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

% *Judgment delivered on: 17.01.2026*

\+ **C.A.(COMM.IPD-PAT) 45/2023**

HIROTSU BIO SCIENCE INC .....Appellant

Versus

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

Advocates who appeared in this case

For the Appellant : Mr. Kshitij Saxena, Mr. Saransh Vijayvargiya & Mr. Daksh Oberoi, Advocates.

For the Respondent : Ms. Manisha Agarwal & Mr. Nipun Jain, Advocates.

CORAM:
HON'BLE MR. JUSTICE TEJAS KARIA

JUDGMENT

TEJAS KARIA, J

INTRODUCTION

1. This is an Appeal under Section 117A of the Patents Act, 1970 ("**Act**") against the order dated 29.08.2023 ("**Impugned Order**") issued by Assistant Controller of Patents and Designs ("**Respondent / Controller**") under Section 15 of the Act rejecting the grant of patent in the Patent

Application No. 201617022947 titled as "*CANCER DETECTION METHOD USING SENSE OF SMELL OF NEMATODE*". ("**Subject Application**").

FACTUAL MATRIX

2. The Appellant filed the National Phase Application with Claim Nos. 1-21 before the Patent Office, Delhi on 04.07.2016, based on the PCT Application No. PCT/JP2014/083320 dated 10.12.2014.

3. The Appellant on 31.10.2017, filed for the request for First Examination Report. Upon receipt of the First Examination Report dated 19.08.2020 ("**FER**"), the Appellant filed a detailed response to the FER on 28.12.2020 ("**Reply**") along with a revised set of claims.

4. After the Reply to the FER, the Appellant received a hearing notice dated 08.02.2023. Thereafter, the Appellant filed two requests for adjournment of hearing and received the hearing notice on 21.03.2023 ("**Hearing Notice**") containing objections stating that the claims do not fulfil the requirements of Sections 2(1)(j), 3(i), 3(j) and sufficiency of disclosure under Section 10(4) of the Act and fixed the hearing on 11.04.2023 ("**Hearing**"). During the Hearing, the Appellant advanced oral submissions in respect of the objections raised in the Hearing Notice.

5. The Appellant filed post-hearing written submissions dated 26.05.2023 along with amended set of claims ("**Written Submissions**"). Subsequent to the filing of the Written Submissions, the Respondent rejected the grant of patent under the Subject Application *vide* the Impugned Order.

6. The Respondent while rejecting the Subject Application in the Impugned Order observed that the Appellant did not fulfil the requirement under Section 3(i) of the Act.

SUBMISSIONS ON BEHALF OF THE APPELLANT

7. The learned Counsel for the Appellant submitted that:

7.1. The present invention is directed to detection, i.e., identifying cancer-specific odour responses in biological samples outside the human body. It does not amount to diagnosis, which requires medical correlation, interpretation, and clinical judgment. Reliance was placed upon Paragraph Nos. [0027] and [0028] of the Complete Specification, which are reproduced hereunder:

> "*[0027] The present invention relates to a **method for detecting cancer**, which is characterized in breeding nematodes in the presence of a subject-derived bio-related substance or a processed product thereof, and **then detecting cancer, for example, using the chemotaxis of the nematodes based on the olfaction thereof as an indicator**.*
>
> *Upon testing whether or not a subject has had cancer, the present inventor has focused on, in one aspect, the chemotaxis of the nematode C. elegans based on the olfaction thereof to a sample derived from the subject.*
>
> *A nematode, Caenorhabditis elegans (hereinafter also abbreviated as "C. elegans"), is a popular organism, which has been widely bred and studied as a model organism for biological study in laboratories over the world. 2 Caenorhabditis elegans is characterized in that the breeding thereof is easy and it has an excellent olfactory system.*
>
> *[0028] Such nematodes exhibit a chemotaxis to an odorant, such as approaching to or escaping from it. Thus, in the present invention, using such a behavior as an indicator, the reactions of nematodes to the smells of cancers will be examined. The reactions of nematodes to the urine of healthy subjects and cancer patients have been examined. As a result, the nematodes have exhibited an avoidance behavior to the urine of the healthy subjects, whereas they have exhibited an attraction behavior to the urine of the cancer patients. As a result of the examination performed on specimens, the*

