc. v. Kenney Manufacturing Company and 501 F.3d 1254 Daiichi Sankyo Co., Ltd. v. Apotax, Inc. The decisions laid down the following principle factors, though not exhaustive, as under: -
>
> > "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**

[78] Ibid.

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field."

[emphasis supplied]

92. In India, an additional factor has been formulated by the Division Bench in **AstraZeneca AB and Another v. Intas Pharmaceuticals Ltd.**[79] for determining the level of skill required of a 'person skilled in the art'. According to the said decision, when a genus-species relationship exists between prior art and patent under scrutiny, and the inventors are identical, the inventors of the genus patent/prior art are presumed to have known of the inventive step required to reach the subsequent species patent. In such cases, the assessment of the inventive step or obviousness is to be done with regard to 'person in the know' and not 'person skilled in the art'. The relevant paragraph of the said judgment is reproduced herein below:

> "29. **It cannot be lost sight of, that the inventor of both, IN 147 and IN 625 and/or of US equivalents thereof was/is the same. The said inventor, as compared to a third person, was best placed to know the inventive step i.e. technical advancement in the invention subject matter of IN 625, over that of the earlier invention subject matter of IN 147.** However, in the description of field of invention of IN 625, neither any technical advancement or difference in efficacy of the new products subject matter thereof over the product subject matter of IN 147 is mentioned nor any economic significance of the new invention claimed. Once the inventor himself, while writing and seeking the patent, has not mentioned so, the subsequent claims of the assignee of the patent, in this regard, at least at the stage of judging *prima facie* case, cannot be accepted and have to be necessarily put to trial.
>
> 30. **The tests of "obvious to a person skilled in the art" and "anticipation by publication" and "use before the date of filing of patent application with complete specification", in the context of an earlier patent and its specifications, in our view, have to be different, when the inventor of both is the same.** The counsel for the appellants/plaintiffs has argued, that owing to delays in obtaining

[79] 2021 SCC OnLine Del 3746

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approvals of Drug Regulators in different jurisdictions, for marketing of a new drug/medicine, after obtaining patent with respect thereto, results in the inventor/patentee being not able to enjoy the exclusivity granted under the Patent Laws to the inventor/patentee, for the full term of the patent. However merely because there are such delays, would not be a reason for the Court to give to the patent a longer life than provided in the statute. The cure therefor is with the Legislature and not with the Courts, by allowing more than one patent with respect to the same invention. The said argument of the counsel for the appellants/plaintiffs has however made us suspicious, that the appellants/plaintiffs, though invented DAPA at the time of seeking IN 147 and/or US equivalent thereof, though 'covered' it therein (to prevent others from inventing it) but intentionally did not disclose it, to subsequently claim patent with respect thereto, and in the interregnum obtain approvals of the Drug Regulators. **When the inventor is the same, the tests aforesaid, in our opinion, cannot be in the context of "person ordinarily skilled in the art" but have to be of the "person in the know". The enquiry, in such a situation, has to be guided by, whether the inventor, while writing first patent, knew of the invention claimed in the subsequent patent.**

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

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the patentee, till the time patentee successively keeps on obtaining patent therefor."

[emphasis supplied]

93. In case of common inventors, the aforesaid 'person in the know' test has been affirmed and reiterated by the Division Bench of this Court recently in **F. Hoffmann -LA Roche AG and Another v. Natco Pharma Limited**[80] for examining the challenge of invalidity raised by a defendant based on the aspect of obviousness under Section 64(1)(f) of the Patents Act. The relevant paragraphs '20.3' to '20.3.3' of the said judgment read as under: -

> **"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.**

[80] 2025 SCC OnLine Del 6390

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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 produced 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."

[emphasis supplied]

94. In the present case, it is a matter of record that five [5] lead inventors are common to both the Genus Patent/IN'964 and the Suit Patent/IN'697. The details of the inventors set out at paragraph '48' of the Defendants' reply to the captioned application and not disputed by the Plaintiff, are as under: -

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INVENTORS OF IN262697 (IMPUGNED PATENT)	INVENTORS OF IN275964 (IN '964)
LAU JESPER	LAU JESPER
DÖRWALD FLORENCIO ZARAGOZA	DÖRWALD FLORENCIO ZARAGOZA
PAW BLOCH	PAW BLOCH
HENSEN THOMAS KRUSE	HENSEN THOMAS KRUSE
MADSEN KJELD	MADSEN KJELD
STEPHENSEN, HENRIK	-
-	JOHANSEN NILS LANGELAND

95. Thus, when the aforesaid factors are applied to the present case, the following conclusions can be drawn:

(a) The problems identified in the Suit Patent/IN'697 are similar or identical to the problem addressed in the relevant prior arts, which is to offer less frequent Type 2 Diabetes injections with an increased half-life period.

(b) Multiple prior arts had already addressed this problem, as discussed in the Suit Patent/IN'697 [see detailed discussion under Steps 2 and 3 below] and specifically addressed by the Genus Patent/IN'964 [prior art].

(c) All prior arts suggest use of GLP-1 analogues for addressing the problem of the Suit Patent/IN'697.

(d) The rapidity of the inventions in the present case is such that the Suit Patent/IN'697 has been filed within less than two [2] years of the closest prior art, i.e., Genus Patent/IN'964.

(e) The technology involved in the present case, which encompasses drug discovery and testing, is highly sophisticated.

(f) The educational background of scientists working in this field

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typically includes a high degree in medicinal chemistry.

(g) The inventors in both the Genus Patent/IN'964 and the Suit Patent/IN'697 are the same.

96. Therefore, for the assessment of inventive step or obviousness in the present case, the 'person skilled in the art' will be a 'person in the know' who is aware of all the prior arts, having a skill matching with the inventors of the Genus Patent/IN'964, i.e., a person skilled in medicinal chemistry. This person will also be capable of working the Genus Patent/IN'964, along with all the examples, revealing its full scope as per the prior art disclosures.

INVENTIVE CONCEPT OF THE SUIT PATENT/IN'697

97. With respect to **Step No.2**, to identify the inventive concept embodied in the Suit Patent/IN'697, a reference may be made to the **Field of the Invention, Background of the Invention**, **Summary of the Invention** and **Claims** given in the Complete Specification of the Suit Patent/IN'697. The relevant parts of the Complete Specification of the Suit Patent/IN'697 are extracted hereinbelow:

> "**FIELD OF THE INVENTION**
> This invention **relates to the field of therapeutic peptides, i.e. to new protracted GLP-1 compounds**.
>
> **BACKGROUND OF THE INVENTION**
> .....
> Many diabetes patients particularly in the type 2 diabetes segment are subject to so-called "needle-phobia"; i.e. a substantial fear of injecting themselves. **In the type 2 diabetes segment most patients are treated with oral hypoglycaemic agents, and since GLP-1 compounds are expected to be the first injectable product these patients will be administered, the fear of injections may become a serious obstacle for the widespread use of the clinically very promising GLP-1 compounds. Thus; there is a need to develop new GLP-1 compounds which can be administered less than once daily, e.g. once every second or third day preferably once weekly,**

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while retaining an acceptable clinical profile.

