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

Reserved on: 21st December, 2024
Date of Decision: 9th October, 2025

\+ **C.A.(COMM.IPD-PAT) 7/2021**

EMD MILLIPORE CORPORATION .....Appellant

Through: Mr. Vineet Rohilla, Mr. Debashish Banerjee, Ms. Vaishali Joshi & Mr. Ankush Verma, Advs.

versus

ASSISTANT CONTROLLER OF PATENTS AND DESIGNS .....Respondent

Through: Mr. Adarsh Ramanujan, *Amicus Curie* & Mr. Parth Singh, Adv. (M: 9868245976)
Mr. Harish V. Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Alexander Mathai Paikaday & Mr. Sagar Mehlawat, Advs.

CORAM:
JUSTICE PRATHIBA M. SINGH

JUDGMENT

PRATHIBA M. SINGH, J.

1. This hearing has been done through hybrid mode.

2. The present appeal involves an interpretation of the exclusion from patentability in respect of diagnostic processes/methods under Section 3(i) of the Patents Act, 1970 (hereinafter "*the Act*").

3. The appeal has been filed under Section 117A of the Act, challenging an impugned order dated 18th February, 2021 passed by the Respondent - Assistant Controller of Patents and Designs.

4. Vide the impugned order the Respondent has refused the Patent Application bearing No.1026/DEL/2012 titled "*Devices and Methods for*

Infrared (IR) Based Quantitation of Biomolecules" (hereinafter "*the subject patent application*") under Section 15 of the Act. The impugned order refusing the application for grant of the patent held that the Claims of the subject patent application are not patentable in view of Section 3(i) of the Act.

I. Factual Background

5. The Appellant is a U.S. Corporation which filed the subject patent application as a Convention application on 3rd April, 2012 before the Indian Patent Office. The Appellant claims priority from a U.S. Patent Application No. 61/457,434 dated 14th April, 2011. The application was originally filed with 24 Claims. However, during the prosecution of the application, the Claims have been amended and the final set of Claims before this Court has 14 Claims.

6. The Appellant had filed the Request for Examination of the subject patent application on 11th June, 2012. Thereafter, the First Examination Report (hereinafter "*FER*") in respect of the subject patent application was issued on 31st October, 2017 by the Controller. The primary objection raised by the Controller was that the Claims of the subject patent were not patentable under Section 3(i) of the Act. The Appellant filed its response to the FER on 27th April, 2018 along with supporting documents and amended the Claims of the subject patent application attempting to overcome the objections raised in the FER by the Controller. However, the Controller was still not convinced with the reply of the Appellant and thereafter, the Appellant was also issued hearing notices dated 26th October, 2020 and 1st December, 2020 by the Respondent. The hearing in respect of the subject patent application was held on 21st December, 2020 which was duly attended by the concerned Agent of the Appellant. Subsequent to the hearing, the Appellant submitted its written

submissions dated 5th January, 2021 in support of patentability of the subject invention along with amended claims and supporting documents.

7. However, the subject patent application was refused by the Respondent *vide* the impugned order dated 18th February, 2021 on the ground that the Claims in the subject patent were not patentable under Section 3(i) of the Act. The operative portion of the impugned order is set out below:

> *"6. Essentially, what is being claimed in claim 1 is* ***a method for detection of biomolecules in a sample.*** *Claim 2 recites that the biomolecule is selected from the group consisting of* ***nucleic acids, proteins, lipids, polysaccharides and lipopolysaccharides****, optionally an* ***endotoxin****. Claim 7 recites that the sample comprises* ***a biological fluid*** *and, optionally, the biological fluid is selected from the group consisting of* ***blood, plasma. serum and urine****. Therefore, it is evident that the claimed method is a diagnostic process which brings it into direct confrontation with Section 3(i) of the Act."*
>
> ***Conclusion***
>
> *7. To conclude, the instant application claims subject-matter (claims 1-11) which is not an invention within the meaning of Section 3(i) of the Act. Therefore, I hereby order the instant application refused."*

8. Accordingly, the present appeal has been preferred by the Appellant.

II. Proceedings in the Appeal

9. The present appeal was first heard on 6th October, 2021 on which date notice was issued to the Respondent.

10. On 21st March, 2022 submissions in part, were heard by this Court and after hearing the parties, the Court had directed the ld. Counsel for the Appellant to seek instructions if the subject invention has been put to commercial use in India or in any other country. On the said date, the delay

in filing the Appeal was condoned by this Court and ***I.A. 13058/2021*** was allowed.

11. Thereafter, on 17th May, 2022, after hearing the parties and considering the FER the Court had directed as under:

> *"3. A perusal of the First Examination Report ("FER") shows that the objections as to the novelty and lack of inventive step were raised in respect of some of the claims. However, in the final impugned order, there is no finding in respect of novelty and inventive steps.*
>
> *4. In view of the above, let a report be filed by the concerned Assistant Controller of Patents and Designs - Mr. Aditya Venkateswara N. C., in respect of novelty and inventive step of the subject patent as well, so that the matter can be comprehensively considered on the next date. The said report shall be placed on record at least one week before the next date."*

12. Further to the directions passed on 17th May, 2022, the Respondent had filed a report dated 12th August, 2022 in respect of the novelty and inventive step of the subject invention. The relevant portion of the said report is extracted hereunder:

> *"To summarise, the subject-matter of final claims 1-14 is novel and involves an inventive step within the meaning of Section 2(1)(j). However, the said claims recite subject-matter which is not an invention within the meaning of the Act as the said subject-matter falls within the scope of Section 3(i)."*

13. In view of the said report of the Respondent on the novelty and inventive step involved in the subject invention, the Court was of the view that the issue that would require adjudication would be *qua* Section 3(i) of the Act. Further, considering that the interpretation of Section 3(i) of the Act would have a bearing on large number of patent applications, on 28th October, 2022

the Court appointed Mr. Adarsh Ramanujan, Advocate as an *Amicus Curiae* to assist the Court in this matter.

14. Thereafter, detailed submissions were made by the ld. Counsels for the parties as also the ld. *Amicus Curiae* on several dates. Further to the said hearings, judgment in the present appeal had been reserved on 21st December, 2024.

III. (A) Submissions on behalf of the Appellant

15. Mr. Vineet Rohilla, ld. Counsel appearing for the Appellant, at the outset submitted that the subject patent has been applied for and granted internationally in several jurisdictions including United States of America, South Korea and European Patent Office.

16. He submits that the manner in which the subject invention uses a membrane is novel and inventive and thus, the subject invention is liable to be granted a patent, inasmuch as the method and process adopted is unique to the Appellant. It is further submitted by Mr. Rohilla, ld. Counsel that the Claims which were anticipated by prior art(s), had already been amended during the process of examination. According to the Appellant, the Respondent has incorrectly held that the subject invention is a non-patentable invention under Section 3(i) of the Act. Reliance is placed by the ld. Counsel on the decision of the Enlarged Board of Appeal of the European Patent Office (hereinafter "*EPO*") dated 16th December, 2005 in ***Case Number G 0001/04*** in respect of a case involving diagnostic methods. In the said decision the EPO has laid down guidelines as to the manner in which the bar under Article 52 of the unamended European Patent Convention (hereinafter "*EPC*") 1973, which stipulated exceptions to patentability, is to be applied. Article 52 of the EPC, 1973 corresponds to Article 53 of the revised EPC, 2000. Ld. Counsel

has placed specific reliance upon the following paragraphs of the said decision:

> *"5. The preparatory documents to the EPC do not elaborate on the term "diagnostic methods". However,* ***according to the established jurisprudence of the EPO, it is accepted that the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include: (i) the examination phase involving the collection of data, (ii) the comparison of these data with standard valued, (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase.*** *In the judgment of the Enlarged Board of Appeal, there is no reason to deviate from this jurisprudence. However, the question to be answered in this context is whether the diagnostic methods referred to in Article 52(4) EPC comprise only the deductive medical or veterinary decision phase consisting in attributing the detected deviation to a particular clinical picture. i.e., the diagnosis for curative purposes stricto sensu, or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison.*
>
> *5.1 Diagnosis in connection with the patent exemption for diagnostic methods practised on the human or animal body under Article 52(4) EPC is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology. It includes a negative finding that t particular condition can be ruled out.*
>
> *5.2 As the deductive medical or veterinary decision phase, diagnosis for curative purposes in itself is an intellectual exercise, unless, as a result of*

developments in the field of diagnostic technology, a device capable of reaching diagnostic conclusions can be used. As an intellectual exercise, pursuant to Article 52(2) EPC, the deductive decision phase is not regarded as an invention within the meaning of Article 52(1) EPC, whereas the method carried out by the device might well represent an invention within the meaning of this provision.

5.3 Since diagnostic methods referred to in Article 52(4) EPC are inventions within the meaning of Article 52(1) EPC (cf. point 4 above), it follows that, in a situation where the deductive medical or veterinary decision phase is a purely intellectual exercise, i.e. a step of a non-technical nature, such a method must necessarily further include preceding steps (cf. point 5 above) of a technical nature, in order to satisfy the requirements of Article 52(1) EPC. The subject-matter of a claim including technical and non-technical features may satisfy the requirements of Article 52(1) EPC if the non-technical features interact with the technical features in order to bring about a technical effect (cf. T 603/89 (OJ EPO 1992, 230), point 2.5 of the Reasons).

