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

Reserved on: 21st December, 2024

Pronouncement on:9th October, 2025

\+ **C.A.(COMM.IPD-PAT) 16/2023**

NATERA INC AND ANR. .....Appellants

Through: Ms. Vindhya S. Mani, Ms. Surbhi Nautiyal, Ms. Naina Gupta, Ms. Harshita Agarwal, Ms. Vedika Singhvi, Mr. Ritwik Sharma, Mr. Bhuvan Malhotra and Mr. Devesh Aswal, Advs. (M: 9717065125)

versus

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

Through: Ms. Arunima Dwivedi, CGSC. (M:9971724716) with Ms. Swati Jhunjhunwala, Ms. Pinky Pawar, Mr. Aakash Pathak along with Mr. Prasad, Deputy Controller.

Mr. Adarsh Ramanujan, *Amicus Curiae*. (M:99999 84703)

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 exclusions from patentability in respect of *diagnostic 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 the impugned order dated 20th March, 2023 passed by the Respondent – Assistant Controller of Patents and Designs.

4. Vide the impugned order the Respondent has refused the Patent Application bearing No. 201817033216 (hereinafter "*the subject patent application*") for the invention titled "*Methods for Lung Cancer Detection*" (hereinafter "*the subject invention*"). The impugned order has refused the grant of subject patent application while holding that Claims 1 to 4 thereto are not patentable under Section 3(i) of the Act. Further, Claims 5 to 8 of the subject patent application have been rejected in view of Section 59 of the Act.

I. Factual Background

5. Appellant No.1 – Natera Inc., is a company registered in California, United Stated of America and is stated to be a leader in the field of clinical genetic, specializing in cell-free DNA testing technology. Appellant No. 2 – UCL Business Ltd., is a wholly owned subsidiary of University College London, having its registered office in London, United Kingdom and is stated to perform functions of knowledge transfer.

6. The subject patent application consisting of Claims 1 to 54 was filed before the Indian Patent Office on 5th September, 2019 and the Appellants claimed priority from US Application 62/323,589 dated 15th April, 2016. The request for examination was filed on 9th April, 2020. It is stated that *vide* communications dated 9th April, 2020 and 28th October, 2020 the Appellants had amended the Claims, whereby, *inter alia,* Claims 18 to 54 were deleted. The Claims were again amended by the Appellants *vide* communication dated 28th October, 2020.

7. The First Examination Report dated 31st August, 2021 (hereinafter "*FER*") was issued by the Patent Office raising various objections, including the following:

(i) Claims 1 to 15 lack novelty under Section 2(1)(j) of the Act;

(ii) Claims 1 to 15 lack inventive step under Section 2(1)(ja) of the Act;

(iii) Claims 1 to 15 are non-patentable under Section 3(d) and Section 3(i) of the Act;

(iv) Claims 1 to 15 do not satisfy the requirements of Section 10(4)(c) of the Act.

8. Accordingly, the Appellants had filed their response to the FER on 25th February, 2022 along with the amended Claims 1 to 15. The Appellants were thereafter provided an opportunity of hearing on 9th December, 2022 which was adjourned at the request of the Appellants. A further opportunity for hearing was granted to the Petitioner on 9th January, 2023 *vide* hearing notice dated 12th December, 2022, (hereinafter "*the hearing notice*"). In the hearing notice, the following objections were raised:

(i) Claims 1 to 15 lack inventive step under Section 2(1)(ja) of the Act;

(ii) Claims 1 to 15 are non-patentable under Section 3(i) of the Act;

(iii) Claims 1 to 15 attract Section 10(4)(c) and Section 10(5) of the Act;

(iv) The subject matter of Claim 15 is broader than the complete specification which is not satisfying the requirement of Section 10(4)(a) of the Act.

(v) Non-submission of details of applications for patents filed outside India in respect of same or substantially same invention in terms of Section 8(1)(b) read with Rule 12(1) the Patent Rules, 2003 (hereinafter "*the Patent Rules*").

(vi) Non-submission of details of the search/ examination report in respect of same or substantially same invention in terms of Rule 12(3) of the Patent Rules.

9. It is stated that certain objections raised in the FER were not mentioned

in the hearing notice and the same were presumed by the Appellants to have been waived by the Respondent.

10. Further to the hearing on 9th January, 2023, the Appellants had filed their written submissions dated 23rd January, 2023 to the objections raised in the hearing notice as also during the hearing. In addition to the same, the Appellants had also amended Claims 1 to 15 such that the same was reduced to amended Claims 1 to 8.