> *accuracy was found to be 100% (Figure 1). Moreover, nematodes have reacted with all of gastric cancers, colon/rectal cancers and pancreatic cancers, including early cancers. Hence, it has been demonstrated that, as with the behavior of cancer detection dogs, nematodes react with cancer-specific smells, which are common in various types of cancers.*"

The Appellant in the abovementioned paragraphs points out that the detection interpretation refers to the primary identification of the presence or absence of cancer using nematode behavioral or neural responses (chemotaxis or olfactory neuron activity). It does not specify cancer type; it only signals cancer v. non-cancer.

7.2. The core inventive feature of the present invention lies in the detection process, which utilizes the olfactory response of nematodes to biological samples for identifying the presence or risk of cancer *in vitro*. The reference to "diagnosis" in the Complete Specification is only illustrative, intended to provide contextual understanding for a person skilled in the art ("**PSITA**") regarding possible downstream applications of the detection result, but does not constitute a claimed diagnostic step.

7.3. A productive analogy can be drawn from the relationship between the specification and the claims. The specification is like a genus and the claims are like the species. Applying this principle, while the specification provides a genus level narrative that includes both detection and diagnostic contexts for technical clarity, the species actually claimed pertains exclusively to *in vitro* detection. The diagnostic elements in the description exist solely for explanatory purposes; to clarify how the detection results may be interpreted or subsequently utilized but these are not part of the claimed process.

7.4. The abovementioned interpretation aligns with established patent jurisprudence, which recognizes that the claims, not the description, determine the scope of legal protection. Here, every independent claim, including Claim Nos. 1 and 5, confines the method to *in vitro* detection or receptor identification carried out outside the human body, without any diagnostic or therapeutic act performed on a patient. Therefore, the diagnostic step referred to in the Complete Specification merely illustrates a subsequent potential use following detection, akin to how a test kit's data may be used by physicians for medical decision-making. It does not render the Subject Application diagnostic in nature under Section 3(i) of the Act.

7.5. Further, the claims define the legal monopoly granted by a patent. The specification serves as an explanatory document, to be referred to only when ambiguity exists in the claims. Claims must be interpreted objectively, in their plain and ordinary meaning, through the eyes of a PSITA as of the effective filing date and the body of the specification cannot be used to extend or cut down the monopoly defined in the claims. This collectively holds that it is unjust to read into a claim something beyond its clear terms, or to import limitations or inferences from the specification unless the claim itself is ambiguous. Reliance was placed upon the following decisions while making the above submission:

a. ***F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd.***, Neutral Citation: 2015:DHC:9674-DB
b. ***FH & B v. Unichem Laboratories***, 1968 SCC OnLine Bom 118
c. ***Merck Sharp and Dohme Corporation & Anr. v. Glenmark Pharmaceuticals***, (2015) 6 SCC 807
d. ***Edward H. Phillips v. AWH Corp.***, 415 F. 3d 1303

7.6. In the Subject Application, the independent claims, particularly Claim Nos. 1 and 10 are directed to an "*in vitro* method for detecting cancer" using nematodes' olfactory behavior as an indicator. The claim language explicitly restricts the scope to "*in vitro*" conditions and no step involves diagnosis, treatment, or medical decision-making on a human or animal body. Thus, when read plainly, the claim falls entirely outside the exclusion of Section 3(i) of the Act.

7.7. Reliance was placed upon the decision in ***EMD Millipore Corporation v. Assistant Controller of Patents and Designs***, Neutral Citation: 2025:DHC:8928 wherein the Court held that the exclusion under Section 3(i) of the Act is not meant to create a blanket prohibition against all inventions related to diagnosis or treatment, but only those that directly involve medical professional judgment or physical intervention in the human or animal body.