[…]

6.2.2 The method steps to be carried out prior to making a diagnosis as an intellectual exercise (cf. point 5.2 above) are related to examination, data gathering and comparison (cf. point 5 above). If only one of the preceding steps which are constitutive for making such a diagnosis is lacking, there is no diagnostic method, but at best a method of data acquisition or data processing that can be used in a diagnostic method (cf. T 385/86, point 3.3 of the Reasons). It follows that, whilst the surgical or therapeutic nature of a method claim can be achieved by a single method step (cf. point 6.2.1 above), several method steps are required to define a diagnostic method within the meaning of Article 52(4) EPC due to

> *the inherent and inescapable multi-step nature of such a method (cf. point 5 above). Consequently, the restrictive interpretation of the patent exemption for diagnostic methods adopted by decision T 385/86 does not amount to setting a different standard for diagnostic methods than that established for methods of surgery or therapy, as has been asserted in decision T 964/99, point 3.6 of the Reasons."*

17. It is the submission of Mr. Rohilla, ld. Counsel, that the subject invention, would be attracted only by points (i) and (ii) in paragraph 5 extracted above *qua* steps involved in diagnosis, examination and comparison, and not points (iii) and (iv), in view of the fact that no symptoms, during the comparison is being claimed for in the patent claims and there is no attribution as well since the Claims do not involve the identification of symptoms or the attribution of such symptoms to a clinical condition. In view of this, ld. Counsel submits that the EPO's guidelines on deciding whether a particular invention relates to diagnostic method or not, ought to be applied in India as well. The non-grant of the patent over the subject invention would result in enormous injustice to the Appellant as the same has been patented in several parts of the world.

18. It is further submitted by Mr. Rohilla, ld. Counsel that the method of a sample holder using an infrared absorption mechanism has been cleared for novelty and inventive step by the Respondent. Such a method can be used for any purpose including in the case of testing blood, water or any form of liquid for that matter. The broad spectrum of possible specimens that can be tested by the claimed method demonstrates that the same would not be hit by Section 3(i) of the Act, inasmuch as the samples contemplated in the Claims could be blood, soil, cosmetic, pharmaceutical sewage and any other liquid products,

etc. Thus, ld. Counsel submits that the analysis using the infrared based method being novel and inventive would not be hit by Section 3(i) of the Act and is therefore entitled for patent.

III.(B). Submissions on behalf of the Respondent

19. On the other hand, Mr. Harish Vaidyanathan Shankar, ld. CGSC appearing for the Respondent, submits that the non-patentability of diagnostic process/methods is expressly mentioned under Section 3(i) of the Act. It is submitted by ld. CGSC that the exclusion of diagnostic process/methods under Section 3(i) of the Act is a result of the obligations under Article 27.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter "*the TRIPS Agreement*"), which permits member States to exclude inventions belonging to certain subject areas from patentability. Ld. CGSC highlights the difference in the language of Article 27.3 of TRIPS and Section 3(i) of the Act to argue that any method of diagnosis would be excluded under Section 3(i) of the Act.

20. Ld. CGSC has placed reliance on the decision of the Supreme Court in ***Novartis AG v. Union of India, (2013) 6 SCC 1*** wherein it was observed that the Indian Patent law has evolved to balance international obligations under the TRIPS Agreement with the commitment to protect and promote public health considerations. Reliance is also placed on the discussion in the said judgement *qua* various provisions of the TRIPS Agreement which provide flexibility to member States for enacting protective provisions in relation to pharmaceutical products and their accessibility to the public at large.

21. It is submitted by the ld. CGSC that the process of diagnosis consists of various steps which are interlinked and cannot be separated into different and distinct sections such as "screening" and "analysis". It is his submission

that testing and diagnostic process would also include preliminary screening tests. In this regard the ld. CGSC has drawn the attention of the Court to Section 83 of the Act which deals with the general principles applicable to working of patented inventions.

22. Further, it is argued by the ld. CGSC that Section 3(i) of the Act does not make a distinction between "*in vivo*" and "*in vitro*" methods of diagnosis. He submits that the Guidelines of the Patent Office also do not make such distinction and that several patent applications for inventions based on *in vitro* methods have been rejected.

23. Ld. CGSC refutes the argument of the Appellant that the reasoning in the decision of the Enlarged Board of Appeal of EPC in ***Case Number G 0001/04*** should be applied in the India as well. He submits that the perspective as per the EPC would be different than what would be the position in India. As per the ld. CGSC, the test laid down in paragraph 5 of ***Case Number G 0001/04*** of the EPC cannot be automatically applied in the Indian context. As per ld. CGSC, a perusal of the Claims would show that the same is for a method and the definition of sample as per the Complete Specification of the subject patent application shows that the same is extremely broad which includes food substances, analytes including biomolecules, water or sewage bodies sample, clinical specimens, cosmetics, pharmaceuticals, etc.

24. It is submitted by the ld. CGSC that since the method has broad based application for various industries, the grant of this monopoly would in effect mean grant of patent for a diagnostic process/method. Thus, the ld. CGSC submits that the subject patent is not liable to be granted in view of the Section 3(i) of the Act. Accordingly, it is prayed by the ld. CGSC that the rejection of the subject patent application by the ld. Controller be upheld.

III.(C). Submissions on behalf of the ld. Amicus Curiae

25. Mr. Adarsh Ramanujan, ld. *Amicus Curiae* has taken the Court through the decision of the Madras High Court in the ***Chinese University of Hong Kong v. Assistant Controller of Patents & Designs, 2023 SCC OnLine Mad 6372*** and has placed reference to broadly the following issues:

i) First, the analysis of Section 3(i) of the Act on the basis of the Statement of Objects and Reasons to the Patents (Amendment) Act, 2002 dated 16th December, 1999 (hereinafter "*SOAR*") when the said provision was amended to include the word 'diagnostic' in it;

ii) Second, he has made a reference to Article 27(3) of the TRIPS Agreement as also Article 53 of the EPC, 2000 to argue that when India had suggested inclusion of this provision in the TRIPS Agreement, it had made reference to the language of the EPC of 1973.

26. Ld. *Amicus Curiae* further submits that there is a drafting error in Section 3(i) of the Act by non-inclusion of the words '*methods for*' prior to the word '*treatment*', suggesting that what is excluded from patentability is "*diagnostic … treatment of human beings*". It is submitted that this is an issue which requires interpreting Section 3(i) of the Act after supplying *casus omissus* with the inclusion of the phrase '*methods for*' *i.e., "diagnostic … [method for] treatment of human beings"*, failing which the said Section would not make any grammatical sense.

27. The ld. *Amicus Curiae* submits that though the Madras High Court in ***Chinese University case (supra)*** did not agree with the view that *casus omissus* ought to be supplied for interpreting Section 3(i) of the Act, the conclusion of the Madras High Court is that both *in vivo* and *in vitro* diagnosis

are excluded by Section 3(i) of the Act. However, the Madras High Court has held, after discussing the opinion of the Enlarged Board of Appeal in ***Case Number G 0001/04***, that if diagnosis for treatment is made, even if the diagnosis is not definitive, then the invention would not be eligible for patent.

28. It is the stand of the ld. *Amicus Curiae* that a plain reading of Section 3(i) makes it clear that it applies only to process claims and not to product claims. The reference to the expression "their products" in the later part of Section 3(i) of the Act is meant to be a reference to animal products. In support of his submission, reference is made to the ***Report on the Revision of the Law in India Relating to Patents for Invention,*** dated September, 1959, authored by Justice N. Rajagopala Ayyangar (hereinafter "*the Ayyangar Committee Report*") to argue that in the context of the definition of invention being a manner of manufacture, the report clarifies by following the decision in ***Canterbury Agricultural College***[1], that the treatment of sheep for increasing the wool yield would not be patentable. Thus, the phrase "their products" does not relate to diagnostic, medicinal, surgical, curative, prophylactic or therapeutic products, but to products of commercial nature derived from animals.

29. It is submitted that the Act does not distinguish between *in vitro* and *in vivo* methods under Section 3(i) of the Act. To buttress this submission, reliance is placed on the difference in the language between EPC, 1973 and EPC, 2000 compared with that of Section 3(i) of the Act. It is submitted by the ld. *Amicus Curiae* that at the time when the TRIPS Agreement was being negotiated, Article 27.3 which provides for exclusions from patentability, was

[1] In the Matter of an Application by the Canterbury Agricultural College for L.P. 36327/54., (1958) 75 RPC 85.

a proposal made by India on the basis of Article 52 of the EPC, 1973. The Article 52(4) of the EPC, 1973 contained the phrase "*practiced on the human or animal body*" which is also present in Article 53(c) of EPC, 2000, thus, creating a distinction between *in vivo* and *in vitro* methods. It is clear from the language of the said Articles that *in vivo* methods would be excluded from patentability, whereas *in vitro* diagnostic methods would be patentable. However, it is pointed out by the ld. *Amicus Curiae* that this phrase "*practiced on the human or animal body*" did not find mention in the final text adopted as the TRIPS Agreement or even in Section 3(i) of the Act. Thus, it is submitted that the requirement of practicing on the human or animal body is no longer a requirement under Section 3(i) of the Act and even tests made or conducted in the laboratories would fall within the scope of Section 3(i) of the Act. Thus, there is no requirement to distinguish between *in vitro* and *in vivo* diagnostic methods.

