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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) 13/2022**

SEQUENOM INC & ANR. .....Appellants

Through: Mr. Debashish Banerjee, Mr. Vineet Rohilla, Ms. Vaishali Joshi, Mr. Ankush Verma, Advs. (M. 9810948290)

versus

THE CONTROLLER OF PATENTS .....Respondent

Through: Mr. Harish Vaidyanathan Shankar, CGSC with Mr. Srish Kumar Mishra, Mr. Alexander Mathai Paikaday & Mr. Sagar Mehlawat, Advs.
Mr. Adarsh Ramanujan, *Amicus Curie.*

AND

\+ **C.A.(COMM.IPD-PAT) 448/2022**

SEQUENOM INC & ANR. .....Appellants

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

versus

THE CONTROLLER OF PATENTS .....Respondent

Through: Mr. Mukul Singh, CGSC with Ms. Ira Singh, Advs. (M. 9818117987)
Mr. Adarsh Ramanujan, *Amicus Curie*.

CORAM:
JUSTICE PRATHIBA M. SINGH

JUDGMENT

PRATHIBA M. SINGH, J.

1. This hearing has been done through hybrid mode.

2. The present appeals involve an interpretation of the exclusions from patentability in respect of diagnostic processes/methods under Section 3(i) of

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the Patents Act, 1970 (hereinafter "*the Act*").

3. These are two appeals filed under Section 117A of the Act, challenging the impugned order dated 12th December, 2019, (hereinafter "*first impugned order*") in ***C.A.(COMM.IPD-PAT) 448/2022*** and impugned order dated 20th January, 2020, (hereinafter "*second impugned order*") in ***C.A.(COMM.IPD-PAT) 13/2022,*** passed by the Assistant Controller of Patents.

4. The Appellants had preferred the following two Patent Applications:

- ***No. 2476/DELNP/2011 (hereinafter "first patent application")***
- ***No. 3139/DELNP/2012 (hereinafter "second patent application")***

Both the first and second patent applications were in respect of inventions titled "*Process and Compositions for Methylation-Based Enrichment of Fetal Nucleic Acid from a Maternal Sample Useful for Non Invasive Prenatal Diagnoses*" (hereinafter "*the subject inventions*"). The Claims in the said two applications were identical, except in respect of the polynucleotide sequences of 'sequence identifier no.' (hereinafter "*SEQ ID No.*") mentioned in Claim 1, of the subject patent applications, *i.e., SEQ ID* 1 to 89 and *SEQ ID* 90 to 261, respectively.

5. *Vide* the first impugned order the Respondent has refused the grant of the corresponding patent application on the grounds that the subject invention lacks inventive step under Section 2(1)(ja) of the Act, and is not patentable under Sections 3(b), 3(d), 3(i) and 3(j) of the Act. Further, *vide* the second impugned order the Respondent has refused the grant of the patent application on the ground that the Claims thereto are not patentable under Section 3(i) of the Act.

6. In both the Appeals, Appellant No. 1 – Sequenom Inc., and Appellant

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No.2 - Sequenom Center for Molecular Medicine, are entities having their registered office in the United States of America.

I. Factual Background in C.A.(COMM.IPD-PAT) 448/2022

7. In this appeal, the Appellants claim priority from a U.S. Patent Application No. 61/192,264 dated 16th September, 2008. The first patent application was originally filed with 28 Claims. However, during the prosecution of the said application, the Claims have been restricted to 10 claims.

8. The Appellants had filed the request for examination of the first patent application on 16th August, 2012. The First Examination Report (hereinafter "*FER*") was issued by the Respondent on 22nd June, 2017, raising various objections including lack of inventive step under Section 2(1)(ja) of the Act and non-patentability under Section 3(b), (d), (i), and (j) of the Act. The Appellants had filed their response to the FER on 13th March, 2018, and after considering the same, the hearing notice dated 8th June, 2018 was issued by the Respondent fixing the date for hearing the Appellants on 3rd July, 2018. In the hearing notice, the Respondent maintained the objections, *inter alia,* under Section 2(1)(ja) of the Act, and Sections 3(b), (d), (i), and (j) of the Act.

9. The Appellants sought adjournment of the personal hearing on two occasions and thus, the Appellants were finally heard on 31st August, 2018. Pursuant to the oral submissions made in favour of patentability of the subject invention, the Appellants also submitted written submissions on 14th September, 2018. However, *vide* the first impugned order, the Respondent has refused the first patent application on the grounds that the subject invention lacks inventive step under Section 2(1)(ja) of the Act, and is not patentable under Sections 3(b), 3(d), 3(i) and 3(j) of the Act.

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10. The Appellants being aggrieved by the first impugned order, have preferred the present appeal.

II. Factual Background in C.A.(COMM.IPD-PAT) 13/2022

11. In respect of the second patent application, the Appellants claim priority from a U.S. Patent Application No. 12/561,241 dated 16th September, 2009. The second patent application was originally filed with 30 Claims. However, during the prosecution of the said application, the number of Claims have been restricted to 11 Claims.

12. The Appellants had filed the request for examination of the first patent application on 21th August, 2013. The FER was issued by the Respondent on 25th October, 2017, raising various objections, *inter alia,* as under:

(i) Claims 1-12 are anticipated in view of the disclosed documents and hence, lack novelty in terms of Section 2(1)(j) of the Act.

(ii) Claims 1-30 lack inventive step under Section 2(1)(ja) of the Act in view of the prior art documents disclosed in the application.

(iii) Claims 1-30 are non-patentable in view of Section 3(b), (d), (i) and (j) of the Act.

13. The Appellants had filed their response to the FER on 18th April, 2018, along with supporting documents and amended Claims 1-16 to overcome the objections raised in the FER. After considering the same, a hearing notice dated 19th September, 2019 was issued by the Respondent fixing the date for hearing the Appellants on 9th October, 2019. In the hearing notice, the Respondent maintained the objections, *inter alia,* under Section 2(1)(j) of the Act, and Sections 3(b), (d), (i), and (j) of the Act.

14. The Appellants twice sought adjournment of the hearing and finally the Appellants were heard on 6th December, 2019, and pursuant to the oral

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submissions made during the said hearing, the Appellants submitted their written submissions on 19th December, 2019, along with amended Claims 1-11.

15. However, *vide* the second impugned order, the Respondent refused the grant of subject patent application on the ground that subject invention is non-patentable under Section 3(i) of the Act.

16. The Appellants being aggrieved by the second impugned order, had preferred the present appeal.

III. Proceedings in the Appeals

17. The ***C.A.(COMM.IPD-PAT) 448/2022*** was initially filed before the Intellectual Property Appellate Board, Delhi Registry-cum-Bench and *vide* order dated 25th September, 2020, notice was issued in the said appeal. Thereafter, the said appeal was transferred to the Delhi High Court pursuant to promulgation of the Tribunal Reforms (Rationalization and Conditions of Service) Ordinance, 2021.

18. *Vide* order dated 21st February, 2024, the said appeal was listed before another ld. Single Judge of this Court, on which date, it was brought to the attention of the Court that a batch of appeals were pending before this Court *qua* the interpretation of Section 3(i) of the Act. Considering the fact that the main ground for rejection of the first patent application was also under Section 3(i) of the Act, the Court directed the said appeal to be listed before this Court. The relevant portion of the said order reads as under:

> *"1. The Appellants' Indian Patent Application No. 2476/DELNP/2011 has been rejected inter alia on the ground of Section 3(i) of the Patents Act, 1970. Both counsel inform the Court that the scope of the aforesaid provision is presently being deliberated by the Bench of Hon'ble Ms. Justice Prathiba M. Singh in a batch of appeals which would have direct bearing on the instant*

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case.