7.8. The ratio laid down in ***EMD Millipore***, (*supra*) squarely applies to the present case. The Appellant's present invention is an *in vitro*, non-clinical detection process that employs nematodes' olfactory response to biological samples to generate a risk indication of cancer presence. The process does not require medical expertise, does not involve any invasive step, and is conducted entirely outside the human body in a laboratory environment.

7.9. The Respondent failed to take into consideration the decision in ***Chinese University of Hong Kong and Sequenom, Inc. v. The Assistant Controller of Patents and Designs***, 2023 SCC OnLine Mad 6372 wherein the Court held that the assessment to be undertaken is whether the test is inherently and *per se* capable of identifying the disease, disorder, or condition for treatment of the person. The test should, in turn, be determined

by assuming that PSITA, including a medical doctor, examine the results. Further, the scope of the expression "diagnostic" in Section 3(i) of the Act should be restricted to *in vivo* processes.

7.10. The Respondent has failed to appreciate the fact that the Claim Nos. 1 to 4 are related to "an *in vitro* method of detecting cancer"; therefore, it is clear that the method of the invention is not performed on human body but *in vitro* i.e., on samples obtained from the subjects. The present claims are related to *in vitro* detection methods and therefore, cannot be regarded as diagnostic method.

7.11. The Respondent failed to acknowledge that the cancer detection service "N-NOSE®" has been in the news and has attracted much attention in India. "N-NOSE®" has already become a business in Japan. In fact, "N-NOSE®" is commercialized in Japan and provides information whether a customer may have cancer risk based on the chemotaxis of nematodes to the smell of the customer's urine, and is not a diagnosis. Therefore, responses of nematodes merely indicate the possibility of cancer and cannot used for diagnosing cancer.

7.12. Accordingly, the Impugned Order is liable to be set aside and the present Appeal shall be allowed.

SUBMISSIONS ON BEHALF OF THE RESPONDENT

8. The learned Counsel for the Respondent submitted that:

8.1. The Appellant argued that the present claims are related to *in vitro* detection methods and therefore, cannot be regarded as diagnostic method. However, it is objected that claims of the Subject Application are a method for detecting and characterizing cancer type in human subjects which is not allowed under Section 3(i) of the Act.

8.2. Section 3(i) of the Act excludes both *in vivo* and *in vitro* methods. In its plain reading, the provision does not qualify any of the exclusions with the phrase "*in vivo*" or "*in vitro*". As a general proposition of law, it is well settled that one is not ordinarily permitted to add or delete words from the statute. Therefore, restricting the claims to the *in vitro* method does not exclude the claimed method from the objection of Section 3(i) of the Act. Reliance was placed upon the decision in ***Union of India v. Hansoli Devi***, (2002) 7 SCC 273 while making the above submission.

8.3. The Appellant further argued that the detection methods differ significantly from diagnostic methods. Diagnostic methods require the skill and knowledge of the physician or surgeon to analyze and interpret symptoms, whereas in the case of detection, the result is not accompanied by a discussion. Detection is viewed as an independent process directly obtained by the detection method, which does not require the skill and knowledge of a physician or surgeon. In this regard, the claimed method is clearly a diagnostic method and it involves all the essential steps of a diagnostic method *viz*.

a. the examination phase involving collection of data,
b. comparison of these data with standard values,
c. the finding of any significant deviation, i.e., a symptom, during the comparison, and
d. the attribution of the deviation to a particular clinical picture, i.e., the deductive medical decision phase.

8.4. Further, merely because the ultimate end-use of a particular claim may be applied by biomedical or veterinary practitioners to diagnose a disease or condition, would not automatically exclude it from patentability.

Furthermore, the Appellant argued that the amended Claim No. 5 is directed to a method for identifying olfactory receptors in nematodes and that this method is for use in deciding which nematodes to use in the cancer detection method, and thus, is not related to the diagnostic method. However, as evident from Claim No. 5 itself that the said method is vital for the purpose of determining the type of cancer as per the claimed diagnostic method i.e., deciding which nematodes to use in the cancer detection method and it is of no use when seen in isolation.