30. Further, it is submitted by the ld. *Amicus Curiae* that though the language of EPC and Section 3(i) differs to some extent, both legislations exclude 'diagnostic methods' from patentability. Thus, it is submitted that the jurisprudence under the EPC interpreting the relevant provisions *qua* non-patentability of diagnostic methods may have significant persuasive value. He has placed reliance on the decision of the Enlarged Board of Appeals of EPO in ***Case Number G 0001/04***, wherein the term "diagnostic method" has been interpreted to exclude method claims that cumulatively include several steps. It is submitted by the ld. *Amicus Curiae* that the said steps include:

a. The examination phase involving the collection of data;
b. The comparison of these data with standard values;
c. The finding of any significant deviation *i.e.*, symptom, during the

comparison, and

d. The deductive medical/veterinary decision phase.

It is argued by the ld. *Amicus Curiae* that the steps dedicated solely for intermediate steps or screening methods that may have diagnostic relevance are not hit by the exclusion.

31. It is his submission that a simple diagnostic method would not by itself be excluded from patenting, especially if it requires any follow up with substantial steps to arrive at the treatment. It is only if the diagnostic process would itself result in reaching a diagnosis for curative purposes without any further substantial activity, the same would be excluded from patentability. The non-grant of patents for diagnostic methods *per se* would result in a large number of innovations being excluded from patentability which was not the object and purpose of the Act.

32. Thus, the only question while interpreting Section 3(i) of the Act, in the context of diagnosis and diagnostic process, is whether the literal language of the Claim has to be seen or the intention has to be seen from the Complete Specification. Ultimately, in the submission of the ld. *Amicus Curiae*, it is the question of Claim construction as to whether merely by the use of the process or methods applied for, a treatment of human beings or animals can be done by the medical practitioner or not. If the answer is yes, then it would be excluded. If the answer is no, it would not be excluded.

33. Finally, it the submission of the ld. Amicus that the plain meaning of the statute should be given effect to if there is no material to support the object and the purpose of the exclusion, as suggested by *Bennion on Statutory Interpretation (7th Ed.).*

34. Ld. *Amicus Curiae* has also handed over two examples of patent

applications which have been refused in Europe on equivalent provisions to Section 3(i) of the Act.

35. Moreover, it is submitted that considering the change in language and deletion of Section 5 of the Act which dealt with the methods or processes of manufacture *vide* Patents (Amendment) Act, 2005, there ought to have been some modification in the language in Section 3(i) of the Act, at the time when the TRIPS Agreement compliant amendments were being enacted. However, since no amendment was made in Section 3(i) of the Act on this aspect, the same should be read in a narrow manner in the context of manner of manufacture and cannot be read as excluding more than what the Section itself contemplates.

36. Ld. *Amicus Curiae* has also argued that the economic effect of the decisions ought to be considered by the Court while interpreting a provision of this nature, especially considering that the patent system is to encourage innovation. In support of this submission, ld. *Amicus Curiae* relies upon the decision of the Supreme Court in ***Shivashakti Sugars Ltd. v. Shree Renuka Sugar Ltd., (2017) 7 SCC 729***. He also emphasises the fact that an analysis of the total patents relating to biological material and medical technology would show that there has been a stupendous growth in the last 40 years in the said areas which are likely to see a high level of innovation which could get excluded from patenting, if Section 3(i) is interpreted in a broad manner.

IV. Analysis

37. The Court has heard ld. Counsels for the parties and the ld. *Amicus Curiae*. Further, the Court has considered the documents placed on record as also the documents handed across by the ld. Counsels during the extensive hearings conducted in this matter.

38. In view of the submission made by the ld. Counsels for the parties as also the ld. *Amicus Curiae*, the following issues arise for consideration of the Court:

(i) What is the scope of exclusions from patentability under Section 3(i) of the Act in respect of diagnostic methods?

(ii) Whether the subject invention is excluded from patentability under Section 3(i) of the Act?

Issue I: Scope of exclusions from patentability under Section 3(i) of the Act in respect of diagnostic methods

39. Exclusions such as those contained in Section 3(i) of the Act also exist in other jurisdictions and before interpreting the scope of Section 3(i) of the Act and exclusions thereof, it would be useful to analyse the legal position in other jurisdictions.

Legal Position in Other Jurisdictions

40. Section 4A of the Patent Act, 1977 of the United Kingdom reads as under:

> *"Section 4A: Methods of treatment or diagnosis*
> *(1) A patent shall not be granted for the invention of –*
> *(a) a method of treatment of the human or animal body by surgery or therapy, or*
> *(b)* ***a method of diagnosis practiced on the human or animal body****.*
>
> *(2) Subsection (1) above does not apply to an invention consisting of a substance or composition of use in any such method.*
>
> *(3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the*

state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art."

41. Similarly, Article 53(c) of the EPC, 2000 also reads as under:

*"**Article 53***
Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality, such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

*(c)**methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods**."*

42. It would be apposite to consider the observations of the Enlarged Board of Appeal of EPO in ***Case Number G0001/07*** wherein while interpreting the term "*treatment by surgery*" it was held as under:[2]

[2] G1/07, point 3.4.2.3. of the Reasons.

"Hence, a narrower understanding of what constitutes by its nature a "treatment by surgery" within the meaning of Article 53(c) EPC is required. It must allow the purpose of the exclusion to be effective but it must also not go beyond it. ***The exclusion serves the purpose of, in the interests of public health and of patients, specifically freeing the medical profession from constraints which would be imposed on them by patents granted on methods for surgical or therapeutic treatment, thus any definition of the term "treatment by surgery" must cover the kind of interventions which represent the core of the medical profession's activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility****.*

These are the physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise. ***It is in this area that the ratio legis of the provision to free the medical profession from constraints by patents comes into play****. Such a narrower understanding rules out from the scope of the application of the exclusion clause uncritical methods involving only a minor intervention and no substantial health risks, when carried out with the required care and skill, while still adequately protecting the medical profession.*

One amicus curiae observed that the administration of diagnostic agents often causes negative side effects. It is therefore convenient to clarify that there is an exclusion from patentability as a surgical method only if the health risk is associated with the mode of administration and not solely with the agent as such.

It was also remarked that it would be absurd if administering a diagnostic agent by an injection was excluded from patentability but administering by inhalation was not. It is not for the Enlarged Board to

> *decide whether a method involving the injection of a contrast agent is in fact excluded from patentability under the definition of "treatment by surgery" given here. As a matter of patent law, however, this argument does not hold good, since, by contrast to one early draft version of Article 52(4) EPC 1973, neither its final version nor Article 53(c) EPC stipulate an overall exclusion of medical methods from patentability**. Both provisions only exclude the therapeutic, diagnostic and surgical methods listed in the Articles. Hence, where a step is neither a therapeutic nor a diagnostic nor a surgical method the legal situation was and is that it is not excluded from patentability**."*

43. It is clear from the above observations, that the exclusion from patentability should be interpreted narrowly to limit its application to the purpose for which it was incorporated *i.e.,* to ensure that medical professionals are not hindered by concerns of patent infringement in the performance of core clinical tasks that require professional medical expertise and carry health risks.

44. The *Guidelines for Examination in the EPO (April 2025)* further highlights the considerations relevant for assessing applications *qua* the term "*treatment by surgery*" and also provides examples of the nature of methods which are contemplated to be excluded or included under Article 53(c) of the EPC:[3]

> *"Whether a claimed method is to be considered surgical treatment falling under the exception of Art. 53(c) should be assessed on a case-by-case basis, taking the individual merits of each case into account. **The reason for the exception is to allow medical and veterinary practitioners to use their skills and knowledge of the***

[3] Part G, Chapter-II-31, 4.2.1.1: Surgery.

best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent *(see G 1/07, Reasons 3.3.6). Any definition of the term "treatment by surgery" must therefore cover the kind of interventions which constitute the core of the medical profession's activities, i.e. the kind of interventions for which its members are specifically trained and for which they assume a particular responsibility (G 1/07, Reasons 3.4.2.3).*

The exclusion applies to substantial physical interventions on the body which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise. The health risk must be associated with the mode of administration and not solely with the agent as such (G 1/07, Reasons 3.4.2.3).

Examples of excluded treatments by surgery are the injection of a contrast agent into the heart, catheterisation and endoscopy.

