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

% *Date of Decision: 31st August, 2026*

\# **CNR No. DLHC010119472025**

\+ C.A.(COMM.IPD-PAT) 7/2025

FRESENIUS KABI IPSUM SRL .....Appellant

Through: Mr. Vishal Sudan and Ms. Neelam Satija, Authorized Representatives.

versus

THE ASST. CONTROLLER OF PATENTS AND DESIGNS & ANR. .....Respondents

Through: Ms. Nidhi Raman, CGSC with Mr. Om Ram and Ms. Nikita Singh, Advocates for R-1.

Mr. Durga Das Bhatla, Ms. Prachi Gupta and Ms. Shivani, Advocates for R-2.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J.

1. This appeal is filed by the Appellant under Section 117A (2) of The Patents Act, 1970 ('1970 Act') challenging order dated 21.11.2024 passed by Respondent No. 1/Assistant Controller of Patents and Designs refusing Patent Application No. IN 201611009993 dated 22.03.2016 in respect of invention titled as *"AN IMPROVED PROCESS FOR THE PREPARATION OF SUGAMMADEX WHICH INVOLVES THE USE OF A SALT OF 3-MERCAPTO PROPIONIC ACID, PREFERABLY THE DI SODIUM SALT OF 3-MERCAPTO PROPIONIC ACID"*.

2. To the extent necessary, the case set up in the appeal is that Appellant operates and is well known in the field of Research and Development and

manufacturing of world class drugs. Appellant provides state-of-the-art drugs and is involved in the process right from development to manufacturing and marketing across the globe and is fast emerging as a leading player in generics on the strength of its comprehensive product portfolio of injectables, orals, intermediates and Active Pharmaceutical Ingredients. Respondent No. 2 is the pre-grant opponent, who filed opposition under Section 25(1) of 1970 Act. The bibliographic details are as follows:-

Patent application No.	IN201611009993
Filing Date	22 Mar. 2016
Applicant	FRESENIUS KABI IPSUM S.R.L.
Publication Date	26 Jan. 2018
Request for Examination Date	14 June 2019
FER Date	30 Mar. 2021
Response to FER date	29 Sep. 2021
Pre-grant opposition filed by Respondent -2	21 Oct. 2021 and filed on 25 Oct. 2021
Reply statement filed by Appellant	25 Feb. 2022
Date of Hearing with reference to Pre-grant Opposition	29 Aug. 2023
Written Submission and relevant documents, filed **by** Appellant	12 Sep. 2023
Written Submission and relevant documents, filed by Respondent -2	12 Sep. 2023
Date of Final Hearing	08 Oct. 2024
Written Submission and relevant documents, filed by Appellant	23 Oct. 2024
Written Submission and relevant documents, filed by Respondent -2	23 Oct. 2024
Date of Refusal	21 Nov. 2024

3. It is stated that the present invention relates to an improved process for preparation of sugammadex, more particularly, to a reaction of an

isolated salt of 3-mercaptopropionic acid with 6-per-deoxy-6-per-halo-y-cyclodextrin to obtain sugammadex, wherein said salt is preferably selected from the group comprising of di sodium salt of 3-mercaptopropionic acid, di potassium salt of 3-mercaptopropionic acid and dilithium salt of 3-mercaptopropionic acid. Essentially, the application relates to use of isolated di-alkali metal salt of 3-mercaptopropionic acid for the preparation of sugammadex, which improves overall purity and/or reaction time of sugammadex. The claimed invention solves the problems that exist in the prior arts such as:-

(a). Obtained purity of sugammadex was not satisfactory;

(b). reaction time of 6-per-deoxy-6-per-halo-ycyclodextrin with 3-mercaptopropionic acid was very high and unsuitable for large scale production;

(c). use of pyrophoric reagents such as sodium hydride is not recommended as their handling is difficult at the time of large scale production of sugammadex; and

(d). use of special techniques such as chromatographic purification and utilization of UV light are difficult to implement and control at the industrial scale.

4. It is stated that in one embodiment of the present invention, there is a process for preparation and purification of 6-per-deoxy-6-per-halo-y-cyclodextrin (Examples 1 and 2 of complete specifications). In another embodiment, the process involves preparation of disodium salt of 3-mercaptopropionic acid (Example 3 of complete specifications). Example 4A provides a process for preparation of sugammadex comprising the following steps:-

(a) dimethyl sulfoxide (500 ml) is de-oxygenated with three cycles

of nitrogen, vacuum and nitrogen at 20-30°C. Disodium salt of 3-mercaptopropionic acid (46 g, 0.306 moles) is added and reaction mass is again deoxygenated with two cycles of nitrogen and vacuum at 20-25°C;

(b) 6-per-deoxy-6-per-chloro-Y-cyclodextrin (25 g, 0.017 moles) is dissolved in dimethyl sulfoxide (100 ml) under nitrogen at 20-30°C and added to the reaction mass at 20- 25°C;

(c) reaction mixture is de-oxygenated with four cycles of vacuum and nitrogen at 20-30°C; and

(d) reaction mixture is heated to 70-75°C and stirred for 4-5 hour at 70-75°C. After the reaction is complete, the reaction mass is slowly cooled to 20-30°C, filtered under nitrogen and washed with dimethyl sulfoxide (100 ml) and ethanol (750 ml) and dried under vacuum at 40-50°C for 15 hours to give 43.7 g crude sugammadex.

5. It is stated that Example 5 also provides the process for preparation of sugammadex as follows: -

(a) dimethyl sulfoxide (200 ml) is de-oxygenated with nitrogen, vacuum and nitrogen at 20-30°C. Disodium salt of 3-mercapto propionic acid (16.6 g, 0.1107 moles) is added and reaction mass is de-oxygenated with nitrogen and vacuum at 20-25°C;

(b) 6-per-deoxy-6-per-chloro-y-cyclodextrin (10 g, 0.0069 moles) is dissolved in dimethyl sulfoxide (50 ml) under nitrogen at 20-30°C and added to the reaction mass at 20- 25°C and the reaction mixture is de-oxygenated with vacuum and nitrogen at 20-30°C;

(c) reaction mixture is heated to 70-75°C and stirred for 4-5 hour at 70-75°C and is then cooled to 20-30°C and diluted with water (250 ml) at 20-35°C; and

(d) dimethyl sulfoxide (180 ml) is slowly added to the reaction mass in two lots at 20-35°C and stirred for 1 hour at 20-30°C and then filtered under nitrogen, washed with 20% water in dimethyl sulfoxide (40 ml), suck dried under vacuum 1-2 hours to give sugammadex with purity 98.28%.

6. It is stated that Example 6 also provides a process for preparation of sugammadex as given in the complete specifications. In the First Examination Report ('FER') issued on 30.03.2021, Respondent No. 1 raised objections under Section 2(1)(ja) for claims 1-16, Section 3(d) for claims 1-16 and other formal requirements and cited prior arts D1: WO2014125501A1 (21.08.2014); D2: WO2016194001A1 (08.12.2016); and D3: WO0140316A1 (07.06.2001). Appellant filed reply dated 28.09.2021 addressing the objections and also amended claims for better clarity and to overcome objections.

7. It is stated that first pre-grant opposition was filed by Ms. Ritu Sharma dated 23.07.2020 and second pre-grant opposition dated 21.10.2021 was filed by Respondent No. 2 raising objection of anticipation in view of prior arts D1-D2 under Section 25(1)(b), lack of inventive step under Section 25(1)(e) in view of D1-D7 and non-patentability under Section 25(1)(f). Respondent No. 1 served notice to the Appellant on the opposition and reply was filed on 25.02.2022. Oral hearings were conducted and in one of the hearings, Respondent No. 2 for the first time raised objection of prior claiming, which was rejected by Respondent No. 1. In the third round of oral hearing on 08.10.2024, written submissions were filed by the parties and vide order dated 21.11.2024, Respondent No. 1 refused the application on grounds of lack of novelty, lack of inventive step and non-patentability under Section 3(d).

