IN THE HIGH COURT OF JUDICATURE AT MADRAS

Judgment reserved on	27.09.2023
Judgment pronounced on	12.10.2023

CORAM:

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

CMA (PT) No.14 of 2023
&
CMP No.16669 of 2023

1. The Chinese University of Hong Kong
   Knowledge Transfer Office, Room 301,
   Pi Ch'iu Building, Shatin,
   N.T. Hong Kong SAR, China.

2. SEQUENOM, INC.
   3595 John Hopkins Court,
   San Diego, California 92121, USA. ... Appellants

v.

The Assistant Controller of Patents & Designs,
The Patent Office,
Intellectual Property Office Building,
G.S.T.Road, Guindy,
Chennai-600 032. ... Respondent

PRAYER IN CMA(PT)/14/2023: This Civil Miscellaneous Appeal filed under Section 117-A of the Patents Act, 1970, prays to set aside the order dated 31st March 2021 passed by the Respondent in Patent Application 4812/CHENP/2012; to hold that the claimed subject matter of Claims 1-12 of the Patent Application No.4812/CHENP/2012 fall outside the scope of Section 3(i) of the Patents Act, 1970 and is thus liable to proceed to grant; and to publish the grant in the journal.

For Appellants : Ms.Vindhya S.Mani,
Mr.Kiran Manokaran,
Ms.Vaishali Joshi,
Mr.Sheerabdhinath, for
M/s.Lakshmikumaran and Sridharan

For Respondent : Mr.S.Diwakar, SPC
Assisted by the Assistant
Controller of Patents & Designs

Amicus curiae : Mr. Adarsh Ramanujan

JUDGMENT

Background

By order dated 31.03.2021, the respondent rejected the application of the appellants for grant of

patent [Indian Patent Application No.4812/CHENP/2012 dated 01.06.2012 (IN 4812)] and the said order is impugned herein.

2. The appellants claim priority from multiple U.S. Provisional Applications for IN 4812, which is the national phase filing derived from a Patent Cooperation Treaty (PCT) application in respect of a claimed invention entitled "Fetal Genomic Analysis From a Maternal Biological Sample".

3. IN 4812 was originally filed with 44 claims. The appellants received the First Examination Report (FER) on 29.11.2012 raising multiple objections, including objections under Sections 2(1)(j), 2(1)(ja), 3(i) and 10(5) of the Patents Act, 1970 (the Patents Act). The appellants responded thereto on 28.05.2018 by deleting original claims 1-33 and submitted amended claims 1-12.

4. At the hearing before the authority, the appellants contended that the determination of the foetal fraction does not

diagnose a disease and that, therefore, the claimed invention is not a diagnostic method.

5. 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 amended claims 1 to 12 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 paragraph [0007] of the complete specification before holding that the claimed invention is a process of diagnosing that the foetus is suffering from genetic or other diseases. In relevant part, the conclusion (at page 448 of the appeal paper book) is as under:

> *"In addition to this as discussed and accepted by the Applicant in the reply, the whole description mentions method of diagnosis. And the claimed method discloses a maternal sample for elucidating the fetal haplotype, sequencing and analysing the sample and a size fractionation step can*

also be performed on the nucleic acid molecule then analysing the size then parental genomes are used as scaffolds which can be compared against genetic information of the fetus obtained from the maternal sample containing fetal DNA and constructing fetal genome from maternal genome and determination of the parental alleles inherited by the fetus. To determine the fractional fetal DNA concentration be useful for determining a cutoff to determine a classification of which haplotype and/or genotype are inherited. Thus it is very clear that the claimed method of determining a fractional concentration of fetal DNA in a biological sample is not patentable u/s 3(i) of the Patents Act, 1970 as the said claims are diagnostic method."

Counsel and contentions

6. Oral arguments were advanced by Ms.Vindhya S. Mani, learned counsel for the appellants; and by Mr.Diwakar, learned SPC, assisted by the Assistant Controller of Patents and Designs, on behalf of the respondent. Mr. Adarsh Ramanujan, learned counsel and author of "Patent Law Cases and Materials, A

Synthesis for India", Thomson Reuters (2021), was heard as *amicus curiae*. For effectively assisting and shining the light on the nuances and intricacies of the issues that arise for consideration, I record my deep appreciation.