Invasive techniques of a routine character which are performed on uncritical body parts and generally carried out in a non-medical, commercial environment are not excluded from patentability. They include e.g. tattooing, piercing, hair removal by optical radiation and micro-abrasion of the skin*."*

45. Further, the Enlarged Board of Appeal has interpreted Article 52(4) of EPC, 1973 (corresponding to Article 53 of the revised EPC, 2000) in respect of exclusions from patentability *qua* diagnostic methods in ***Case Number G 0001/04,*** wherein several points of law were referred for decision under Article 112 (1)(b) of the EPC, 2000, including the following:

"1(a) Are "diagnostic methods practised on the human

or animal body" within the meaning of Article 52(4) EPC (hereinafter: "diagnostic methods") only those methods containing all the procedural steps to be carried out when making a medical diagnosis, ie. the examination phase involving the collection of relevant data, the comparison of the examination data thus obtained with the standard values, the finding of any significant deviation (a symptom) during that comparison and, finally, the attribution of the deviation to a particular clinical picture (the deductive medical decision phase), or

1(b) is a claimed method a "diagnostic method" even if it only contains one procedural step that can be used for diagnostic purposes or relates to the diagnosis?"

46. The discussion of the Enlarged Board of Appeal while deciding the above issues would be relevant for consideration and the relevant portions of the same are set out hereunder:

"5. The preparatory documents to the EPC do not elaborate on the term "diagnostic methods". However, ***according to the established jurisprudence of the EPO, it is accepted that the method steps to be carried out when making a diagnosis as part of the medical treatment of humans or the veterinary treatment of animals for curative purposes include: (i) the examination phase involving the collection of data, (ii) the comparison of these data with standard values, (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase. In the judgment of the Enlarged Board of Appeal, there is no reason to deviate from this jurisprudence****. However, the question to be answered in this context is whether the diagnostic methods referred to in Article 52(4) EPC comprise only the deductive medical or veterinary*

decision phase consisting in attributing the detected deviation to a particular clinical picture, i.e. the diagnosis for curative purposes stricto sensu, or whether they are also meant to include one or more of the preceding steps related to examination, data gathering and comparison.

5.1 Diagnosis in connection with the patent exemption for diagnostic methods practised on the human or animal body under Article 52(4) EPC is the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology. It includes a negative finding that a particular condition can be ruled out.

[…]

6.2.1 Methods of surgery within the meaning of Article 52(4) EPC include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance. Methods of therapy referred to in Article 52(4) EPC concern the curing of a disease or malfunction of the human or animal body and cover prophylactic treatment such as immunisation against a certain disease. ***According to the established jurisprudence of the boards of appeal, a method claim falls under the prohibition of Article 52(4) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy****. For example, within the meaning of Article 52(4) EPC, a claim including the feature "performing a lumbar puncture to deliver epidural injections" is to be considered to relate to a method of surgery, and a claim including the feature "administering a substance for prophylactic reasons" is to be regarded as a method of therapy.* ***It follows that the surgical or therapeutic nature of a method claim can perfectly be established by a single method step***

without contravening Article 84 EPC. Diagnostic methods, however, differ in this respect from the methods of surgery and therapy.

6.2.2 The method steps to be carried out prior to making a diagnosis as an intellectual exercise (cf. point 5.2 above) are related to examination, data gathering and comparison (cf. point 5 above). ***If only one of the preceding steps which are constitutive for making such a diagnosis is lacking, there is no diagnostic method, but at best a method of data acquisition or data processing that can be used in a diagnostic method*** *(cf. T 385/86, point 3.3 of the Reasons). It follows that, whilst the surgical or therapeutic nature of a method claim can be achieved by a single method step (cf. point 6.2.1 above),* ***several method steps are required to define a diagnostic method within the meaning of Article 52(4) EPC due to the inherent and inescapable multi-step nature of such a method*** *(cf. point 5 above). Consequently, the restrictive interpretation of the patent exemption for diagnostic methods adopted by decision T 385/86 does not amount to setting a different standard for diagnostic methods than that established for methods of surgery or therapy, as has been asserted in decision T 964/99, point 3.6 of the Reasons.*

6.2.3. If diagnosis as the deductive medical or veterinary decision phase is a purely intellectual exercise (cf. point 5.2 above), the feature pertaining to the diagnosis for curative purposes and the features relating to the preceding steps which are constitutive for making the diagnosis represent the essential features of a diagnostic method within the meaning of Article 52(4) EPC. Thus, in order to satisfy the requirements of Article 84 EPC, an independent claim relating to such a method must include these features. By way of contrast, if such a claim contained only one single feature relating to a particular step out of several preceding steps, and serving diagnostic purposes or being related

to diagnosis for curative purposes (cf. T 964/99), the above-mentioned requirements would not be met. Since diagnosis for curative purposes is the final conclusion resulting from a thorough and comprehensive evaluation of the clinical picture by assessing all the data gathered in the preceding steps as a whole, it would indeed be inconsistent with the multi-step nature of making a diagnosis for curative purposes if one were to consider such a claim to relate to a diagnostic method as referred to in Article 52(4) EPC. ***Intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes stricto sensu as referred to under point 5 above, which consists in attributing the detected deviation to a particular clinical picture. It follows that a method for obtaining such results or findings does not constitute a sufficient basis for denying patentability by virtue of Article 52(4) EPC.*** *To decide otherwise would give rise to such a broad interpretation of the scope of the exclusion from patentability under Article 52(4) EPC in respect of diagnostic methods that it could hardly be reconciled with the requirement of legal certainty.*

[…]

6.4.2 Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body. Thus, each of the method steps of a technical nature referred to under point 6.4.1 above is either invasive or non-invasive. The non-invasive method steps may involve direct physical contact with the human or animal body or may be practised at a certain distance to it. Furthermore, the performance of each one of these method steps may or may not involve the use of data collecting devices and/or diagnostic equipment for measurement and analysis purposes. It follows that each and every one of these method steps satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the

human or animal body, necessitating the presence of the latter.

6.4.3 However, if - unlike the situation considered under point 6.4.2 above - some or all of the method steps of a technical nature referred to under point 6.4.1 above are carried out by a device without implying any interaction with the human or animal body, for instance by using a specific software program, these steps may not be considered to satisfy the criterion "practised on the human or animal body", because their performance does not necessitate the presence of the latter. By the same token, this criterion is neither complied with in respect of method steps carried out in vitro in a laboratory. This also covers method steps carried out in vitro by diagnostic devices known as DNA microarrays. Therefore, the arguments in favour of a broad interpretation of the scope of the exclusion from patentability under Article 52(4) EPC, submitted in an amicus curiae brief (cf. paragraph III.(b)(ii) above), and which are based on method steps of this kind, are not convincing."

47. The intention behind these provisions is clearly to provide immunity to medical practitioners, technicians, nursing attendants and other persons, who may be coming in contact with human beings or animals requiring diagnosis or treatment. Thus, any process used by such persons using their own skill and knowledge for diagnosis or medicinal, surgical, curative, prophylactic, therapeutic treatment would be excluded from patentability. For example, if the medical practitioner finds a new process of diagnosing diabetes by looking at a patient's skin, such a process would not be patentable as it would be permissible for all practitioners to use that process. However, if a tool is developed for diagnosing diabetes by merely placing the same on the skin of a human being, such a tool or product can be patented. Further, if a method is

developed for diagnosing diabetes, which is non-invasive in nature *i.e.*, an *in vitro* method, such method can also be patented in the European Union and the United Kingdom.

48. Thus, a perusal of the above would show that as per the settled jurisprudence in the European Union, a diagnostic method for curative purposes would involve a multi-step process including -

(i) examination for collection of data,

(ii) comparison of the collected data with standard values,

(iii) finding significant deviations in the collected data,

(iv) deductive medical decision phase.

Any method or process which does not involve any one of the above steps would not qualify as a diagnostic method for curative purposes and would at best be a method for data acquisition or data analysis. Even if the invention seeks to disclose a product, method or process which gives intermediate findings of diagnostic relevance would not be excluded from patentability. The above findings are based on a narrow interpretation of the Article 52(4) of EPC, 1973, which has been adopted by the Enlarged Board of Appeals to balance the conflicting considerations *i.e.*, ensuring that the medical practitioners are free to take actions which they consider suited to diagnose illness, while at the same time, not hampering innovation in the field of diagnostics.

49. The legal position in the European Union and United Kingdom can thus be summarized as under:

i. The exclusion of *diagnostic methods* from patentability under the above discussed provisions is a public policy exclusion, which is meant to give adequate freedom to doctors, veterinarians and other medical

practitioners to firstly diagnose and then administer appropriate treatment to a human or an animal.

ii. The exclusion only covers methods of treatment involving surgery, therapy and diagnosis. However, surgical instruments, therapeutical apparatus or diagnostic tools are not excluded.

iii. The exclusion does not cover methods, which are non-surgical and non-therapeutic. For example, if a method is intended to promote the growth or to increase the yield or quality of products derived from the animals then the said method would be patentable.

iv. The exclusion applies in respect of diagnostic methods practiced on humans or animals, thus, tools for measuring or recording any characteristics which do not directly lead to diagnosis would not be covered.

v. The exclusion applies only in respect of living humans and animals and not on dead humans or animal bodies. For example, postmortem tools would not be excluded from being patented.

vi. If a method or process has a feature involving a physical activity like an action for conducting surgery or therapy, such a process or method would be excluded. For example, the method of stitching used for closing a wound or cut during a surgery would be excluded from being patented.

vii. Merely because a technique may be invasive in nature, it does not mean that it is excluded from being patented. Thus, tools and machines used for ultrasound, endoscopy, colonoscopy, LASIK eye surgery, etc., can also be patented even if they may be invasive or non-invasive.

viii. Therapeutic treatment includes both curative medical treatment and prophylactic treatment. Therapy would, therefore, mean both the preventive therapy or curative therapy as per the EPO.

ix. In case of diagnostic methods, all intellectual exercises required for diagnosis would be excluded from patentability.