8. Mr. Vishal Sudan, authorized representative of the Appellant argued the matter and submitted that the impugned order deserves to be set aside on multiple grounds. It was contended that serious procedural illegalities as also violations of principles of natural justice have been committed by Respondent No. 1 and this vitiates the impugned order without entering into merits of the case. Section 14 of 1970 Act read with Rule 129 of the Patents Rules, 2003 ('2003 Rules') casts a duty on Respondent No. 1 to grant hearing to an applicant before exercising any discretionary power that is likely to affect the applicant adversely. Section 14 specifically provides that where, in respect of an application for patent, report of the Examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of 1970 Act/2003 Rules, Controller shall communicate the gist of the objection to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard, before proceeding to dispose of the application and Rule 129 provides that before exercising any discretionary power, which is likely to affect an applicant for a patent, Controller shall give the applicant a hearing after giving 10 days' notice of hearing, ordinarily. In the instant case, while the Appellant was afforded hearing under Section 25(1) but no hearing was granted under Section 14 and thus, the mandate of the said provision is violated.

9. It was further urged that paragraph 09.04(12) of the 'Manual of Patent Office, Practice and Procedure', provides that no patent will be refused without giving an opportunity of being heard under Section 14 of 1970 Act and paragraph 09.04(10) stipulates that after hearing the applicant, Controller may specify or permit such amendment as he thinks fit and grant

the patent. More specifically, where a pre-grant opposition is filed, paragraph 09.06(10) is attracted, which provides that on consideration of the statement and evidence filed by the applicant, the representation including statement and evidence filed by the opponent, submissions made by the parties and after hearing the parties, if so requested, Controller may either reject the representation or require complete specification and documents to be amended to his satisfaction before the patent is granted or refused, by passing a speaking order under Section 15 and he shall simultaneously decide the application and the representation, ordinarily within one month from completion of the proceedings. Therefore, as per the scheme of 1970 Act and Patent Manual, Controller is required to grant an opportunity of hearing under Section 14 in Chapter IV and cannot shut this right of the applicant only because hearing has been granted under Section 25(1) in Chapter V.

10. It was further urged that Section 14 deals with the 'applicant' and Examiner's report and procedural safeguards are provided in Rule 129, while Section 25(1) speaks of 'any person' filing a representation. While the hearing under Section 14 is triggered by Examiner's report, the trigger under Section 25(1) is third party representation. Right of hearing under Section 14 is statutory and between the Controller and the applicant and mandatory, while right of hearing in Section 25(1) is procedural and governed by Rule 55(5) and based on opponent's request and involves the Controller, the opponent and the applicant. To buttress his plea, Mr. Sudan relied on the judgment of the Division Bench of this Court in ***Novartis AG v. Natco Pharma Limited and Another, 2024 SCC OnLine Del 152***, where the Court held that examination under Section 14 and opposition under Section 25(1) are independent and separate processes though statutorily

structured to proceed parallelly and it would be incorrect to understand the provisions of 1970 Act and 2003 Rules as contemplating convergence of the two.

11. Mr. Sudan referred to the judgment of Co-ordinate Bench of this Court in ***Zydus Healthcare Ltd. v. Assistant Controller of Patents and Designs and Ors., MANU/DE/5739/2025***, wherein Court has held that pre-grant opposition and examination of patent are two separate proceedings and pre-grant opponent cannot be countenanced to have right of hearing in the examination process, meaning thereby one is not a substitute for the other and both provisions and procedures involved operate in two different fields. Reliance was also placed on the judgment of the Bombay High Court in ***AIC246 AG & Co. KG v. The Patent Office of India and Ors., MANU/MH/2111/2026***, wherein Court set aside the order of the Controller on the ground that there was denial of opportunity of hearing under Section 14 *albeit* hearing was granted under Section 25(1), observing that to condone such a course of action would, in effect, permit the Controller to bypass the mandatory provisions of Chapter IV and procedure for examination prescribed in the Patent Manual, thereby allowing the Controller to act in a manner wholly inconsistent with the statutory framework. Furthermore, this would not only result in the applicant being deprived of a statutory right of hearing under Section 14 but also enable the Controller to reject the patent without passing an order under Section 15, the only provision governing grant or refusal of patent, as also permit the Controller to act in an arbitrary manner and adopt a different procedure for different matters.

12. Reliance was also placed on an earlier judgment of this Court in ***Ferid Allani v. Union of India and Others, 2008 SCC OnLine Del 1756***, where it

was held that Rule 129 is a statutory rule and casts a duty on the Controller to give a hearing to an applicant, before exercising any discretionary power, which is likely to affect an applicant for a patent, adversely. This judgment was subsequently followed by IPAB in ***Abraxis Bioscience LLC a company organized under the laws of USA of 11755 Wilshire Blvd., 20th Floor, Los Angeles CA 90025 USA v. Union of India, Through the Secretary, Ministry of Commerce and Industry "Udyog Bhawan", New Delhi-110001 & Ors., 2014 SCC OnLine IPAB 100***, holding that non-grant of opportunity under Section 14, which is a mandatory provision, amounts to flagrant violation of principles of natural justice.

13. It was argued that the stand of Respondent No. 1 taken in reply to the appeal that grant of separate hearing would not have altered the outcome of the application, is wholly untenable and *ex facie* contrary to the mandatory statutory framework prescribed under 1970 Act and judicial precedents on the subject. A post-order assertion speculating that the outcome would have remained unchanged cannot legitimize or condone a clear breach of mandatory statutory safeguard. Non-following of the mandate of Section 14 has resulted in denial of patent for an important invention and that too, without an opportunity to address objections and seek amendments to possibly overcome them.

14. It was urged that the other apparent flaw in the impugned order is that it is a non-speaking order. The order does not address various questions which Respondent No. 1 ought to have answered with reasons, such as: (i) whether disclosure of D1 is explicit or implicit while assessing novelty; (ii) which is the closest prior art for determining inventive step; (iii) whether present invention demonstrates any technical advancement or existing knowledge or possesses any economic significance or both, which could

make the invention non-obvious to a person skilled in the art; (iv) why the step of isolation of salt in the claimed invention is allegedly not a new step; (v) why the product obtained in the present invention, though free of impurities compared to product obtained from prior art, is not a new product; and (vi) why technical features such as obtainment of pure product, reduced reaction time compared to prior art processes and use of isolated salt of 3-mercaptopropionic acid, do not constitute novel or inventive features over cited references.

15. It was submitted that Respondent No. 1 has also not considered that in several other jurisdictions where corresponding patents have been granted, as in USA, CN, EU, AU and HK, novelty in the invention has been acknowledged. Also, the experimental data given in the specification was not considered and there is no reason and/or justification for not doing so. Referring to the judgement in ***LAVA International Limited v. Telefonaktiebolaget LM Ericsson, 2024 SCC OnLine Del 2497***, it was emphasized that Respondent No. 1 has completely overlooked the guidelines for assessment of novelty and inventive step in the Patent Manual, which *inter alia* require identification of the closest prior art, distinguishing technical features, objective technical problem and an assessment of obviousness, without hindsight analysis.

