2023:MHC:4616

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

Judgment reserved on	05.10.2023
Judgment pronounced on	12.10.2023

CORAM:

THE HON'BLE MR. **JUSTICE SENTHILKUMAR RAMAMOORTHY**

CMA (PT) No.1 of 2023 & C.M.P.No.13206 of 2023
&
W.P.No.7666 of 2023 &
W.M.P.Nos.7828 & 7832 of 2023

The Chinese University of Hong Kong
Knowledge Transfer Office, Room 301,
PI CH'IU Building, Shatin, N.T. Hong Kong SAR
Represented by its
Constituted Attorney/Authorised Signatory,
Mr.Appalla Taraka Subrahmanyam ... Petitioner
(in W.P.No.7666/2023)
& Appellant
(in CMA(PT)/1/2023)

v.

The Assistant Controller of Patents & Designs,
The Patent Office,
Intellectual Property Office Building,
G.S.T.Road, Guindy,
Chennai-600 032. ... Respondent
(in CMA(PT)/1/2023) &
(in W.P.No.7666/2023)

PRAYER IN CMA(PT)/1/2023: This Civil Miscellaneous Appeal filed under Section 117 A of the Patents Act, 1970, to set aside the order dated 26th March 2021 passed by the Respondent in Patent Application 4863/CHENP/2012 as the same is contrary to law,

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manifestly erroneous and wholly unjust and consequently direct the respondent to restore the Appellant's patent for further prosecution.

PRAYER IN W.P.No.7666 of 2023: Writ Petition is filed under Article 226 of the Constitution of India to issue a Writ of Certiorarified Mandamus calling for the records of the order dated 26th March 2021 passed by the Respondent in Patent Application 4863/CHENP/2012 and quashing the same and consequently direct the respondent to restore the petitioner's patent for further prosecution.

For Appellant/Petitioner (in both CMA and WP)	:	Ms.Archana Shanker Mr.K.Premchandar Mr.N.C.Vishal Mr.N.Shrivatsav
For Respondent (in both CMA and WP)	:	Mr.AR.L.Sundaresan, ASGI Assisted by Mr.R.Rajesh Vivekanandan, DSG
Amicus curiae	:	Mr. Calab Gabriel

COMMON JUDGMENT

Background

By order dated 26.03.2021, the first respondent rejected the application of the Chinese University of Hong Kong for grant of patent [Indian Patent Application No.4863/CHENP/2012 dated 04.06.2012 (IN 4863)]. The said order was originally challenged by filing W.P.No.7666 of 2023. Upon the constitution of this Division, CMA (PT) No.1 of 2023 was filed assailing the same order. For the

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sake of convenience, throughout this order, the Chinese University of Hong Kong is referred to as the appellant.

2. The appellant originally filed Application No. PCT/EP2010/066935 under the Patent Co-operation Treaty (PCT). IN 4863 is the national phase application derived from the said PCT application.

3. In relation to IN 4863, the appellant received the First Examination Report (FER) on 17.11.2017 raising multiple objections, including objections under Section 3(i) and (k) of the Patents Act, 1970 (the Patents Act). The appellant responded thereto on 14.05.2018 and submitted revised claims. The claims were further revised, pursuant to receipt of the notice of hearing on 07.05.2019, by introducing disclaimers stating that the invention involved a non- diagnostic method and was carried out *in vitro* on a biological sample.

4. The amended claim 1, as of 07.05.2019, of the appellant is as under:

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"1. A non-diagnostic in vitro method for measuring a sequence imbalance in a biological sample from a pregnant female subject, wherein the biological sample includes nucleic acid molecules that are part of nucleic acid sequences, the nucleic acid molecules from the fetus and the pregnant female subject, the method comprising:

for each of a plurality of the nucleic acid molecules in the biological sample:

measuring a size of the nucleic acid molecule;

identifying which nucleic acid sequence the nucleic acid molecule is derived;

a computer system determining a size distribution of the nucleic acid molecules corresponding to a first sequence of the identified nucleic acid sequences; and

based on the determined size distribution, determining a classification of whether a sequence imbalance exists for the first sequence."

5. At the hearing before the authority, the appellant contended that the detection of a sequence imbalance does not *ipso facto* lead to the conclusion that there is foetal chromosomal aneuploidy and, therefore, it cannot be concluded on the basis of paragraph [0006] or the other paragraphs of the complete

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specification that the claimed invention is a diagnostic method for detection of foetal chromosomal aneuploidy. By the impugned order, except amended claims 23, 34 and 46, the amendments relating to the other claims were held to be permissible under Section 59 of the Patents Act. It was concluded, however, that amended claims 1 to 46 lack an inventive step in view of prior art documents, D1 and D2.

6. The Assistant Controller of Patents examined the issue of applicability of Section 3 of the Patents Act to the claimed invention and reached the conclusion that claims 1 to 22, 24 to 33 and 35 to 45 are not patent-eligible under Section 3(i) of the Patents Act because the said claims qualify as a diagnostic method. In support of such conclusion, the Assistant Controller relied upon paragraphs [0006] to [0009] of the complete specification before holding that the claimed invention is a process of diagnosing foetal chromosomal aberrations by measuring the size distribution of foetal chromosomal nucleic acid molecules. In relevant part, the final conclusion (at page 144 of convenience compilation – Part II) is as under:

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"..... Thus the claimed diagnostic method 1-43 involves a number of steps leading towards identification of a size-based analysis to perform a prenatal diagnosis of a sequence imbalance (e.g. a fetal chromosomal aneuploidy) in a biological sample obtained from a pregnant female subject, a size distribution of fragments of nucleic acid molecules for an at-risk chromosome can be used to determine a fetal chromosomal aneuploidy. And other sequence imbalances, such as a sequence imbalance in the biological sample (containing mother and fetal DNA), where the imbalance is relative to a genotype, mutation status, or haplotype of the mother. Such an imbalance can be determined via a size distribution of fragments and a ranking of a size distribution (e.g. a statistical value representing a size distribution) of fragments from respective chromosomes relative to each other are used to determine an imbalance. For instance, a ranking of the size of fragments of the at-risk chromosome in the test sample can be compared to the ranking for the at-risk chromosome that was obtained from a reference biological sample. Thus a diagnosis can be performed based on the comparison. As an example, if the ranking changes (e.g. indicating a reduction in size of the nucleic acid fragments) by

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a specified amount then a diagnosis that a fetal chromosomal aneuploidy exists in the at-risk chromosome may be made. Here the amended claims 01-43 include all the above mentioned steps and thereby it makes possible to decide the general physical state of an individual and it clearly constitutes a method of diagnosis.

In view of the above, the requirements of objection no 2 communicated in the hearing notice is not met as the amended claims 01-43 filed on 07/05/2019 are not patentable as per the provisions of Section 3(i) of Patents Act 1970. Therefore, it is hereby decided that the patent application 4863/CHENP/2012 is refused under section 15 of the Act."

Counsel and contentions

7. Oral arguments were advanced by Ms.Archana Shanker, learned counsel for the appellant; and by Mr.AR.L.Sundaresan, learned Additional Solicitor General of India (ASGI), assisted by Mr.Rajesh Vivekanandan, Deputy Solicitor General, on behalf of the respondent. Mr. Calab Gabriel, learned counsel, who has had considerable experience in patent law, made submissions at the hearing on 05.10.2023 to assist the Court.

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8. Ms.Archana Shanker submitted that the method envisages carrying out *in vitro* analysis of fragments of nucleic acid molecules taken from a biological sample containing both foetal and maternal DNA. She further submitted that sequence imbalances are identified by examining the size distribution of such nucleic acid molecules, including by using a computer programme. Upon receipt of objections, she submitted that two express disclaimers were introduced by the appellant to the effect that the method is non-diagnostic and performed *in vitro*. In view of such disclaimers, learned counsel contended that Section 3(i) of the Patents Act is not applicable.

9. Learned counsel submitted that the words "diagnostic, therapeutic" after the word "prophylactic" in Section 3(i) were introduced by an amendment under Act 38 of 2002 and that there is no comma between 'prophylactic' and 'diagnostic'. On such basis, a tentative argument was raised to the effect that diagnostic is qualified by prophylactic. Learned counsel proceeded to the weightier contention that the object and purpose of the amendment is to prevent the grant of patents to methods of diagnosis

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performed by a medical doctor on patients so as to ensure that medical doctors are in a position to adopt the best methods of diagnosis and treatment, without the apprehension that a patent infringement action would be initiated against them. Keeping in mind the said object and purpose, learned counsel contended that the expression "diagnostic" in Section 3(i) should be construed as limited to diagnostic methods practised on the human body.

10. In support of the above construction of Section 3(i), learned counsel placed reliance on manuals of patent practice and procedure issued periodically by the Controller of Patents. By way of illustration, learned counsel pointed out that the Draft Manual of Patent Office Practice and Procedure published in 2005 (the Draft Manual of 2005) referred expressly to methods of treatment of human beings practised on the human body. In fact, she pointed out that it was stated expressly therein that methods of diagnosis performed on tissues or fluids, which have been permanently removed from the body, were excluded. She also referred to paragraph 4.9.14 of the Manual of Patent Office Practice and Procedure 2008 and contended that it contains identical language.

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With reference to paragraph 08.03.06.08 of the Manual of Patent Office Practice and Procedure 2010 (the 2010 Manual), she submitted that it states that "methods of diagnosis practised on the human and animal body is not patentable", thereby indicating that diagnosis undertaken *in vitro* is patent eligible. Clause 9.03.05.08 of the Manual of Patent Office Practice and Procedure, published on 26.11.2019 (the 2019 Manual) and the Guidelines for Examination of Biotechnology Applications for Patents, published in March 2013 (the 2013 Guidelines), were also referred to in this regard.

11. The next contention of learned counsel was that only diagnostic methods for the treatment of human beings with a view to render such human beings free of disease fall within the scope of Section 3(i). In order to substantiate this contention, learned counsel referred to the language of Section 3(i) and contended that the expression "to render them free of disease" also applies to and qualifies treatment of human beings, including by use of diagnostic processes.

12. By relying upon principles of interpretation, such as *ejusdem generis* and *noscitur a sociis,* she contended that the word

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'diagnostic' should be interpreted by taking into account the words with which it is associated in Section 3(i). Since Section 3(i) also uses expressions such as "other treatment of human beings" and "to render them free of disease", she contended that a method would qualify as diagnostic only if it is intended for the treatment of human beings for purposes of rendering them free of disease.

13. In support of the contention that the expression diagnostic method should be confined to *in vivo* diagnosis, the opinion of the Enlarged Board of Appeal (the EBoA) in case No.G 0001/04 (the EBoA opinion) was relied upon. The said opinion was also relied upon to contend that the expression 'diagnostic' is applicable only if all the following four method steps in diagnosis are carried out:

> *(i) the examination phase involving the collection of data,*
> *(ii) the comparison of such data with standard/reference 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*

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clinical picture, i.e. the deductive medical or veterinary decision phase.