50. After considering the above jurisprudence in other jurisdictions, it would be expedient to discuss the legislative history of Section 3(i) of the Act in the Indian context.

Legislative history of Section 3(i) of the Act

51. At the outset, it is noted that Section 3(i) or any other similar provision did not exist in the Patents and Designs Act, 1911 (hereinafter "*1911 Act*"). The definition of invention under the 1911 Act required the existence of a novel method of manufacture. Hence, it is clear that processes or methods which are medicinal, surgical, curative, prophylactic, therapeutic would have been automatically excluded under the 1911 Act.

52. In fact it appears that the requirement of a novel method of manufacture as a condition for patentability may have led to the exclusion of some methods from patentability. Thus, even the Ayyangar Committee Report recorded that medicinal, surgical, curative, prophylactic and other treatment of man or processes for the treatment of plants or animals are considered as non-patentable universally. Such processes and methods did not involve any manufacture and hence, were obviously non-patentable. However, a need was felt by the Committee to add this as a specific exclusion under the 1911 Act, which required methods of manufacture for patentable inventions, as there was no provision covering the said exclusions. The addition of this exclusion

was recommended in the Ayyangar Committee Report in the following terms:

> *"327. I would suggest a revision of the terms of clause 3 first, by **an exhaustive enumeration of claims which are not patentable** and secondly, by making a change in the matter contained in sub clause (d), in relation to "substances produced by chemical processes or intended for food or medicine".*
>
> *328. I would redraft the clause as follows:—*
>
> > *"3. What is not patentable.—The following shall not be patentable under this Act and shall be deemed always not to have been patentable:— […]*
> >
> > *(e) Processes for medicinal, surgical, curative, prophylactic and other treatment of man and processes for similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.*
> >
> > *[…]*
>
> *332. As regards para (e) inventions of medicinal or surgical treatment of man are universally not patentable. Similarly curative processes for the treatment of plants or animals have been held not to be "a manner of new manufacture" and therefore not patentable in the U.K. (vide Rau's application, 52 RPC 362—production of lupin seeds of high oil content); in the matter of American Chemical Paint Coy's Application,1 (treatment of cotton plants). In the matter of an application by the Canterbury Agricultural College (treatment of sheep for increasing the wool yield). It appears therefore that this type of invention is unpatentable in India also under the Indian Patents and Designs Act, 1911 when the statute uses the same words "manner of new manufacture". To avoid doubt and clarify the law, I have included the inventions specified in paragraphs (d) and (e) in the first sub-clause—which has retrospective effect."*

53. Following the above recommendations, Section 3(i) was added for the first time in the Act. The provision then read as under:

> *"Section 3(i) - any process for the **medicinal, surgical, curative, prophylactic or other treatment** of human beings or any process for a similar treatment of animals **or plants** to render them free of disease or to increase their economic value or that of their products."*

54. It is observed by the Court, as was also pointed out by the ld. *Amicus Curiae,* that India's communication to the Negotiating Group on TRIPS Agreement during the Uruguay rounds of multilateral trade negotiations, suggested express mentioning of the exclusions from patentability as is followed in patent laws across the world. The language of the exclusion *qua* diagnostic methods, as suggested by India, is identical to that found in Article 52 of the EPC, 1973. Thus, the suggestion made by India, if adopted, would have acknowledged a distinction between *in vivo* and *in vitro* methods. However, the final text of the TRIPS Agreement under the Article 27.3 (a), which also excluded diagnostic, therapeutical and surgical methods, makes no such distinction between *in vivo* and *in vitro* methods. The said provision reads as under:

> *"Article 27*
> *Patentable Subject Matter*
> *1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

> *2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
>
> *3. Members may also exclude from patentability:*
> *(a)* ***diagnostic, therapeutic and surgical methods for the treatment of humans or animals****;*
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."*

55. Post the TRIPS Agreement the Patents Act 1970 was amended *vide* the Patent (Amendment) Act, 2002, and the words '*diagnostic*' and '*therapeutic*' were added into Section 3(i) of the Act. Surgical processes were already covered. The term '*or plants*' was thereafter deleted from Section 3(i), as the exclusion related to plants was incorporated in a modified form in Section 3(j) of the Act. The relevant portions of the amended Section 3(i) and (j) are reproduced hereunder:

> *"(i) any process for the medicinal, surgical, curative, prophylactic,* ***diagnostic, therapeutic*** *or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.*

> *(j) plants and animals in whole or any part thereof other that micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."*

56. The exclusions from patentability under Section 3(i) of the Act, therefore, was initially inserted at a time when method of manufacture was a necessary pre-condition for grant of a patent under Section 5 of the Act. However, when the exclusion in Section 3(i) was amended, the method of manufacture requirement was no longer in existence. The definition of invention has itself changed over the years and the exclusion, in the opinion of this Court, has to, therefore, be interpreted in the context of the evolved definition of *invention*.

57. Presently, in India, both products or new processes are patentable so long as they are novel, inventive and are capable of industrial application. The exclusion of methods/processes under Section 3(i) of the Act has to be, therefore, construed along with Section 2(1)(j) and 2(1)(ja) which define *'invention'* and *'inventive step'*, respectively. The intention behind the provision has to be deciphered, contextually and in line with the present statutory provisions.

58. All processes and methods for diagnostic purposes or are therapeutic in nature, which are used by medical practitioners or professionals, and are easily passed on to their peers and colleagues are not patented. This would ensure that no one individual or corporation is able to monopolize the implementation of these processes and methods or prevent the use thereof. Peer reviewed medical journals are published from time to time wherein medical practitioners or researchers freely disclose the processes or methods

used by them in their daily routine, which could either be surgical, therapeutic, curative, diagnostic, prophylactic or medicinal. Such methods or processes which form the core of medical practitioners' activities *i.e.,* the activities for which they are specifically trained and assume express responsibility/liability, if allowed to be patented, could hinder the use of the same by medical practitioners. It could also impede such medical professionals from rendering their patients free of disease or provide them with required medical attention and care.

59. In the opinion of this Court, this exclusion was only intended to safeguard the autonomy and efficacy of the medical profession in delivering essential care, not to create a blanket bar on patent protection for all innovations relating to diagnosis or treatment. Accordingly, a nuanced interpretation is warranted, one that excludes only those methods which directly implicate professional judgment and involve invasive or high-risk procedures, while allowing for the patenting of ancillary tools, devices, and non-invasive methods, especially those practiced *in vitro* or outside the human/animal body. Such an approach upholds the delicate balance between incentivising innovation in health related technology and preserving unhindered access to performing essential medical procedures.

60. Accordingly, the manner in which processes which involve physical intervention in the patient's body, must be performed by trained medical professionals, fall within the scope of the exclusion, whereas novel methods for performing cosmetic procedures such as a hair removal technique may not. For example, a method or process used by a nurse or a doctor for measuring blood pressure would not be patentable but a novel product for measuring blood pressure would be patentable. The former would impede medical

professionals, while the latter may spring innovation. This is notwithstanding the fact that both may involve invasive or non-invasive techniques. The distinction lies in the purpose, context, and nature of the intervention, whether it pertains to core medical activity requiring professional judgment and carrying inherent risk, or whether it constitutes a low-risk, routine procedure commonly performed in non-medical, commercial settings. This distinction reflects a consistent principle of patent law, also applicable for interpretation of Section 3(i) of the Act, that exclusions from patentability are to be applied narrowly and purposively, so as not to unduly stifle innovation in technical fields, particularly those that lie outside the direct domain of clinical medical practice. Accordingly, in interpreting Section 3(i) of the Act, which uses similar language as Art. 53(c) of the EPC, the same rationale ought to guide the analysis, *i.e.*, to preserve the freedom of medical practitioners in clinical settings, while still enabling the protection of technical solutions, tools, or methods that are either in vitro or non-clinical in nature.

61. While, safeguarding this critical aspect, the intention behind enacting Section 3(i) of the Act is to ensure that the practice of medicine and various critical steps involved therein are not hindered in any manner by the grant of patents. It is not meant to disregard or discourage innovation in the field of medicine. A plain reading of Section 3(i) of the Act would also make it clear that the intention is to exclude process claims and not product claims. Thus, tools and products irrespective of whether they are *in vivo* or *in vitro* are entitled to grant of patent even if they can be used in the process of performing surgery, diagnosis or therapy, provided they satisfy the conditions under Section 2(1)(j) and 2(1)(ja) of the Act. However, each product claim would have to be analysed on a case to case basis since, laying down an objective

test could be quite challenging as a close scrutiny would be required to decipher as to what is patentable and what is not.