7. Ms. Vindhya Mani submitted that the object and purpose of the amendment to Section 3(i) is to prevent the grant of patents to methods of diagnosis 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. In fact, learned counsel referred to the communication from the Indian Permanent Mission to the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights and pointed out that the said communication indicated clearly that only diagnostic methods practised on the human body would be patent ineligible. 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.

8. 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 Manual of Patent Office Practice and Procedure published in 2010 (the 2010 Manual), at paragraph 08.03.06.08, 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. Paragraph 08.03.05.08 of the Manual of Patent Office Practice and Procedure, published in 2011 (the 2011 Manual) and the Guidelines for Examination of Biotechnology Applications for Patents, published in March 2013 (the 2013 Guidelines), were also relied upon in this regard.

9. Learned counsel further submitted that the method envisages carrying out *in vitro* analysis of fragments of nucleic acid molecules taken from a biological sample containing both the foetal and maternal DNA, and the determination of the foetal fraction by following the process set out in the amended claims, including by using a computer programme. Learned counsel pointed out that such foetal fraction is the proportion of cell free DNA (cfDNA) originating from the foetus in the biological sample. Dilating further, learned counsel contended that the claimed invention is a non-invasive prenatal screening test (NIPT), which does not uncover pathology. She also contrasted NIPT with invasive tests such as amniocentesis and chorionic villi sampling which are diagnostic. By determining foetal fraction, learned counsel submitted that pathology cannot be uncovered without further testing.

10. By relying upon principles of interpretation, such as *noscitur a sociis,* she contended that the word '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.

11. In support of the contention that the expression diagnostic method should be confined to *in vivo* diagnosis, the order 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 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 impugned order and 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.

12. Mr. Adarsh Ramanujan made submissions next. His first submission was that Section 3(i), as amended by Act 38 of 2002, contains a drafting error in the nature of *casus omissus.* According to him, the *casus omissus* should be filled by reading the first limb of Section 3(i) as "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other methods for treatment of human beings...." With regard to *casus omissus,* he relied on the judgments of the Supreme Court in *Union of India & Anr. v. Hansoli Devi & Ors.,(2002) 7 SCC 273* and *Padma Sundara Rao & Anr. v. State of T.N. & Ors., (2002) 3 SCC 533.*

13. Turning to the submissions on diagnostic being limited to *in vivo* diagnosis, learned counsel referred to the communication from the Indian Permanent Mission to the Negotiating Group for the Trade-Related Aspects of Intellectual Property Rights proposing language that limited patent

ineligibility to diagnostic methods practised on the human body. According to learned counsel, the proposal by India was inspired by Article 52(4) of the European Patent Convention 1973 (EPC 1973). By placing for my consideration Article 30(3) of the draft treaty that preceded the TRIPS Agreement, learned counsel submitted that the draft treaty contained language identical to Article 27(3)(a) of the TRIPS Agreement, and that this provides evidence that the Indian proposal did not find favour with the Negotiating Group.

14. Mr. Adarsh Ramanujan then traced the evolution of the provision relating to exclusions from patent eligibility in Indian patent law. By starting with the Ayyangar Committee Report of 1959 and the Patents Bill that followed, he contended that the Patents Bill did not contain exclusions. According to him, the exclusion of methods of treatment of human beings has its provenance in the judgment entitled *In the matter of C&W's*

Application for a Patent (1914) 31 RP.C. 235. He also pointed out that the exclusion was justified on the ground of non-vendibility or lack of industrial application, and not on the ground of public policy. He also referred to *Schering AG's Application [1971] RP.C. 337* in this regard.

15. Mr. Adarsh Ramanujan next submitted that the public policy justification for exclusion from patent eligibility emerged later. By pointing out that patent protection is available both for pharmaceutical products and medical equipment/devices, he submitted that the public policy exclusion is not all-encompassing or comprehensive. He also shone the spotlight on the fact that compulsory licensing is available as a counter balance as regards pharmaceutical patents, whereas such counter balance is unavailable as regards methods of treatment of human beings.