2. In the present appeal, there are multiple grounds of rejection of Appellants' application, including Section 3(i) of the Act. However, since the ground of challenge on Section 3(i) is common to the batch of appeals being heard by the aforesaid Bench, to ensure uniformity in decisions, in the opinion of the Court, the Appellants should also be afforded an opportunity to put forth their contentions before the said Bench.

3. Accordingly, subject to the orders of the Hon'ble Judge-in-charge (Original Side), let the instant appeal be also tagged along with C.A.(COMM.IPD-PAT) 13/2022 and connected matters on 04th March, 2024."

19. Correspondingly, in ***C.A.(COMM.IPD-PAT) 13/2022*** notice was issued on 24th January, 2022. The Court heard the parties on 17th May, 2022, before listing the said appeal along with the lead matter in the batch of appeals dealing with interpretation of Section 3(i) of the Act *i.e.,* ***C.A.(COMM.IPD-PAT) 7/2021*** titled ***EMD Millipore Corp. v. Assistant Controller of Patents***. The relevant portion of the said order reads as under:

"2. The present appeal arises out of the impugned order dated 20th January, 2020 passed by the Assistant Controller of Patents and Designs, by which the Appellant's Patent application bearing no. 3139/DELNP/2012 has been rejected on the ground that it is a non-patentable invention under Section 3(i) of the Patents Act, 1970 (hereinafter, "Act").

3. The submission of ld. Counsel for the Appellant is that the disclosed invention relates to a screening test, and not a diagnostic test. Reliance is placed upon the difference between a screening test and a diagnostic test to argue that until the foetus is born, there would be no diagnosis and only a screening of the foetus to check as

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to whether there is a possibility of the foetus suffering from any abnormalities. Therefore, he submits that the subject patent would not be hit by Section 3(i) of the Act.

4. On the other hand, ld. Counsel for the Respondent relies upon the definition of 'Pre-Natal Diagnostic Test' under Section 2(k) of the Pre- Conception and Pre-Natal Diagnostic Techniques Act, 1994 ("PCPNDT Act"), to argue that any testing of a pregnant woman's blood, tissue, amniotic fluid, etc. would constitute a 'Pre-Natal Diagnostic Test'. On the strength of the said definition, it is submitted by the Respondent that the claimed invention is clearly non-patentable under Section 3(i) of the Act.

5. In rejoinder, ld. Counsel for the Appellant submits that considering the legislative intent behind the enactment of the PCPNDT Act, the broad definition of 'Pre-Natal Diagnostic Test' under Section 2(k) cannot be made applicable to the subject patent.

6. List along with ***C.A.(COMM.IPD-PAT) 7/2021*** *on 24th August, 2022."*

20. The present two appeals were heard along with a batch of appeals raising the common issue of interpretation of Section 3(i) of the Act. Further, considering that the interpretation of Section 3(i) of the Act would have a bearing on a large number of patent applications, on 28th October, 2022 the Court appointed Mr. Adarsh Ramanujan, Advocate as an *Amicus Curiae* to assist the Court in this matter.

21. Thereafter, detailed submissions were made by the ld. Counsels for the parties as also the ld. *Amicus Curiae* on several dates. Subsequently, the judgment in the present set of appeals has been reserved on 21st December, 2024.

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IV. Submissions on behalf of Appellants

22. Mr. Debashish Banerjee, ld. Counsel appearing for the Appellants in both the appeals, at the outset submits that the subject inventions in these appeals do not relate to a diagnostic method. The subject invention in both these appeals relate to the steps prior to reaching the stage of diagnoses *i.e.,* the subject inventions are '*Non-Invasive Pre-Natal Screening Tests*' (hereinafter "*NIPTs*"). He submits that it is a well-acknowledged fact that conduct of any test on the foetus to check for genetic abnormalities, either through '*Chronic Villus Sampling'* or '*amniocentesis*', is fraught with risk. However, such tests are necessary for determining any foetal abnormalities. Thus, it is submitted that elimination through prior screening as to whether undergoing such risky tests is required or not has its own advantages, which the subject inventions relate to.

23. He submits that the purpose of the two subject inventions is for enabling screening of a pregnant mother during the first trimester itself, by drawing a blood sample from the mother and separating the DNA of the mother from the foetal DNA. After the separation an assessment is done as to whether the foetus ought to be put through any test or not. It is argued that the subject inventions do not diagnose any medical condition, however, they eliminate any unnecessary testing of the foetus.

24. The submission of Mr. Banerjee, ld. Counsel is that the term 'diagnostic method' has to be given its ordinary meaning in the context of the purpose of the Act. He submits that the definition of *'pre-natal diagnostic techniques'* as defined under the Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 (hereinafter "*the 1994 Act*") cannot be used as an interpretative aid for Section 3(i) of the Act. The object of the two Acts is completely different.

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Under the 1994 Act, diagnostic is defined broadly in order to ensure that misuse is not permitted - whereas the purpose of the Patents Act is to foster innovation through grant of patents. Therefore, it is the submissions of Mr. Banerjee, ld. Counsel that a common definition for diagnostic methods would, therefore, not be permissible.

25. He, further, submits that Section 3(i) of the Act is in the nature of an exclusionary clause or an exception and should, therefore, be read narrowly. Reliance is placed upon the decision of the Division Bench of this Court in ***F. Hoffmann-La Roche Ltd. v. Cipla Ltd., 2015 SCC OnLine Del 13619*** and the judgment of the Supreme Court in ***N.R. Dongre and Ors. v. Whirlpool Co. and Anr., (1996) 5 SCC 714***. Reliance is also placed upon observations of this Court in ***Swami Ramdev v. Facebook, 2019 SCC OnLine Del 10701*** to argue that as technology progresses the law has to keep pace with technology and exclusion of one full area of innovation from patentees would not be encouraging for innovators.

26. He then moved on to distinguish between a screening test and a diagnostic test similar to the test laid down in the judgement of the Madras High Court in ***Chinese University of Hong Kong and Anr. v. Assistant Controller of Patents & Designs, 2023 SCC OnLine Mad 6372.*** According to Mr. Banerjee, ld. Counsel, there is a fundamental difference between a screening test and diagnostic tests. It is submitted that a diagnostic test confirms the presence or absence of a disease on the basis of which a decision can be made by the medical practitioner. However, an NIPT is merely used to eliminate the need for diagnosis. The ld. Counsel relies upon various medical literature to distinguish between diagnostic and screening tests.

27. According to ld. Counsel, the question as to whether a test is a

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diagnostic test or not is a mixed question of fact and law. He submits that a perusal of the Complete Specifications in ***C.A.(COMM.IPD-PAT) 13/2022*** would show that the manner in which the test results are given in the subject test is more in the nature of an outcome which is in the form of probability or percentage.

28. On a query from the Court as to whether the invention has been commercialised by the Appellants, reference is made to a publication in the Review of Obstetrics and Gynaecology (2013 Edition)[1] where the accuracy of the detection of the Appellants' test has been set out to show its efficiency. The risks are also set out in this publication where distinction has been given on false positives and false negatives in the NHS. The sensitivity and specificity of the test as has been published is quite high.