11. However, the subject patent application was refused by the Respondent *vide* the impugned order, *inter alia,* on the ground that the Claims in the subject patent application were not patentable under Section 3(i) of the Act. The impugned order is set out below:

> *"The objections in First Examination Report (FER) under Section 12 and 13 of Patents Act were not complied within the prescribed period. An opportunity of hearing under Section 14 of Patents Act was offered to the applicant through office letter dated 12/12/2022. The Patent agent for the applicant has appeared for the hearing.*
>
> *2. The objections of the said hearing notice were discussed during the hearing. Regarding objection to amended claims 1-8, applicant has made submission which was found not persuasive in view of following observations.*
>
> ***The subject matter of claim 1-4 is not patentable u/s 3(i) of the Act as it claims a method for tracking presence of single nucleotide variants associated with tumor mutations in an individual suspected of having lung squamous cell carcinoma. Para [0040] of the description itself states that methods and compositions provided herein improve the detection, diagnosis, staging, screening, treatment, and management of lung cancer. Therefore, the present set of claims is***

related to treatment/ diagnosis of lungcancer and is not allowed u/s 3(i) of The Patents Act, 1970.

Newly added claims 5-8 attract section 59 of The Patents Act, 1970 as 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.

Consequently, the outstanding objections of the said hearing notice are maintained and claim 1-8 are not allowed. This application for grant of patent is refused under Section 15, The Patents Act, 1970."

12. Aggrieved by the said refusal of grant of the subject patent application, the Appellants have approached this Court in the present appeal.

II. Proceedings in the appeal

13. The present appeal was first heard on 13th July, 2023 on which date the Court had issued notice after considering the grounds for refusal mentioned in the impugned order. The matter was also tagged with '***EMD Millipore Corp. v. Assistant Controller of Patents'*** bearing no. ***C.A.(COMM.IPD-PAT) 7/2021*** which also involved the interpretation of Section 3(i) of the Act.

14. Thereafter, detailed arguments were heard by the Court in the connected appeals on behalf of the parties on several dates. Submissions were also heard by the Court on behalf of Mr. Adarsh Ramanujan, ld. *Amicus Curiae* appointed in ***EMD Millipore (supra)*** *vide* order dated 28th October, 2022, for assistance of the Court in the interpretation of Section 3(i) of the Act.

15. On 18th September, 2024, Mr. Prasad, Deputy Controller, appearing virtually, was queried by the Court in respect of the subject patent application. Considering the submissions made, the Court had directed the said official to

file a report on the issue as to whether the subject invention satisfies the threshold of inventive step under Section 2(1)(ja) of the Act. In addition to the above the Court had observed and directed as under:

> *"3. Let Mr. Prasad, Deputy Controller, CGPDTM place on record a report by the next date of hearing, as to whether the subject invention in* ***C.A.(COMM.IPD-PAT) 16/2023*** *satisfies the threshold of inventive step under Section 2(1)(ja) of the Patents Act, 1970.*
>
> *4. Insofar as the objection as to Section 3(i) of the Patents Act, 1970 is concerned, he seeks to rely on a decision of the United States Court of Appeals for the Federal Circuit in* ***Ariosa Disgnostics, Inc., Natera v. DNA Diagnostics Center Inc. (2014-1139, 2014-1144, decision dated 12th June, 2015).***
>
> *5. Let the same be also filed as part of the report dealing with both the aspect of inventive step of the subject patent application, and the U.S. decision on Section 3(i) of the Patents Act, 1970. As part of the report to be placed on record, the Patent Office may also deal with submission made relating to Section 59 of the Patents Act, 1970, as to whether once the claims are amended, the original claims which are a part of the PCT application in the specification, may be referred to or not for the purpose of amendment in the claims."*

16. On 4th October, 2024, the report of the Deputy Controller in terms of the previous order was handed across by the ld. Counsel for the Respondent and the same was directed to be brought on record by the next date.

17. Thereafter, on 21st December, 2024, after considering the said report as also the submissions of the parties, the present appeal along with connected appeals was reserved for judgement.

III.(A). Submissions on behalf of the Appellant

18. On behalf of the Appellant, Ms. Vindhya S. Mani, ld. Counsel has at the outset taken the Court through the impugned order to argue that the two grounds on which the Claims have been rejected are:

(i) Claims 1 to 4 are hit by Section 3(i) of the Act and

(ii) Claim 5 to 8 are not liable to be allowed as they are beyond the scope of the claims which were filed by the Appellant.

19. Ms. Mani, ld. Counsel firstly points out that in the FER, the objections relating to novelty and inventive step were raised and after the reply to the FER, in the hearing notice, only the objection as to inventive step has been raised. Ms. Mani, ld. Counsel claims that the Appellant had convincingly distinguished the prior art which was cited by the Patent Office in the FER and thus in the final order, there is no reference to novelty objection or inventive step objection.