SUMMARY OF THE INVENTION

The invention provides **a GLP-1 analog having a modification of at least one non-proteogenic amino acid residue in positions 7 and/or 8 relative to the sequence GLP-1 (7-37) (SEQ ID No 1), which is acylated with a moiety to the lysine residue in position 26, and where said moiety comprises at least two acidic groups, wherein one acidic group is attached terminally.**

The present invention also provides pharmaceutical compositions comprising a compound according to the present invention and the use of compounds according to the present invention for preparing medicaments for treating disease.

The invention provides a method for increasing the time of action in a patient of a GLP-1 analog, characterised in acylating said GLP-1 analog with a moiety B-U' as disclosed in any of the preceding claims, on the lysine residue in position 26 of said GLP-1 analog.

.....

We claim:

1. A GLP-1 analog **having at least one non-proteogenic amino acid residue in positions 7 and/or 8 relative to the sequence GLP-1(7-37), which is acylated with a moiety B-U' to the lysine residue in position 26,** wherein

(i) B-U' comprises at least two acidic groups one of which is attached terminally;

(ii) U' is selected from

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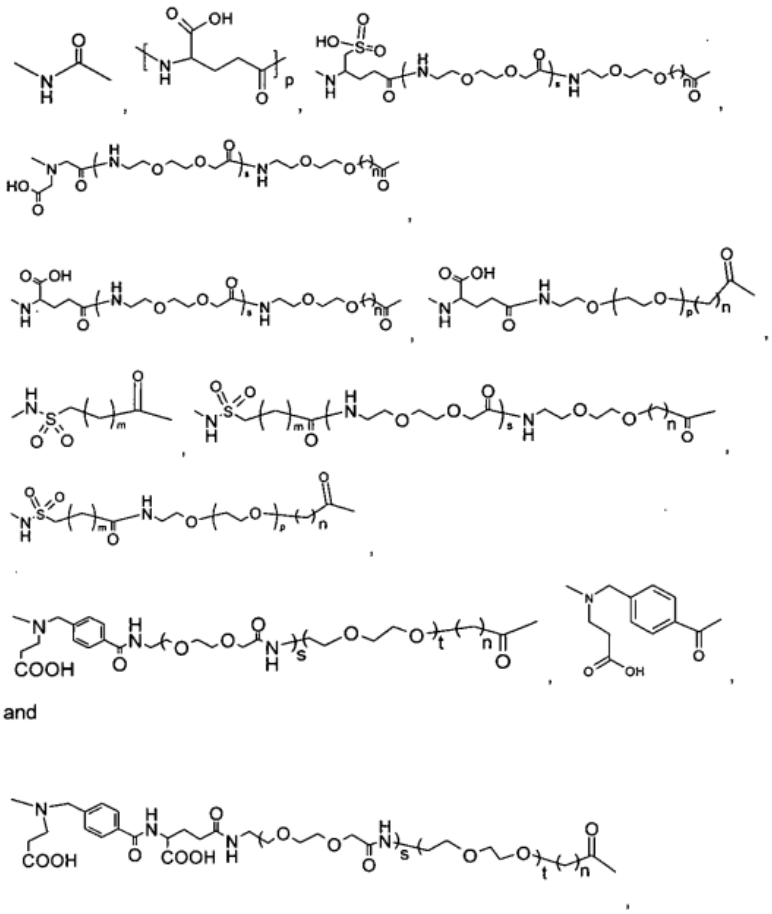
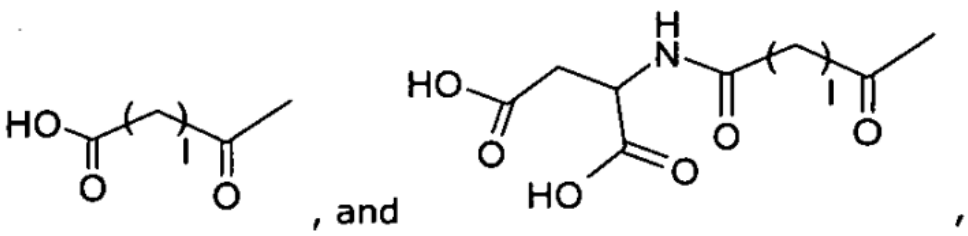


and

Wherein:
m is 0, 1, 2, 3, 4, 5, or 6,
n is 1, 2, or 3,
s is 0, 1, 2, or 3,
t is 0, 1, 2, 3, or 4,
p is 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17,18, 19, 20, 21, 22, or 23; and
(iii) B is an acidic group selected from



wherein I is 12, 13, 14, 15, 16, 17, 18, 19, or 20.

……

23. A compound according to any one of the preceding claims, which is selected from [since multiple structures are specifically claimed

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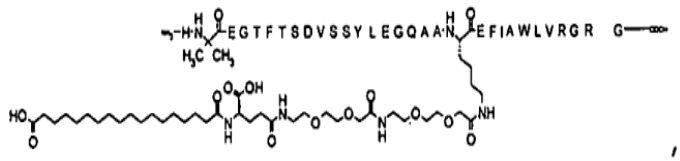
here, for the sake of brevity, only the relevant compound is listed here]



N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib^{8},Arg^{34}]GLP-1-(7-37)peptide,

"

98. From the relevant paragraphs of the Complete Specification as extracted above, it is clear that the 'inventive concept' of the Suit Patent/IN'697 is to provide novel GLP-1 analogues including the Semaglutide compound having a modification of at least one [1] non-proteogenic amino acid residue in positions seven [7] and/or eight [8] relative to the sequence GLP-1 (7-37) (SEQ ID No 1), which is acylated with a moiety to the lysine residue in 26th position, and where the said moiety comprises at least two [2] acidic groups, wherein one [1] acidic group is attached terminally.

These compounds are suggested to have a longer half-life and thereby require administration of this injectable compound in Type 2 Diabetes patients once every second or third day, or once weekly, while retaining an increased clinical profile.

99. The relevant features of the Semaglutide compound forming part of the inventive concept have also been set out by the Plaintiff in its rejoinder. The relevant paragraph is reproduced below: -

> "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:**

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

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

10.3. Lys at position 26 acylated on its side chain with a moiety that comprises two "OEG" groups, a γ-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 supplied]

COMMON GENERAL KNOWLEDGE IN THE PRIOR-ARTS AT THE PRIORITY DATE

100. With respect to **Step No.3**, the hypothetical 'person in the know', who is a person skilled in medicinal chemistry possessing a skillset equivalent to the inventors of Genus Patent/IN'964, as identified in Step No.1, will be aware of the relevant prior arts as a whole. The prior arts identified in this assessment are as follows:

1. The Patent numbered IN' 275964, titled "NOVEL CONJUGATES OF GLP-1" ['Genus Patent/IN'964']
2. C.F. Deacon, Dipeptidyl peptidase IV resistant analogues of glucagon-like peptide-1 which have extended metabolic stability and improved biological activity, 1998 ['Deacon (1998)']
3. Lotte Bjerre Knudsen, Glucagon-like Peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes, 2004 ['Knudsen (2004)']

101. For this step, it would be relevant to discuss the motivation for the 'person in the know' to combine the relevant prior arts and the teachings therein to arrive at the Suit Patent/IN'697, i.e., the Semaglutide compound.