8.5. The specifications provide the context in which claims / amended claims are interpreted. Complete Specification of the Subject Application admit that the process sought to be patented is a diagnostics process. Further, the Complete Specification of the Subject Application provides that the process sought to be patented is not limited to just screening process for diagnosing cancer before it happens; but it also a general diagnosing method for cancer. It is clear that the Appellant's averment to the effect that specifications can expand or limit the scope of claims is not applicable here because here, there is a contrast between the import of the specifications versus the import of the amended claims. Assuming that the amended claims claim only screening and that too without eliminating the need of further tests because the claims cannot be read contrary to specifications. Reliance was placed upon the following decisions while making the above submission:

a. ***The Chinese University of Hong Kong*** (*supra*)
b. ***Natera Inc. and Anr. v. Assistant Controller of Patents and Designs***, Neutral Citation: 2025:DHC:8937

c. ***Sequenom Inc. & Anr. v. the Controller of Patents***, Neutral Citation: 2025:DHC:8926

8.6. In light of the above, the Impugned Order shall be upheld and the present Appeal is liable to be set aside.

ANALYSIS AND FINDINGS

9. The present invention relates to the cancer detection method using the olfactory system of nematodes. The Appellant's Subject Application was refused on the ground of not fulfilling the requirements under Section 3(i) of the Act. The inventor of the present invention has found that cancer can be detected by using the chemotaxis of nematodes based on the olfaction thereof or the response of olfactory neuron.

10. The analysis observed by the learned Controller under the Impugned Order is reproduced hereunder:

> *"Section 3(i):*
> *In response to para 4 regarding non-patentability under section 3(i) in the hearing notice; the argument given by the applicant is not persuasive and method claimed in presently amended claims 1-11 is not allowable under section 3(i) of the Patents Act.*
> *The applicant argues that the present claims are related to in-vitro detection methods and therefore cannot be regarded as diagnostic method.*
> *However, it is objected that instant application claims a method for detecting and characterizing cancer type in human subject which is not allowed under section 3(i) of The Patent Act.*
> *Regarding Section 3(i) of the Patents Act, 1970, as it stands today, reads as follows:*
>
> *"What are not inventions.-*
>
> *The following are not inventions within the meaning of the 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."

From the above, Section 3(i) excludes both in vivo and in vitro methods. In its plain reading, the provision does not qualify any of the exclusions with the phrase "in vivo" or "in vitro". As a general proposition of law, it is well settled that one is not ordinarily permitted to add or delete words from the statute [Union of India v. Hansoli Devi, (2002) 7 SCC 273 @ para 9 - Pg. 12@19-21 of present Submissions].

Therefore, by restricting the claims to in vitro method does not exclude the claimed method from the objection of section 3(i).

Further, applicant argues that, the detection methods differ significantly from diagnostic methods. Diagnostic methods require the skill and knowledge of the physician or surgeon to analyse and interpret symptoms, whereas in the case of detection, the result is not accompanied by a discussion. Detection is viewed as an independent process directly obtained by the detection method, which does not require the skill and knowledge of a physician or surgeon.

However, claimed method clearly a diagnostic method and in involves all the essential steps of a diagnostic methods viz.

i) the examination phase involving collection of data,
ii) 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 decision phase.

Further, merely because the ultimate end-use of a particular claim may be applied by biomedical or veterinary practitioners to diagnose a disease or condition, would not automatically exclude it from patentability.

Furthermore, applicant argues that amended claim 5 is directed to a method for identifying olfactory receptors in nematodes and that this

method is for use in deciding which nematodes to use in the cancer detection method, and thus is not related to the diagnostic method.

However, as evidence from the claim 5 itself that the said method is a one of the preparatory step of claimed diagnostic method i.e. deciding which nematodes to use in the cancer detection method and it is of no use when seen in isolation. Further, limitations of claim 5 refers to a diagnostic method and therefore claim 5 and dependent claims attracts the objection under section 3 (i).”