20. Reference is then made by the ld. Counsel to Claim 1 of the complete specification to argue that this claim has various features. The first feature is that the individual over whom the testing is done is someone who is already suspected of having '*lung squamous cell carcinoma*' which is a '*Non-Small Cell Lung Cancer'* (hereinafter "*NSCLC*"). This is also clear from the fact that within Claim 1 itself, the detection is of single '*Single Nucleotide Variants'* which are associated only with this '*lung squamous cell carcinoma*'. Thus, it is argued that there is no diagnosis which is taking place in the subject test. In persons who already suffer from NSCLC, the detection that the method proposes to make is as to the nature and identification of the single *nucleotide* variant. The said identification by using a bespoke Polymerase Chain

Reaction (hereinafter "*bespoke PCR*") is customized to suit only one person by generating specific primers.

21. It is submitted that the intention behind the subject test is to assess as to how many individuals who suffer from NSCLC have a particular variant. The results could be used both for the purposes of research as also for checking predisposition of a particular person. The sensitivity of the test is to the extent that it can detect circulating DNA to the 0.01% variable. The method is also intended to check as to which mutations have the propensity to contact this particular form of a cancer. It is submitted that the applications could be several in respect of such methods, however, at least two clear applications are for research and for doing a predisposition test. The fact that such individuals undergoing the subject test are already known to have this specific lung cancer itself shows that this is neither a diagnostic method and nor is it being used for the purposes of any treatment.

22. Reference is made to Section 3(i) of the Act as also to the decision of the Madras High Court in ***Chinese University of Hong Kong and Anr. V. Assistant Controller of Patents & Designs, 2023 SCC OnLine Mad 6372*** to argue that as per the said judgment, the word '*diagnostic*' is to be limited to diagnostic processes that disclose pathology for treatment of human beings. In the present appeal, the subject method does not disclose any pathology for treatment. It merely identifies the kind of the single *nucleotide* variant that is present.

23. She further submits that the pre-disposition of a person could enable such individuals to take various precautions and the same may not actually result in any treatment to the said individual, as the possibility of the person developing lung cancer is also not a definite prediction made by the subject

test.

24. Insofar as the second objection in respect of Claims 5 to 8 is concerned, it is her submission that Claim 5 of the amended Claims was already contained in Claims 41 & 42 of the PCT Claims. The new Claims 5 to 8 were also within the earlier filed claims in the PCT application and thus, objections under Section 59 of the Act have been wrongly raised.

25. Ms. Mani also relies upon the recent decision of the coordinate Bench of this Court in ***Axcess Limited v. Controller of Patents and Designs***, ***2024:DHC:7041*** to argue that if the amended claims are within the scope of the original PCT claims, the amendment would not be liable to be rejected. She also relies upon the decision of another Coordinate Bench of this Court in ***Allergan Inc. v. Controller of Patents, 2023 SCC OnLine Del 295.***

26. Further, Ms. Mani, ld. Counsel made submissions in respect of the amendment of the claims which were disallowed by the Patent Office. She, firstly, refers to the impugned order where the Patent Office has held that the newly added claims 5 to 8 are hit by Section 59 of the Act and hence, the same are disallowed. It is her submission that originally when the PCT Application was filed, the complete specification had claims 41, 42, 43, 47 & 52 which were all dependent claims on Claims 1 to 31. Once, the PCT Application had entered the national phase in India, the Appellant had undertaken a voluntary amendment by filing Form 3 under the Act. In the first voluntary amendment the Appellant had deleted various claims which are clearly illustrated in the chart below:

Pending claim	Amended claims	Support from the as-filed specification of the instant Application
1	1	Amended; Support for the amendment can be found in paragraphs 0042 and 0186-0188
2-3	2-3	Amended; For consistency with amended claim 1
4-10	4-10	No change
11-12	-	Cancelled
13	11	Amended; For consistency with amended claim 1
14	12	Amended; Supported by pending claim 14 and amended claim 1
15	13	Amended; For consistency with amended claim 1
16-17	14-15	Renumbered and Amended for antecedence
18-54	-	Cancelled

27. Thereafter, a second voluntary amendment was carried out by the Appellant which is illustrated by the following chart:

Amended claim	Pending Claim	Support
1-3	1-3	Amended; Support can be found through out the pending claims and as-filed specification of the instant Application.
4-15	4-15	No Change.