102. The Genus Patent/IN'964, in its Complete Specification under the heading 'Background of the Invention' and 'DETAILED DESCRIPTION

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OF THE INVENTION', solves the problem of lower half-life of the anti-diabetic polypeptides and provides therapeutic GLP-1 analogues with increased half-life for the treatment of Type 2 Diabetes. The same is reproduced herein below:-

"**BACKGROUND OF THE INVENTION**

…

The number of known endogenous peptides and proteins with interesting biological activities is growing rapidly, also as a result of the ongoing exploration of the human genome. Due to their biological activities, many of these polypeptides could in principle be used as therapeutic agents. **Endogenous peptides are, however, not always suitable as drug candidates because these peptides often have half-lives of few minutes due to rapid degradation by peptidases and/or due to renal filtration and excretion in the urine. The half-life of polypeptides in human plasma varies strongly (from a few minutes to more than one week). Similarly. The half-life of small molecule drugs is also highly variable. The reason for this strong variability of plasma half-lives of peptides, proteins. or other compounds is, however, not well understood. Thus. there is a need to modify therapeutic compounds to provide longer duration of action in vivo while maintaining low toxicity and therapeutic advantages.**

Serum albumin has a half-life of more than one week. and one approach to increasing the plasma half-life of peptides has been to derivatize the peptides with a chemical entity that binds to serum albumin."

DETAILED DESCRIPTION OF THE INVENTION

"……

In one embodiment of the invention a compound awarding to the invention wherein the **therapeutic polypeptide is a GLP-1 peptide is used for the preparation of a medicament for the treatment or prevention of hyperglycemia, type 2 diabetes**, impaired glucose tolerance, type1 diabetes, obesity, hypertension, syndromeX, dyslipidemia, cognitive disorders, atheroschlerosis, myocardial infarction, coronary heart disease and other cardiovascular disorders, stroke, inflammatory bowel syndrome, dyspepsia and gastric ulcers."

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[emphasis supplied]

103. The scientific literature, Deacon [1998], in its introduction, identifies the problem it seeks to address, as modifying GLP-1 analogues for obtaining more DPP IV-resistant and stable GLP-1 analogues, which will increase the half-life period of the drug. The relevant paragraph is reproduced here as follows:

> "Recent studies have shown that GLP-1 itself is the subject of further enzyme cleavage. In particular, dipeptidyl peptidase IV (DPP IV; EC 3.4.14.5) is important, resulting in a metabolite which is N-terminally truncated by 2 amino acids. The resulting peptide, GLP-1 (9–36) amide, is an endogenous metabolite which is an antagonist in vitro. **Moreover, exogenously administered GLP-1 is also rapidly degraded in both diabetic and non-diabetic subjects, with GLP-1 (9–36)amide being the major metabolite. In a strain of rats lacking DPP IV, this metabolite is not formed [14]. DPP IV is highly specific and has strict substrate requirements, raising the possibility of developing analogues which the enzyme is unable to cleave. Studies with another peptide substrate of DPP IV, growth hormone-releasing factor (GRF), have shown that analogues with N-terminal amino acid substitutions have some resistance to the enzyme's action. <u>The present study was undertaken to examine whether small modifications of the N-terminus of GLP-1 would also confer resistance to degradation by DPP IV, while retaining the peptide's biological activity.</u>**"

[emphasis supplied]

104. The scientific literature, Knudsen [2004], in its introduction, identifies the problem addressed in it as the extremely short biological half-life of GLP-1analogue, which limits its therapeutic application in Type 2 Diabetes. The relevant paragraph is as follows:

> "Type 2 diabetes is increasingly becoming a worldwide epidemic. Currently there is much focus on the glucagon-like peptide-1 (GLP-1) peptide hormone as the basis for a potential new treatment paradigm for type 2 diabetes. **<u>The two major drawbacks of the drugs currently utilized in the treatment of type 2 diabetes are that (1)</u>**

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during their long-term administration body weight increases and (2) the disease progresses over time, also evidenced by an increasing loss of *β*-cell function"

.....

The GLP-1 receptor was cloned in 1992 and is a G-protein-coupled receptor from the B family also referred to as the secretin/glucagon family. The ligands in this family are mainly large peptide hormones. Small molecule antagonists especially for the glucagon receptor have been described, but no small-molecule agonists have been described in the literature. **Thus, the GLP-1 based compound class will most likely be peptides and the challenge is that the natural hormone is degraded rapidly by the enzyme dipeptidyl peptidase IV (DDPIV) and cleared by the kidneys resulting in a half-life of less than 2 min after iv administration and a clearance higher than that of the normal cardiac output. GLP-1 exists in two equipotent naturally occurring forms, GLP-1(7-37) and GLP-1(7-36) amide, the former corresponding to proglucagon (78-108). The numbering of GLP-1 starts with 7 because it was originally believed that GLP-1(1-37) was the active hormone. It was later discovered that the real hormone was formed after cleaving off the first 6 N-terminal amino acids and then the 7 numbering system begun. The primary metabolite of GLP-1, GLP-1(9-36) amide or GLP-1(9-37), has a greatly decreased affinity for the GLP-1 receptor and may even be an antagonist or a partial agonist. The magnitude and duration of the blood glucose lowering ability of natural GLP-1 have been shown to be dependent on a continuous supply of pharmacological levels. Thus, the efficacy of a GLP-1-like drug will be dependent on the duration of action of the compound or the formulation even though some of the long-term benefits of GLP-1 compounds, like increasing *â*-cell mass, may not require constantly elevated GLP-1 levels. Another potential limitation is that the only known pharmacologically induced side effect is nausea, occurring via the inhibition of gastric emptying.** However, there seems to be tachyphylaxis to this side effect so that long-term efficacy can be obtained without major gastrointestinal side effects. Nevertheless, this issue of nausea as a side effect is probably the most important one to resolve in future clinical trials."

[emphasis supplied]

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105. From the afore-extracted paragraphs of the prior arts, it is clear that the Genus Patent/IN'964 along with Deacon [1998] and Knudsen [2004] addresses the similar problem as the Suit Patent/IN'697, which is for making GLP-1 analogues with increased stability and resistance to DPP-IV enzyme, thereby increasing half-life and reducing the frequency of administration of the drug for the treatment of Type 2 Diabetes. Thus, a 'person in the know' will be motivated to combine these prior arts to address the problem identified in the Suit Patent/IN'697.