Since the method involved in the claimed invention does not include clinical diagnosis, i.e. the fourth method step set out above, learned counsel contended that it is not a diagnostic method for the purposes of section 3(i) of the Patents Act. By referring to the manuals of practice and procedure of the Patent Office, learned counsel submitted that the above four method steps were endorsed, adopted and followed therein. In fact, learned counsel submitted that the impugned order also refers to the above four method steps.

14. She relied upon the order of the *Delhi High Court in AGC Flat Glass Europe SA v. Anand Mahajan and Others, 2009 SCC OnLine Del 2826* on the significance of disclaimers in delimiting and curtailing the scope of the monopoly claim, and in order to substantiate the contention that the impugned order did not take into account the disclaimers of the appellant.

15. Learned counsel also submitted that amended claims can be filed at the appellate stage because an appeal is an

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extension of the original proceeding. In support of this contention, she placed reliance on the judgment of the Delhi High Court in *Societe Des Produits Nestle SA v. The Controller of Patents and Design and Another, 2023/DHC/000774*, where the Delhi High Court concluded that it is permissible for parties to amend their claims in proceedings before the Court. In line with the above contention, the following revised claim 1 (as on 2.08.2023) was submitted for consideration:

> *"1. A computer implemented non-diagnostic in vitro method for measuring a sequence imbalance in a biological sample from a pregnant female subject, wherein the biological sample includes nucleic acid molecules that are part of nucleic acid sequences, the nucleic acid molecules from the fetus and the pregnant female subject, the method comprising:*
>
> *for each of a plurality of the nucleic acid molecules in the biological sample;*
>
> *measuring a size of the nucleic acid molecule;*
>
> *identifying which nucleic acid sequence the nucleic acid molecule is derived;*
>
> *a computer system determining a size distribution of the nucleic acid molecules*

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corresponding to a first sequence of the identified nucleic acid sequences; and

based on the determined size distribution, determining a classification of whether a sequence imbalance exists for the first sequence."

Later, on 5.10.2023, another set of amended claims 1-43 was filed before this Court. The last amended claim 1 (current claim 1) is as under:

"1. A computer implemented method for measuring a sequence imbalance in a biological sample from a pregnant female subject, wherein the biological sample includes nucleic acid molecules that are part of nucleic acid sequences, the nucleic acid molecules from the fetus and the pregnant female subject, the method comprising:

measuring a size of the nucleic acid molecule for each of a plurality of the nucleic acid molecules in the biological sample;

identifying which nucleic acid sequence the nucleic acid molecule is derived;

determining a size distribution of the nucleic acid molecules corresponding to a first sequence of the identified nucleic acid sequences; and

determining a classification of whether a

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sequence imbalance exists for the first sequence based on the determined size determination."

16. In response to these contentions, Mr.AR.L.Sundaresan submitted that the complete specification and, in particular, paragraph [0006] thereof discloses that the claimed invention enables diagnosis of foetal chromosomal aneuploidy by identifying sequence imbalances. Consequently, the method is diagnostic. In response to the contention that the expression 'diagnostic' in Section 3(i) should be confined to *in vivo* diagnosis, learned ASGI submitted that Section 3(i) does not contain any indication that the diagnostic process should be limited to *in vivo* diagnosis. If it were the intention of Parliament to exclude *in vitro* diagnosis, learned ASGI submitted that the text of Section 3(i) would have contained an indication that *in vitro* diagnosis is excluded. Both in respect of the meaning of the expression *in vitro* and in support of interpreting the word "diagnostic" broadly, he relied on the judgment of the Division Bench of the Bombay High Court in *Merind Ltd. v. State of Maharashtra 2004 SCC OnLine Bom 1269*. He further submitted that the golden rule is to interpret a statutory provision literally unless literal interpretation would result in manifest absurdity. In this case,

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he submitted that construing the expression 'diagnostic' literally does not render it absurd. By relying on paragraphs 10 to 10.2 of the judgment of the Supreme Court in *Hira Singh & Anr. v. Union of India & Anr.,(2020) 20 SCC 272,* where the Supreme Court held that the quantity of neutral substances should also be reckoned while determining commercial quantity under the Narcotic Drugs and Psychotropic Substances Act, 1985, he submitted that the word "diagnostic" should be construed broadly and not narrowly.

17. As regards the contention that the process of diagnosis should include all four method steps, he contended that the EBoA opinion is not binding on this Court. By laying emphasis on the use of the word 'process' in Section 3(i), learned ASGI further contended that every method step involved in the process of diagnosis qualifies as a diagnostic method under Section 3(i). After also placing for consideration the judgment of the Supreme Court on interpretation of Section 3(d) in *Novartis AG v. Union of India & Ors., (2013) 6 SCC 1*, he concluded that the impugned order is in conformity with the requirements of the Patents Act and that no interference is warranted.

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18. After orders were originally reserved in this matter, arguments were heard in *The Chinese University of Hong Kong v. The Assistant Controller of Patents and Designs, CMA (PT) No.14 of 2023,* which also involves interpretation of Section 3(i) of the Patents Act. In that case, apart from the submissions of learned counsel for the respective parties, I had the benefit of the submissions of Mr. Adarsh Ramanujan, learned counsel, who appeared as *amicus curiae.* After observing arguments in that case, learned counsel for the appellant requested that permission be granted to provide clarifications. By acceding to that request, the matter was listed on 05.10.2023 and, on that date, both Ms. Archana Shanker and Mr. Rajesh Vivekanandan made brief submissions. In addition, Mr. Calab Gabriel, learned counsel and patent law expert, made brief submissions to assist the Court.