29. Finally, ld. Counsel has taken the Court through the Claims in both the patent applications. It is submitted that the steps mentioned in the Claims make it clear that the same do not lead to any result or diagnosis on the existence of the foetal abnormality. The subject inventions merely screen people who would be required to undertake further tests for diagnosis of the foetal abnormalities. It is his submission that this would fall in the category of tools which could be used for the purpose of diagnosis or even tools which themselves give no results as to the existence or non-existence of foetal abnormalities. Thus, he submits that both applications ought to be granted.

V. <u>Submissions on behalf of Respondent</u>

30. Mr. Harish V. Shankar, ld. CGSC appearing for the Respondent in ***C.A.(COMM.IPD-PAT) 13/2022*** submits that the non-patentability of

[1] Norwitz ER, Levy B. Noninvasive prenatal testing: the future is now. Rev Obstet Gynecol. 2013;6(2):48-62.

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

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

32. It is submitted by the ld. CGSC that the process of diagnosis consists of various steps which are interlinked and cannot be separated into different and distinct sections such as "screening" and "analysis". It is his submission that testing and diagnostic process would also include preliminary screening tests. In this regard the ld. CGSC has drawn the attention of the Court to Section 83 of the Act which deals with the general principles applicable to working of patented inventions.

33. Further, it is argued by the ld. CGSC that Section 3(i) of the Act does not make a distinction between "*in vivo*" and "*in vitro*" methods of diagnosis.

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He submits that the Guidelines of the Patent Office also do not make such distinction and that several patent applications for inventions based on *in vitro* methods have been rejected.

34. It is his submission that a perusal of the specifications in the second patent application would show that the Appellants' claims themselves are to the effect that there is a determination of the presence of foetal aneuploidy. Further, the summary of the specification would also show that there is determination of various factors such as foetal nucleic acid, foetal sex and foetal chromosome abnormality such as aneuploidy. It is submitted that these would also make it clear that the Appellants themself are positioning the subject invention as a substitute for amniocentesis. The Appellants' test is not a precursor to amniocentesis but a substitute to the same as per the specifications. In fact, accuracy of the Appellants' test is being claimed for more than 99% and therefore it is clear that the applied invention relates to diagnostic test or diagnostic method and is not a screening test.

35. He further highlighted the fact that the WHO material relating to screening contrasts screening with early diagnosis and not with diagnosis *per se*. These are completely different concepts in the sense that screening is general and early diagnosis is for detection of conditions with people who have symptoms. The Appellant's test is actually a diagnosis test and not a mere screening test as is being positioned.

36. Mr. Mukul Singh, ld. CGSC, on the other hand, appearing for the Respondent in the second appeal *i.e.,* ***C.A.(COMM.IPD-PAT) 448/2022***), submits that one of the tests that can be applied by the Court or patent office for determining whether any invention constitutes a diagnostic process/method is to see if the test is invasive or not. Since, in the subject

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invention the sample is being extracted from the body of the patient, the test is an invasive test and therefore, the same is not patentable under Section 3(i) of the Act.

37. Mr. Singh, ld. CGSC submits that a reading of the Complete Specification of the first patent application would make it clear that the same enables non-invasive prenatal diagnosis, including sex determination, blood typing and other genotyping, and detection of preeclampsia in the mother. Further, it is argued that though not claimed, but as per the disclosure and scope of the subject invention mentioned in the Complete Specification, the present method can be employed for sex determination with the detection of different markers specific for sex determination. Considering the same, it is submitted that the subject invention in non-patentable under the Act.

VI. Rejoinder submissions on behalf of the Appellants

38. Mr. Banerjee, ld. Counsel appearing for the Appellants in rejoinder submits that the patent applications were filed way back in 2012 and at that time the difference between NIPT tests and diagnostic tests was not so well known or well established. In fact as of April, 2022, the U.S. Food and Drug Administration (hereinafter "*FDA*") had released certain publications to distinguish between NIPS/NIPT[2] tests and diagnostic tests. As per the FDA, NIPS tests are screening tests which could also give false positives and the same are not diagnostic tests which have more definite results. It is submitted that the fact that certain language may be used in the specification may not be determinative. It has to be adjudged on the basis of the actual contribution which is being made to the art by the invention.

[2] *Non-Invasive Pre-Natal Screening* or *Non-Invasive Pre-Natal Testing*

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VII. Submissions on behalf of the ld. Amicus Curiae

39. 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.

40. 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.

41. 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

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held, after discussing the opinion of the Enlarged Board of Appeal in ***Case Number G 0001/04***, that if diagnosis for treatment is made, even if the diagnosis is not definitive, then the invention would not be eligible for patent.

42. It is the stand of the ld. *Amicus Curiae* that a plain reading of Section 3(i) makes it clear that it applies only to process claims and not to product claims. The reference to the expression "their products" in the later part of Section 3(i) of the Act is meant to be a reference to animal products. In support of his submission, reference is made to the ***Report on the Revision of the Law in India Relating to Patents for Invention,*** dated September, 1959, authored by Justice N. Rajagopala Ayyangar (hereinafter "*the Ayyangar Committee Report*") to argue that in the context of the definition of invention being a manner of manufacture, the report clarifies by following the decision in ***Canterbury Agricultural College***[3]*,* 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.

43. 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. The

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

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

44. 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

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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.

45. 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.

46. 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.

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

48. Ld. *Amicus Curiae* has also handed over two examples of patent applications which have been refused in Europe on equivalent provisions to

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Section 3(i) of the Act.

49. 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.

50. 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.

VIII. Analysis and 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 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

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Court:

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

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

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

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.*

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> *(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:[4]

> *"Hence, a narrower understanding of what constitutes by its nature a "treatment by surgery" within the*

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

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

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

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

It was also remarked that it would be absurd if administering a diagnostic agent by an injection was excluded from patentability but administering by inhalation was not. It is not for the Enlarged Board to decide whether a method involving the injection of a contrast agent is in fact excluded from patentability

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> *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:[5]

> *"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***

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

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> ***treatment might be covered by a patent*** *(see G 1/07, Reasons 3.3.6). Any definition of the term "treatment by surgery" must therefore cover the kind of interventions which constitute the core of the medical profession's activities, i.e. the kind of interventions for which its members are specifically trained and for which they assume a particular responsibility (G 1/07, Reasons 3.4.2.3).*
>
> *The exclusion applies to substantial physical interventions on the body which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise. The health risk must be associated with the mode of administration and not solely with the agent as such (G 1/07, Reasons 3.4.2.3).*
>
> ***Examples of excluded treatments by surgery are the injection of a contrast agent into the heart, catheterisation and endoscopy.***
>
> ***Invasive techniques of a routine character which are performed on uncritical body parts and generally carried out in a non-medical, commercial environment are not excluded from patentability. They include e.g. tattooing, piercing, hair removal by optical radiation and micro-abrasion of the skin****."*

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*

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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*

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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***

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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

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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

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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

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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

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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.

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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 Patents and Designs Act, 1911 (hereinafter *"1911 Act"*). The definition of invention under the 1911 Act required the existence of a novel method of manufacture. Hence, it is clear that processes or methods which are medicinal, surgical, curative, prophylactic, therapeutic would have been automatically excluded under the 1911 Act.

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

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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."*

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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, 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.*

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> *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.*

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> *(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

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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

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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

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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*

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individual (e.g. a fitness test) is considered to be diagnostic.

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

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

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

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

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

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

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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.

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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

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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

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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

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

81. For determining whether the subject inventions are excluded from patentability under Section 3(i) of the Act, this Court would first examine the nature of the claimed processes, the technical character, and the context of their application.