16. Without prejudice to these objections, Mr. Sudan submitted that even on merits, the refusal of the patent application is illegal. The claimed invention relates to a process for preparing sugammadex using an isolated salt of 3-mercaptopropionic acid. An isolated salt of 3-mercaptopropionic acid is a distinct, relatively purified and stable chemical entity, capable of independent characterization and its use is not merely cosmetic, since it affects: (a) reaction reproducibility; (b) yield and purity; and (c) scalability

for industrial manufacturing.

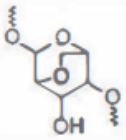
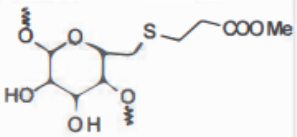
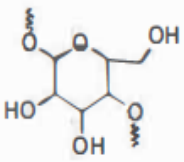
17. It was argued that Respondent No. 1 failed to appreciate that prior art D1 does not disclose the entire or the exact claimed invention. D1 relates to a process for preparation of sugammadex but at no stage, it discloses an isolated salt of 3-mercaptopropionic acid. Present invention uses isolated salt, which leads to formation of sugammadex with a purity of over 98%. The process in D1, which is relied upon by Respondent No. 1 as prior art destroying novelty involves *in situ* generation of salt using sodium methoxide, which introduces variability. Use of isolated salt of 3-mercaptopropionic acid versus *in situ* use, is fundamentally a different chemical process, since isolated salts are comparatively purified, stable and can be characterized as compounds, where as *in situ* are transient intermediates, formed and consumed immediately within the reaction, without isolation and may not be characterized and this distinction is not without significance. It is settled principle of patent law that anticipation must be explicit and prior art must disclose every element of claimed invention in a clear and unambiguous manner and even a single distinguishing technical feature, if absent in the prior art, suffices to establish novelty.

18. Respondent No. 1, it was contended, failed to appreciate that claimed process introduces a novel technical feature, not disclosed by D1. Prior art D1 does not teach or suggest the procedural and chemical nuances of employing an *in situ* disodium salt nor does it enable the skilled person to replicate the claimed invention without undue experimentation. Prior art processes lead to formation of three impurities, of which two impurities are completely absent in the present invention and the third is at substantially lower level. The claimed invention consistently

delivers high percentage purity and the reaction process therein is significantly more efficient with reduced reaction time relative to prior art processes.

19. It was further submitted that direct comparison of the processes in D1 and the claimed invention establishes that experimental results of the claimed invention are distinct, superior and technically distinguishable from D1. To demonstrate the key differences, reference was made to the following tables:-

Table A:

Impurity	WO'316 (Ref. Ex. 1) area-% HPLC	WO'937 (Ref. Ex. 2) area-% HPLC	WO'501 (Ref. Ex. 3) area-% HPLC	Examples of the present application area-% HPLC		
				Ex. 4C	Ex.5	Ex.6
 Intramolecular ether-SGX Impurity I	0.24	1.84	0.38	ND	ND	ND
 Methyl ester-SGX Impurity II	ND	ND	0.74	ND	ND	ND
 Hydroxy-SGX Impurity III	1.20	1.45	1.57	0.45	0.24	0.37

SGX = Sugammadex; ND = Not Detected

WO2012/025937A1 (Ref. Example 2)	12 Hours	94.35
WO2014/125501A1 (Ref. Example 3)	12-14 Hours	88.50
Example of the present application (Example 4C)	4-5 Hours	98.53
Example of the present application (Example 5)	4-5 Hours	98.28
Example of the present application (Example 6)	4-6 Hours	98.0

It is evident from the comparative data that process of present application requires lesser time for its completion and leads to higher purity of sugammadex.

WO2012/025937A1 (Ref. Example 2)	12 Hours	94.35
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Example of the present application (Example 6)	4-6 Hours	98.0

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20. It was explained from the table that formation of impurity II in D1 is inseparably tied to presence of sodium methoxide, which is its essential

reagent, while present invention consciously omits sodium methoxide, resulting in complete absence of impurity II and this decisive chemical and mechanical divergence destroys any allegation of anticipation and confirms the novelty of present invention over D1. Mr. Sudan took the Court through a tabular comparison of the processes in claimed invention and D1 as follows:-

IN 201611009993 (Applicant's process)	***D1 (WO2014125501)***
Example 3: Preparation of di-sodium salt of 3-mercapto propionic acid *3-mercapto propionic acid (50 g, 0.47 moles) was added to tetrahydrofuran (500 ml) under nitrogen atmosphere and the reaction mixture was cooled to 5-10°C. A solution of* ***sodium hydroxide*** *(37.68 g, 0.94 moles) dissolved in 50 ml of water was added and the reaction mixture* ***was stirred for 1 hour*** *at 15-20°C. Dimethylformamide (250 mL) was added to the reaction mixture at 15-20°C and the reaction mixture* ***was stirred for 1 hour*** *at 15-20°C. The suspension was filtered and washed with tetrahydrofuran:dimemylformamide (1:1) (200 ml).* *The wet solid was stirred in tetrahydrofuran (500 ml) and dimethylformamide (250 ml) at 20 to 25°C* ***for 1 hour*** *under nitrogen atmosphere. The suspension was filtered, washed with tetrahydrofuran : dimethylformamide (1:1) (200 ml) and dried under vacuum at 45-50°C for 15 Hours to give 72 g of disodium salt of 3-mercaptopropionic acid. The*	*Example: 2 Preparation of Sugammadex sodium* *To a mixture of 1 10.2 g, (15 equ.) 3-mercapto propionic acid and 800 ml Dimethyl formamide (DMF), a 30 percent solution of* ***sodium methoxide*** *(373.9 g, 30 equ) in methanol was added at 20-25 degrees centigrade and* ***stirred for 1 hour*** *at the same temperature. The compound from example- 1 (100 g) was added to the reaction mixture at 25-30 degrees Cand heated to 75-80 degrees centigrade* ***and maintained at the 75-80 degrees centigrade for 12 to 14 hours****. After completion of the reaction, the reaction mass was cooled to 20- 25 degrees centigrade, then methanol (1000 ml) was added to the reaction mass* ***and stirred for 2 hours at the same temperature.*** *The resultant solid was filtered, washed with methanol (200 ml) and dried for 60-65 degrees centigrade for 8 hrs.* *The crude product was dissolved in water (294 ml) and methanol (294 ml), treated with activated carbon (39.2 g, 20 percent w/w) and was*

obtained product had a purity of 97 area-% HPLC. *Example 4: Preparation of Sugammadex* *Example 4A: Dimethyl sulfoxide (500 ml) was de-oxygenated with three cycles of nitrogen, vacuum and nitrogen at 20-30°C. The di-sodium salt of 3- mercaptopropionic acid (46 g, 0.306 moles) was added and the reaction mass was again de-oxygenated with two cycles of nitrogen and vacuum at 20-25°C. The 6- per-deoxy-6-per-chloro-Y-cyclodextrin (25 g, 0.017 moles) was dissolved, in dimethyl sulfoxide (100 ml) under nitrogen at 20-30°C and added to the reaction mass at 20-25°C. Then the reaction mixture was de-oxygenated with four cycles of vacuum and nitrogen at 20-30°C. The reaction mixture was heated to 70-75°C* ***and stirred for 4-5 hour*** *at 70-75°C. After completion of the reaction, the reaction mass was slowly cooled to 20-30°C, then filtered under nitrogen, washed with dimethyl sulfoxide (100 ml), ethanol (750 ml) and dried under vacuum at 40-50°C for 15 Hours to give 43.7 g crude sugammadex.*	*filtered through celite, washed the carbon cake with purified water (98 ml). The filtrate was heated to 50-55 degrees centigrade and slowly methanol (2646 ml) was added at the same temperature. The contents were cooled to 20 to 25 degrees centigrade and* ***stirred for 2 hours*** *at the same temperature. The resulted solid was washed with methanol (200 ml) and dried under vacuum at 60-65 degrees centigrade for 14 hours. The obtained product had yield of 70.34 percent and HPLC purity of 99.43 percent.*