106. Further analysing each prior art, it could be discerned that Knudsen [2004] teaches GLP-1 (7-37) analogues as a potential new treatment paradigm for Type 2 Diabetes. It recognises the potential of GLP-1 analogues for the beneficial treatment of Type 2 Diabetes. It identifies that the GLP-1 analogue has a short half-life due to DPP-IV-mediated cleavage and rapid clearance. It discusses that, in the potency-decreasing Structure Activity Relationship ['SAR'] of GLP-1, acylation at the 8th position of the N-terminus results in a compound about 20 times less potent than a GLP-1 analogue. The SAR figure for the GLP-1 analogue is shown in Figure 3. The said Figure specifically acknowledges that modification at the 8th position, i.e., 'Ala', of GLP-1 analogues would enhance/achieve DPP-IV stability. The said Figure 3 is reproduced below:

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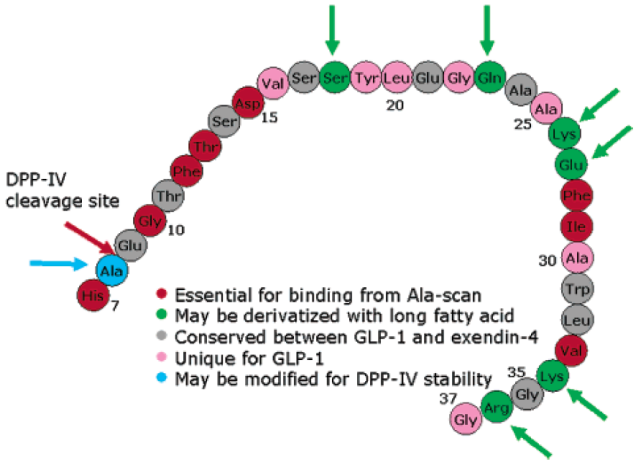

Figure 3. SAR figure of GLP-1. All sites essential for binding from Ala-scan are also conserved between GLP-1 and exendin-4. Sites that are possible to modify with fatty acids are only color-coded as such. They are all unique for GLP-1 at the same time.

107. Deacon [1998] teaches that GLP-1 analogues have excellent potential in Diabetes therapy due to their glucose-dependent stimulation and highlights that their efficacy is, however, limited by rapid degradation, primarily by DPP-IV.

This paper examined four [4] analogues,[81] which were N-terminally substituted for metabolic stability, and concluded that all four [4] analogues were more resistant to DPP-IV. 'Aib' analogue with substitution at the 8th position is identified as an analogue that was found to be DPP-IV resistant, giving it a longer half-life in the patient's body. This study demonstrated that small alterations in the N-terminus of GLP-1 analogue confer resistance to DPP-IV-mediated degradation; such analogues retain biological activity and exhibit improved metabolic stability. This study also shows the IC50 value of Aib^{8}-GLP-1 (7–37) as between 0.45–0.05^{b}.

108. The Genus Patent/IN'964 has teachings of GLP-1(7-37) analogues for treatment of Type 2 Diabetes that are similar to those taught in the Suit Patent/IN'697 for achieving a similar therapeutic effect by increased half-

[81] Analogues, substituted at position 8 of GLP-1 analogue with either threonine (Thr8-GLP-1 (7–37)), glycine (Gly8-GLP-1 (7–37)), serine (Ser8-GLP-1 (7–36) amide) or a-aminoisobutyric acid (Aib8-GLP-1

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life. The Genus Patent/in'964 contains teaching on all the features of the Suit Patent/IN'697 as already identified in Step No. 2. The teachings in the Genus Patent/IN'964 include the Example 61 compound, which only differs from the Semaglutide compound in terms of 'Ala' at its 8th position instead of 'Aib'. This feature has also been specifically taught in Claim 16 of the Genus Patent/IN'964 and in multiple other examples/compounds listed therein.

109. Therefore, from the prior arts discussed above, a 'person in the know' will be aware of GLP-1(7-37) analogue [Knudsen] as a preferred candidate for the treatment of Type 2 Diabetes. Knudsen also teaches that modifying 'Ala' at the 8th position of GLP-1 analogue will result in increased half-life period [Figure 3 of Knudsen]. Further, Deacon teaches GLP-1 (7-37) analogues with 'Aib' at the 8th position, with a longer half-life and greater potency [Table 3 of Deacon]. The Genus patent/IN'964 further teaches a set of GLP-1(7-37) analogues exhibiting increased half-life and potency for the treatment of Type 2 Diabetes, with reduced administration frequency and prolonged stability. The Genus Patent/IN'964, through Claim 16, also specifically teaches substitution of 'Ala' at the 8th position of native GLP-1 (7-37) analogue with 'Aib'.

DIFFERENCE BETWEEN PRIOR ARTS AND SUIT PATENT/IN'697

110. With respect to **Step No.4,** this Court will now address the difference between the common general knowledge in prior arts and the Suit Patent/IN'697.

111. The Semaglutide compound of the Suit patent is different from the known native GLP-1 (7-37) analogues [specifically, example 61 of the Genus Patent/IN'964] in terms of a single substitution of 'Aib' in the 8th position, which gives it an increased half-life period and therapeutic

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property, as noted above in paragraph '40' of this judgment. Therefore, the difference of prior arts from that of the Suit Patent/IN'697 is that there is no single compound identical to the Semaglutide compound taught in any of the prior arts. The difference between the common general knowledge taught in the identified prior arts and the Suit Patent/IN'697 can be summarised as under:

Feature	**Claimed Invention**	**The Genus Patent/IN'964**	**Deacon (1998)**	**Knudsen (2004)**
The GLP-1 (7-37) analogue	Present	Present in Claim 11 and 12	Present	Present
The GLP-1 (7-37) analogue with α-aminoisobutyric acid (Aib) at 8th position	Present	Present specifically as Claim 16 and in several illustrated compounds. Though not present in Example 61 compound.	Present	Modification of 'Ala' at 8th position suggested but substitution with 'Aib' specifically not present
Amino acid lysine (Lys) with arginine (Arg) at position 34.	Present	Present	Not present	Present
Lys at position 26 acylated on its side chain with a moiety that comprises two "OEG" groups, a γ-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)	Present	Present	Not present	Not present
Increased half-life period of GLP-1 analogues for treatment of Type 2	Present 69 hrs for	Present 35 hrs for	Teachings for achieving	Teachings for achieving