(A) C.A.(COMM.IPD-PAT) 13/2022

82. A perusal of the Complete Specifications of the subject patent applications reveals that in the field of the invention, the technology is described as under:

> *"**FIELD***
> *The technology in part relates to prenatal diagnostics and enrichment methods."*

83. Further, the Background of both the Complete Specifications captures that NIPT[6] is quite prevalent in order to detect pregnancy-related conditions, including complications during pregnancy and genetic defects of the foetus. Usually, such procedures which are in the state of the art, as spelt out in the background, were being done through '*Chronic Villus Sampling*' or amniocentesis using cells isolated from foetus. These were invasive

[6] Non-Invasive Pre-Natal Screening Tests.

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procedures which are considered riskier and hence, thereafter, non-invasive procedures have also emerged.

84. The Summary section of both the Complete Specifications clearly captures that the purpose of the inventions is to detect foetal genetic traits, including the presence and absence of foetal nucleic acid, foetal sex and foetal chromosomal abnormalities, such as aneuploidy. The method involves enriching of the foetal nucleic acid taken from the maternal biological sample. The enrichment is based on differential methylation between foetal and maternal nucleic acid consisting of various steps. The ultimate intention of the invention is to determine the amount of foetal nucleic acid at several locations of a target chromosome in comparison with a reference chromosome. The result would determine whether there is a foetal aneuploidy or not. Similarly, for other detections as well, the same process is used.

85. One of the embodiments given in both the Complete Specifications of the invention disclosed is when the nuclei acid sequence includes one or more polynucleotide sequences of sequence ID no.12261. This particular sequence ID is part of various embodiments in the Complete Specifications of both the patent applications. The methods of conducting the sequence analysis are also set out. One of the embodiments also includes determining the amount of one or more 'Y' chromosomes specific sequences in a sample which would also help in sex determination. Some of the embodiments given in the Complete Specifications can be summarised as under:

1. **Methylation-specific binding and elution method:** One embodiment provides a method for enriching foetal DNA in a maternal sample by exploiting methylation differences. The maternal sample (e.g., blood or plasma) is treated with a methylation-specific DNA-binding agent (such

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as a methyl-CpG binding domain protein), which binds both foetal and maternal DNA. Bound DNA is then eluted in fractions using buffers of increasing salt concentration or other conditions. Because foetal and maternal DNA have different CpG methylation patterns, this process separates them into different fractions – for example, foetal DNA (which is often more highly methylated at certain loci) can be eluted separately from maternal DNA. The resulting fractions are enriched for foetal nucleic acid, which can then be analyzed or amplified as needed.

2. **Restriction enzyme digestion method:** Another embodiment uses methylation-sensitive restriction enzymes to selectively remove maternal DNA. In this method, a maternal blood sample is treated with one or more restriction enzymes (such as HhaI or HpaII) that cut DNA only at unmethylated CpG sites. If a target genomic region is hypermethylated in maternal DNA but hypomethylated in foetal DNA (or vice versa), the enzyme will cleave the maternal DNA but leave the foetal DNA intact. As a result, the remaining intact DNA is enriched for foetal sequences. This enriched foetal DNA can be collected and used for downstream analysis. In some embodiments, multiple enzymes can be used together to improve selectivity.

3. **Capture or separation of differentially methylated DNA:** A related embodiment describes physically separating or "capturing" foetal nucleic acids from maternal nucleic acids based on methylation state. For example, sequences containing one or more CpG sites from the identified epigenetic marker loci are targeted. These sequences can be isolated by probes or other capture agents that bind differentially methylated DNA. By selecting for DNA fragments that contain the

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specific CpG island sequences and have the foetal methylation signature, the method captures foetal DNA out of the sample. The captured DNA, now enriched for foetal-specific loci, is collected for further processing.

4. **Foetal DNA preparation via amplification:** This embodiment covers methods to prepare amplified foetal DNA sequences after separation. First, foetal DNA is enriched from the maternal sample using methylation-based separation. Then, the isolated foetal DNA serves as a template for an amplification step such as PCR or hybrid capture with subsequent amplification. For instance, primers or probes specific to one of the foetal-specific marker sequences are used to amplify that target region. The amplification produces a DNA amplicon or library representing the foetal nucleic acid sequence of interest. This process involves hybridization, capture, or PCR, and it generates foetal-specific DNA in solution for analysis.

5. **Foetal DNA quantification (Foetal Quantifier):** One embodiment is a method for measuring the amount of foetal DNA in a maternal sample. After enriching foetal DNA by differential methylation, the sample is quantified by introducing internal "competitor" DNA sequences of known concentration. These competitors mimic the target sequence but are distinguishable (for example, by a small sequence variation). The mixture is then analyzed (by techniques like PCR with mass spectrometry readout, quantitative sequencing, or digital PCR) to determine the ratio of foetal DNA to competitor. Because the competitor concentration is known, the absolute amount of foetal DNA can be calculated. This quantification yields the total foetal DNA copy number and can confirm the presence or absence of foetal DNA or measure foetal

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fraction in the sample.

6. **Foetal DNA concentration determination:** A related method computes the foetal DNA concentration i.e. percentage of total DNA in the sample. It first measures the total DNA amount in the maternal sample. Then it selectively enriches foetal DNA and quantifies the remaining foetal DNA. By comparing the amount of foetal DNA to the total DNA, the percentage of foetal DNA (foetal fraction) is determined. This approach improves diagnostic sensitivity, and it does not require foetal polymorphisms or bisulphite treatment. Similar to the quantification method, it can use competitors, PCR, or sequencing to count foetal molecules before and after enrichment.

7. **Chromosomal aneuploidy detection:** Another embodiment provides a method to detect foetal chromosomal abnormalities (aneuploidies) using methylation enrichment. The method selectively removes maternal DNA and then measures foetal DNA from specific chromosomes. After digesting maternal DNA, the amount of foetal DNA from a target chromosome (such as chromosome 21) is measured and compared to foetal DNA from a reference chromosome such as a different autosome. A statistically significant increase or decrease in the target-to-reference ratio indicates an extra or missing chromosome. Quantification can be done by PCR assays, sequencing, or mass spectrometry. This method thus diagnoses aneuploidy by comparing foetal chromosomal dosage after methylation-based enrichment.

8. **Copy-number abnormality analysis:** This embodiment detects broader chromosomal abnormalities by comparing copy numbers of target and control sequences in enriched DNA. Both a target locus and a control

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locus are co-enriched by the methylation-based separation. Then copy-number analysis such as quantitative PCR or digital counting is performed on both loci in the same fraction. If the target locus has a higher or lower copy number than the control by a significant amount, a chromosomal abnormality is indicated. In a related approach, target and control DNA are first bound to the methylation-binding agent and then eluted; copy number is analyzed in the eluted fractions to determine any imbalance. This allows detection of aneuploidies without relying on polymorphic differences.

9. **Allelic ratio analysis:** A further embodiment detects abnormalities by comparing allelic ratios of target versus control loci after methylation separation. Target and control DNA are bound and eluted using a methylation-specific binding agent, yielding separate DNA fractions. Allelic ratio tests are performed on the eluted target and control DNA. By comparing the allelic ratios between target and control, it is possible to infer chromosomal abnormalities if the ratios differ beyond expected ranges. This method assumes the target and control loci have similar methylation, so they behave alike during enrichment; deviations in their allelic ratios thus reflect aneuploidy. The method can detect foetal disorders and can utilize known SNPs within the target and control sequences.