62. At this stage it would be pertinent to consider that the '*Guidelines for Examination of Biotechnology Applications for Patent*' of the patent office which were published earlier in 2013 were broader in nature. However, the Manual of Patent Office Practice and Procedure, 2019 defines diagnostic method and gives illustrative examples which are excluded from the patentability as under:

> *"**Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention.***
>
> *This provision excludes the following from patentability:*
> *a) Medicinal methods: for example a process of administering medicines orally, or through injectables, or topically or through a dermal patch.*
>
> *b) Surgical methods: for example a stitch-free incision for cataract removal.*
>
> *c) Curative methods: for example a method of cleaning plaque from teeth.*
>
> *d) Prophylactic methods: for example a method of vaccination.*
>
> *e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic.*

f) Therapeutic methods: The term 'therapy' includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable.

g) Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry.

h) Further examples of subject matter excluded under this provision are: any operation on the body, which requires the skill and knowledge of a surgeon and includes treatments such as cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body and further includes methods of abortion, induction of labour, control of estrus or menstrual regulation.

i) Application of substances to the body for purely cosmetic purposes is not therapy.

j) Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus.

k) Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable."

63. A perusal of paragraphs (e), (f) & (h) would show that one of the categories excluded from patentability are methods or processes, that are performed on the human body. However, this by itself would not mean that

products, processes, or tools that assist in diagnosing or in therapy would be excluded from patentability. Such a qualification of adding medical practitioners in the exclusion, could pose challenges once artificial intelligence is used in diagnosis or treatment. However, even with the advent of Al tools and assistive diagnosis by Large Language Models (LLMs), the intervention of a medical practitioner would be required for the diagnosis or prescribing of treatment. Thus, the results, which could be produced using Al software, would be no different than the results produced using other types of software. The AI tools would merely assist in diagnosis or therapy and cannot substitute the judgment or decision of the medical practitioner as to the conclusion of the medical condition or the treatment to be given.

64. The bio-technology industry, medical device industry, equipment manufacturers, the manufacturers of products such as artificial limbs etc., make enormous contribution to render patients free of pain. Such products, which may be used by professionals for diagnosing, treating or performing surgeries can be patented. However, the processes used by the professionals in implementing these tools or products by themselves would not be patentable. Any process that would impede a medical practitioner from performing the surgery in a particular way or diagnosing in a particular way, or fixing an artificial limb etc., would not be patentable. Further, a new process, which may be devised for diagnostic purposes either in the form of a product *cum* process, a product *per se*, would be patentable so long as the three conditions of patentability are satisfied.

65. Thus, in view of the above discussion, the salient points for interpretation of Section 3(i) of the Act may be summarised as under:

(i) Products used for diagnosis or therapeutic purposes, including kits, equipment, machines, and physical products, which satisfy the conditions of patentability do not fall within the scope of exclusions under Section 3(i) of the Act and would hence be patentable.

(ii) A perusal of the various terminologies used in Section 3(i) of the Act shows that the exclusions are meant for processes which are employed by medical practitioners, para-medical personnel, nurses, etc. The interpretation of key terms in Section 3(i) of the Act in the context of other provisions of the Act would be as under:

(a) 'Medicinal process' would mean processes which are used for administration of medicines such as a process for oral administration, a process for administration through intravenous therapy, a process for administration of medicine through topical, transdermal or subcutaneous routes or a process through insertion of the medicine, etc. but would not include medicinal products, medicines, medical devices, or even patentable product by process inventions.

(b) 'Surgical process' means a process of performing surgery. However, surgical tools, surgical implements including surgical methods using novel tools and implements would all be patentable. For example, the manner of conducting a colonoscopy or heart transplant surgeries, including the method for sutures or the manner of creating an incision, etc., which are commonly used by surgeons would not be patentable. However, a novel product such as an innovative scalpel used in conducting the surgery would be patentable.

(c) ‘Curative process’ - this terminology is quite ambiguous and vague, considering the various other terms and expressions used in Section 3(i) of the Act. Curative means “*treatments and therapies aimed at eliminating a disease, injury, or illness to restore a person's health to its prior state*”. Thus, a process adopted by a medical practitioner for curing or healing a disease would not be patentable, but tools and products or novel patentable methods used for the same would not be excluded.

(d) ‘Prophylactic process’ means a process for prevention of disease, for example, a process of administering a vaccine or a process of conducting cancer screening, blood test etc., would not be patentable. However, preventive tools, preventive products or preventive mechanisms which qualify the test of patentability would not be excluded.

(e) ‘Diagnostic process’ - The manner in which diagnosis is performed would not be patentable, for example, the manner of checking blood pressure using different tools, the manner of doing a swab test, the process of checking glucose levels, etc., would not be patentable. However, diagnostic products, diagnostic tools, diagnostic devices are patentable so long as they satisfy the test of patentability and they do not unfairly monopolize processes of diagnosis which are to be generally used by medical practitioners, nurses etc. It is also clear that Section 3(i) does not make any distinction between *in vivo* or *in vitro* processes.

(iii) Tools which could be used for the purpose of diagnosis would also not be covered by the exclusion and would be patentable. However, if tools only consist of software-based tools, which utilize data for the purpose of diagnosis, they would have to be examined under Section 3(k) of the Act for further technical effect and for satisfying the conditions for patentability. In addition, it would have to be checked if these tools or processes by themselves give results which are capable of clear interpretation as to the existence or non-existence of a medical condition.

(iv) The phrase *"to render them free of disease or to increase their economic value"* qualifies only treatment of animals and not of human beings;

(v) Mere identification of the regimen for the use of certain medicines in a particular manner or frequency or form would be excluded from patentability.

(vi) Methods of treatment of plants are not covered by Section 3(i) of the Act and would be patentable so long as the test of Section 3(j) of the Act is satisfied.

66. The interpretation of Section 3(i) of the Act or equivalent provisions in foreign jurisdictions has been a challenge for Courts and Tribunals which are attempting to strike a balance between protecting genuine innovations on the one hand and ensuring that grant of patents does not impede medical practitioners and those working in the field of medicine from using day to day processes, which are required to be employed in the field of medicine for human beings or even for animals. There may be a need for taking a re-look

at the wording of this provision in order to remove ambiguity and vagueness and provide further clarity, consistency and predictability in patenting. This would, however, be in the realm of policy and the Legislature.

Issue II: Exclusion from patentability of the subject invention under Section 3(i) of the Act

67. The subject patent application relates to an improved method for the quantitative analysis of biomolecules using infra-red (IR) spectroscopy. A perusal of the detailed description of the subject patent reveals that conventionally, IR spectroscopy involves generating a calibration curve based on known concentrations of analytes to interpret absorption peaks. However, existing methods often require repeated generation of such curves, which is time-consuming and inefficient. However, the subject patent application proposes a different approach that enables the reuse of previously generated calibration data by refining the curve-generation methodology through algorithmic and spectral adjustments. The process is applicable to a wide range of samples including human plasma, food, cosmetics, water, sewage, and fuels. Notably, the invention does not claim any process for diagnosing a disease or interpreting medical conditions, but rather seeks protection for a technical method that enhances the efficiency of IR spectroscopic analysis performed *in vitro* on a removed sample.

68. For determining whether the subject patent is excluded from patentability under Section 3(i) of the Act, this Court would first examine the nature of the claimed process, its technical character, and the context of its application.

69. A perusal of the Complete Specification of the subject invention reveals that the same acknowledges that infra-red spectroscopy is a commonly used

analytical tool for analysis of samples. Specifically, the patent relates to quantitative analysis of bio molecules by generation of a calibration curve. The object of the invention is to reduce the time required for generating such a curve and to eliminate the need for its repeated regeneration. The quantification of analytes in a sample is carried out by analysing the nature of the peaks generated through the infra-red absorption spectrum. This method could be used in infra-red spectroscopy for conducting various experiments and to analyse the nature of the sample. The subject invention, thus, has application across different medical conditions and is not restricted to any specific medical condition. The bio-molecule to be quantitatively analysed could be human plasma or even food substances and other samples such as water samples, sewage samples, cosmetic samples, medical samples or even fuels. Merely because of the fact that it is capable of being used for infra-red spectroscopy to be conducted on humans or animals would not exclude the said process or method from patentability as the manner in which the results of the spectroscopy are to be analysed is not being patented. The manner in which the curve is to be read is also not to be patented. It is the method of conducting the quantization of bio molecules in a new form of infra-red spectroscopy that is sought to be patented. The products based on this form of spectroscopy could also have varying implementation and applications across industries and such a method would not attract exclusion under Section 3(i) of the Act.