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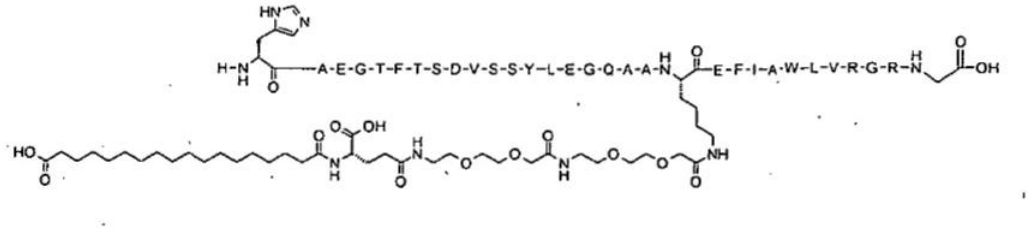
Diabetes	Example 4 in the data filed with the Indian Patent Office in 2014	Example 61 compound; 43 hours for Example 54 compound in the data filed by the Indian Patent Office in 2014	increased half-life is present	increased half-life is present

OBVIOUSNESS TO THE PERSON IN THE KNOW

112. With respect to **Step No.5**, the question to be determined is whether the Semaglutide compound of the Suit Patent/IN'697, is obvious to 'a person skilled in the art'/ 'person in the know', from the cited prior arts, i.e., the Genus Patent/IN'964, Deacon et al. [1998] and Knudsen et al. [2004].

113. The Defendants have relied upon Example 61 given in the specification of the Genus Patent/IN'964 which has also been claimed as a specific compound in Claim 21 of the Genus Patent/IN'964 to contend that the Semaglutide compound in the Suit Patent/IN'697 is nothing more than an 'obvious modification' of the said example, when considering the teachings in the Genus Patent/IN'964 itself as well as Deacon [1998] and Knudsen [2004]. Example 61 of the Genus Patent/IN'964 is reproduced as under: -



$N^{\varepsilon 26}$-[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

114. So also, the Semaglutide compound of Suit Patent/IN'697 as set out in

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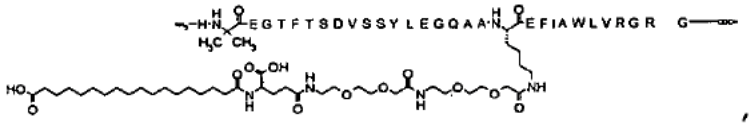
Claim 23 is reproduced as under: -



N-ε^{26}-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy)acetyl][Aib^{8},Arg^{34}]GLP-1-(7-37)peptide,

115. The comparison between the Semaglutide compound, as claimed in the Suit Patent/IN'697 and the Example 61 compound, as claimed in the Genus Patent/IN'964, as filed by the Plaintiff, has already been reproduced at paragraph '40' of this judgment.

116. As highlighted by both the Plaintiff and the Defendants, the 'only' distinction between Example 61 compound given in the Genus Patent/IN'964 and the Semaglutide compound in the Suit Patent/IN'697 is the presence of amino acid, i.e., 'Aib' in the Semaglutide compound instead of 'Ala' at the 8th position in Example 61.

117. The Defendants have highlighted that the substitution of 'Ala' at the 8th position with 'Aib' has been specifically claimed by the Plaintiff in Claim 16 of the Genus Patent/IN'964, which is preceded by the advantages of such substitution in Claims 14 and 15 therein. The Defendants have also highlighted that Claim 18 of the Genus Patent/IN'964 contains 29 of 38 examples with 'Aib' at the 8th position, and Claim 21 of the Genus Patent/IN'964 contains 40 out of 61 examples with 'Aib' at the 8th position of the GLP-1 analogue. Claims 14, 15 and 16 of the Genus Patent/IN'964 read as under: -

> "14. A compound as claimed in any one of the previous claims, wherein said **GLP-1 peptide is a DPP-IV protected GLP-1 peptide**.

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15. A compound as claimed in claim any one of the previous claims, wherein **said compound is DPP-IV stabilised.**

16. **A compound as claimed in any one of the previous claims, wherein said GLP-1 peptide comprises an Aib residue in position 8.**"

[emphasis supplied]

118. The Defendants have further relied upon Deacon [1998] and Knudsen [2004] to contend that there are sufficient teachings in these documents to constitute common general knowledge that GLP-1 analogue that are DPP-IV protected and DPP-IV stabilised as disclosed in Claims 14 and 15 of the Genus Patent/IN'964 could be achieved by substituting 'Ala' with 'Aib' at the 8th position of the GLP-1 analogue.

119. The Defendants have stated that the advantages of substitution of 'Aib' at the 8th position in the GLP-1 analogue for enhanced resistance to DPP-IV leading to greater stability and longer half-life period is part of common general knowledge and has been known in the literature since at least the 1990s [Deacon publication], which teaches a 'person skilled in art' to substitute 'Ala' with 'Aib' at the 8th position in a GLP-1 analogue for the reasons stated in the article.

120. The Defendants have also referred to 'Knudsen [2004]' for contending the existence of common knowledge for a 'person skilled in art' that the GLP-1 analogue often have a very short half-life in the body and therefore, require albumin binding modifications to extend their duration of action. The Defendants have also relied upon Figure 3 in 'Knudsen [2004]' to show the teaching for a 'person skilled in art' with respect to the modification of 'Ala' at the 8th position for enhanced DPP-IV stability.

121. The Defendants, in their reply to I.A. 14076/2025, have summarised their contention on 'obviousness' as under: -

"106. **An invention is considered obvious when a person skilled**

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in the art, in view of the prior art and common general knowledge, would have had a reasonable expectation of success in arriving at the claimed invention through routine experimentation or logical modifications. In the present case, the compound Semaglutide is nothing more than an obvious modification of known GLP-1 analogues, specifically the one disclosed in Example 61 of IN275964, when considering well-established teachings in Deacon (1998) and Knudsen (2004).

107. **Example 61 of IN '964 discloses a GLP-1 compound with Alanine at position 8 and an acylated lysine at position 26, structurally differing from Semaglutide only in the replacement of Alanine with 'Aib' (2-methylalanine) at position 8. The Deacon (1998) publication explicitly teaches that substitution of Alanine with 'Aib' at position 8 in GLP-1 analogues significantly improves DPPIV resistance and metabolic stability without compromising receptor activity. Likewise, Knudsen (2004) corroborates that Aib8- modified GLP-1 analogues exhibit enhanced pharmacokinetic profiles and are promising candidates for diabetes therapy. Given that Aib was already established as a preferred substitution for Alanine to enhance stability, a skilled person would be directly motivated to modify the compound of Example 61 using this substitution, with a clear expectation of obtaining Semaglutide or a compound with similar enhanced half-life. In this case, the Plaintiff secured two independent patents with differing lifespans for the same compound, i.e., Semaglutide, by characterizing the second patent as a selection invention.**

108. It is important to note that **the Impugned Patent discloses the technical effects as increase in time of action more than about 40 hours. However, IN'964 compounds are having half-life more than about 40 hours. Thus, the purported effect of the Impugned Patent is already achieved by IN'964 compounds (See, Example 54 of IN'964 having half-life of 43 hours. Hence, the subject matter of claims 1-30 of the Impugned Patent is obvious and lacks inventive step for the foregoing reasons.** Since, the Impugned Patent has failed to disclose any inventive step over the cited prior art documents as required under Section 2(1)(ja) of the Patents Act, the Impugned Patent is also liable to be revoked under Section 64(1)(d) of the

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Patents Act."