28. Both these amendments *i.e.*, first and the second amendment, were prior to the issuance of the FER. Upon the issuance of the FER, in the reply to the same, the Appellant had sought to further amend the claims. The same are as under:

Amended Claim No.	Pending Claim No.	Exemplary Basis (based on the pending claims and specification as filed)
1	1	Amended; support from pending Claim 1; as filed PCT claims 46 and 53; Paragraphs [0004], [0053], [0186] of the filed specification of the instant Application
2	2	No change
-	3-6	Cancelled
3	7	Renumbered and amended to adjust dependency.
-	8-9	Cancelled
4	10	Renumbered and amended to adjust dependency.
-	11-15	Cancelled
5	-	Added; support from as filed PCT claims 41 and 42 of the as-filed specification of the instant Application
6	-	Added; support from as filed PCT claim 43 of the as-filed specification of the instant Application
7	-	Added; support from as filed PCT claim 47 of the as-filed specification of the instant Application
8	-	Added; support from as filed PCT claim 52 of the as-filed specification of the instant Application

29. Therefore, after the filing of the PCT application there were two voluntary amendments prior to the examination by the Patent Office. Claims 1 to 15 were examined and in reply to the FER, the 3rd amendment was carried out. Finally, after the hearing, with the written submissions a substantial number of claims were deleted and 4 claims i.e., Claims 5 to 8 were added by the Appellant. The four claims were original PCT Claims 41, 42, 43, 47 & 52. Claims 41 & 42 which were originally in the PCT were merged into claim one.

30. The submission, therefore, is that the amended claims were well within this scope of the originally filed specification and also had support in the said

specification. Ms. Mani concedes that the Specification filed with the amendments, however, would not have these claims, but the amendments have to be tested on the anvil of the originally filed Specification. Reference is made to Section 59 of the Act to argue that under the said provision, there are three limbs and the amendment to the examined claims is not hit by any of the conditions contained the said section.

31. According to the ld. Counsel, the claims after amendment would have been within the scope of the originally filed complete specification. The word specification in Section 15 of the Act has to be therefore, read to mean the originally filed specification and not the amended specification during the process of prosecution. She relies upon the following judgments:

i) Syngenta Limited vs Controller of Patents and Designs, C.A.(COMM.IPD-PAT) 471/2022 [decided on 13th October, 2023]

ii) Nippon A And L Inc. vs The Controller of Patents, [2022 SCC OnLine Del 1909]

iii) Commonwealth Scientific and Industrial Research Organisation vs The Assistant Controller of Patents (T)CMA(PT)/14/2023 [decided on 4th October, 2023]

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

32. Ms. Arunima Dwivedi, ld. CGSC had appeared for the Respondent and submitted at the outset that the impugned order is a well-reasoned order with clear elaboration for refusal of the grant of patent which was passed after hearing the Appellants. It is stated that the subject invention not only involves performing a multiplex PCR amplification reaction on nucleic acids isolated from a sample, but also involves, a determination step of the single nucleotide variants present in the *lung squamous cell carcinoma*. It is argued that since

the subject invention involves a diagnosis whereby the *lung squamous cell carcinoma* can be treated, the corresponding Claims 1 to 4 would not be permissible under Section 3(i) of the Act.

33. It is stated that since under Section 3(i) of the Act the term used is "*diagnostic method*" it is clear that the same does not contemplate a distinction between *in vivo* and *in vitro* methods. Accordingly, it is stated that the argument of the Appellants on this aspect is untenable.

34. In response to the argument of the Appellants that for a "*diagnostic method*" there must be a conclusive discovery or identification of the illness, it is submitted that reading of the Claim 1 itself shows that the illness for which the individual is to be tested is *lung squamous cell carcinoma*. Further, reliance is placed on the impugned order wherein it is stated as under:

> "*Para [0040] of the description itself states that methods and compositions provided herein improve the detection, diagnosis, staging, screening, treatment, and management of lung cancer.*"

35. As noted above, during the course of hearing on behalf of the Patent Office, Mr. Prasad, Deputy Controller of Patents was present. On a query from the Court, he submitted that the question of inventive step had not been examined in the impugned order as the objection under Section 3(i) of the Act had been raised. He seeks to point out that upon the FER being issued by the Patent Office, the Appellant had amended its Claims from the 54 original Claims and had restricted it to 15 Claims. The now amended Claims 5 to 8 were not part of the original Claims and the Appellant is seeking to argue that they are within the scope of the PCT claims.

36. Further, Ms. Arunima Dwivedi, ld. Counsel along with Mr. Prasad, the

Deputy Controller, submits that from the practical point of examination of the patent application, if the argument of the Appellant in respect of Section 59 of the Act is accepted, it would be totally impractical as the amendment would have to be seen at every point with the original specification which the patent office does not do. The Patent Office had allowed the voluntary amendments and there was an order which was passed by the Patent Office. Thus, the Patent Office cannot be asked to go back to the PCT Application. The ld. Counsel submits that if the Appellant had not filed Form 3 voluntarily, then it may have been open to the Appellant to file for an amendment, but in the facts of this case it would not be permissible.

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

37. 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.

38. 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.