10. **Maternal DNA quantification:** In one embodiment, the focus is on measuring maternal DNA by methylation-based enrichment. For example, foetal DNA is first selectively removed by digesting maternal DNA and the remaining DNA is predominantly maternal. The maternal DNA amount is then quantified using standard assays. By subtracting

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this measured maternal DNA from the total DNA in the original sample, the foetal DNA amount can be inferred. This approach provides an alternative way to obtain foetal DNA levels and can support the diagnosis of foetal traits once the foetal fraction is known.

11. **Isolated foetal DNA composition (specific sequences):** One composition embodiment is a purified preparation of foetal-derived DNA fragments that include one or more of the disclosed epigenetic marker sequences. This composition is essentially an isolated piece of foetal genomic DNA in which the nucleotide sequence contains one or more of the specified sequences from the invention. The sequence may be a portion of a gene or a CpG island containing the marker. In some embodiments, these foetal DNA fragments are provided in solution and are enriched relative to any maternal DNA. The composition may also include, for instance, a methylation-binding protein that can bind to methylated CpGs in the DNA.

12. **Isolated foetal DNA composition (CpG sites):** Another composition embodiment is a purified foetal DNA fragment that specifically includes one or more CpG dinucleotides from the epigenetic marker sequences. That is, the fragment comes from a genomic region that contains CpG sites of interest within one of the SEQ ID NOs:1–261. This isolated DNA can be part of a gene region or a CpG island. It may be provided in solution and enriched for foetal DNA content. It can also optionally include an agent such as an MBD protein that binds methylated CpGs, which may be useful in storage or further manipulation.

13. **Enrichment kit:** A practical embodiment is a kit containing all necessary reagents to perform the methylation-based enrichment

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methods. For example, the kit includes a methylation-sensitive binding reagent such as a recombinant methyl-CpG binding protein fused to an Fc domain to separate methylated DNA. It may also contain buffers, control DNA for competitors and other components needed for the various enrichment and quantification steps. This kit enables a laboratory to carry out the described methods for isolating and analyzing foetal DNA from maternal samples.

86. The Complete Specifications then proceed to the drawings showing the design of the recombinant protein and various other figures which provide tables and sequences. The drawings and the tables would also show that although one of the embodiments is in respect of a device, the claims however are not related to a kit, and the claims are for a process/ method invention.

87. The detailed description of the Complete Specifications of the subject patent applications also includes the manner in which the blood sample can be acquired, DNA can be extracted and how methylation can be performed and analysed. The manner in which amplification of nucleotide sequences is to be done, and the determination of nucleotide sequence is to be done is also set out. In respect of foetal aneuploidy, a separate section called '*detection of foetal aneuploidy*' is contained in the specification. The manner in which data is processed for identifying the presence or absence of any chromosomal abnormality is also set out. Examples of implementation of the invention are also set out in the specification.

88. The Claims originally filed were 30 in number. During the prosecution of the subject patent application the same were reduced to 11. Claim 1 as finally filed was claim 13 of the originally filed claims. The claims which were finally rejected read as under:

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"<u>WE CLAIM</u>

1. An in-vitro method for determining the presence of a fetal aneuploidy, comprising:

a) contacting nucleic acid from a female, which nucleic acid comprises fetal nucleic acid and maternal nucleic acid, with a methylation sensitive restriction enzyme that digests the maternal nucleic acid at a plurality of loci selected from loci of SEQ ID NOs: 90-163, 176, 179, 180, 184, 188, 189, 190, 191, 193, 195, 198, 199, 200, 201, 202, 203, 205, 206, 207,208, 209, 210, 211, 212, 213, 214, 225, 226, 231, 232, 233, 235, 241, 257, 258, 259, and 261, wherein the plurality of loci comprises loci that are hypermethylated in fetal nucleic acid, thereby enriching the fetal nucleic acid;

b) amplifying the loci, or portion thereof, not digested in (a) in an amplification reaction, thereby generating amplification products;

c) sequencing the amplification products of (b), thereby generating sequencing products;

d) determining from the sequencing products of (c) the amount of fetal nucleic acid for a plurality of loci of a target chromosome;

e) determining the amount of fetal nucleic acid from a reference chromosome; and

f) comparing the amount of fetal nucleic acid for the plurality of loci of the target chromosome to the amount of fetal nucleic acid for the reference chromosome, whereby a statistically significant difference between the amount of fetal nucleic acid for the plurality of loci of the target chromosome and the amount of fetal nucleic acid for the reference chromosome determines the presence of a fetal aneuploidy. The method as claimed in claim 1, wherein the plurality of loci comprises one

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or more loci selected from loci of SEQ ID NOs: 176, 179, 180, 184, 188, 189, 190, 191, 193, 195, 198, 199,200, 201,202, 203, 205, 206, 207, 208, 209, 210. 211, 212, 213, 214, 225, 226, 231, 232, 233, 235, 241, 257, 258, 259, and 261.

3. The method as claimed in claim 1, wherein the plurality of loci comprises one or more loci selected from loci of SEQ ID NOs: 193, 200, 208, 209, 213, 214, 231, 232, 235, and 241.

4. The method as claimed in claim 1, wherein the plurality of loci comprises the locus of SEQ ID NO: 213.

5. The method as claimed in claim 1, wherein the plurality of loci comprises one or more loci selected from loci of SEQ ID NOs: 200, 208, 231, 232, and 241.

6. The method as claimed in claim I, wherein the plurality of loci comprises the locus of SEQ ID NO: 209.

7. The method as claimed in claim 1, wherein the plurality of loci comprises the locus of SEQ ID NO: 214.

8. The method as claimed in claim 1 wherein the amount of fetal nucleic acid at between 3 and 15 loci on each of the target chromosome and the reference chromosome is determined.

9. The method as claimed in claim I, wherein the amount of fetal nucleic acid at 16 or more loci on each of the target chromosome and reference chromosome is determined.

10. The method as claimed in claim 1, wherein determining the amount of fetal nucleic acid for the target chromosome and the reference chromosome comprises use of a competitor-based amplification

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method.

11. The method as claimed in claim 1, wherein the sequencing method comprises sequencing by synthesis."

89. A reading of claim 1 would show that the method sought to be patented is described as an *in vitro* method for determining the presence of foetal aneuploidy by comparing the amount of foetal nucleic acid for the plurality of loci between the target chromosome and reference chromosome, thereby detecting any abnormality.

90. The argument on behalf of the Appellants is that this mere detection would not lead to a treatment as various confirmatory tests would be required to be undertaken before any treatment or remedial action is taken.