[emphasis supplied]

122. However, according to the Plaintiff, the Defendants' contentions are based on hindsight reconstruction undertaken with the knowledge of the Semaglutide compound disclosed in the Suit Patent/IN'697. It is stated that in the absence of the information given in the Suit Patent/IN'697, the Defendants would have had to consider individual substituents in the large list of multiple substituent options forming part of the Genus Patent/IN'964, with no teaching of how to combine which substituents at which positions to arrive at a compound akin to Semaglutide compound with a higher half-life. It is stated that there is no teaching in Genus Patent/IN'964 as to why Example 61 compound should be selected out of the 66 examples enlisted in the Complete Specifications; further, there is no teaching as to:

a) Why GLP-1 (7-37) analogue is to be selected;
b) Why 'Ala' should be substituted with 'Aib' at the 8th position; and
c) Why it should be combined with lysine at the 26th position, acylated with two (2) acidic groups, out of which one is attached terminally with arginine at the 34th position.

123. The Plaintiff contended that in none of the prior arts, i.e., 'Deacon [1998]', 'Knudsen [2004]' or the Genus Patent/IN'964, the Semaglutide compound, having all combinations of substituents would lead to the synthesis of the Semaglutide compound, was known. It is thus contended that the test of obviousness has to be applied to the invention as a whole and not with respect to individual constituents thereof.

124. This Court, upon independent analysis of the Genus Patent/IN'964, Knudsen [2004] and Deacon [1998] as detailed in the above steps 3 and 4; at this prima facie stage finds merit in the Defendant's submissions that the Semaglutide compound i.e., Suit Patent would be obvious to the 'person in

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the know', on account of the teaching in the afore-referred prior arts. The selection of GLP-1(7-37) for the efficient treatment of Type 2 Diabetes is evident from all three [3] prior arts; the remaining two features also find clear teaching in the Genus Patent/IN'964. More specifically, the only difference as per Step No. 4 in the Example 61 compound is the 'Aib' at the 8th position.

Considering the 'person skilled in the art' in these facts is a 'person in the know', such a person with skill level matching the inventors of the Genus Patent/IN'964 would have the requisite knowledge and motivation to select Example 61 from the Genus Patent/IN'964 and substitute 'Ala' with 'Aib' in light of the teachings in all the prior arts. The selection is also justified upon perusal of the efficacy data[82] submitted by the Plaintiff itself during prosecution of the Genus Patent/IN'964 on 22nd October 2014, which showed that it had tested the Example 61 compound. According to the said data, the inventors of Genus Patent tested only a few compounds out of 66 compounds. Example 61 is one of the few compounds that were tested, and it had higher potency and a longer half-life. Therefore, the 'person in the know' had a clear motivation to carry out further experimentation with this compound, i.e. Example 61.

125. Therefore, a 'person in the know', taking example 61 for further study with specific teachings of Claim 16 of the Genus Patent/IN'964 that the 8th position in the GLP-1 analogue is to be substituted with 'Aib' will reach the Semaglutide compound. The advantage of such a substitution is also specifically taught in Claims 14[83] and 15[84] of the Genus Patent/IN'964, i.e., to obtain a GLP-1 analogue, which is more DPP-IV resistant and stable.

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[82] Page No. 737 of the Plaintiff's Documents Volume-IV.

[83] 14. A compound as claimed in any one of the previous claims, wherein said GLP-1 peptide is a DPPIV protected GLP-1analogue.

[84] 15. A compound as claimed in-claim any one of the previous claims, wherein said compound is

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This has also been specifically taught in Knudsen [2004] and Deacon [1998] as a substitution which enhances the stability of GLP-1 analogues by conferring resistance to DPP-IV–mediated enzymatic cleavage.

126. Moreover, in Claim 18 of the Genus Patent/IN'964, 29 out of 38 Examples have 'Aib' at 8th position, and Claim 21 of the Genus Patent/IN'964 contains 40 out of 61 Examples with 'Aib' at 8th position of the GLP-1 analogue.

127. Thus, on a conjoint reading of Claims 14, 15, 16, and 18 of the Genus Patent/IN'964 with the teachings in the Deacon[1998] and Knudsen[2004], 'a person in the know' would have had motivation to substitute 'Aib' at the 8th position in the GLP-1 analogue of Example 61 compound with an expectation of increasing the half-life period.

Therefore, the contention of the Plaintiff that comparison of Example 61 of the Genus Patent/IN'964 in light of other relevant claims therein with the Semaglutide compound is a hindsight analysis by the Defendants stands no merit.

128. In similar facts and circumstances a Division Bench of this Court in **F. Hoffmann-LA Roche AG and Another v. Natco Pharma Limited**[85], has held that such minor modification in the compound of genus patent vis-à-vis species patent as done in the present case, which is well within the skillset of the 'person in the know' will result in evergreening and is therefore vulnerable to credible challenge under Section 64(1)(f) of the Patents Act. The relevant paragraphs are as follows:

> "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

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DPPIV stabilised.

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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.*"

[emphasis supplied]

129. Thus, this Court is satisfied that the single substitution made to the GLP-1 analogue of Example 61 compound of the Genus Patent/IN'964 to arrive at the Semaglutide compound in the Suit Patent/IN'697 were obvious

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to try for a 'person skilled in the art', or in this case, the 'person in the know' with a reasonable expectation of success, i.e. to obtain GLP-1(7-37) analogue with increased half-life for effective treatment of Type 2 Diabetes.

130. Therefore, this Court is of the prima facie opinion that the Suit Patent/IN'697 is vulnerable on the ground of obviousness on account of the claims and compounds disclosed in the Genus Patent/IN'964 as well as the teaching in the prior art in Deacon [1998] and Knudsen [2004].

E. ADDITIONAL RELEVANT FACTS ESTABLISHING EVERGREENING

131. In the facts of the present case, it has also been brought to the notice of this Court by the Defendants that the Plaintiff has pleaded at paragraph '27' of the plaint that the Semaglutide compound was invented in 2004 itself, which is contemporaneous with the filing of the Genus Patent/IN'964 in 2004 [filed on 17.09.2004]. The relevant paragraph is reproduced below:

> "27**. Further research and innovation led to the invention of the GLP-1 receptor agonist, semaglutide, in 2004.** This was a significant breakthrough since being safe. potent and having a superior half-life meant that it could be dosed as infrequently as once a week when administered subcutaneously. This constituted a tremendous improvement over native GLP-1. It was also a highly significant improvement over known GLP-1 receptor agonists. In 2019, a further major breakthrough happened with the FDA approval of oral semaglutide, being the first oral GLP-1 treatment for type 2 diabetes which further expanded treatment options and reduced barriers."