39. 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 of the European Patent Office 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 grant of patent.

40. It is the stand of the ld. *Amicus Curiae* that a plain reading of Section 3(i) of the Act 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.

41. 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 a proposal made by India on the basis of Article 52 of the EPC, 1973. 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

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

methods.

42. 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.

43. 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.

44. 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.

45. Finally, the submission is 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.)*.

46. Ld. *Amicus Curiae* has also handed over two examples of patents which have been rejected in Europe on equivalent provisions to Section 3(i) of the Act.

47. 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.

48. 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.

49. Further, in respect of the amendment of claims, ld. *Amicus Curiae* has submitted that Section 13(3) of the Act clearly makes a distinction between the amended specification and the original specification. Once a specification is amended, therefore, the original specification would be of no avail and any amendment, thereafter, would have to be tested on the benchmark of the amended specification.

50. He further submits that some guidance can be obtained from the Ayyangar Committee Report wherein, the scope of amendments has been discussed and the same have been categorised into two stages: pre acceptance amendments and post acceptance amendments. Under the Patents and Designs Act, 1911 (hereinafter "*the 1911 Act*"), pre-acceptance amendments were not advertised but post-acceptance amendments were advertised. Thus, the Ayyangar Committee Report makes a clear distinction that, if an application has been advertised and the complete specification has been put into public domain, the concept of what is not claimed is disclaimed would clearly apply. However, if on facts, if Claim 1 of the PCT Application and Claim 1 of the amended specification is similar in nature and what is sought to

be added is merely dependent claims, since dependent claims do not expand the scope of the original claim, the same could be considered for being allowed.

IV. Analysis & Findings:

51. Heard ld. Counsels for the parties and the ld. *Amicus Curiae.* 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.

52. 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?

(iii) Whether Claims 5 to 8 of the subject patent application would be impermissible in view of Section 59 of the Act?

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

53. 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

54. 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."

55. 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****."*

56. 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]

"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*

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

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**."*

57. 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.

58 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 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,***

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

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*."*

59. 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?"*

60. 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."*

61. 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.

62. 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.

63. 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.

64. 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

65. At the outset, it is noted that Section 3(i) or any other similar provision did not exist in the 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.

66. 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."

67. 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."*

68. 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, the 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."*

69. 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."*

70. 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*.

71. 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.

72. 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.

73. 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.

74. 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.

75. 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.

76. 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: <u>any operation on the body</u>, 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."*

77. 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.

78. 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.

79. 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.

80. 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, and

Issue III: Whether the Claims 5 to 8 of the subject patent application would be impermissible in view of Section 59 of the Act?

81. The subject invention provides a non-invasive, *in vitro* method to detect and monitor genetic mutations associated with lung cancer, specifically *lung squamous cell carcinoma*, using blood samples. A set of known single-nucleotide variant (hereinafter "*SNV*") loci correlating to lung cancer are targeted. Nucleic acids from the patient's blood are subjected to a specially-configured multiplex PCR to amplify dozens or even hundreds of these loci simultaneously. The PCR conditions are tailored to ensure efficiency in amplifying multiple short fragments to promote balanced amplification of many targets. After amplification, high-throughput sequencing is used to read portions of each amplicon and identify which SNVs are present. It is claimed that by performing these steps, the subject method can determine whether tumor-specific mutations (which may have been pre-characterized from a tumor biopsy in some embodiments) or known lung cancer signature mutations are present in the concerned individual's bloodstream. The detection of such cancer-associated SNVs in blood can indicate the presence of a tumor and allows "*tracking*" of those mutations over time.

82. It is claimed that the invention thus enables early diagnosis or monitoring of lung cancer in a minimally invasive manner and can further quantify mutation allele frequencies to distinguish clonal (dominant) mutations from sub-clonal ones. In sum, the stand of the Appellants is that the claimed method is a laboratory technique for amplifying and detecting tumor-derived DNA in a blood sample with high sensitivity and confidence. Appellants claim that the subject method does not itself treat the patient, nor explicitly declare a diagnosis in the claim – it yields genetic data that a clinician could use in diagnosis or treatment planning.

83. 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.