19. Mr. Calab Gabriel submitted that only testing carried out to uncover pathology should be construed as diagnostic in Section 3(i) because the word "diagnostic" is placed in close association with the words "treatment of human beings". He illustrated this submission by stating that a blood test carried out to

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ascertain and specify the blood group on the driving licence should not be construed as diagnostic. His next submission was that the word "diagnostic" should be construed as limited to tests for treatment to cure human beings of disease and that it should not apply to testing for cosmetic purposes. His last submission was that technological developments in testing methods, especially genomic testing, should be fostered and not hindered by patent law, including the interpretation thereof.

20. Ms. Archana Shanker relied on the principle formulated in the EBoA opinion and contended that intermediate findings of diagnostic relevance should not be confounded with diagnosis. Since the claims of the appellant are limited to analysis of nucleic acid molecules to measure size relative to reference values, and provide a ranking on such basis by using a computer programme, she contended that the claimed invention does not partake of the essential feature of diagnosis, namely, clinical deduction. As regards the embodiments described in the complete specification, she submitted that they are no more than examples of potential industrial application. She also submitted that the claimed invention

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merely identifies one property, size distribution, of nucleic acid molecules. By once again referring to the manuals of practice and procedure published by the Patent Office, she reiterated in conclusion that the Patent Office's understanding of Section 3(i) is that it applies only to *in vivo* and not *in vitro* testing. Such understanding is further reflected, according to learned counsel, in the grant of patents to several applications in respect of *in vitro* diagnosis.

Discussion, analysis and conclusions

Construction of Section 3(i)

21. The construction of Section 3(i) of the Patents Act is at the heart of this dispute. Section 3(i) is set out below:

> *"3.What are not inventions -*
>
> *The following are not inventions within the meaning of this Act,-*
>
> *....*
>
> *(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*

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value or that of their products."

Before delving deeper, a minor argument is dealt with. Because the text of Section 3(i) does not contain a comma between prophylactic and diagnostic, a tentative argument was made by the appellant that it should be confined to prophylactic or preventive diagnosis. Aside from the fact that punctuation is not determinative, this contention is liable to be rejected because the Patents (Amendment) Act, 2002 (Act 38 of 2002) contains a comma after the word prophylactic but the comma was not placed within the quotation marks as is evident from the following relevant provision thereof:

"4. In Section 3 of the principal Act,-

(d) in clause (i),-

(i) after the word "prophylactic", the words "diagnostic, therapeutic" shall be inserted;"

Therefore, the missing comma is no more than printer's devil. Besides, such contention is wholly incompatible with one of the principal contentions of learned counsel for the appellant that the diagnostic method should be adopted for the treatment of human beings so as to render them free of disease.

22. Section 3(i) contains the following two limbs:

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(a) any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings; or

(b) 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.

In my view, each limb of Section 3(i) is distinct and self-contained. I draw this conclusion for the following reasons. First, the first limb deals with human beings and the second with animals. Secondly, the disjunctive 'or' separates the two limbs. Thirdly, the second limb opens with the expression " any process for a similar treatment of animals" and proceeds to set out three purposes of treatment: to render them free of disease or increase their economic value or that of their products. Of these, the latter two purposes are clearly inappropriate and inapplicable to human beings because treatment of human beings is never intended to increase their economic value or that of products produced by them. Thus, it is clear that the second part of Section 3(i) deals only with the treatment of animals and thereafter sets out three objects and purposes of treatment. When viewed in isolation, the first purpose "to render them free of disease" could apply to human beings. However, keeping in mind

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that the first and the second limbs deal with distinct subjects; they are separated by the disjunctive "or"; and the pronoun "them" is used after the antecedent "animals", I conclude that said pronoun is referable only to the last antecedent "animals" and not to human beings. Apart from the above reasons, it bears mention that treatment is provided not only to free/cure a person of disease but also for prophylactic purposes, to alleviate pain, prevent aggravation of or to better manage a condition or disorder. Hence, I reject the contention that the word "diagnostic" in Section 3(i) should be confined to treatment of human beings to render them free from disease.

23. Proceeding further with the analysis of Section 3(i), it opens with the phrase "any process for the" and the following express terms are set out: medicinal, surgical, curative, prophylactic, diagnostic and therapeutic. When read with any of the above express terms, the opening phrase remains incomplete and does not make complete sense. For example, "any process for the medicinal" is incomplete and the same would be the case if the word "medicinal" were to be replaced with "surgical" and so on.

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Therefore, each of the above express terms becomes meaningful only if read along with the succeeding words as: "any process for the medicinal treatment of human beings" and so on. This construction works perfectly if each express term describes a form of treatment and such is the case with all express terms except "diagnostic", and this statement calls for explanation. A human being may be treated for a disease or disorder or condition by administering medicines, performing surgery or by administering therapy involving medicines or other forms of treatment such as radiation or a combination thereof. If such treatment is administered in order to cure the human being of a disease, it is curative. On the other hand, if medicine or vaccination is administered to prevent a human being from developing a disease or to prevent a more severe manifestation of such disease, it is prophylactic. The common thread running through the following categories - medicinal, surgical, curative, prophylactic and therapeutic - is that they are clearly methods of treatment of human beings. Apart from the above mentioned specific processes, Section 3(i) contains the generic expression "or other treatment of human beings". The use of the disjunctive "or" followed by the expression

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"other treatment" indicates that it refers to forms of treatments other than the specific forms enumerated above. The enumeration of multiple forms of treatment followed by the generic "or other treatment" also indicates that the word "treatment" is intended to be construed widely.