11. Aggrieved by the Impugned Order, the learned Counsel for the Appellant submitted that the present invention is directed to detection, that is, identifying cancer-specific odour responses in biological samples outside the human body and it does not amount to diagnosis, which requires medical correlation, interpretation, and clinical judgment. The Appellant further submitted that the detection interpretation refers to the primary identification of the presence or absence of cancer using nematode behavioural or neural responses (chemotaxis or olfactory neuron activity). It does not specify cancer type; it only signals cancer v. non-cancer. There are 11 claims with 3 independent claims in the Written Submissions. The independent claims are reproduced hereunder:

“WE CLAIM:
1. An in vitro method for detecting cancer, characterized by detecting cancer using, as an indicator, the reaction of nematodes to the smell of a subject-derived bio-related substance or a processed product thereof,
wherein when the nematodes show a positive response to the smell of the subject-derived bio-related substance or a processed product thereof, the response result serves as the indicator to make a determination that the subject has cancer or has cancer risk, and
wherein the bio-related substance or a processed product thereof is a body fluid, cells, tissues, a culture of the cells or tissues, or a preservative solution of the cells or tissues.

***** ***** *****

5. A method for identifying an olfactory receptor in nematodes, characterized by using mutant nematodes modified with at least one

selected from the group consisting of deletion of olfactory receptors, inhibition of expression or function of olfactory receptors, and high expression or high-functionalization of olfactory receptors; and a body fluid, cells, tissues, a culture of the cells or tissues, or a preservative solution of the cells or tissues of cancer patients; and identifying an olfactory receptor by testing responses of the mutant nematodes to the body fluid, cells, tissues, the culture of the cells or tissues, or the preservative solution of the cells or tissues.

***** ***** *****

10. An in vitro method for identifying cancer types, characterized by identifying cancer types using, as an indicator, the reaction of nematodes to the smell of a subject-derived bio-related substance or a processed product thereof, the method comprising the following steps:

(a) detecting cancer by the method as claimed in any one of claims 1 to 4;

(b) testing the reaction to the smell of a sample, which has been detected to have cancer in the step(a), by using modified nematodes, which have been prepared by modifying a receptor identified by testing the reaction to a smell in nematodes engineered to inhibit the expression of a gene encoding an olfactory receptor; and

(c) when the reaction to the smell is different between the modified nematodes and the nematodes used in the step (a), the reaction result serves as an indicator to make a determination that the cancer types corresponding to the identified receptor are cancer types as a target of the identification."

12. As per the learned Counsel for the Appellant, the core inventive feature of the present invention lies in the detection process, which utilizes the olfactory response of nematodes to biological samples for identifying the presence / risk of cancer *in vitro*. The specification is like a genus which serves as an enabling disclosure, ensuring that PSITA can practice the invention without undue experimentation, while the claims are like species. It is case of the Appellant that the said interpretation aligns with established patent jurisprudence recognizing claims, not the description, that determine the scope of legal protection.

13. Therefore, the Appellant submitted that in the Subject Application, the independent claims (particularly Claim Nos. 1 and 10) are directed to "an *in vitro* method for detecting cancer" using nematodes' olfactory behavior as an indicator. In other words, the claim language explicitly restricts the scope to "*in vitro*" condition. The Appellant also relied on Paragraph Nos. 51 and 52 of ***The Chinese University of Hong Kong*** (*supra*) and argued that the assessment to be undertaken is whether the test is inherently and *per se* capable of identifying the disease, disorder or condition for treatment of the person. The relevant paragraphs are reproduced hereunder:

> *"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 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 recognize that several technological advancements have been made in diagnosis,*

> *especially by using genomic tools. With a view to incentivize 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."*

14. *Per contra*, the Respondent while relying on the Paragraph No. 30 of the decision in ***The Chinese University of Hong Kong*** (*supra*) submitted that that Section 3(i) of the Act, in contrast to Article 52(4) of the EPC, does not contain the expression "practised on the human or animal body", therefore, reinforces the conclusion that the expression "diagnostic" under the said Section 3(i) of the Act extends both to *in vitro* and *in vivo* diagnosis. The relevant paragraph is reproduced hereunder:

> *"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."*

15. The Respondent also relied upon the decision in ***Natera Inc. and Anr.*** (*supra*) which describes that the manner in which diagnosis is performed under the "diagnostic process" is important to determine the patentability. The relevant paragraphs are reproduced hereunder:

> *"61. The intention behind these provisions is clearly to provide immunity to medical practitioners, technicians, nursing attendants and other persons, who may be coming in contact with human beings or animals requiring diagnosis or treatment. Thus, any process used by such persons using their own skill and knowledge*

> *for diagnosis or medicinal, surgical, curative, prophylactic, therapeutic treatment would be excluded from patentability. For example, if the medical practitioner finds a new process of diagnosing diabetes by looking at a patient's skin, such a process would not be patentable as it would be permissible for all practitioners to use that process. However, if a tool is developed for diagnosing diabetes by merely placing the same on the skin of a human being, such a tool or product can be patented.*
>
> ***** ***** ****
>
> *79…. (e)* ***'Diagnostic process' - The manner in which diagnosis is performed would not be patentable, for example, the manner of checking blood pressure using different tools, the manner of doing a swab test, the process of checking glucose levels, etc., would not be patentable****. However, diagnostic products, diagnostic tools, diagnostic devices are patentable so long as they satisfy the test of patentability and they do not unfairly monopolize processes of diagnosis which are to be generally used by medical practitioners, nurses etc.* ***It is also clear that Section 3(i) does not make any distinction between in vivo or in vitro processes****…*
>
> **** **** ****
>
> *99. This Court also notes that the subject invention may have been patented in some foreign jurisdictions, however, the statutory prohibition in India being what it is, the mere grant in foreign jurisdictions would not lead to grant of the patent in India."*

16. On this, the Appellant argued that the Claim Nos. 1 to 4 of the present invention relates to "an *in vitro* method of detecting cancer" and therefore, it is clear that the method of the invention is not performed on human body but *in vitro* that is on samples obtained from the subjects.

17. Contrary to the submission of the Appellant, the Paragraph No. 79 of ***Natera Inc. and Anr.*** (*supra*) clearly notes that the Section 3(i) of the Act does not make any distinction between *in vivo* or *in vitro* processes. Both ***The Chinese University of Hong Kong*** (*supra*) and ***Natera Inc. and Anr.*** (*supra*) have clearly interpreted that Section 3(i) of the Act prohibits both *in vivo* and *in vitro* processes. Therefore, Section 3(i) of the Act does not differentiate between the *in vivo* and *in vitro* processes.

18. To understand the present invention, it is important to peruse the Complete Specification of the Subject Application to determine the object and the detail of the method claimed. According to the Complete Specification, the problem solved by the present invention is to detect the cancer by using the chemotaxis of nematodes based on the olfaction / the response of olfactory neuron. The problem solved by the preset invention is reproduced hereunder:

> *"MEANS TO SOLVE THE PROBLEM*
> *[0008]*
> *As a result of intensive studies directed towards solving the aforementioned problem, the present inventor has found that cancer can be detected, using the chemotaxis of nematodes based on the olfaction thereof 5 or the response of olfactory neuron, thereby completing the present invention."*

19. The Complete Specification under the title "Effect of the Invention" states that the method of the present invention under the Subject Application also involves the collection and analysis of samples. The relevant paragraph is reproduced hereunder:

> *"EFFECT OF THE INVENTION*
> *[0013]*
> *According to the present invention, a method for detecting cancer using a nematode is provided. According to the method of the present invention, cancer can be detected with high sensitivity and at low costs. Moreover, according to the method of the present invention, collection and analysis of samples are carried out easily, and also, it is inexpensive. Furthermore, the method of the present invention is able to detect early cancer. Therefore, the method of the present invention is extremely useful for clinical tests for cancer."*