84. A perusal of the complete specification of the subject invention shows that it is titled as "*Methods of Lung Cancer Detection*". The field of the invention is defined as under:

> *" **FIELD OF THE INVENTION***
> ***[0002]** The disclosed inventions **relate generally to methods for detecting nucleic acid mutations** and fusions using amplification methods such as the polymerase chain reaction (PCR)."*

85. The complete specification also sets out the background of the subject invention which reads as under:

> *" **BACKGROUND OF THE INVENTION***
> ***[0003]** Detection of mutations associated with cancers whether prior to diagnosis, in making a diagnosis, for disease staging or to monitor treatment efficacy has traditionally relied or solid tumor biopsy samples. Such sampling is highly invasive and not without risk of potentially contributing to metastasis or surgical complications. Better and less invasive methods are needed for detecting mutations associated with cancer."*

86. A perusal of the field and the background of the subject invention would show that the purpose of the invention is to detect mutations associated with cancer using methods such as PCR method. Such PCR methods are well known in the field of diagnosis. The summary sets out various embodiments of the manner in which amplification methods such as PCR is used. This

summary sets out how sets of amplicons are generated using a multiplex amplification reaction on nucleic acids. The said nucleic acids are isolated from the sample of blood from an individual suspected to having *lung squamous cell carcinoma*. If the amplicons span even one single nucleotide variant which is known to be associated with lung care, then the presence of squamous cell carcinoma is diagnosed.

87. As per Claim 2 the subject method would also identify/ diagnose the stage of lung squamous cell carcinoma being 1a, 1b or 2a of squamous cell carcinoma. The various embodiments primarily disclosed in the complete specification would show that there are certain other stages of carcinoma which are mentioned. However, in each stage, the test which is contemplated in the subject invention is either for detecting presence of carcinoma or for supporting a lung cancer diagnosis. The relevant paragraphs of the summary of the invention which show that the subject invention is meant to determine the presence of carcinoma or to support the lung cancer diagnosis is set out below:

> *"**SUMMARY OF THE INVENTION***
> ***[0004]** Provided herein in one embodiment, is a method for determining the single nucleotide variants present in a lung squamous cell carcinoma. The method in this embodiment, includes generating a set of amplicons by performing a multiplex amplification reaction on nucleic acids isolated from a sample of blood or a fraction thereof from an individual suspected of having a lung squamous cell carcinoma, wherein each amplicon of the set of amplicons spans at least one single nucleotide variant loci of a set of single nucleotide variant loci known to be associated with lung cancer; and*

[0005] *determining the sequence of at least a segment of each amplicon of the set of amplicons, wherein the segment comprises a single nucleotide variant loci, thereby determining the single nucleotide variants present in the squamous cell carcinoma.*

[0006] *In another embodiment, provided herein is a* ***method for supporting a lung cancer diagnosis for an individual suspected of having lung cancer from a sample of blood or a fraction thereof from the individual****. The method includes generating a set of amplicons by performing a multiplex amplification reaction on nucleic acids isolated from the sample, wherein each amplicon of the set of amplicons spans at least one single nucleotide variant loci of a set of single nucleotide variant loci known to be associated with lung cancer; and*

[0007] *determining the sequence of at least a segment of each amplicon of the set of amplicons, wherein the segment comprises a single nucleotide variant loci, thereby determining whether one or more single nucleotide variants are present in the plurality of single nucleotide variant loci. According to illustrative embodiments,*

[0008]the absence of a single nucleotide variant supports a diagnosis of stage 1a, 2a, or 2b adenocarcinoma*,*

[0009]the presence of a single nucleotide variant supports a diagnosis of squamous cell carcinoma or a stage 2b or 3a adenocarcinoma, and/or

[0010]the presence of 5, 10, 15 or more single nucleotide variants supports a diagnosis of squamous cell carcinoma or a stage 2b or 3 adenocarcinoma*.*

[0011]<u>In certain embodiments, the presence of 5, 10, or 15 or more single nucleotide variants supports a diagnosis of squamous cell carcinoma or a stage 3 adenocarcinoma.</u>"

88. As is clear from the above, the summary also shows that some of them embodiments of the invention are meant to support the diagnosis of squamous cell carcinoma or stage three carcinoma. Further, other portions of the Complete Specification also point to detection of other stages of carcinoma.

89. It is noted that the Claims in this case have been amended on five occasions:

Set of claims	No. of claims
Original set of claims	54
Second set of claims (9th April 2020)	15
Third set of claims (28th October 2020)	15
Fourth set of claims (25th February 2022)	15
Fifth set of claims	8

90. At this stage it would be relevant to consider the final Claims which were rejected by the Respondent and the same read as under:

"***<u>I/We Claim:</u>***

1. A method for tracking presence of single nucleotide variants associated with tumor mutations in an individual suspected of having lung squamous cell carcinoma, comprising performing a multiplex PCR amplification reaction on nucleic acids isolated from a sample of blood or a fraction thereof from the individual wherein the multiplex PCR amplification reaction

comprises forming an amplification reaction mixture by combining a polymerase, nucleotide triphosphates, nucleic acid fragments from a nucleic acid library generated from the sample of blood or fraction thereof, and a set of primers that each binds within 150 base pairs of the single nucleotide variant loci, or a set of primer pairs that each span a region of 160 base pairs or less comprising the single nucleotide variant loci, an annealing time of at least 15 minutes and a primer concentration in the amplification reaction of between 1 and 10 nM inclusive, wherein each of the single nucleotide variant loci are known to be associated only with lung squamous cell carcinoma; and each amplicon of the set of amplicons spans at least one single nucleotide variant loci of a set of 25 to 1000 single nucleotide variant loci known to be associated with lung cancer; and determining the sequence of at least a segment of each amplicon of the set of amplicons thereby determining the single nucleotide variants present in the lung squamous cell carcinoma.