21. It was articulated that even the reaction time is tremendously decreased in comparison to prior art processes. Reaction time pertains to period required for chemical conversion and formation of a product and drying time pertains to physical removal of solvent or moisture and involves no chemical reaction and therefore, taking out the drying time, the two processes are technically independent and different and in fact, drying is not required to complete the reaction. Notably, claim 4 expressly recites the

drying step as optional (step III), evidencing patentee's intent that drying is not an inherent part of the reaction. An optional step cannot be read into the required step and in the instant invention, the isolated product is dried in Example 3, when it is prepared in bulk. Drying in this context is performed solely to facilitate storage and subsequent use of isolated salt in later reaction step as needed e.g. in Example 4, where about 46 g was used and then in Example 5, where 16.6 g was used and this is possible only because the product is isolable as a salt. Importantly, the isolated product may be used immediately after isolation without any drying step as clarified in claim 4.

22. It was also argued that Respondent No. 1 has erroneously disregarded the experimental data, which demonstrates that the process disclosed in D1 yields an impure product and has observed that percentage purity does not fall within the concern of the Patent Office, which is an abdication of statutory duty to assess the invention on technical merits and if this stand is accepted, no inventive step would be evaluated. The difference in the claimed invention and prior art D1 being in the use of isolated salt of 3-mercaptopropionic acid and *in situ* salt is significant and could not be disregarded. In ***Avery Dennison Corporation v. Controller of Patents and Designs, 2022 SCC OnLine Del 3659***, this Court held that simplicity in invention should not deter the Court from granting a patent as even seemingly simple differences may demonstrably impact the product and could be patentable. In the said decision, Court also gave due to consideration to the fact that corresponding patents were granted in other jurisdictions, whereas in the instant case, Respondent No. 1 has completely overlooked this fact.

23. It was argued that Respondent No. 1 has also erred in refusing the

application by holding that the distinction is an obvious modification. It is well settled that obviousness must be assessed from the stand point of a person skilled in the art without benefit of hindsight analysis. None of the prior art documents teach, suggest or motivate the person skilled in the art to isolate the salt prior to the reaction and on the contrary, the prior art integrates salt formation within the reaction mass, thereby teaching away from the claimed approach. The attempt to construct a mosaic of D1, D3, D4 and D7 to allege obviousness, is contrary to the observations of this Court in ***Avery Dennison (supra)***, where it was held that a hindsight reconstruction by using the patent in question as a guide through the maize of prior art references so as to achieve the result of the claim in the suit, is to be avoided. Though it would be tempting to put together a combination of prior arts, but this requires a significant degree of hindsight, both in selection of relevant disclosures from these documents and also in disregarding the irrelevant or unhelpful teachings in them. Respondent No. 1 has even failed to discuss why a person skilled in the art would take D1 as the start point and combine teachings of D3, D4 and D7 with D1.

24. Supporting the impugned order, Ms. Nidhi Raman, learned CGSC argued that Respondent No. 1 has correctly allowed the pre-grant opposition and refused the patent application on grounds of lack of novelty, lack of inventive step and non-patentability under Section 3(d), relying on prior arts D1, D3, D4 and D7 and the order is a well-reasoned and speaking order. Appellant's claim of denial of hearing is ill-founded inasmuch as the Appellant was heard multiple times before the impugned order was passed and authorized representative of the Appellant has himself admitted in the appeal that there were three rounds of oral hearing. Appellant also filed two sets of written submissions on 12.09.2023 and 23.10.2024 and there is no

law which mandates any further opportunity of hearing. Hearing was granted under Section 25(1) and grant of separate hearing under Section 14 would have made no difference to the final outcome and thus there is no violation of principles of natural justice.

25. It was urged that even on merits, Appellant has no case. Respondent No. 1 correctly determined that claimed invention lacks novelty in light of the disclosure in prior art D1. Appellant's claimed invention relates to "*a process for preparing sugammadex of formula I, comprising the steps of: (a) reacting* ***6-per-deoxy-6-per-halo-γ-cyclodextrin of compound of formula II****, wherein, X is chlorine, bromine or iodine; with an* ***isolated salt of 3-mercapto propionic acid****, selected from the group comprising of disodium salt of 3-mercapto propionic acid, di lithium salt of 3-mercapto propionic acid, di potassium salt of 3-mercapto propionic acid, in suitable organic solvent to obtain sugammadex;* and *(b)* ***Optionally****, purifying the sugammadex"* and thus, the technical feature of the said process could be referred to as a reaction of ***6-per-deoxy-6-per-halo-γ-cyclodextrin of compound of formula II*** with ***salt of 3-mercapto propionic acid*** *(disodium salt of mercapto propionic acid)* and the purification step is optional. The core chemical transformation claimed by the Appellant is identical to the process disclosed in Example 2 of D1, which explicitly states: "*the process involves reacting 3- mercaptopropionic acid with sodium methoxide to get the in-situ salt of 3-mercapto propionic acid and* ***reaction of the in-situ salt of 3-mercapto propionic acid with 6-per-deoxy-6-per-halo-γ-cyclodextrin****. The crude product undergoes purification, resulting in 99.43% HPLC purity after drying".* In both cases, the essential reaction is the substitution between a 6-per-deoxy-6-per-halo-γ-cyclodextrin (Formula II) and the disodium salt of 3-mercaptopropionic acid to yield sugammadex. There is thus complete

identity of the starting materials and the final products of the claimed invention and D1.

26. Appellant's primary argument is that the essential difference in the claimed invention and D1 is the of isolated salt of 3-mercaptopropionic acid and *in situ* salt. However, this distinction is irrelevant as both the processes use the same reactant and it does not matter whether the salt is procured from outside or prepared in the laboratory. In both cases, reaction is carried out using disodium salt of 3-mercaptopropionic acid and hence, there is no novelty in the claimed invention. As correctly identified by Respondent No.1, the technical feature is the reaction between two principal reactants i.e., *"reaction of 6-perdeoxy- 6-per-halo-y-cyclodextrin"* and *"salt of 3-mercapto propionic acid"* and D1 explicitly discloses this exact technical feature. Therefore, disclosure in D1 is sufficient to anticipate the claimed process.

27. It was also argued that the claimed invention lacks inventive step in light of disclosures in D1 or D3, either alone or in combination of D1, D3, D4 and D7. The claimed process when assessed against the state of the prior art would be obvious to a person skilled in the art and the alleged distinctions are nothing more than routine and predictable modifications of known processes, devoid of any technical advancement or surprising effect that would warrant the grant of patent. D1 discloses (Example 2) *"To a mixture of 110.2 g, (15 equ.) 3-mercapto propionic acid and 800 ml DMF, a 30% solution of sodium methoxide (373.9 g, 30equ) in methanol was added at 20-25°C and stirred for 1 hour at the same temperature. The compound from example-1 (100 g) was added to the reaction mixture at 25-30°C and heated to 75-80°C and maintained at the 75-80°C for 12 to 14 hours. After completion of the reaction, the reaction mass was cooled to 20-25°C, then*

methanol (1000 ml) was added to the reaction mass and stirred for 2 hours at the same temperature. The resultant solid was filtered, washed with methanol (200 ml) and dried for 60-65°C for 8 hrs." The purification process disclosed in D1 is *"The crude product was dissolved in water (294 ml) and methanol (294 ml), treated with activated carbon (39.2 g, 20% w/w) and was filtered through celite, washed the carbon cake with purified water (98 ml). The filtrate was heated to 50-55°C and slowly methanol (2646 ml) was added at the same temperature. The contents were cooled to 20 to 25°C and stirred for 2 hours at the same temperature. The resulted solid was washed with methanol (200 ml) and dried under vacuum at 60-65°C for 14 hours. The obtained product had yield of 70.34% and HPLC PURITY OF 99.43 %."*. Similarly, D3 discloses the preparation of sugammadex by reaction in dry DMF of 6-per-deoxy-6-perhalo-γ-cyclodextrin with the *in situ* disodium salt of 3-mercapto propionic acid.