24. The odd one out, as indicated above, is 'diagnostic'. Diagnosis, in the context of medical science, is a method of identifying the existence or non-existence of a disease or disorder or condition and/or the site, extent, severity or other aspects thereof. Undoubtedly, such identification *per se* cannot be construed as a form of treatment. Consequently, the expression "any process for the diagnostic treatment of human beings" does not make complete sense unlike in the case of the forms of treatment dealt with in Section 3(i) and discussed in the preceding paragraph. One solution would be to consider it as *"casus omissus"* and add words such as "method for" after diagnostic. I am not inclined to resort to such option because "any process for the ... diagnostic ... or other method for treatment of human beings" is not syntactically correct because the word "process" at the beginning of the provision is

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incompatible with the proposed word "method", both being analogous. More importantly, it does not resolve the fundamental problem of diagnosis or the diagnostic method not being a form of treatment. Hence, I propose to make sense of the expression "any process for the diagnostic...or other treatment of human beings" with reference to both text and immediate context.

25. Diagnosis - whether by physical examination and/or an analysis of symptoms or by use of diagnostic devices or running laboratory tests - is an essential pre-requisite for rational treatment. Sometimes the link between diagnosis and treatment is close and immediate, such as, typically, in the case of coronary angiography and angioplasty; whereas, at other times, there could be a long interval between diagnosis and, for example, treatment by surgery. Whether the interval is short or long, diagnosis and treatment are understood as distinct processes. Because the word "diagnostic" is juxtaposed in Section 3(i) with words such as "medicinal" or "surgical", which are undoubtedly forms of treatment, learned counsel for the appellant contended that the expression 'diagnostic' should not be construed in isolation but should be understood

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noscitur a sociis, i.e. in association with the accompanying words of Section 3(i) read as a whole. In principle, I concur. When viewed in context, i.e. in association with "forms of treatment", I conclude that the word "diagnostic" should be limited to diagnostic processes that disclose pathology for the treatment of human beings. After dealing with other contentions of the appellant, I propose to examine the different purposes for which testing of human beings may be carried out a little further down the road.

26. I now turn to the contention that such diagnostic processes should be confined to *in vivo* diagnosis. The text of Section 3(i) was amended by Act 38 of 2002 by including the words "diagnostic, therapeutic". As is evident from the language of Section 3(i), there is no indication therein that the word "diagnostic" should be confined to *in vivo* diagnosis. Even if the net were to be cast wider, I find nothing in the language of Section 3 or in any other provisions of the Patents Act that lead to the inference that the expression 'diagnostic' should be confined to *in vivo* diagnosis. Although text and statutory context do not support the construction placed on Section 3(i) by learned counsel for the appellant, I

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requested her to place on record the Statement of Objects and Reasons of the Patents (Second Amendment) Bill, 1999. In relevant part, the Bill provided as under:

> *"4. Some of the salient features of the Bill are as under:*
> *(b) to modify Section 3 of the present Act to include exclusions permitted by TRIPS Agreement and also subject-matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable inventions."*

She also placed on record the parliamentary debates relating to the Patents (Second Amendment) Bill, 1999. Neither the Statement of Objects and Reasons of the Patents (Second Amendment) Bill, 1999 nor the parliamentary debates relating thereto throw any light on the scope of the expression "diagnostic". As is evident from the above extract from the Statement of Objects and Reasons, however, there is clear indication therein that Section 3 of the Patents Act was amended to include exclusions from patent eligibility as permitted under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).

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TRIPS Agreement

27. Article 27 of the TRIPS Agreement, which deals with patentable subject matter, is set out below:

Article 27

Patentable Subject Matter

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

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

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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."

28. Clause 3(a) of Article 27 enables members to exclude from patent eligibility the following: 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. Article 27(3)(a), thus, indicates clearly that the diagnostic method should be for the treatment of humans or animals, but no other limitation or restriction on the scope of the expression "diagnostic methods" is discernible from Article 27(3)(a). The *travaux préparatoires* or preparatory materials leading to the conclusion of an international treaty is a recognised source for the construction of such

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international treaty both under the Vienna Convention on the Law of Treaties, 1969, and customary international law. Interestingly, the communication from the Permanent Mission of India, which was forwarded to the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights on 10 July 1989, contained the following proposed language, as regards inventions that are patent-ineligible:

> *"(iii) Methods for treatment of the human or animal body by surgery or therapy or diagnostic methods practised on the human or animal body."*

The above proposal, however, does not find expression in the draft text of the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, which contained language identical to Article 27(3)(a) of the TRIPS Agreement. Therefore, I conclude that the *travaux préparatoires* of Article 27(3)(a) also does not support exempting *in vitro* diagnostic processes or methods from patent ineligibility.

Patent Office Manuals

29. As regards the contention that a narrow interpretation was placed on Section 3(i) by the Patent Office, as exemplified by its manuals, I find that both the Draft and Final Manual of 2005

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clearly exclude patent eligibility only in respect of *in vivo* diagnostic methods. Likewise, paragraph 4.9.14 of the 2008 Manual and paragraph 08.03.06.08 of the 2010 Manual also contain substantially similar language. Such language is, however, not present in the 2019 Manual, which defines diagnostic methods as under:

> *"(e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic."*

After defining diagnostic methods in the above manner, the 2019 Manual provides several examples of subject matter excluded under Section 3(i). Among such further examples is diagnosis practised on the human or animal body. The 2013 Guidelines are in identical language. Thus, while earlier versions of the patent manuals of practice and procedure limit patent ineligibility to *in vivo* diagnosis, there is nothing in the presently applicable final manual or guidelines which supports the construction that *in vivo* diagnostic methods are excluded. Besides, it should be borne in mind that the manuals of the Patent Office are not determinative of the scope of

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Section 3(i) and, at most, they are indicative of the manner in which the Patent Office understood the provision.