132. The Plaintiff has confirmed this fact/timeline in its rejoinder to the captioned application. The relevant paragraph from the said rejoinder is as follows:

> "83.1. **The reference in paragraph 27 of the plaint to the invention of Semaglutide in 2004 merely indicates the Plaintiff's internal research and development timeline and does not, in any manner, constitute an admission that Semaglutide was publicly known, disclosed, or anticipated prior to the priority date of the suit**

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> **patent IN'697, i.e., 18.03.2005.** The Plaintiff has made no admission that Semaglutide was publicly known before the said priority date (18.03.2005) and therefore, cannot be a ground of invalidity as sought to be misconstrued by the Defendants. It is submitted that for an admission to have any legal effect, it must be clear, categorical, and unequivocal."

133. The Defendants have raised this submission to buttress their contention that the Semaglutide compound was known to the Plaintiff at the time of filing the Genus Patent/IN'964 itself. Therefore, as per the Defendants, the grant of the Suit Patent/IN'697 has resulted in evergreening and double patenting.

134. This Court has considered the aforesaid fact and submissions.

135. It is apparent from the record and also from the analysis of the credible challenge under Section 64(1)(f) of the Patents Act, in the above paragraphs, that both the inventions in the Genus Patent/IN'964 and Suit Patent/IN'697 claimed the same inventive concept, i.e., GLP-1 analogues with an enhanced half-life, resulting in a drug with enhanced therapeutic efficacy for treating Type 2 Diabetes, as compared to the prior existing GLP-1 analogue i.e., Liraglutide which had a lesser half-life requiring administration of drug once a day.

136. In this regard, the Plaintiff, on 22nd October 2014, during the prosecution of the Genus Patent/IN'964 and on 18th June 2013, during prosecution of the Suit Patent/IN'697 before the Indian Patent Office, had for the first time submitted data for the therapeutic efficacy of some of the examples/compounds claimed in Genus Patent/IN'964 and Suit Patent/IN'697, to contend that the half-life of the compounds therein is higher than the Liraglutide compound. The efficacy data from both patents were shown in contrast with the efficacy of Liraglutide compound. The only difference between the GLP-1 analogues produced in the Genus

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Patent/IN'964 and the Suit Patent/IN'697, as per the efficacy data filed with the Indian Patent Office, was a difference in half-life.

137. It is the argument of the Plaintiff that even though both Genus Patent/IN'964 and Suit Patent/IN'697 claim the same inventive concept, Semaglutide compound was not specifically disclosed in the Genus Patent/IN'964, but only in the Suit Patent/IN'697.

138. However, in the Complete Specification of the Genus Patent/IN'964, the Plaintiff has specified that the invention of Genus Patent/IN'964 could also be extended to further combinations as suggested in the Genus Patent/IN'964. The Complete Specification of Genus Patent/IN'964 further stipulates that the 66 examples enlisted therein are merely 'illustrative' and the claim therein is not limited to the said examples/compounds. The relevant paragraphs of the Complete Specification of the Genus Patent/IN'964 are as follows:

> "**It should be understood that any suitable combination of the compounds according to the invention with one or more of the above-mentioned compounds and optionally one or more further pharmacologically active substances are considered to be within the scope of the present invention.**
> The present invention is further **illustrated** by the following examples which, however, are not to be construed as limiting the scope of protection. The features disclosed in the foregoing description and in the following examples may, both separately and in any combination thereof be material for realising the invention in diverse forms thereof."
>
> [emphasis supplied]

139. This is also apparent from the written submissions, dated 22nd October 2014, submitted by the Plaintiff before the Indian Patent Office during the prosecution of the Genus Patent/IN '964. The relevant paragraph of the said written submission[86] is as follows:

[86] Paragraph A.3 at Page 269 of Plaintiff's Documents Volume-IV.

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> "**examples 1 to 66 are provided for the purpose of illustration, the practice of the invention encompasses all the usual variations, adaptations and/or modifications that come within the scope of the following claims. Claims 1 to 26 therefore, define the scope of the invention for which protection is claimed.**"
>
> [emphasis supplied]

140. Now, in light of the analysis of the credible challenge under Section 64(1)(a) of the Patents Act, it, prima facie appears to this Court that the specific disclosures in the Genus Patent/IN'964 enable 'a person skilled in the art' to arrive at Semaglutide compound, thus making it unambiguously a part of the claims of Genus Patent/IN'964.

141. At this juncture, it is also pertinent to again note that the Plaintiff in the Form 27 filed with the Indian Patent Office has claimed that the drug containing the Semaglutide compound is the commercial product worked from invention claimed in the Genus Patent/IN'964. Thereafter, regarding the Suit Patent/IN'697 as well, the Plaintiff has made identical declaration. The effect of this declaration has already been discussed in the analysis of the credible challenge under Section 64(1) (a) of the Patents Act to hold that the Semaglutide compound is prior claimed in the Genus Patent/IN'964.

142. From the analysis above, following facts are discernible:

(i) Semaglutide compound was originally invented in 2004 itself when the Genus Patent/IN'964 was filed;

(ii) Both the Genus Patent/IN'964 and Suit Patent/IN'697 were addressing identical inventive concepts;

(iii) As per the analysis of credible challenge under Section 64(1)(a) of the Patents Act, the Genus Patent/IN'964 have specific claims/disclosures enabling Semaglutide compound;

(iv) As per the analysis of credible challenge under Section 64(1)(f) of the

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Patents Act, the therapeutic efficacy sought to be achieved by the Semaglutide compound was obvious for a person in the know.

143. Thus, from the aforesaid factors, this Court infers that the Plaintiff invented the Semaglutide compound in 2004, which is contemporaneous to the time of filing the Genus Patent IN'964, but wilfully withheld the Semaglutide compound from the Patent Office and artificially created a second patent [Suit Patent/IN'697] that were filed at a later filing date after the Genus Patent/IN'964, to extend the monopoly already granted with the acceptance of the Genus Patent/IN'964.

144. Therefore, it can be concluded that the Genus Patent/IN'964, which discloses the Semaglutide compound has enjoyed protection for a period of twenty [20] years; however, the protection for the same remains extended due to the Suit Patent/IN'697, resulting in double patenting and, thereby, evergreening. These facts, at this prima facie stage, further strengthen the credible challenge raised by the Defendants to the Suit Patent/IN'697 on the ground of Section 64(1)(a) and 64(1)(f) of the Patent Act.

F. OTHER GROUNDS

145. In view of the findings of a strong prima facie case under Section 64(1)(a), 64(1)(e) and 64(1)(f), no findings are being returned on the remaining grounds as the same will be tested at trial.