28. Therefore, assuming that using isolated salt of 3-mercapto propionic acid constitutes a technical difference from *in situ,* a person skilled in the art of synthetic organic chemistry is routinely faced with the choice of either preparing a reagent within the reaction mixture (*in situ*) or preparing it separately, isolating it and then adding it to the reaction. D1 and D3 teach the essential reaction i.e., substitution between a 6-per-deoxy-6-perhalo-γ-cyclodextrin (Formula II) and the disodium salt of 3-mercapto propionic acid to yield sugammadex. A skilled person seeking to implement this known reaction would naturally and without any inventive faculty consider the option of using a pre-formed isolated salt as an obvious alternative to the disclosed *in situ* method. Such a modification is a mere workshop improvement and falls squarely within the ambit of routine experimentation.

29. It was argued that D4 discloses the preparation of halo-cyclodextrin by treating it with a halogenating agent in an organic solvent, followed by treatment with an aqueous base. Therefore, D4 renders the claimed process obvious by making it clear that the preparation of a key starting material, the 6-per-deoxy-6-per-halo-γ-cyclodextrin, was already well known in the art. D4 explicitly discloses a method for preparing this halo-cyclodextrin. A person skilled in the art, when tasked with performing the main reaction disclosed in D1 or D3, would naturally and routinely seek the established methods to procure or synthesize the necessary starting materials and the combination of these documents would be entirely straightforward for a skilled person i.e., first prepare the halo-cyclodextrin intermediate using the known method taught in D4, then use this intermediate in the subsequent, known sugammadex-forming reaction taught in D1 or D3. There is no inventive skill in combining these steps.

30. Insofar as prior art D7 is concerned, Ms. Raman submitted that D7 discloses the method of preparation of disodium salt of 3-mercaptopropionic acid by reacting equimolar amount of 3-mercaptoproponic acid sodium salt (0.001 mol) in (20ml) ethanol with NaOH (0.002 mol) in (10 ml) absolute ethanol. Claimed invention is devoid of inventive step and is obvious to a person skilled in the art in light of the disclosure in D7 when combined with the disclosure of D4 and/or D1 and/or D3. The primary process for preparing sugammadex is well-established in the art. D1 and D3 both disclose the preparation of sugammadex by reacting 6-per-deoxy-6-per-halo-γ-cyclodextrin with the *in situ* generated disodium salt of 3-mercaptopropionic acid in a suitable solvent. D7 explicitly teaches a method for preparation of the disodium salt of 3- mercaptopropionic acid by reacting its sodium salt with NaOH in ethanol. Furthermore, D4 discloses

the preparation of a key starting material, halo-cyclodextrin. A person skilled in the art, looking to perform the reaction taught in D1 or D3, would find it entirely obvious to prepare the necessary reactants using established methods. The choice between preparing the disodium salt of 3-mercaptopropionic acid *in situ* (as in D1/D3) or preparing it separately as per the method in D7 before adding it to the reaction is merely a matter of routine workshop choice, which in no manner can be considered as an inventive step. Therefore, combining the disclosures of D7 and D4 with the main process of D1 and/or D3 would be an obvious modification for any person skilled in the art.

31. In response to the argument of the Appellant that the claimed process yields a product of significantly higher purity than of D1 (99.43%), it was argued that Appellant's own comparative data presented in Table B directly contradicts this assertion, showing that the process achieves a purity of only 98% to 98.53%. Moreover, Appellant has itself in the independent claim, claimed purifying sugammadex as an optional step. Appellant's claim of shorter reaction time (4-5 hours) is based on a selective and misleading presentation of data overlooking the significant time required to separately prepare and isolate the salt of 3-mercapto propionic acid. In contrast, the 12-14-hour timeframe disclosed in D1 encompasses the entire integrated process, including the salt formation.

32. It was lastly submitted that there is no infirmity in refusing the application for non-patentability under Section 3(d) of 1970 Act, which provides *inter alia* that mere use of a known process, machine or apparatus is not invention unless such known process results in a new product or employees at least one new reactant. In the instant case, the process in the claimed invention is for preparation of sugammadex and uses known

starting materials to produce a known end product sugammadex. The reaction of 6-per-deoxy-6-per-halo-y-cyclodextrin with salt of 3-mercaptopropionic acid is a known process and disclosed in D1 and D3 and therefore, the claimed process does not involve any new reactant or result in a new product.

33. Arguing on behalf of Respondent No. 2, Mr. Durga Das Bhatla, learned counsel joins Ms. Raman in defending the impugned order. It was argued that in the pre-grant opposition, reliance was correctly placed on D1 which confirms with each and every feature of claimed invention. Example 2 of D1, more particularly, discloses the same reactants i.e., disodium Salt of 3-mercaptopropionic Acid and 6-perdeoxy-6-per-halo-γ-cyclodextrin, which combine to form the same product sugammadex. Further, prior art D1 discloses that the base and acid have to be used in a defined stoichiometric ratio of 1:2 (between acid and base) i.e., the ratio required to prepare disodium salt of 3-mercaptopropionic acid. In D1, 3-mercaptopropionic acid is used in an amount of 15 equ and sodium methoxide is used in an amount of 30 equ, thereby maintaining an acid-to-base ratio of 1:2. On similar lines, Example 3 of claimed invention employs 3-mercaptopropionic acid in an amount of 0.47 moles while sodium hydroxide is used in an amount of 0.94 moles. Therefore, sodium hydroxide is present in two equivalents relative to 3-mercaptopropionic acid, establishing a stoichiometric ratio of 1:2 between the acid and the base. When strict stoichiometric ratio of reactants i.e., 1:2 is maintained, there is no excess base in the reaction medium and in this light, the assertion of the Appellant that by isolating disodium salt, formation of impurities is precluded due to presence of excess base in the medium, is incorrect. Moreover, before the next reactant 6-perdeoxy-6-per-halo-γ-cyclodextrin

enters the reaction medium, sufficient time and temperature condition are provided in D1 to help complete the first reaction i.e., preparation of disodium salt of 3-mercaptopropionic acid. The reaction medium is stirred for one hour at 15-20°C to allow the first part of the reaction to complete and therefore, when the next reactant enters the reaction medium, almost all the base would have already exhausted. Thus, the claimed process is nothing but another way of presenting the same known process of the prior art.

34. It was contended that the claim of the Appellant that its invention differs from D1 because the disodium salt of 3-mercaptopropionic acid is isolated before reaction, has no relevance inasmuch as the step of formation of disodium salt of 3-mercaptopropionic acid *in situ*, is an inherent disclosure in D1 as the final reaction is essentially and mandatorily consummated between the disodium salt of 3-mercaptopropionic acid and 6-perdeoxy-6-per-halo-γ-cyclodextrin. The fact that disodium salt of 3-mercaptopropionic acid is prepared *in situ* in prior art documents is admitted by the Appellant during prosecution of the patent application and in this regard, reference was made to reply to FER and both written submissions.