The EBoA opinion

30. The appellant relied upon the EBoA opinion for two purposes: (i) to contend that the word "diagnostic" should be confined to *in vivo* diagnosis; and (ii) to contend that a process would not qualify as diagnostic unless all four method steps in diagnosis are involved. Before turning to the EBoA opinion, it is instructive to set out Article 52(4) of the Convention on the Grant of European Patents, 1973 (European Patents Convention/EPC) which is as under:

> *"52(4) Methods for treatment of the human or animal body by surgery or therapy and* ***diagnostic methods practised on the human or animal body*** *shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substance or compositions, for use in any of these methods".*
> *(emphasis added)*

31. The EBoA noticed the language of Article 52(4) of the

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EPC and, in particular, the expression "diagnostic methods practised on the human or animal body", and, on that basis, in paragraph 6.1 of the opinion, concluded that the text of the provision itself gives an indication favouring a narrow interpretation. The fact that Section 3(i), in contrast to Article 52(4) of the EPC, does not contain the expression "practised on the human or animal body", reinforces the conclusion that the expression "diagnostic" in Section 3(i) extends both to *in vitro* and *in vivo* diagnosis. This leads to the issue as to whether all the method steps involved in diagnosis should be involved in a process for it to qualify as a diagnostic process.

32. The EBoA noticed that the preparatory documents of the EPC do not contain any pointers on the scope of the expression "diagnostic methods". By relying on the established jurisprudence of the EBoA, the EBoA also concluded that diagnosis involves four method steps, namely, (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

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decision phase.

33. Thereafter, the EBoA recognised that there are two possible constructions of Article 52(4): a narrow construction that excludes diagnostic methods practised on the human or animal body only if all the above mentioned four method steps are involved or a broad interpretation excluding all method steps relating to diagnosis or of value for the purpose of diagnosis. By adopting the narrow interpretation, the EBoA reasoned that "intermediate findings of diagnostic relevance must not be confounded with diagnosis for curative purposes *stricto sensu ...* which consists in attributing the detected deviation to a particular clinical picture" and concluded that all the four method steps outlined above should be involved in the diagnostic method for it to be excluded from patent protection. The operative portion of the order is set out below:

> *"1. In order that the subject-matter of a claim relating to a diagnostic method practised on the human or animal body falls under the prohibition of Article 52(4) EPC, the claim is to include the features relating to:*
>
> *(i) the diagnosis for curative purposes*

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stricto sensu representing the deductive medical or veterinary decision phase as a purely intellectual exercise,

(ii) the preceding steps which are constitutive for making that diagnosis, and

(iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

2. Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may neither depend on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. Moreover, no distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it.

3. In a diagnostic method under Article 52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes stricto

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sensu must satisfy the criterion "practised on the human or animal body".

4. Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body; a preceding step of a technical nature thus satisfies the criterion "practised on the human or animal body" if its performance implies any interaction with the human or animal body, necessitating the presence of the latter."

34. While drawing the above conclusion, the EBoA was acutely conscious of the fact that the last method step involving diagnosis for curative purposes is a purely intellectual exercise and that a patent cannot be granted in relation thereto unless performed by a device. From the conclusions, it is also evident that the EBoA was of the view that the participation or non-participation of medical doctors in the constitutive method steps involved in diagnosis is not relevant to determine whether the method is diagnostic. Effectively, if the conclusion of the EBoA were to be endorsed and followed, provided the deductive decision is excluded, methods which involve all the three constitutive method steps that precede and form the basis of the curative decision would be patent eligible. The

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implications of this approach warrant discussion.

35. With regard to *in vivo* diagnosis, such as by use of ultrasound devices, endoscopy, computer tomography (CT) scans, magnetic resonance imaging (MRI) and coronary angiography, the processes of diagnosis are ordinarily performed by or under the supervision of medical doctors. Even if performed by a technician under supervision, the results are generally provided along with the clinical diagnosis. Therefore, it is probable, albeit not certain, that in such processes all the four method steps specified by the EBoA would be involved.

36. By contrast, while carrying out *in vitro* diagnosis, the first three method steps may be carried out by persons other than medical doctors, even without supervision by medical doctors, whereas the fourth method step may only be carried out by a medical doctor. Consequently, more often than not, the first three method steps would be undertaken separately by persons qualified in allied sciences or by qualified technicians who would provide such data to the medical doctor. On such basis, the medical doctor would

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make the clinical diagnosis (i.e. the non-patentable fourth step). Therefore, in the context of *in vitro* diagnosis, if the approach of the EBoA were to be adopted, the Section 3(i) exclusion would be circumvented with ease.

37. As is evident from the Guidelines for Examination of the European Patent Office (the EPO Guidelines) and subsequent decisions of the Technical Board of Appeal of the EPO with regard to the application of the EBoA opinion, some principles were formulated and measures taken to preclude circumvention by clever patent claims drafting. The EPO Guidelines (March 2023) contain *inter alia* the following guidance:

> "*The requirement that the final decision phase be included in the independent claim as an essential feature is to be applied only if it is clear from the application/patent as a whole that the inevitable result of the findings leads unambiguously to a particular diagnosis : this will have to be decided by the division on a case-by-case basis."*

In Case Number T 0125/02 dated 23 May 2006, the Board of Appeal of the EPO dealt with claims relating to a method of ascertaining the

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current lung function of a human subject, which included a claim for interpreting a deviation between the recorded values of the subject and reference values, and concluded that "the method, be it positive or negative, is sufficient to decide upon the therapeutic action to be taken in response to the diagnosis". On such basis, the patent application was rejected.