2. The method according to claim 1, wherein the lung squamous cell carcinoma is a stage 1a, 1b, or 2a squamous cell carcinoma.

3. The method according to claim 1, wherein the method further comprises determining the variant allele frequency for each of the single nucleotide variants from the sequence determination.

4. The method according to claim 1, wherein nucleic acids are isolated from a tumor of the individual and single nucleotide variants are identified in the tumor for the set single nucleotide variant loci before determining the sequence of at least a segment of each amplicon of the set of amplicons for the sample of blood or fraction thereof.

5. The method according to any one of claims 1-4, wherein a single nucleotide variant call is made if the confidence value for the presence a single nucleotide variant is greater than 90% or 95%.

6. The method according to any one of claims 1-4, wherein the set of single nucleotide variance loci comprises all of the single nucleotide variance loci identified in the TCGA and COSMIC data sets for lung cancer.

7. The method according to any one of claims 1-4, wherein an efficiency and an error rate per cycle are determined for each amplification reaction of the multiplex amplification reaction of the single nucleotide variance loci, and the efficiency and the error rate are used to determine whether a single nucleotide variant at the set of single variant loci is present in the plasma sample.

8. The method according to any one of claims 1-4, wherein the primers in the set of primers, are designed to minimize primer dimer formation."

91. A perusal of the impugned order would show that Claims 1 to 4 have been rejected as being non-patentable under Section 3(i) of the Act. Further, Claims 5 to 8 have been rejected on the ground that these claims go beyond the originally filed specifications/ claims.

92. The submission of Ms. Mani, ld. Counsel on behalf of the Appellants is that PCR is a known amplification reaction however, this invention relates to a bespoke PCR which is performed on tumour tissues. It is also her submission that the subject invention does not give conclusive discovery or identification of the exact cause of illness or problem and therefore, it is not diagnostic in nature.

93. In the opinion of this Court, this submission is completely meritless as identification of the exact illness, problem or cause would merely be one of the elements of diagnosis. The term 'diagnosis' itself would mean the process of obtaining a result as to whether any particular medical condition exists or not as also the stage thereof, if any. It cannot be accepted that only those methods which ***finally confirm*** the presence of a particular illness, disease or medical condition would be a diagnostic method. In view of the discussion hereinabove on interpretation of diagnostic methods, where the result of performing a method would ***initially confirm*** the absence of a particular illness, disease, genetic defect, medical condition etc., or negation of the same in an individual, the said method would also fall within the scope of diagnosis - irrespective of the said method being performed as an *in vivo or invitro test*.

94. Furthermore, the argument that a diagnostic method would require identification of a particular cause of the illness or medical condition is also untenable. For example, in the case of cancer, it is publicly known that there could be numerous factors which may cause cancer, especially lung cancer, such as pollution, smoking, etc., however, the diagnosis itself is not meant to identify the cause for cancer, but the existence or absence of the carcinoma *i.e.,* cancer. Thus, the test that is professed by the Appellant that diagnosis is meant to identify the exact cause of illness or a problem is not an acceptable test.

95. In respect of the subject invention, the complete specification in the present case, leaves, no manner of doubt in the language which is used that upon conducting a test through an amplification method using bespoke PCR, the presence of cancerous cell is sought to be established/ identified. The relevant paragraphs of the detailed description of the subject invention reads

as under:

> *"**DETAILED DESCRIPTION OF THE INVENTION***
>
> ***[0040]Methods and compositions provided herein improve the detection, diagnosis, staging, screening, treatment, and management of lung cancer**. Methods provided herein, in illustrative embodiments analyze single nucleotide variant mutations (SNVs) in circulating fluids, especially circulating tumor DNA. The methods provide the advantage of identifying more of the mutations that are found in a tumor and clonal as well as subclonal mutations, in a single test, rather than multiple tests that would be required, if effective at all, that utilize tumor samples. **The methods and compositions can be helpful on their own, or they can be helpful when used along with other methods for detection, diagnosis, staging, screening, treatment, and management of lung cancer, for example to help support the results of these other methods to provide more confidence and/or a definitive result.***
>
> ***[0041]** Accordingly, provided herein in one embodiment, is a method for determining the single nucleotide variants present in a lung squamous cell carcinoma by determining the single nucleotide variants present in a ctDNA sample from an individual, such as an individual having or suspected of having, squamous cell carcinoma, using a ctDNA SNV amplification/sequencing workflow provided herein.*
>
> ***[0042]In another embodiment, provided herein is a method for detecting lung sqaumous cell carcinoma** in a sample of blood or a fraction thereof from an individual, such as an individual suspected of having a cancer, that includes determining the single nucleotide variants present in a sample by determining the single nucleotide variants present in a ctDNA*