35. It was also urged that reaction of the disodium salt of 3-mercaptopropionic acid and 6-perdeoxy-6-per-halo-γ-cyclodextrin is implicit in what is explicitly stated in D1 and in support of this plea, reliance was placed on the decision of the European Board of Appeal in T701/09, wherein it was held that direct and unambiguous disclosure is not limited to explicit or literal statements, but equally includes implicitly disclosed information which a reader skilled in the art would unequivocally gather from the overall context of a cited document. Implicit disclosure has been defined as disclosure which a person skilled in the art would objectively

consider as necessarily implied in the explicit content. In the instant case, it is a known fact that the reaction is being consummated between salt of 3-mercaptopropionic acid and 6-perdeoxy-6-per-halo-γ-cyclodextrin and the reaction time and conditions are provided in D1 for the prior step i.e., reaction of base and 3-mercaptopropionic acid (stirred for one hour at 15-20°C) to allow preparation of the disodium salt of 3-mercaptopropionic acid by way of exhaustion of base. Accordingly, D1 anticipates every feature of the claimed invention and therefore, the prior art discloses preparation of 6-perdeoxy-6-per-halo-γ-cyclodextrin; disodium salt of 3-mercaptopropionic acid prepared *in situ* by reaction of base with 3-mercaptopropionic acid wherein *inter se* ratio of acid and base is fixed i.e., 1:2; time and temperature parameters to allow the said step to complete; subsequent addition of 6-perdeoxy-6-per-halo-γ-cyclodextrin and preparation of final product; purification steps; better HPLC purity of final product; and lesser overall reaction time and thus, the claimed invention lacks novelty in view of D1.

36. It was further argued that Respondent No. 1 has correctly held that claimed invention lacks inventive step. The claimed process involves routine and predictable modifications of known processes, without any technical advancement or unexpected results. D1 details the reaction of 3-mercaptopropionic acid with 6-per-deoxy-6-per-halo-γ-cyclodextrin in DMF using sodium methoxide, including specific conditions and purification methods that achieve high yield and purity. Similarly, D3 teaches preparation of sugammadex by reacting 6-per-deoxy-6-per-halo-γ-cyclodextrin with the *in situ* generated disodium salt of 3-mercaptopropionic acid in dry DMF, thereby disclosing the same essential reaction. Minor variations in the claimed invention such as isolating the salt are obvious choices to a skilled chemist and do not confer inventive step. D1 is the closet

prior art and discloses the preparation of sugammadex by reacting 6-perdeoxy-6-per-chloro-γ-cyclodextrin with disodium 3-mercaptopropionic acid generated *in situ*, followed by purification with water and methanol to achieve 99.43% purity. Insofar as purity and purification process are concerned, it was urged that the claimed invention when compared with Example 2 of D1 makes it clear that even at the stage of final purification, the results achieved in the claimed invention are not superior to prior art and D1 achieves higher purity than the present invention as follows:-

Comparison of Product Purity

Document/Example	Purity of Sugammadex
Example 4C (Present Application)	98.53 area-% HPLC
Example 5 (Present Application)	98.28 %
Example 6 (Present Application)	98.0 area-% HPLC
Example 2 (D1)	99.43 %

37. The next plank of the argument of the Appellant that the reaction claimed in the claimed invention is completed in a shorter time as compared to prior art, is misleading. The preparation and isolation of disodium salt in solid form takes approximately 18 hours in Example 3. This dried salt is thereafter used in Example 4A, where the reaction is carried out for about 20-21 hours followed by Example 4B, which includes further processing and drying, taking approximately 14 hours, followed by Example 4C, comprising final purification and drying, taking approximately 18 hours. Accordingly, the total time taken for the overall process is approximately 71 hours, while in Example 2 of D1, the reaction is completed in approximately 39 hours. It is not correct for the Appellant to argue that drying time should not be considered since drying is essential step in preparation of disodium salt, which is evident from the fact that in the following step in Example 4, disodium salt is used as dried disodium salt instead of wet salt.

38. It was next argued that D3 further demonstrates that preparation and use of alkali metal salts of 3-mercaptopropionic acid is well known. D3 discloses stoichiometric formation of disodium salts and reaction with halo-cyclodextrin in DMF, followed by purification. Therefore, steps in the claimed invention, including salt formation, reaction conditions, solvent choice and purification are already known, rendering claims 1, 2, 11 and dependent claims obvious in view of D1 and D3 and there is no inventive skill. D4 and D7 further support obviousness. D4 discloses preparation of halo-cyclodextrin intermediates using halogenating agents in DMF and D7 explicitly describes preparation of disodium 3-mercaptopropionate and thus combining these teachings constitutes routine experimentation and does not involve inventive skill.

39. It was urged that in addition to lacking novelty and inventive step, the claimed invention is barred under Section 3(d) of 1970 Act as it merely uses a known process without employing any new reactant or producing a new product. Section 3(d) excludes patentability for the mere use of a known process unless it results in a new product or uses at least one new reactant. D1 already discloses the reaction of 6-per-deoxy-6-per-chloro-γ-cyclodextrin with the disodium salt of 3-mercapto propionic acid to produce final product i.e., sugammadex and the claimed invention also uses the same reactants and yields the same product. Importantly, Appellant has admitted in response to FER that in D1 and D3, the salt of 3-mercaptopropionic acid is prepared *in situ* and reacted with halo-γ-cyclodextrin to obtain sugammadex. The alleged advantages of higher purity and reduced reaction time are unfounded since D1 already achieves higher purity (99.43% by HPLC) and a shorter overall reaction time when the salt preparation step is properly accounted for. Therefore, the claimed invention with claims 1-16,

fails on all grounds under Sections 25(1)(b), 25(1)(e) and 25(1)(f) of 1970 Act and the impugned order calls for no interference.

40. Heard learned counsels for the parties and examined their submissions.

41. Present appeal pertains to a Provisional Patent Application IN 201611009993 dated 22.03.2016 in respect of claimed invention titled *"AN IMPROVED PROCESS FOR THE PREPARATION OF SUGAMMADEX WHICH INVOLVES THE USE OF A SALT OF 3-MERCAPTO PROPIONIC ACID, PREFERABLY THE DI SODIUM SALT OF 3-MERCAPTO PROPIONIC ACID"*. On a pre-grant opposition dated 21.10.2021 being filed by Respondent No. 2 on 25.10.2021, patent application was refused on grounds of lack of novelty under Section 25(1)(b), lack of inventive step under Section 25(1)(e) and non-patentability under Section 3(d) of 1970 Act, vide order dated 21.11.2024.

42. Mr. Sudan appearing for the Appellant has taken multiple grounds to assail the impugned order. The first ground is embedded in violation of laid down procedure for grant of patent as also principles of natural justice. In a nutshell, the argument was that Respondent No. 1 failed to afford an opportunity of hearing under Section 14 *albeit* hearing was granted under Section 25(1). Before embarking on examination of this contention, it will be useful to refer to the statutory framework under the 1970 Act as also the 2003 Rules. Section 11(A) of 1970 Act deals with publication of applications for patent and Section 11(B) provides for Request for Examination. Once a request is received by the Controller of Patents, the same is required to be referred to an Examiner, who then makes an enquiry in respect of matters enumerated in Section 12(1)(a) to (d) and submits a report to the Controller. Enquiry under Section 13 is directed against

anticipation by publication or the subject matter of the application forming part of any other claim or claim specification published on or after the date of filing of applicant's complete specification and Section 13(2) mandates examination of the application not just against any publication in India but also elsewhere in any document other than those mentioned in sub-Section (1).