70. The core of the subject patent application lies in improving the efficiency and reliability of quantitative analysis using infra-red spectroscopy, by reducing calibration time and avoiding repeated generation of calibration curves. The process is conducted entirely outside the human or animal body

and does not involve any step that can be characterised as diagnostic in nature when practiced on the body. Further, the invention does not require or entail any clinical decision-making or medical judgment based on patient-specific data. Consequently, the process is clearly a technical innovation, which is distinct from a diagnostic method *per se*. Accordingly, such an in-vitro analytical method, claimed in the present invention cannot be excluded from patentability under Section 3(i) of the Act.

71. It is to be noted that the patent has already been granted in Europe where similar exclusions exist under Article 53(c) of the EPC, 2000. The Respondent's decision, holding that the subject patent is hit by exclusions under Section 3(i) of the Act, is therefore, not sustainable. The said objection as raised by the Controller is, accordingly, set aside.

72. During the pendency of this appeal, the Court had called a report from the Patent Office on a question as to whether the subject patent application satisfied the conditions of patentability under Section 2(1)(j) and 2(1)(ja) of the Act. The conclusion of the Assistant Controller of Patents & Designs in the report dated 12th August, 2024 is as under:

> *"To summarise, the subject-matter of final claims 1-14 is novel and involves an inventive step within the meaning of Section 2(1)(j). However, the said claims recite subject-matter which is not an invention within the meaning of the Act as the said subject-matter falls within the scope of Section 3(i)."*

73. Thus, the subject invention satisfies the requirements of Sections 2(1)(j) and 2(1)(ja) of the Act and is eligible for grant of patent. However, the Court also has to consider the objection raised under Section 59 of the Act as to whether the amendments in the claims were permissible or not.

74. Section 59 of the Act governs the amendment of patent applications and specification. The said provision is set out below:

> *"Section 59 – Supplementary provisions as to amendment of application or specification:*
>
> *(1)* ***No amendment of an application*** *for a patent or a complete specification or any document relating thereto shall be made except* ***by way of disclaimer, correction or explanation, and no amendment thereof shall be allowed****, except for the purpose of incorporation of actual fact, and* ***no amendment of a complete specification shall be allowed, the effect of which would be that the specification as amended would claim or describe matter not in substance disclosed or shown in the specification before the amendment****, or that any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.*
>
> *(2) Where after the date of grant of patent any amendment of the specification or any other documents related thereto is allowed by the Controller or by the High Court, as the case may be,—*
>
> *(a) the amendment shall for all purposes be deemed to form part of the specification along with other documents related thereto;*
>
> *(b) the fact that the specification or any other documents related thereto has been amended shall be published as expeditiously as possible; and*
>
> *(c) the right of the applicant or patentee to make amendment shall not be called in question except on the ground of fraud.*
>
> *(3) In construing the specification as amended, reference may be made to the specification as originally accepted."*

75. A perusal of the above provision would reveal that no amendment of a

patent application is permitted if the effect of such amendment is that the specification as amended would claim or describe matter not in substance disclosed in the specification before the amendment, or that the amended specification would claim any matter not falling within the scope of the claims of the specification before the amendment. Further, the provision permits amendments only by way of disclaimer, correction, or explanation. Any amendment that introduces new matter or results in a broadening of the scope of the claims beyond what was originally disclosed in the Complete Specification is expressly prohibited.

76. The above principles under Section 59 of the Act have also been analysed and highlighted by this Court in ***Open TV Inc. vs. The Controller of Patents and Designs and Anr., (2023:DHC:3305).*** The relevant extracts of the decision of this Court in ***Open TV (Supra)*** are set out below:

> *"50. The fundamental principle governing amendment of Claims is therefore, that amendments are permissible in the Claims so long as the said amendments are within the scope of the originally filed Claims as filed and do not expand the said Claims. Thus, reduction or narrowing down a Claim is permissible, but broadening, widening or expansion of Claims is not permissible.*
>
> *51. The only issue remaining is whether at the appellate stage amendments to the Claims are permissible at the instance of patent applicant. In a recent decision of a Coordinate Bench of this Court in* ***Nestle (supra)****, the Court was considering the question as to whether amendments can be directed at the appellate stage. The Court, after considering the law of amendments of Claims, observed as under:*
>
> > *"30.* ***There is no provision in the Act, which specifically bars the amendment of a patent***

specification at the appellate stage. *Amendment of patent applications and specifications are covered in Chapter X of the Act. Sections 57 to 59 of the Act are the provisions that govern the same.*

xxxx xxxx xxxx

33. In view of the above, there is no specific bar for the amendment even at a subsequent stage. Only requirement under the Act is that the amendment has to fulfil the requirements under Section 59 of the Act and the consideration that has to be kept in mind is that the amended Claims are not inconsistent with the earlier Claims in the original specification."

52. In the above case of ***Nestle (supra)****, the Court permitted the Appellant to revert to the originally filed claims which had been given up due to objections raised by the Patent Office. After considering Section 15 of the Act, the Court held that since the Controller has the power of directing amendment to a patent application, a High Court in appeal would also have similar powers. It also observed that the appeal is a continuation of the proceedings before the original forum and thus, amendments are permissible at the appellate stage. The relevant paragraphs of the judgment are set out below:*

"34. Now, a reference may also be made to Section 15 of the Act, i.e., where a Controller has been given the power to require an application to be amended to his satisfaction. The said provision reads as under:

*"[**15. Power of Controller to refuse or require amended applications, etc., in certain cases.**-Where the Controller is satisfied that the application or any specification or any other document filed in pursuance thereof does not comply with the requirements of this Act or of any rules made thereunder, the Controller may refuse the*

application ***or may require the application, specification or the other documents, as the case may be, to be amended to his satisfaction before he proceeds with the application and refuse the application on failure to do so.]"***

35. It is axiomatic that if the Controller has been given the power to direct an amendment to the patent application, the High Court, which is sitting in appeal over the decision of the Controller, should also have similar powers to direct the patent applicant to amend Claims to its satisfaction.

36. Further, it is a settled position of law that an appeal is a continuation of the proceedings of the original court. The appellate jurisdiction involves a re-hearing on law as well as on facts. Reference in this regard may be made to a recent judgement of the Supreme Court in ***Ramnath Exports Pvt. Ltd. v. Vinita Mehta & Anr****, (2022) 7 SCC 678.*

xxxx xxxx xxxx

39. ***Thus, in conclusion, I observe that if the High Court, in appeal is considering the issue of grant of patent, it should necessarily have the same powers as given to the Controller under Section 15 of the Act, which includes power to require amendment. Further, the appellate proceedings challenging the refusal of grant of a patent, questions of facts need to be re-examined comprehensively and therefore, a liberal view has to be taken with regard to amendment of Claims"***

53. Thus, amendments having been held to be permissible at the appellate stage, this Court is of the opinion that irrespective of whether the amendment is directed by the Court or is at the instance of Patent Applicant, so long as the requirements as laid down under Section 59 of the Act are fulfilled such that the

amended claims are within the scope of original claims, is not breached, the amendment is permissible."

77. In light of the legal position outlined above and for the purposes of examining the validity of the objection raised under Section 59 of the Act, both the sets of Claims of the subject patent application filed before the Patent Office shall be set out. The purpose of doing so is to assess, based on the disclosure and scope of the invention, whether the amendments made by the Appellant are in the nature of disclaimer, correction, or explanation, and whether they remain within the scope of the originally filed claims. Both the originally filed Claims and the amended Claims of the subject patent application are set out below:

"Claims

Originally Filed Claims

1. A method quantitation of one or more biomolecules in a sample, the method comprising the steps of:

(a) providing a sample holder comprising a porous membrane which comprises a hydrophilic region surrounded by a hydrophobic region for sample containment;

(b) contacting the hydrophilic region of the membrane with sample volume;

(c) drying the sample volume on the membrane;

(d) exposing the sample volume on the membrane to an infrared beam comprising a wavelength in the spectral range of 4000-400 cm^{-1} or any portion of the spectral range of 4000-400 cm^{-1}, thereby to obtain an infrared absorption spectrum;

i) wherein one or more absorption peak areas in the infrared absorption spectrum correlates with quantity of one or more biomolecules in the sample.

2. The method of claim 1, wherein the one or more

biomolecules is selected from the group consisting of nucleic acids, proteins, lipids, polysaccharides and lipopolysaccharides.

3. The method of claim 2, wherein the lipopolysaccharide is an endotoxin,

4. The method of claim 1, wherein method does not require a user to generate a calibration curve each time a sample is analyzed for quantitation of the one or more biomolecules.

5. The method of claim 1, wherein sample volume ranges from 0.1-20 µl.

6. The method of claim 5, wherein sample volume is 1µl or less.

7. The method of claim 1, wherein the porous membrane is contained within a device.

8. The method of claim 7, wherein device is a sample holder card.

9. The method of claim 1, the sample comprises a biological fluid.

10. The method of claim 9, wherein the biological fluid is selected from the group consisting of blood, plasma, serum and urine.

11. The method of claim 1, wherein the sample comprises cell or tissue lysate.

12. The method of claim 1, wherein the sample is a crude sample.

13. The method of claim 8, the sample holder card comprises a porous membrane which comprises an area within which the sample is contained on the membrane.