91. The question, therefore, is whether such a detection method would be patentable or not.

92. Ld. Counsel for the Appellants has tried to distinguish between what are known as NIPTs or '*non-invasive prenatal testing*' and definitive diagnostic testing. Reliance is placed upon certain material to argue that there is a difference between a screening test and diagnostic test. The fundamental difference being, as per the Appellants, that diagnostic tests are definitive whereas screening tests may give false-positives. The following illustrative chart is used for representing this difference between the two categories of tests:

Screening Tests	***Diagnostic Tests***
The goal of screening test in NIPT is to identify women with pregnancies who can be at high risk of chromosomal abnormalities or birth defects.	*Diagnostic testing for NIPT allows patients to know with as much certainty as possible whether their pregnancy may be affected by a particular genetic condition.*

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Screening tests are recommended to females with advanced maternal age or maternal age of 35 years of older on the estimated date of delivery i.e., females suspected to have high risk pregnancies.	*Diagnostic tests are recommended, inter alia, in cases where screening tests are positive for aneuploidy.*
Eg. Cell Free Fetal DNA testing	*Eg. Amniocentesis and CVS*

93. On the basis of the above illustration, it is argued by ld. Counsel for the Appellants, that the subject invention does not qualify as a diagnostic treatment for the following reasons:

> *"Can the subject invention qualify as diagnostic treatment?*
> *18. In view of the above it is submitted that the subject invention, being a NIPT, is not a diagnostic treatment for the following reasons.*
> ** The objective of the test is to determine the amount of fetal DNA at certain target loci and then comparing them with the reference chromosomes.*
> ** Though the test is being performed on the foetal DNA, the impact of the results are on the mother/pregnant female. Thus, on receiving the results of the screening test claimed in the subject invention, the only two options that a medical practitioner would advise is either to terminate the pregnancy or continue with the same, either of which is neither equivalent to rendering a human free of diseases nor a method of treatment.* ***A doctor/medical practitioner cannot and will not recommend a termination of pregnancy based on the results of any NIPT screening and would advice the patient to undergo amniocentesis or CVS.***
> ** The chromosomal abnormalities detected in the fetal genetic material leads to genetic disorders that do not have a cure thus, inherently, the test is incapable of being a diagnostic treatment."*

94. Further, the case of the Appellants is that the decision of the Madras High Court in ***Chinese University (supra)*** holds that definitive identification

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is not the requirement of the statute under 3(i) of the Act and therefore, even such screening tests would be non-patentable under 3(i) of the Act if the screening test is capable of identifying the existence or non-existence of a particular medical condition, disease or abnormality. The relevant portion of the decision in ***Chinese University (supra)*** reads as under:

> *"**Screening and Diagnosis***
>
> *49. In medical literature, a distinction is often drawn between screening and diagnosis. Such distinction is typically made on the basis that asymptomatic persons are screened, persons at risk of any disease, disorder or condition are put through preliminary tests for early diagnosis and symptomatic persons are put through diagnostic tests. This raises the question whether such screening of asymptomatic persons would qualify as diagnostic for purposes of Section 3(i). In my view, if a screening test is capable of identifying the existence or non-existence of a disease, disorder or condition and/or the site, extent, severity or other aspects thereof for treatment of human beings, irrespective of whether the person concerned is symptomatic or asymptomatic, such screening test would qualify as a diagnostic test. In other words, the label used for the test - be it screening or anything else - is not determinative.*
>
> *50. Medical literature also makes the distinction between screening and diagnosis on the basis that diagnostic tests are required to confirm the results of screening tests. Even in the specific context of non-invasive prenatal testing (NIPT), reference may be made to the publication by Medline Plus titled "What is non-invasive prenatal testing (NIPT) and what disorders it can screen for" and the publication by the American Clinical Laboratory Association "Screening v. Diagnostic : Understanding Non-invasive Prenatal Screening". Adopting this approach, in my view, is also not in consonance with the meaning of "diagnostic" in*

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Section 3(i), i.e. capable of uncovering the pathology. Put differently, if the screening test identifies the disease, disorder or condition albeit subject to confirmation by definitive tests, it would still qualify as "diagnostic" for purposes of Section 3(i) because the provision does not use the qualifier "definitive".

51. What is determinative, therefore, of whether a test is diagnostic is to ask the question whether the test is inherently and per se capable of identifying the disease, disorder or condition for treatment of the person. It bears repetition that such capability of the test should, in turn, be determined by assuming that person(s) skilled in the art, including a medical doctor, examine the results. If the person(s) skilled in the art would not be in a position to diagnose the disease, disorder or condition, as the case may be, on the basis of the process because the process is not designed to diagnose diseases, disorders or conditions, such process, whether labelled as screening or anything else, would not qualify as diagnostic for purposes of Section 3(i). In order to clarify, I provide one illustration in the context of non-invasive prenatal testing. It is conceivable that a novel and inventive process to isolate the cell free foetal DNA from the biological sample may be invented. This process cannot per se uncover pathology and, therefore, would not qualify as "diagnostic" as per the principle formulated above. I recognise that the line of demarcation between diagnostic and non-diagnostic tests may not always be bright and could blur on occasion; even so, there is sufficient support both in the text and immediate context of the expression "diagnostic" in Section 3(i) to reach the above conclusion. The corollary would be that the Controller would be required to make this determination on a case-by-case basis. Into which category, the claimed invention falls remains to be considered."

95. Thus, as per the Madras High Court, where it is not possible to diagnose

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merely on the basis of the result provided by the claimed method, the same would be eligible for patent protection and would not be barred under Section 3(i) of the Act.

96. At this stage, it would also be relevant to consider the tests suggested by the ld. *Amicus Curiae* for determining whether a test would be a diagnostic method or not:

> *"16. Rather, to invoke Sec.3(i), there must be a link between the claimed method and the consequent treatment, which cannot be remote. Sec.3(i) would only exclude claims where the outcome of the claimed method by itself and without more, would be actionable from the point of view of treatment. Merely because the activity in question may generate or assist in generating data or information that can have diagnostic relevance at a subsequent stage, will not make the activity a "diagnostic method for treatment." The test cannot be whether the claimed method is practiced in the healthcare sector. Similarly, the test also cannot be whether the claimed method could, after subsequent steps, be used by a medical professional to diagnose and determine treatment.*
>
> *17. Incidentally, the Enlarged Board of Appeals reached the same conclusion in respect of Art. 53(c) of the EPC, 2000, i.e., claimed methods that precede the final diagnosis step, such as data gathering or data analysis, are not excluded [G01/04 (2005) pr.6.2.3]. The Madras High Court has also reached the same conclusion [The Chinese University of Hong Kong & Anr. v. Assistant Controller of Patents, 2023:MHC:4617, at prs.23, 40, 45]*
> *18. There are several such examples of inventions where performing the claimed method does not inevitably result in diagnosis for curative purposes. Illustrative examples of the same are put forth in Annexure G."*

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97. Thus, as per the ld. *Amicus Curiae* and the Appellants, if the method is only one part of the data gathering process prior to treatment, it would still be patentable.

98. On the basis of the above legal position, the issue that arises is whether the subject invention is a NIPT and is, therefore, different from a diagnostic test.

99. A perusal of the Complete Specifications and the Claims would show that the tests when performed reveal the clear possibility of existence of aneuploidy or any other foetal disorder. The test can also be used for determining the presence of 'Y' chromosome nucleic acid. The Appellants have relied on the following material to argue that difference ought to be brought about between screening and diagnosis:

(i) Britannica Online Encyclopaedia[7]:

> *"The diagnostic process is the method by which health professionals select one disease over another, identifying one as the most likely cause of a person's symptoms. Symptoms that appear early in the course of a disease are often more vague and undifferentiated than those that arise as the disease progresses, making this the most difficult time to make an accurate diagnosis. Reaching an accurate conclusion depends on the timing and the sequence of the symptoms, past medical history and risk factors for certain diseases, and a recent exposure to disease. The physician, in making a diagnosis, also relies on various other clues such as physical signs, nonverbal signals of distress, and the results of selected laboratory and radiological and other imaging tests. From the large number of facts obtained, a list of possible diagnoses can be determined,*

[7] Rakel, Robert Edwin. "diagnosis". Encyclopedia Britannica, 6 Apr. 2025, https://www.britannica.com/science/diagnosis.

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which are referred to as the differential diagnosis.

The physician organizes the list with the most likely diagnosis given first. Additional information is identified, and appropriate tests are selected that will narrow the list or confirm one of the possible diseases."