sample using a ctDNA SNV amplification/sequencing workflow provided herein. The presence of 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or 15 SNVs on the low end of the range, and 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 30, 40, or 50 SNVs on the high end of the range, in the sample at the plurality of single nucleotide loci is indicative of the presence of squamous cell carcinoma."

96. The detailed description of the invention also makes it abundantly clear that the intention of the subject invention is to obtain a definitive result. The various embodiments in the invention are intended to determine whether it is lung cancer or whether it is *squamous cell carcinoma* or *adenocarcinoma* and what is the stage of *carcinoma*. The Complete Specification read along with the final Claims leaves no manner of doubt that the subject invention is for a process of diagnosing and determining lung cancer *i.e., squamous cell carcinoma,* along with the stage at which the same is present in an individual. The subject invention is clearly hit by Section 3(i) of the Act, especially considering the fact that the complete specification even confirms that in some embodiments there is a definitive result being obtained as well.

97. This Court is conscious of the fact that insofar as cancer is concerned, the nature of the disease may require further test to be performed on the patient before the treatment begins, however, this by itself cannot, in any manner, neutralise or dilute the purpose of the subject invention *i.e.,*that the process is meant to detect lung cancer.

98. It would also be necessary to observe that one cause of concern for this Court is that various claims which have been filed from time to time have tried to create a veil so that the claims can escape the objection of Section 3(i). However, as held in ***Novartis AG v. Union of India, (2013) 6 SCC 1*** skilful

drafting would not help in such cases. The observation of the Supreme Court is as under:

> *"134. However, before leaving Hogan [Hogan, In re, 559 F 2d 595 (CCPA 1977)] and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent;* ***where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers****, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent."*

99. This Court also notes that the subject invention may have been patented in some foreign jurisdictions, however, the statutory prohibition in India being what it is, the mere grant in foreign jurisdictions would not lead to grant of the patent in India.

100. Thus, in view of the above discussion and considering the Complete Specification read with the final Claims clearly shows that the subject patent is for a process for diagnosis and detection of lung cancer. The statute as it stands, therefore, would not permit the grant of subject patent.

101. It is made clear that the question as to whether in order to enable innovation in the field of biotechnology, such an embargo should exist or not would fall in the realm of policy considerations, which is beyond the remit of this Court.

102. It is also necessary to consider that during the pendency of this appeal,

the Court had called for a report from the Patent Office of the subject invention *qua* inventive step and Section 59 of the Act. The relevant portion of the report given by the Patent Office reads as under:

> *"In view of the above, the method of detection of a single nucleotide variants (SNV) in lung squamous cell carcinoma patients from their blood samples using a multiplex PCR with primers along with statistical algorithmic model is known from the disclosure of D1.* ***By combining the disclosure of D1 along with D2 and D3, it is obvious for a person skilled in the art to arrive at the present invention. Therefore, inventive step for amended claims 1-8 cannot be acknowledged u/s 2(1)(ja) of the Patents Act, 1970 (as amended).***
>
> *Xxxx*
>
> *As the Patents Act under section 3(i) does not distinguish method of treatment as in-vitro or in-vivo,* ***the present application relating to a method of detection of single nucleotide variant, a natural phenomena using known techniques in the prior art leading to a diagnosis of cancer particularly lung squamous cell carcinoma is not patentable.***
>
> *Xxxx*
>
> *As the applicant* ***has voluntarily disclaimed claims 11-12, 18-54 before the processing of application at FER stage, the claims 5-8 drawing support once again from original PCT claims 41,42, 23,47 and 52 at the time of hearing written submission is not allowable under*** *Section 59 of the Patents Act 1970 as such incorporation of adding new claims would not fall within the scope of disclaimer, correction or explanation."*

103. Insofar as opinion of the Patent Office on inventive step or Section 59

of the Act is concerned, the same is not being gone into inasmuch as this Court is of the opinion that subject patent is hit by Section 3(i) of the Act.

104. In view of the above discussion, the appeal of the Appellants against the refusal of grant of subject patent application fails and is liable to be dismissed.

105. 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.

106. Accordingly, the present appeal along with pending applications if any is disposed of in the above terms.

PRATHIBA M. SINGH
JUDGE

OCTOBER 9, 2025
dk/msh