14. The method of claim 1, wherein the porous membrane is an ultrafiltration membrane.

15. The method of claim 1, wherein the porous membrane is a microporous membrane.

16. The method of claim 1, wherein the porous membrane comprises a polymeric material selected from the group consisting of PVDF (Polyvinylidene fluoride), polytetrofluoroethylene, hydrophilic polytetrofluoroethylene, polyethylene and

polypropylene.

17. The method of claim 13, wherein the area for sample containment on the membrane comprises a hydrophilic region surrounded by hydrophobic region.

18. The method of claim 17, wherein the hydrophobic region is created by plasma treatment of a hydrophilic porous membrane.

19. The method of claim 17, wherein the sample is contained within the hydrophilic region.

20. The method of claim 17, wherein the hydrophobic is created by heat treatment of a hydrophilic porous membrane.

21. A sample holder card for use in the method of claim 1, wherein the sample holder card comprises a porous membrane which comprises a hydrophilic region surrounded a hydrophobic region, wherein the sample is contained within the boundaries of the hydrophilic region.

22. The sample holder card of claim 21, wherein the diameter of the hydrophilic region ranges 2.0 mm through 10mm.

23. The sample holder card of claim 21, wherein the diameter of the hydrophilic region ranges 3.0 mm through 6 mm.

24. A method for quantitation of one or more biomolecules in a sample, the method comprising the steps of:

(a) providing a sample holder card comprising a porous membrane which comprises a hydrophilic region surrounded by a hydrophobic region for sample containment;

(b) contacting the hydrophilic region of the membrane with a sample volume;

(c) drying the sample volume on the membrane;

(d) detecting the presence of water on the membrane using infrared absorbance and repeating step (c), if necessary, until no water is

detected; and

(e) exposing the sample volume on the membrane to an infrared beam comprising a wavelength in the spectral range of 4000-400 cm^{-1} or any portion of the spectral range, thereby to obtain an infrared absorption spectrum.

f) wherein one or more absorption peak areas in the infrared absorption spectrum correlates with the quantity of the one or more biomolecules in the sample.

Amended Claims

1. A method for quantitation of one or more biomolecules in a sample (50), the method comprising the steps of:

(a) providing a sample holder (22) comprising a porous membrane (14) which comprises a hydrophilic region (24) surrounded by a hydrophobic region (26) for sample containment, wherein the hydrophobic region is created either by plasma treatment of a hydrophilic porous membrane or wherein the hydrophobic region is created by heat treatment of a hydrophilic porous membrane;

(b) contacting the hydrophilic region of the membrane with a sample volume, wherein the hydrophilic region has a diameter;

(c) drying the sample volume on the membrane; and

(d) exposing the sample volume on the membrane to an infrared beam having a diameter equal to or larger than the diameter of the hydrophilic region, and comprising a wavelength in the spectral range of 4000-400 cm^{-1} or any portion of the spectral range of 4000-400 cm^{-1}, thereby to obtain an infrared absorption spectrum;

wherein one or more absorption peak areas in the

infrared absorption spectrum correlates with the quantity of the one or more biomolecules in the sample.

2. The method as claimed in claim 1, wherein the one or more biomolecules is selected from the group consisting of nucleic acids, proteins, lipids, polysaccharides and lipopolysaccharides, optionally an endotoxin.

3. The method as claimed in claim 1, wherein the method does not require a user to generate a calibration curve each time a sample is analyzed for quantitation of the one or more biomolecules.

4. The method as claimed in claim 1, wherein sample volume ranges from 0.1-20 µl and optionally, 1 µl or less.

5. The method as claimed in claim 1, wherein the porous membrane is contained within a device.

6. The method as claimed in claim 5, wherein the device is a sample holder card, comprising a porous membrane which comprises an area within which the sample is contained on the membrane.

7. The method as claimed in claim 1, wherein the sample comprises a biological fluid and, optionally, the biological fluid is selected from the group consisting of blood, plasma, serum and urine.

8. The method as claimed in claim 1, wherein the sample comprises cell or tissue lysate, optionally a crude sample.

9. The method as claimed in claim 1, wherein the porous membrane is an ultrafiltration membrane or a microporous membrane.

10. The method as claimed in claim 1, wherein the porous membrane comprises a polymeric material selected from the group consisting of PVDF (Polyvinylidene fluoride), polytetrofluoroethylene, hydrophilic polytetrofluoroethylene, polyethylene and polypropylene.

11. The method as claimed in claim 1, further comprising the step of detecting the presence of water

on the membrane using infrared absorbance and repeating step (c), if necessary, until no water is detected.

12. A sample holder card for use in the method as claimed in claim 1, wherein the sample holder card comprises a porous membrane which comprises a hydrophilic region surrounded by a hydrophobic region, wherein the sample is contained within the boundaries of the hydrophilic region.

13. The sample holder card as claimed in claim 12, wherein the diameter of the hydrophilic region ranges from 2.0 mm through 10 mm.

14. The sample holder card as claimed in claim 12, wherein the diameter of the hydrophilic region ranges from 3.0 mm through 6 mm."

78. A perusal of the originally filed claims shows that initially, the subject patent application included multiple independent claims. Claim 1 and Claim 24 were drafted as independent method claims, while Claim 21 introduced a separate product claim concerning the use of a sample holder card for implementing the first independent method Claim. In the originally filed Claims, Claim 1 described a method for quantitation of one or more biomolecules using a porous membrane with hydrophilic and hydrophobic regions and analysis by infrared absorption spectroscopy. Further, Claim 24, which was also drafted as an Independent Claim, also method-based, introduced an additional procedural step involving the detection of residual water on the membrane before IR exposure. These two Claims, while overlapping in their technical subject matter, independently set out distinct embodiments of the invention.

79. In contrast, the amended Claims consolidated the invention into a single, independent method claim, which incorporates the key procedural

elements from both originally filed method claims. The final Claim 1 specifies that the porous membrane is part of a sample holder (element 22) and includes a hydrophilic region surrounded by a hydrophobic region (elements 24 and 26), with the latter being created through either plasma or heat treatment. The final Claim further introduces a limitation requiring that the infrared beam used in the analysis must have a diameter equal to or larger than the diameter of the hydrophilic region. This Court is conscious of the fact that this specific limiting feature was not present in the originally filed independent claims. However, the said embodiment is disclosed in the Complete Specification, at paragraph [0023], as a preferred embodiment. This amendment, therefore, does not introduce any new matter but merely incorporates a preferred embodiment into the Claim. The inclusion of this limitation narrows the scope of the claim and enhances its precision, and is accordingly, permissible under Section 59 of the Act.

80. While the originally filed Claims included two independent method claims (Claims 1 and 24), it also contained a product claim describing the use of the sample holder card (Claim 21) for implementing Claims 1. In the amended claims, the subject patent is consolidated into a single independent method claim, Claim 1. This results in a more streamlined and technically narrowed claim structure. Further, the procedural aspect concerning water detection, previously found in Claim 24, now appears in dependent Claim 11. The structural features of the sample holder card, earlier described in Claim 21 and related Claims, are now included as dependent Claims 12 to 14. A key addition in the amended Claim 1 is the limitation requiring that the infrared beam diameter be equal to or larger than the hydrophilic region. This Court is conscious of the fact that this aspect was not stated in the originally filed

claims. However, the said feature is expressly present as a preferred embodiment in the Complete Specification, at paragraph [0023]. The said paragraph explains the need for such a relationship to ensure accurate quantitation. Accordingly, in the opinion of this Court, this amendment does not introduce new matter or increase the scope. Rather, it incorporates a preferred embodiment into the claims, providing greater technical precision. Since it narrows the scope of the invention, it qualifies as an explanatory amendment, incorporating an actual fact, without adding any subject matter or changing the scope of the Claims, the same is permissible under Section 59 of the Act.

81. Accordingly, it is clear that the amended Independent Claim does not seek to expand the protection beyond the originally claimed subject matter. Rather, it reflects a refinement of the claimed invention, with greater structural clarity and functional specificity. Therefore, the amendments are in the nature of explanation and clarification and do not introduce any new technical feature that was not already disclosed. Accordingly, the amended claim falls within the scope of what was originally disclosed and claimed, and the requirements of Section 59 of the Act stand duly satisfied.

82. In view of the above, since the exclusion under Section 3(i) of the Act would not be applicable in the present case and the application satisfies the test of novelty and patentability, the subject patent application deserves to now proceed for grant of patent.

83. The Court records its deep appreciation for the able assistance provided by Mr. Adarsh Ramanujan, ld. Amicus Curie and the ld. Counsels for the parties.

84. The appeal is allowed and disposed of in the above terms. Pending

application(s), if any, is also disposed of.

85. List before the Patent Office on 31st October, 2025 for completion of necessary formalities and for grant of patent to the Appellant.

86. The Registry is directed to supply a copy of the present order to the office of the Controller General of Patents, Designs & Trademarks of India on the e- mail- llc-ipo@gov.in for compliance of this order.

PRATHIBA M. SINGH
JUDGE

OCTOBER 9, 2025
dk/msh