43. Next in the statutory scheme and framework is Section 14, which casts a duty on the Controller to communicate the gist of objections to the applicant where the report of the Examiner is adverse to the applicant or requires any amendment of the application, specification or other documents to ensure compliance with the provisions of 1970 Act and 2003 Rules and to give an opportunity to the applicant to respond to the objections. This is the stage of issuance of FER. Section 15 is a repository of the power of the Controller to either refuse the application or require the applicant to amend the specification and/or the documents therewith. This entire process, commencing from Section 12 to Section 14, is the '*examination process*', basis which the Controller exercises the power Section 15.

44. Relevant to the instant case is also Section 25 of 1970 Act, which deals with '*opposition proceedings*' and this commences upon publication of the application for patent but before it is granted and as sub-Section (1) of Section 25 indicates, the pre-grant opposition can be filed by 'any person', in writing, on grounds enumerated in Section 25(1)(a) to (k). Section 25(2) deals with post-grant opposition, which can be filed by 'any person interested' but within one year from the date of publication and on grounds mentioned in Section 25(2)(a) to (k). For the sake of completeness, be it mentioned that it is now judicially settled that objections under Section 25(1) can be filed not only by a person engaged in or in promoting research

in the same field to which the invention relates but by any individual or entity, which may seek to oppose the grant on grounds specified therein and may include a person, who may have no direct, present or tangible interest in the patent or one whose rights are not adversely affected.

45. The neat legal nodus that arises for consideration before this Court is whether Respondent No. 1 was justified in denying opportunity of hearing to the Appellant under Section 14 for the reason that hearing was granted during the pre-grant opposition proceeding under Section 25(1). This question need not detain this Court as it stands answered in earlier decisions of this Court and other High Courts. In ***Novartis AG (supra)***, the Division Bench held that the examination process under Chapter IV and opposition process under Chapter V though statutorily structured to proceed parallelly, are independent and separate and it would be wholly incorrect to understand the provisions of 1970 Act and 2003 Rules as contemplative of convergence or merger. Examining the statutory framework from Section 11(A) to Section 15 as also Section 25(1) and (2), the Division Bench observed that rejection of an opposition does not and inevitably result in a patent application being granted and notwithstanding the rejection of a representation, Controller is legally as well as statutorily bound and obliged to examine the application based on the FER as well as on his own individual evaluation of whether the patent is liable to be granted under law. Emphasizing on the importance of pre-grant opposition, it was observed that since at this stage representation can be made by any person, it will be incorrect to characterize the proceeding as adversarial and in fact, this stage opens the floor for eliciting a multitude of opinions extending beyond direct stakeholders and enables the Controller to gather insights from a broad spectrum of sources and leads to comprehensive exploration of

objections and perspectives aiding the Controller in making an informed decision and therefore, it will be incorrect to view these proceedings as representing a *lis*.

46. Having said that, the Division Bench also observed that notwithstanding invitation of objections, Controller has to independently satisfy that the application merits acceptance and this independence is vital to uphold the credibility of the patent system ensuring that decisions are made impartially, based on the merits of the applications and therefore, the Court is unable to sustain the theory of merger advocated by the Respondents. It was held that both the 1970 Act as well as the 2003 Rules clearly envisage a dichotomy between the examination process and opposition process and it was important to maintain a clear distinction between the two, as the separation helps in striking a balance between the need for a rigorous examination and the task of including various perspectives in the decision-making process.

47. Pertinently, it was also observed by the Division Bench that an opponent of a pre-grant opposition only plays a role in aiding the Controller in conducting a comprehensive examination of the patent application and thus does not have a right of hearing in the examination process undertaken under Section 14 and the opponent's right to hearing is circumscribed by grounds in Section 25(1), where the opponent has a platform to present arguments and evidence, limited to the challenges raised. Therefore, the upshot of the decision of the Division Bench is that Sections 14 and 25(1) are two distinct statutory pathways and do not merge and any theory of convergence must be rejected. This simply means that a hearing granted to an applicant seeking grant of patent under Section 25(1) operates in a different field and cannot be a reason enough to take away the opportunity

of hearing envisaged separately under Section 14 of 1970 Act.

48. In ***AIC246 AG (supra)***, the Bombay High Court was deciding a petition against an order passed by the Controller refusing the patent application under Section 25(1), without affording a hearing to the applicant under Section 14. The Court observed that prior to the filing of pre-grant opposition, Controller had issued notice to the Petitioner and scheduled hearing under Section 14, however, upon receipt of opposition, the hearing was cancelled noting that a fresh hearing under the said provision will be granted in due course but despite this, the Controller proceeded to reject the application solely under Section 25(1), without granting a hearing under Section 14 and without passing an order under Section 15. Court held in doing so, Controller had not only acted contrary to the express assurance to the Petitioner but also in disregard of the legal position laid down by the Division Bench of this Court in ***Novartis AG (supra)*** and paragraphs 09.04(12) and 09.06(10) of Patent Manual, which clearly provides that no patent shall be refused without affording an applicant an opportunity of being heard under Section 14 and after a hearing under Section 25(1), the Controller is bound to pass a speaking order under Section 15, simultaneously deciding the application and the opposition. The Court also relied on the judgment of the Calcutta High Court in ***UPL Limited v. Union of India and Others, 2025 SCC OnLine Cal 7944,*** wherein it was held that opposition proceedings under Section 25(1) and examination proceedings under Chapter IV are distinct statutory processes and must be adjudicated separately, though a composite and reasoned order may be passed under Section 15. The Bombay High Court negated the contention of the Respondents therein that separate hearings under the two provisions will result in duplication of proceedings.

49. Significantly, the Bombay High Court further observed that the Controller has consistently adopted a practice, as evident from several orders placed before the Court by the Petitioner, to treat the proceedings under Chapters IV and V as separate and distinct and to condone a course of action where the hearing under Section 14 is denied, will permit the Controller to bypass mandatory provisions of Chapter IV and the procedure prescribed under the Patent Manual, thereby allowing the Controller to act in a manner wholly inconsistent with statutory framework. This would not only result in the applicant being deprived of statutory right of hearing under Section 14 but would also enable the Controller to reject the patent without passing an order under Section 15 and will be completely arbitrary.

50. Coming to the instant case in light of the aforementioned judgements, there is merit in the contention of the Appellant that there is violation of Section 14 of 1970 Act as also 2003 Rules. Provisions of Section 14 clearly envision grant of opportunity of hearing to an applicant where the report of the Examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of the 1970 Act and 2003 Rules, before proceeding to dispose of the application, after notifying the gist of objections to the applicant. The argument of the Appellant is strengthened by reading of Rule 129, which provides that before exercising any discretionary power, which is likely to affect an applicant for a patent adversely, Controller shall give the applicant an opportunity of hearing, after giving 10 days' notice, ordinarily.