38. Similarly, in Case Number TT 0143/04, in the context of method claims relating to Alzheimer's disease, the Technical Board of Appeal of the EPO, by decision dated 12 September 2006, rejected the appeal on the ground that "neither Article 52(4) of the EPC nor G 1/04 requires that only reliable diagnostic methods which by themselves lead to an unambiguous result are excluded from patentability."

39. By contrast, in the context of a claimed invention for a radiation detector for tymphanic temperature measurement, in Case Number T 1255/06, by decision dated 23 September 2008, the Board of Appeal of the EPO held that claim 16 therein "does not allow *per se* the attribution of the detected deviation to a particular

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clinical picture" and was, therefore, patent eligible.

40. The jurisprudence of the EPC, thus, indicates that all four method steps of diagnosis should be involved for a diagnostic method to be patent ineligible but that the fourth method step would become liable to be included as an essential feature if it is clear from the patent application as a whole that the inevitable results of the tests would lead to a particular diagnosis; the reliability thereof being of limited significance. In effect, while interpreting Article 52(4) and 53(c) of the EPC, it was recognised that the requirement that all four method steps be involved could lead to clever patent claims drafting to circumvent patent ineligibility, and the "inevitable results of the test" was evolved as a filter to weed out patent ineligible claims camouflaged by clever claims drafting.

41. As discussed earlier, Section 3(i) uses the word "diagnostic" in juxtaposition with forms of treatment, such as medicinal, surgical and therapeutic, and in association with the words "other treatment of human beings". By taking note of the

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above and recognising that Section 3(i) differs materially from Articles 52(4) and 53(c) of the EPC inasmuch as Section 3(i) excludes from patent eligibility any process for the diagnostic treatment of human beings, whereas Article 52(4) and 53(c) exclude only diagnostic methods practised on the human body, I conclude that the word "diagnostic" should receive a construction which is in consonance with text and context. Such construction does not call for curtailment by limiting the scope of "diagnostic" to *in vivo* or definitive diagnosis. Equally, expansion is not called for by extension to any process relating to or of some value in diagnosis. Instead, the standard I propose is to examine the claims, in the context of the complete specification, to determine whether it specifies a process for making a diagnosis for treatment. Such determination should be made by assuming that a person(s) skilled in the art, including a medical doctor, examines the claims and complete specification. If it is concluded that a diagnosis for treatment may be made, even if such diagnosis is not definitive, it would be patent ineligible, whereas, if diagnosis for treatment cannot be made, it would be patent eligible. As a corollary, one final issue falls for consideration: is there a case to exclude certain types

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of tests from the ambit of the expression "diagnostic" in Section 3(i) and I deal with this issue next.

42. The language of Section 3(i) uses the expression "diagnostic...or other treatment of human beings" and thereby appears to point in the direction of examining embodiments or use cases of processes to determine if they are diagnostic. Nonetheless, it should not be lost sight of that patent eligibility is decided at the threshold by examining claims that could have multiple use cases. Consequently, in the context of diagnostic processes, I am of the view that the embodiments of a claimed invention are relevant only for the purpose of ascertaining whether the process of the claimed invention *per se* points to a diagnosis for treatment. If such process does not uncover pathology for any reason, it would not be diagnostic for purposes of Section 3(i).

43. A potential red herring would be to conflate the diagnostic process with the purpose of testing. In order to illustrate this point, a few examples may be considered. Testing is undertaken in course of clinical trials to understand the efficacy of

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drugs on multiple parameters such as safety, potency, toxicity, side effects, contraindications and so on. Such testing is not for purposes of treating those involved in the clinical trial. Similarly, testing of particular ethnic or racial groups may be undertaken to understand the propensity of such groups to develop specific diseases or disorders. Such testing is also not for treatment but to identify patterns. Testing may also be undertaken, for instance, of skin type to decide on the use of cosmetic processes or products. The methods or processes adopted in the above three illustrations may potentially also be used in relation to medical treatment. Therefore, from the perspective of deciding a patent application, use cases are relevant only for the limited purpose of ascertaining whether the claimed invention can *per se* uncover pathology and form the basis of treatment.

Screening and Diagnosis

44. 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

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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.

45. 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 vs Diagnostic: Understanding Non-invasive*

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Prenatal Screening". Adopting this approach, in my view, is also not in consonance with the meaning of "diagnostic" in 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".

46. What is determinative, therefore, of whether a process is diagnostic is to ask the question whether the process 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 process should, in turn, be determined by assuming that a person(s) skilled in the art, including a medical doctor, examines 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

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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.

Claimed invention: diagnostic?

47. The appellant contended that the claimed invention cannot be construed as a diagnostic process for treatment of human beings because the appellant does not diagnose the medical condition and merely provides data in relation to sequence

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imbalance by a size distribution analysis of DNA fragments taken from a biological sample, including by using a computer programme. The appellant also contended that the patent eligibility of the claimed invention cannot be tested by examining one of the use cases or embodiments of the claimed invention and should be tested on the basis of the amended claims which delimit and fix the boundaries of the claimed invention.