V. BALANCE OF CONVENIENCE AND IRREPARABLE INJURY

146. The Plaintiff at paragraph '59' of the plaint has pleaded that it manufactures the Semaglutide compound in India. The Defendants filed I.A. 17802/2025 to contend that this is a false assertion made in the plaint, and in fact, the Plaintiff does not carry out any manufacturing in India. The Plaintiff has since clarified that it indeed does not carry out any manufacturing of the drug containing the Semaglutide compound and, in fact, imports these drugs in India for sale.

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147. Mr. Gopal Subramanium, learned senior counsel appearing for the Defendants, after concluding arguments stated on instructions that the Defendants will abide by the statement recorded in the order dated 29th May 2025. He stated that the Defendants will only export the drugs to countries where the Plaintiff does not hold the patent for the Semaglutide compound, and the Defendants will not sell the impugned drugs in India. The Defendants have also filed an affidavit of their representatives to this effect on 29th May 2025.

148. The statement of the Defendants is accepted as an undertaking to the Court and taken on record. The Defendants are bound down to the said statement. It is directed that the Defendants will not sell the impugned drugs in India until the Suit Patent/IN'697 has expired. The Defendants are, however, directed to maintain an account of the drugs manufactured and exports carried out by them for the entire period from the commencement of manufacture until the expiry of the Suit Patent/IN'697 for the purposes of the trial.

149. In view of the undertaking of the Defendants that they will not sell the impugned drugs in India as well as the direction of the Court to the Defendants to not sell the impugned drugs in India until the expiry of the Suit Patent/IN'697, this Court is of the considered opinion that the interest of both parties stands balanced. The Defendants have been further bound down to their statement and restricted to exporting the impugned drugs only to countries in which Plaintiff does not hold a patent. There will be no loss of revenue to the Plaintiff within India. The Defendants have been directed to maintain accounts of the stock manufactured and exported, therefore in case the Plaintiff succeeds, the Plaintiff will be compensated by damages.

150. Though this Court has returned a prima facie finding on credible challenge of invalidity of Suit Patent/IN'697 in favour of the Defendants,

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the Court is not releasing the Defendants from their undertaking not to undertake sales in India, in view of the fact that the Defendants have failed to clear the way before they started manufacturing, which shows their procedural mala fide. It is pertinent to note that, after the Genus Patent/IN'964 had expired, the Defendants had applied for a license to the Plaintiff for manufacturing the Semaglutide compound. The Defendants were therefore aware and conscious of the existence of the Suit Patent/IN'697, and it failed to 'clear the way' before commencing manufacturing in India. The Defendants have a history of litigation vis-à-vis the Semaglutide compound in USA and therefore the Defendants are well aware about the Plaintiff's proprietary claims. The Defendants however chose to set up its manufacturing facilities in India and commence manufacturing without challenging the Suit Patent/IN'967. The Defendants had filed the revocation petition only after being served with a cease-and-desist notice as well as commencing manufacturing. This is in clear violation of the well-established legal principles of clearing the way, which has been settled by the Division Bench in **Merck Sharp and Dohme Corporation & Another Vs. Glenmark Pharmaceuticals**[87] and recently elucidated by a coordinate bench of this court in **FMC Corporation & Ors. v Natco Pharma Limited**[88]**.** According to this judgment, a prudent defendant has a burden to file a revocation petition or a suit for declaration of non-infringement against the patent that they might infringe through their manufacturing activity. The relevant paragraphs of the said judgment are given below:

> "104. As per ***Terrell on the Law of Patents***[14], the defendant can avoid an interlocutory injunction in situations where litigation is bound to ensue if the defendant introduces his product, provided he *clears the*

[87] 2015 SCC OnLine Del 8227
[88] 2025 SCC OnLine 8582

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way first. This can be achieved by using the procedures for revocation and declaration of noninfringement.

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

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

> *"xxx xxx xxx*
>
> *87. A related concern that this Court heeds - the fourth principle operative in this case - is that of the chronology of events and Glenmark's decision to release Zita without first challenging Januvia or Janumet. Undoubtedly, the Act creates a right to oppose patents even after grant.* ***There is no obligation to only utilize the pre or post grant opposition mechanisms. Neither does a patent benefit from a presumption of validity if it is challenged in the course of an infringement suit. However, if a defendant is aware that there may be a possible challenge to its product, but still chooses to release the drug without first invoking revocation proceedings or attempting to negotiate, that is surely a relevant factor.*** *The defendant's legal right to challenge the patent at any point in time is intact, but that does not mean that this factor cannot determine the interim arrangement. This is more so where Glenmark today argues that MSD ought to have disclosed international patent applications for SPM and Sitagliptin plus Metformin since they were the "same or substantially the same" as the suit patent under Section 8. That is Glenmark's stated position. Such being the state of things, it is surely reasonable for Glenmark to detect the possibility to challenge, when a US patent application for SPM filed by it was opposed by MSD.* ***Despite this, Glenmark released the drug without initiating revocation proceedings under the Act, which is also a right vested in Glenmark that would have***

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obviated the need for the interim arrangement we are today considering. *This does not mean that Glenmark's right to question the validity of the patent in an infringement is affected, but the manner of challenge is a relevant factor against it at the interim stage.* ***As Justice Jacob noted in both Smithkline Beecham cases (supra):***

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

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

[Emphasis supplied]

151. The Defendants herein are regular litigants and have been parties to several patent infringement actions in the Court, whether as a plaintiff or a defendant and are therefore well versed with the legal reasoning behind the principle of clearing the way. The Defendants, therefore, by proceeding to commence setting up of manufacturing facilities and manufacture without challenging the Suit Patent/IN'697 did so at its own peril and therefore there is no balance of convenience in their favour so as to entitle them to sell the impugned drugs in India until the expiry of Suit Patent/IN'697, which is imminent being 20th March, 2026.

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VI. CONCLUSION

152. Accordingly, the Plaintiff has failed to make out a prima facie case for the grant of an interim injunction. On the basis of the discussion above, this Court is of the view that any damages suffered by the Plaintiff can be adequately compensated, if deemed appropriate, after the trial has been concluded in accordance with law.

153. Since the Plaintiff is not manufacturing in India and only importing to India, this Court accepts the undertaking by the Defendants and permits them to manufacture the impugned drug in India and export it to countries where the Plaintiff does not have a Patent registration.

154. In view of the fact that the Defendants have started manufacturing the impugned drug in April 2025, the Defendants shall place on record the details, quantity, and value of the products manufactured and sold.

155. It is clarified that the observations recorded above are only prima facie and confined to the adjudication of the present application for interim relief, based solely on the submissions and material placed on record at this stage. Nothing stated herein shall be treated as an expression on the merits of the matter, which shall be examined independently at trial, uninfluenced by any observations in this order.

156. Accordingly, the captioned application is dismissed.

MANMEET PRITAM SINGH ARORA, J

DECEMBER 02, 2025/rhc/msh/hp/mt/aa/fv/mg

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