(ii) Wilson & Jungner's principles of screening[8]:

"The era of modern screening began in 1968 with a landmark publication by Wilson & Jungner for WHO (3), which stated:

Screening is the presumptive identification of unrecognized disease or defect by the application of tests, examinations, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment."

(iii) The American College of Medical Genetics and Genomics policy statement[9]:

"WHERE DOES NIPS FIT INTO THE ANEUPLOIDY SCREENING PARADIGM?
NIPS is, as the acronym implies, a screening test to identify pregnancies at risk for common autosomal aneuploidies (e.g., trisomy 21, 18, and 13).® Some laboratories also offer screening for sex chromosome aneuploidies.

For women seeking a definitive diagnosis, invasive procedures for diagnostic testing, such as amniocentesis or chorionic villus sampling, should be offered.

---

[8] Wilson J, Junger G. Principles and practice of screening for disease. Geneva: World Health Organization; 1968.
[9] ACMG statement on noninvasive prenatal screening for fetal aneuploidy Gregg, Anthony R. et al. Genetics in Medicine, Volume 15, Issue 5, 395 – 398.

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WHAT ARE THE CURRENT LIMITATIONS OF NIPS?

1. Risk assessment is limited to specific fetal aneuploidies (trisomy 13, 18, and 21) at this time. Some platforms also screen for sex chromosome abnormalities. Approximately 50% of cytogenetic abnormalities routinely identified by amniocentesis will not be detected when trisomy 21, 18, and 13 are the only aneuploidies being screened. When patients <35 years or >35 years are considered separately, 75 and 43% of cytogenetic abnormalities will be missed, respectively.

2. Chromosomal abnormalities such as unbalanced translocations, deletions, and duplications will not be detected by NIPS. Therefore, when fetal anomalies are detected, invasive diagnostic testing and cytogenomic microarray analysis are more likely to detect chromosomal imbalances than NIPS and may be a better testing option.

3. NIPS is not able to distinguish specific forms of aneuploidy. For example, NIPS cannot determine if Down syndrome is due to the presence of an extra chromosome (trisomy 21), a Robertsonian translocation involving chromosome 21, or high-level mosaicism. Identification of the mechanism of aneuploidy is important for recurrence risk counselling and emphasizes the importance of diagnostic testing following NIPS.

xxx

2. NIPS is not diagnostic, therefore, confirmatory test (Chronic villus sampling of amniocentesis) is recommended and the risks of those procedure should be reviewed."

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(iv) National Center for Biotechnology Information, United States of America[10]:

> *"How are Tests Performed?*
> *Two main types of prenatal testing are performed during pregnancy. The first type of testing is known as screening. Screening tests are used to identify women with an increased chance to have a baby with certain chromosomal abnormalities. Screening tests do not identify birth defects such as genetic diseases. Results that reveal a chance over a certain cutoff level are called "positive results," and these women are offered further testing. Screening tests are not diagnostic. And while the majority of fetuses with a chromosomal condition are identified through screening, some affected fetuses with a chromosomal condition receive a normal or "negative" screening result.*
>
> *The second type of prenatal testing is known as diagnostic testing because these tests can determine definitively if the developing fetus has a certain genetic condition or birth defect.*
>
> *Screening and diagnostic tests may be performed in either the first or second trimester of pregnancy as follows."*

(v) National Health Services, United Kingdom:

> *NHS Screening*
> *Screening is a way of finding out if people have a higher chance of having a health problem, so that early treatment can be offered or information given to help them make informed decisions.*

[10] Genetic Alliance; The New York-Mid-Atlantic Consortium for Genetic and Newborn Screening Services. Understanding Genetics: A New York, Mid-Atlantic Guide for Patients and Health Professionals. Washington (DC): Genetic Alliance; 2009 Jul 8. APPENDIX H, PRENATAL SCREENING AND TESTING.

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What is screening?
Screening is a way of identifying apparently healthy people who may have an increased risk of a particular condition. The NHS offers a range of screening tests to different sections of the population.

The aim is to offer screening to the people who are most likely to benefit from it. For example, some screening tests are only offered to newborn babies, while others such as breast screening and abdominal aortic aneurysm screening are only offered to older people.

Screening results
If you get a normal result (a screen negative result) after a screening test, this means you are at low risk of having the condition you were screened for. This does not mean you will never develop the condition in the future, just that you are low risk at the moment.
If you have a higher-risk result (a screen positive result), it means you may have the condition that you've been tested for.

At this point, you will be offered further tests (called diagnostic tests) to confirm if you have the condition. You can then be offered treatment, advice and support.

Finding out about a problem early can mean that treatment is more effective. However, screening tests are not perfect and they can lead to difficult decisions about having further tests or treatment.
Xxx

The risks and limitations of screening include:
Screening tests are not 100% accurate. You could be told you have a problem when you do not - this is called a "false positive" and may lead to some people having unnecessary further tests or treatment as a result of screening. A screening test could also miss a problem -

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this is called a "false negative" and could lead to people ignoring symptoms in the future.

** Some screening tests can lead to difficult decisions. For example, if a pregnancy screening test tells you your baby has a higher chance of having a particular condition, you may then be faced with a decision about having further diagnostic tests that involve a risk to your pregnancy. If the diagnostic test is positive, you may then need to decide whether to continue with your pregnancy.*

** Finding out you may have a health problem can cause considerable anxiety.*

** Even if your screening test result is normal or negative (meaning you are not at high risk), you could still go on to develop the condition."*

(vi) Review in Journal of Obstetrics and Gynaecology[11]:

"Commercial NIPT:
Are We There Yet?
A number of companies have been spearheading the effort to develop the next generation of NIPT tests, including Sequenom Center for Molecular Medicine (San Diego, CA), Verinata Health (Redwood City, CA), Ariosa Diagnostics (San Jose, CA), and Natera. These companies all use a sequencing-based approach for gathering the genetic information contained within the cDNA. In some cases, MPSS is the sequencing methodology of choice, whereas targeted sequencing is utilized by others. Each entity utilizes a unique and proprietary algorithm for interpretation of the genetic data. Although the exact technology may vary, the implications for clinical practice are the same; namely, these are all screening tests performed by analyzing

[11] Supra note 1.

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cfDNA in a sample of maternal blood, and all positive test results should be confirmed by amniocentesis or CVS before acting upon the information."

A table showing the sensitivity and specificity of the subject invention is as under[12]:

Comparison of Techniques for Prenatal Diagnosis Using Cell-Free DNA

Company	Technical Approach	Accuracy of Detection: Anomaly	Sensitivity (%)	Specificity (%)	Depends on Measurement of Specific Loci or Alleles?	Maternal/ Paternal Samples Used?	Study
Sequenom Center for Molecular Medicine (San Diego, CA)	MPSS	T21	98.6	99.8	No	No	Fan HC et al,[72] Chiu RW et al,[76] Palomaki GE et al,[78] Chen EZ et al,[79] Ehrich M et al,[99] Liao GJ et al,[100] Palomaki GE et al.[73a]
		T18	100	99.7			
		T13	91.7	99.0			
		45,X	—	—			
		47,XXY	—	—			
Verinata Health (Redwood City, CA)	MPSS	T21	100	100	No	No	Fan and Quake,[74] Sehnert AJ et al,[84] Bianchi DW et al.[77a]
		T18	97.2	99.8			
		T13	78.6	99.4			
		45,X	93.8	99.8			
		47,XXY	—	—			
Ariosa Diagnostics (San Jose, CA)	Targeted sequencing + DANSR + FORTE	T21	100	100	Yes (chromosome 21, 18 and 13)	No	Sparks AB et al,[75] Sparks AB et al,[80] Ashoor G et al,[82] Ashoor G et al.[86]
		T18	98	100			
		T13	—	—			
		45,X	—	—			
		47,XXY	—	—			
Natera (San Carlos, CA)	Targeted sequencing + PS	T21	100	100	Yes (SNPs)	Yes	Zimmermann B et al,[85] Rabinowitz M et al,[91] Nicolaides et al.[92]
		T18	100	100			
		T13	100	100			
		45,X	100	100			
		47,XXY	100	100			

100. A review of the above material would show that these resources clearly distinguish between two different stages, the screening stage, and the confirmatory diagnostics stage. The publications record that any positive test results after the initial screening would require confirmation by amniocentesis and CVS before acting upon the same. However, the sensitivity and specificity of the Appellants' test would show that it is extremely accurate having 98.6% sensitivity and 99.8 % specification.