16. With reference to the manuals of practice and procedure of the Patent Office, he submitted that Section 3(i) was long understood as only excluding *in vivo* diagnostic processes. As regards the EBoA opinion, he submitted that the EBoA was conscious that the four method requirement could result in clever patent claims drafting to circumvent patent exclusion. By referring to the Guidelines for Examination in the European Patent Office (EPO Guidelines) and the decisions of the Technical Board of Appeal of the EPO in the following subsequent decisions, namely, Case No. T 529/19 dated 24 April 2023, Case No. T 125/02 dated 23 May 2006, case No. T 143/04 dated 12 September 2006, he submitted that the Technical Board of Appeal only grants patents if the claimed invention does not point unambiguously to a clinical diagnosis and that the EPO Guidelines provide similar guidance. He thus concluded his submissions by stating that the above submissions be taken note of while deciding the matter.

17. In response to these contentions, Mr.Diwakar submitted that the complete specification and, in particular, paragraph [0007] thereof discloses that the claimed invention enables diagnosis of genetic diseases. 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 SPC 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 SPC submitted that the text of Section 3(i) would have contained an indication that *in vitro* diagnosis is excluded.

18. 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 SPC 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 Pre-Conception and Pre-Natal Diagnostic Techniques Act, 1994 (the PNDT Act), learned counsel submitted that sex determination is feasible through the process outlined in the claimed invention and, therefore, grant of patent would be in the teeth of the above statute.

19. These submissions were supplemented by the Assistant Controller, who pointed out that the process described in the claimed invention enables the genome of the foetal cells to be constructed and that thereby chromosomal aberrations can be diagnosed.

Discussion, analysis and conclusions

Construction of Section 3(i)

20. 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 value or that of their products."*

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

(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 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.

22. 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. 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 "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.

23. 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. The solution proposed by Mr. Adarsh Ramanujan was to consider it as *"casus omissus"* and add words such as "methods for" after "other". I am not inclined to resort to such option because "any process for the ... diagnostic ... or other methods for treatment of human beings" is not syntactically correct because the word "process" at the beginning of the provision is not compatible with the proposed word "methods", 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.

24. 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 appellants contended that the expression 'diagnostic' should not be construed in isolation but should be understood *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 appellants, I propose to examine the different purposes for which testing of human beings may be carried out a little further down the road.

25. 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

appellants, I 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).

TRIPS Agreement

26. 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.

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."

27. 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 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

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

The EBoA opinion

29. The appellants 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 (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)*

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

31. 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 decision phase.

32. 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 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 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."

33. 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 implications of this approach warrant discussion.

34. 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.

35. 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 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.

36. 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, which were placed for consideration be learned *amicus curiae,* 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 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.

37. Similarly, in Case Number T 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."

38. 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 clinical picture" and was, therefore, patent eligible.

39. 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.

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

41. 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 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).

42. 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 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

43. 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.

44. 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 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".

45. 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.

Claimed invention: diagnostic?

46. The appellants contended that the claimed invention cannot be construed as a diagnostic process for treatment of human beings because the claimed invention does not diagnose the medical condition and merely identifies the foetal fraction. The appellants 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.

47. 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 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 relevant paragraph of the complete specification and independent claims of the appellant are examined.

48. In the impugned order, the Assistant Controller referred to and reproduced paragraph [0007] of the complete

specification and concluded that the claimed method is diagnostic and, consequently, patent ineligible under Section 3(i). Paragraph [0007] is as under:

> *"[0007] Certain embodiments of the present invention can provide methods, systems, and apparatuses for determining at least a portion of the genome of an unborn fetus of a pregnant female. A genetic map of the whole genome or for selected genomic region(s) can be constructed of the fetus prenatally using a sample containing fetal and maternal genetic material (e.g. From a blood sample of the pregnant mother). The genetic map can be of sequences that a fetus has inherited from both of its father and mother, or just those of one of the parents. Based on one or several of such genetic maps, the risk that the fetus would be suffering from a genetic disease or predisposition to a genetic or other diseases or a genetic trait can be determined. Other application of embodiments are also described herein."*

49. The above paragraph should be understood in the context of the amended claims. The amended claim 1 and 9 of the

appellants are as under:

"1. A method of determining a fractional concentration of fetal DNA in a biological sample taken from a pregnant female, the fetus having a father and a mother being the pregnant female, wherein the biological sample contains a mixture of maternal and fetal nucleic acids, the method comprising:

analysing a plurality of nucleic acid molecules from the biological sample, wherein analyzing a nucleic acid molecule includes:

identifying a location of the nucleic acid molecule in the human genome; and

determining a respective allele of the nucleic acid molecule;

a computer system determining one or more first loci, wherein the fetal genome is heterozygous at each first loci such that the fetal genome has a respective first and second allele at that first loci, and wherein a maternal genome is homozygous at each first loci such that the maternal genome has two of the respective second allele at that first loci, the first allele being different than the second allele, wherein determining a specific locus to be one of the one or more first loci

includes:

determining a cutoff value for a number of predicted counts of the respective first allele at the specific locus, the cutoff value predicting whether the maternal genome is homozygous and the fetal genome is heterozygous, wherein the cutoff value is determine based on a statistical distribution of number of counts for different combinations of homozygosity and heterozygosity at the specific locus;

based on the analysis of the plurality of nucleic acid molecules, detecting the respective first allele and the respective second allele at the specific locus;

determining a number of actual counts of the respective first allele based on the analysis of the plurality of nucleic acid molecules from the biological sample; and

determining the specific locus in one of the first loci when the number of actual counts is less than the cutoff value;

for at least one of the first loci:

determining a first number P of counts of the respective first allele and a second number Q of counts of the respective second allele; and

calculating the fractional concentration based on the first and second numbers."

"9. A method of determining a fractional concentration of fetal DNA in a biological sample taken from a pregnant female, the fetus having a father and a mother being the pregnant female, wherein the biological sample contains a mixture of maternal and fetal nucleic acids, the method comprising:

enriching the biological sample obtained from the pregnant female for nucleic acid molecules in a target region;

sequencing a plurality of nucleic acid molecules from the enriched biological sample, the sequencing being specific to the target region, wherein the sequencing results are analyzed to:

identifying a location of the nucleic acid molecule in the human genome; and

determine a respective allele of the nucleic acid molecule;

determining one or more first loci, wherein the fetal genome is heterozygous at each first loci such that the fetal genome has a respective first and second allele

at that first loci, and wherein a maternal genome is homozygous at each first loci such that the maternal genome has two of the respective second allele at that first loci, the first allele being different than the second allele;

for at least on of the first loci;

determining a first number P of counts of the respective first allele and a second number Q of counts of the respective second allele; and

determining the fractional concentration based on the first and second numbers."

50. On examining claims 1 and 9 of the amended claims submitted by the appellants before the Assistant Controller, it is evident that the biological sample is drawn from the pregnant female subject. The nucleic acid molecules in such biological sample are tested with a view to identify the foetal fraction, i.e. the proportion of cell free foetal DNA in the biological sample. Medical literature indicates that the foetal fraction should be not less than 4% to enable further testing to identify chromosomal

aberrations, such as chromosomal aneuploidies. Until that stage is reached, pathology is not uncovered and, consequently, treatment is not possible.

51. Thus, the claimed invention is *per se* incapable of identifying the existence or otherwise of a disease, disorder or condition and further testing would be required for such purpose. In effect, it provides an indicator, foetal fraction, which is relevant for further testing to arrive at a diagnosis. In my analysis of the word "diagnostic" in Section 3(i), I concluded that the scope should not be unduly curtailed by limiting it to *in vivo* or definitive diagnosis. I also concluded that its scope should not be unduly expanded by implying the words "relating to" diagnosis. In my view, determination of foetal fraction is related to diagnosis but is not "diagnostic". The contention of learned SPC that the test may be used for sex determination under the PNDT Act is also not relevant from a patent application evaluation perspective because

the said statute prohibits sex selection and prescribes penalties in respect thereof. Therefore, the impugned order calls for interference. In the FER and hearing notice, objections were raised on grounds of lack of novelty and unity of invention and obviousness in respect of original claims 1-33. After all those claims were deleted, as regards amended claims 1-12, the only objection was on the basis of Section 3(i). Since such objection stands rejected as untenable, the application shall proceed to grant.

52. 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.

53. For reasons set out above, CMA(PT)No.14 of 2023 is allowed without any order as to costs and consequently IN 4812 shall proceed to grant based on amended claims 1-12. Consequently, the connected miscellaneous petition is closed.

12.10.2023

Index : Yes/No
Internet : Yes/No
Neutral Citation : Yes/No
kal

To

The Assistant Controller of Patents & Designs,
The Patent Office,
Intellectual Property Office Building,
G.S.T.Road, Guindy,
Chennai-600 032.

SENTHILKUMAR RAMAMOORTHY J.0

kal

Pre-delivery judgment made in
CMA (PT) No.14 of 2023
&
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