51. In this context, reliance was correctly placed by the Appellant on the decision of this Court in ***Ferid Allani (supra)***, where the Court held that Rule 129 of 2003 Rules was inserted by the Patents (Amendment) Act, 2002

dated 25.06.2002 w.e.f. 20.05.2003 and this statutory Rule casts a duty on the Controller to give a hearing to an applicant before exercising any discretionary power, which is likely to affect the applicant adversely and on this ground alone, remanded the matter to the Controller, holding that the Petitioner therein had been deprived of the opportunity. Respondent No. 1 was thus under a statutory mandate to grant opportunity of hearing to the Appellant under Section 14 before taking a decision to refuse the application solely on the grounds taken by Respondent No. 2 in the pre-grant opposition. Appellant is also right in its submission that non-grant of hearing under Section 14 has deprived the Appellant of an important right to respond to the objections raised and if necessary, carry out amendments to overcome them and that this is not merely a procedural violation, but violation of a substantive right and goes to the root of the matter. With the provisions of Section 14 being clear as day and in light of wealth of judicial precedents on the mandate of hearing under the said provision, I am unable to accept the contention of Respondent No. 1 echoed by Respondent No. 2, that grant of hearing under Section 25(1) was sufficient and there was no requirement of granting further or separate hearing under Section 14 or worse that the outcome would have been no different. This serious omission of Respondent No.1, in my view, vitiates the impugned order and the matter deserves re-consideration. To complete the discussion, I may also extract hereunder for ease of reference, relevant clauses from the Patent Manual, which in no uncertain terms provide for a hearing to the applicant under Section 14 before taking a decision on grant or otherwise of a patent:-

> *"Consideration of Report by Controller and issuance of First statement of objection/ First Examination Report (FER) 1)*
>
> *1) The Controller considers the report of the examiner ordinarily within one month from the date of the receipt of such report and a gist of*

objections, if any, is sent to the applicant in the form of a report-First Examination Report (FER)-along with the application and specification, if required. If there is no objection to the grant of patent and no pre-grant opposition under Section 25 (1) is pending, the patent is granted at the earliest.

xxx xxx xxx

10) After hearing the applicant, the Controller may specify or permit such amendment as he thinks fit and grant the patent.

xxx xxx xxx

12) No patent is refused without giving an opportunity of being heard under Section 14 of the Act."

52. In light of the aforesaid finding, *albeit* it is not necessary to go into the merits of the case, however, it only needs to be noted that on the technical aspects of the claimed invention and to overcome the objections raised, Appellant had brought forth what in its perception were differences in the prior arts and the claimed invention. As the impugned order indicates, the patent application has been refused on grounds of lack of novelty, lack of inventive step for claims 1-16 in light of alleged disclosures in D1, D3, D4 and D7 as also non-patentability under Section 3(d), holding that the claimed process does not involve any new reactant and nor it results in any new product.

53. The claimed invention relates to a process of preparing sugammadex using an isolated salt of 3-mercaptopropionic acid. Appellant brought forth that an isolated salt of 3-mercaptopropionic acid is a distinct, relatively purified and a stable chemical entity capable of independent characterization and its use is not merely cosmetic as it affects reaction reproducibility, yield and purity as also scalability for industrial manufacturing. On the other hand, prior art processes lead to formation of impurities, some of which are completely absent in the claimed invention and others are substantially low. It was also brought forth that experimental results of claimed invention are

distinct, superior and technically distinguishable from those disclosed in D1, where the formation of impurity is inseparably tied to presence of sodium methoxide, which is an essential reagent in D1, while present invention omits sodium methoxide and consequently, there is complete absence of one of the impurities of D1. Appellant highlighted the feature of decreased reaction time in claimed invention compared to the prior arts as also the high percentage of purity.

54. In my view, the impugned order appears to be largely influenced by the fact that the difference in the use of isolated salt of 3-mercaptopropionic acid or an *in situ* salt is merely cosmetic and *arguendo*, even if it is assumed that there is a technical difference on this score with the prior art D1, substitution of isolated salt of 3-mercaptopropionic acid for *in situ* prepared disodium salt of 3-mercaptopropionic acid is an obvious modification to any person skilled in the art. Respondent No.1 has not considered the stand of the Appellant that use of isolated salt of 3-mercaptopropionic acid versus *in situ* use, is fundamentally a different chemical process since isolated salts are comparatively purified, stable and can be characterized as compounds, whereas *in situ* are transient intermediates, formed and consumed immediately within the reaction, without isolation and may not be characterized and this distinction is not without significance, particularly, when this technical difference was having resultant effect on yield, purity and scalability for industrial manufacturing and thus was a new technical feature not disclosed in D1. It was rightly contended by the Appellant that anticipation must be explicit and prior art must disclose every element of claimed invention in a clear and unambiguous manner and even a single distinguishing technical feature, if absent in the prior art, suffices to establish novelty.

55. On the aspect of the purity of the compound produced through claimed invention being significantly higher than disclosed in D1, Respondent No. 1 has observed that the issue of percentage purity in prior art processes does not fall within the concern of the Patent Office, which to my mind, is fallacious and accepting this stand would shut analysis of many claimed inventions. The issue of absence of impurities due to non-use of sodium methoxide has also not been given any weightage in the impugned order and importantly, the experimental data provided by the Appellant has not been considered. Appellant rightly submits that simplicity in the invention should not be a deterrent in granting patent. The differences cited by the Appellant may appear superficial or simple but could have an impact on the product concerned and therefore, ought to have been dealt with on a serious note by Respondent No. 1.

56. Appellant is also right in its contention that Respondent No. 1 has not addressed several other related but important aspects such as: (i) whether disclosure of D1 is explicit or implicit while assessing novelty; (ii) which is the closest prior art for determining inventive step; (iii) whether present invention demonstrates any technical advancement or existing knowledge or possesses any economic significance or both, which could make the invention non-obvious to a person skilled in the art; (iv) why the step of isolation of salt in the claimed invention is allegedly not a new step; (v) why the product obtained in the present invention, though free of impurities compared to product obtained from prior art, is not a new product; and (vi) why technical features such as obtainment of pure product, reduced reaction time compared to prior art processes and use of isolated salt of 3-mercaptopropionic acid, do not constitute novel or inventive features over cited references.

57. There is also merit in the submission that without any reason forthcoming in the order, Respondent No.1 has constructed a mosaic of prior arts D1, D3, D4 and D7 to come to a conclusion that the claimed invention lacks obviousness and in doing so has adopted a hindsight approach, which has been condemned by Courts in several judgments. In fact, there is no reasoning in the order as to why a person skilled in the art would take D1 as the starting point and combine teachings of D3, D4 and D7 with D1 and if so, how the claimed invention will be obvious to the person skilled in the art.

58. Since there is non-grant of hearing under Section 14, this Court is of the view that the matter requires reconsideration by Respondent No.1 and for this reason, Court is not delving into the rival submissions of the parties on merits of the claimed invention or the pre-grant opposition, including the merits of the impugned order, lest it prejudices either party. However, it was crucial to flag issues raised by the Appellant, which were required to be considered and addressed by Respondent No.1, but have not been so addressed on merits so that while taking a fresh decision on the patent application, these issues are examined and determined.

59. Accordingly, for all the aforesaid reasons and without expressing any opinion on the merits of the case, the impugned order dated 21.11.2024 is set aside and the matter is remanded back to Respondent No. 1 for fresh consideration of Patent Application No. IN 201611009993 dated 22.03.2016 in respect of claimed invention titled *"AN IMPROVED PROCESS FOR THE PREPARATION OF SUGAMMADEX WHICH INVOLVES THE USE OF A SALT OF 3-MERCAPTO PROPIONIC ACID, PREFERABLY THE DI SODIUM SALT OF 3-MERCAPTO PROPIONIC ACID"*. Fresh decision will be taken by Respondent No. 1 within a period of six months from today

in accordance with law. Respondent No. 1 shall comply with the procedures laid down in Sections 14 and 15 as also Section 25 of 1970 Act and Rule 129 of 2003 Rules. Needless to state, final decision will be taken after granting opportunity to the Appellant as also Respondent No.2 and without being influenced by the impugned order.

60. The appeal is disposed of in the aforesaid terms.

JYOTI SINGH, J.

AUGUST 31, 2026
S.Sharma