[12] *ibid,* pg. 57.

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101. Considering the Complete Specifications along with the medical literature relied upon by Appellants', it is clear that upon performing the Appellants' test a large number of pregnant women would be eliminated from the process of undergoing the confirmatory diagnostic test. This is especially true in view of the high percentage of sensitivity and specificity of the result of the test as claimed by the Appellants. Hence, a decision is made that no further treatment is required for such women.

102. In the opinion of this Court, when the language of the Section 3(i) of the Act uses the word diagnostic, the same would include positive and negative diagnosis. The persons who are eliminated from undergoing further confirmation tests in respect of any medical condition, genetic abnormality etc., shows that there is a tangible result achieved by the method/ test which is being performed. It would defeat the purpose of Section 3(i) of the Act, if a test is held to be patentable merely because the test does not confirm the presence of a particular medical condition, although it does eliminate the need for further examination in respect of that medical condition.

103. There is enormous concern expressed that if such a test is not allowed to be patented, it could lead to stultifying of innovation. The Court has already held above in respect of issue (i), that product claims are not excluded under Section 3(i) of the Act. Thus, equipment and devices are not excluded by 3(i) of the Act and only processes and methods which may be required to be performed by professionals for diagnosing would be excluded. The subject innovation in fact falls in the narrow compass, i.e., grant of a patent would exclude use of the said method for detecting the medical condition. Therefore, the inventions are liable to be excluded under Section 3(i) of the Act.

104. In addition, the Court is also conscious of the fact that one of the

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embodiments in the Complete Specification of the second patent application, also deals with determination of presence of 'Y' chromosome nucleic acid, which would also be prohibited in terms of Section 3A of the 1994 Act. The said section reads as under:

> *"3A.* ***Prohibition of sex-selection****- No person, including a specialist or a team of specialists in the field of infertility, shall conduct or cause to be conducted or aid in conducting by himself or by any other person, sex selection on a woman or a man or on both or on any tissue, embryo, conceptus, fluid or gametes derived from either or both of them."*

105. Thus, the subject invention would also be hit by section 3(b) of the Act.

106. The Patent Office has also raised issues of lack of novelty and inventive steps. Since, the subject invention is being held to be non-patentable under Sections 3(b) and 3(i) of the Act, the said two issues are not being gone into.

107. Accordingly, the appeal of the Appellants against the non-grant of subject patent application is dismissed in above terms.

(B) C.A.(COMM.IPD-PAT) 448/2022

108. The present patent application is also very similar to the patent application in ***C.A.(COMM.IPD-PAT) 13/2022*** and the purpose of this application is also to detect foetal genetic traits including the presence or absence of foetal nucleic acid and quantity thereof, to check foetal sex and foetal chromosomal abnormalities.

109. A perusal of the Complete Specification itself would show that there are various embodiments which are explained in the patent application. The primary difference between the present application and the one in ***C.A.(COMM.IPD-PAT) 13/2022*** is the location of the polynucleotide

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sequences. In the present application, the foetal nucleic acid comprises of polynucleotide sequences of SEQ ID Nos 1 to 89, whereas the earlier application deals with SEQ ID Nos. 90 onwards. It is noted that the said SEQ ID Nos. were, thereafter, reduced to SEQ ID No. 1 to 39 during the prosecution of the subject application. The final rejected claims read as under:

> *"1. An in-vitro method for preparing fetal nucleic acid, which comprises:*
>
> *a) contacting nucleic acid from a female, which nucleic acid comprises fetal nucleic acid and maternal nucleic acid, the combination of the fetal nucleic acid and the maternal nucleic acid comprising total nucleic acid in the sample, with a reagent that specifically digests nonmethylated maternal nucleic acid at 3 or more loci selected from SEQ ID NOs: 1-39 from chromosome 13, 18 or 21, thereby enriching the fetal nucleic acid; and*
>
> *b) preparing nucleic acid comprising fetal nucleic acid by a process in which fetal nucleic acid separated in part a) is utilized as a template.*
>
> *2. The method as claimed in any of the preceding claims, wherein the agent that specifically digests non-methylated maternal nucleic acid is a methylation-sensitive restriction enzyme.*
>
> *3. The method as claimed in claim 2, wherein two or more methylation-sensitive restriction enzymes are used in the same reaction.*
>
> *4. The method as claimed in any of the preceding claims, wherein the process of step b) is an amplification reaction.*
>
> *5. The method as claimed in any of the preceding claims, wherein the process of step b) is a method for determining the absolute amount of fetal nucleic acid.*
>
> *6. The method as claimed in any of the preceding claims, wherein three or more of the polynucleotide sequences of SEQ ID NOs: 1-59 are prepared.*
>
> *7. The method as claimed in any one of the preceding*

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claims, wherein fetal nucleic acid at 4, 5, 6, 7, 8, 9, 10, 15, 20, 30, 40, 50 or more loci is prepared.
8. The method as claimed in claim 6, wherein the plurality of loci optionally comprises a locus of SEQ ID NO: 42.
9. The method as claimed in claim 6, wherein the plurality of loci optionally comprises a locus of SEQ E) NO: 52.
10. The method as claimed in claim 6, wherein the plurality of loci comprises a locus of SEQ ID NO: 33."

110. The process of amendment conducted by the applicant would show that the purpose of this invention is also to generate biomarkers. The process is based on methylation of the nucleic acid in a sample and after determining the foetal nucleic acid, the same is then compared to determine the existence of abnormalities including aneuploidy.

111. As noted above, it is clear from the reading of the two patent applications that the same are in respect of identical inventions, which differ only in respect of the polynucleotide sequence of SEQ IDs. Thus, the analysis of the Court in respect of the subject patent application in ***C.A.(COMM.IPD-PAT) 13/2022*** would squarely cover and bind the Appellants in respect of the present patent application as well.

112. This Court 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.

113. While there can be no doubt that the subject invention could be a useful invention, the mere fact that it is an *in vitro* method would by itself be insufficient to make the invention patentable, so long as the purpose of the process is to diagnose a medical condition. Thus, as the subject invention

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through the method or process of methylation of the samples derived from the pregnant woman, *albeit* in a laboratory set up, provides a result which would be sufficient to eliminate the pregnant woman from further tests, the same would be hit by Section 3(i) of the Act.

114. 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.

115. In view of the above discussion, this Court is of the view that 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.

116. Accordingly, the present two appeals along with pending applications, if any, are disposed of in the above terms.

PRATHIBA M. SINGH
JUDGE

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