48. In order to decide whether the contention of the appellant is correct, it is necessary to set out the basic science behind non-invasive prenatal testing. Human cells have 23 pairs of chromosomes comprising 22 autosomal pairs and one pair of sex chromosomes, and one of each pair is derived from the mother and father of such human being. These chromosomes, in turn, contain DNA. Testing for chromosomal aberrations could only be done previously by adopting invasive methods such as chorionic villi sampling (CVS) or amniocentesis. Both these methods, therefore, involve some risk of foetal damage. Instead, recent advancements enable testing on a blood sample drawn from a pregnant female with a foetus of not less than a threshold gestational age (usually

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not less than 10 weeks). Such testing is done by using techniques that identify and work on cell-free DNA (cfDNA) fragments after identifying the foetal fraction in the biological sample. The proportion of cfDNA in maternal blood that comes from the placenta is the foetal fraction. DNA sequencing is undertaken by adopting methods such as massively parallel or high throughput sequencing and, on such basis, sequence imbalances, if any, are ascertained. By plotting the site and nature of imbalance, chromosomal aberrations, whether numerical or by way of mutations such as deletion, duplication and the like, may be identified. Chromosomal aneuploidy is a numerical aberration in which there is an extra chromosome (trisomy, three instead of two) or a missing chromosome (monosomy, one instead of two). By way of illustration, a trisomy of chromosome 21 is referred to as Down's syndrome and a trisomy of chromosome 18 is referred to as Edward's syndrome. Against this backdrop, the claims of the appellant are examined.

49. On examining claim 1 of the amended claim submitted by the appellant before the Assistant Controller or the current claim

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1, it is evident that the biological sample is drawn from the pregnant female subject. The nucleic acid molecules in such biological sample are tested by undertaking sequencing to determine the size distribution of the nucleic acid molecules by comparing the same with reference values. As discussed earlier, in the impugned order, the Assistant Controller referred to and reproduced paragraphs [0006], [0007], [0008] and [0009] of the complete specification, examined amended claim 1 in that context, and concluded that the claimed method is diagnostic and, consequently, patent ineligible under Section 3(i). Paragraphs [0006] and [0008] are as under:

> *"[0006] Certain embodiments of the present invention can provide systems, methods, and apparatus can use a size-based analysis to perform a prenatal diagnosis of a sequence imbalance (e.g. a fetal chromosomal aneuploidy) in a biological sample obtained from a pregnant female subject. For example, a size distribution of fragments of nucleic acid molecules for an at-risk chromosome can be used to determine a fetal chromosomal aneuploidy. Some embodiments can also detect other sequence imbalances, such as a sequence imbalance in the biological sample (containing mother and fetal DNA), where the*

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imbalance is relative to a genotype, mutation status, or haplotype of the mother. Such an imbalance can be determined via a size distribution of fragments (nucleic acid molecules) corresponding to a particular sequence relative to a size distribution to be expected if the sample were purely from the mother, and not from the fetus and mother. A shift (e.g. to a smaller size distribution) can signify an imbalance in certain circumstances."

"[0008] In another embodiment, a difference between a size (e.g. A statistical value representing a size distribution) of the fragments of the at-risk chromosome and a size of the fragments of a reference chromosome is used. For example, if the difference in the size is greater or smaller than a cutoff (also called a threshold), then a diagnosis that a fetal chromosomal aneuploidy exists in the at-risk chromosome can be made."

50. The contention of learned counsel for the appellant that embodiments of the claimed invention should not be reckoned for determination of the claims cannot be accepted. Although the claims delimit the scope and ambit of the monopoly claim, the embodiments set out in the complete specification can and should be examined to assess whether the process is *per se* diagnostic. In

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my view, if the amended claim 1 or current claim 1 is examined in the context of the above and other paragraphs of the complete specification, it follows that person(s) skilled in the art would be able to arrive at a diagnosis as to whether a specific chromosomal aberration, such as an aneuploidy, exists by adopting this process. For some understanding of size distribution analysis, reference may be made to the article "*Size-based molecular diagnostics using plasma DNA for noninvasive prenatal testing" by Stephanie C.Y. Yu et al*, *dated June 10, 2014, Proceedings of the National Academy of Sciences, Volume 111, No.23, pages 8583-8588.* If a positive result for a chromosomal aneuploidy is returned, medical literature indicates that a medical doctor is likely to opt for definitive diagnosis by undertaking chorionic villi sampling or amniocentesis. It is also possible that the claimed invention may be more effective in identifying certain autosomal aneuploidies and less effective with chromosomal mutations or sex chromosomal monosomies and trisomies. On those counts, however, it cannot be concluded that the process described by the claimed invention is not diagnostic because neither definitive nor comprehensive diagnosis is a prerequisite to qualify as diagnostic. Once it is concluded that the

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claims are patent ineligible, it is not necessary to deal with the other grounds of decision, such as lack of inventive step, and sufficient to record that the impugned order does not warrant interference.

51. Before drawing the curtain, I am, nonetheless, constrained to make a few observations. My conclusions in this matter are founded on an interpretation of Section 3(i) by examining the text thereof in context. I notice that the Patent Office has granted patents to *in vitro* processes and there is inconsistency. I also recognise that several technological advancements have been made in diagnosis, especially by using genomic tools. With a view to incentivise inventors in these cutting-edge areas, albeit without compromising on the public policy exclusion from patent eligibility of methods of diagnosis and treatment adopted by medical doctors, there is a case to consider options such as restricting the scope of the expression "diagnostic" in Section 3(i) to *in vivo* processes and counter balancing by providing for compulsory licensing. Since this is squarely within the province of law makers, I stop with urging such reconsideration.

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52. For reasons set out above, CMA (PT) No.1 of 2023 and W.P.No.7666 of 2023 are dismissed without any order as to costs. Consequently, connected miscellaneous petitions are closed.

12.10.2023

Index : Yes/No

Internet : Yes/No

Neutral Citation: Yes/No

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To

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SENTHILKUMAR RAMAMOORTHY J.

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CMA (PT) No.1 of 2023 & C.M.P.No.13206 of 2023
&
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W.M.P.Nos.7828 & 7832 of 2023

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