20. Further, the Paragraph Nos. [0027] and [0028] of the Complete Specification of the Subject Application states that the accuracy was found 100% in detection of cancer. The chemotaxis index has the values from +1

to -1, where the chemotaxis index has a plus value when the nematodes are attracted to the sample, i.e., urine of the subject have cancer. On the other hand, when the nematodes avoid the sample, the chemotaxis index has a minus value. The method involves the repetition of the analysis to be performed on the specimen, and the mean of the repeated chemotaxis index value is calculated. This would increase the accuracy of the result. Under the heading "Embodiments for carrying out the Invention", the Complete Specification states as reproduced hereunder:

> *"The reactions of nematodes to the urine of healthy subjects and cancer patients have been examined. As a result, the nematodes have exhibited an avoidance 20 behavior to the urine of the healthy subjects, whereas they have exhibited an attraction behavior to the urine of the cancer patients. As a result of the examination performed on 30 specimens, the accuracy was found to be 100% (Figure 1)."*

21. Further, Paragraph No. [0030] of the Complete Specification of the Subject Application states that the present cancer diagnosis system is able to detect early cancer, even at early cancer stage 0 or 1, can be detected with high accuracy. The Paragraph No. [0030] of the Complete Specification is reproduced hereunder:

> *"[0030]*
> *(i) The present cancer diagnosis system is able to detect early cancer. Even early cancer of stage 0 or 1 can be detected with high accuracy. A specimen, which had been determined to be negative by an existing tumor marker at the time point of urine collection (2011), has been tested positive by this test. This 10 patient has developed cancer during two years in the follow-up observation. That is to say, cancer undetectable by the existing tumor markers can be detected by the present invention.*
> *(ii) The presence of many types of cancers can be diagnosed by a single test. That is, many types of cancers can be diagnosed by a single medical examination. To date, it 15 has been confirmed that gastric cancer, colon/rectal cancer, esophageal cancer, pancreatic cancer, prostate cancer, bile duct cancer, breast cancer, malignant*

lymphoma, gastrointestinal stromal tumor, cecal cancer, and lung cancer can be detected by the present cancer diagnosis system.
(iii) The present cancer diagnosis system has high sensitivity. 20 In a test using 30 specimens, the present cancer diagnosis system has been able to detect cancers at sensitivity/specificity of 100%. Moreover, even in a mid-scale test (using 242 specimens), the present cancer diagnosis system has been able to detect cancers in cancer patients at a sensitivity of 100% and at a specificity of 95%."

22. Based on the above discussion of the Complete Specification, under the Subject Application, the following can be asserted:

a. Based on the repetition of the analysis to be performed on the specimen, the outcome / result is highly accurate. As per Paragraph No. [0030] of the Complete Specification, the present cancer diagnosis system is able to detect early cancer, even early cancer stage 0 or 1, and can detect with high accuracy.

b. The invention relates to a method of detecting cancer involving the steps like collection of data, comparison of the data with standard values, and that leads to a conclusion based on the result.

23. Therefore, as per the Complete Specification, the claimed method can detect cancer, including early-stage cancer, with a high rate of accuracy. Therefore, the claimed method leads to the detection of cancer.

24. The Appellant submitted that the detection methods differ significantly from diagnostic methods. The Paragraph Nos. 51 and 52 of ***The Chinese University of Hong Kong*** (*supra*) interpret the provision of not to limit the scope of the word "diagnosis" under the Section 3(i) of the Act to *in vivo* cases only. As per the said decision, the *in vitro* cases should also fall under the scope of the Section 3(i) of the Act. On the other hand, the Respondent, relied on Paragraph No. 30 of the said decision, which states that the absence of the expression "practised on the human or animal body"

in Section 3(i) of the Act reinforces the conclusion that the expression "diagnostic" in Section 3(i) of the Act extends both to *in vitro* and *in vivo* diagnosis.

25. The Paragraph No. 55 of ***The Chinese University of Hong Kong*** (*supra*) also states that if the invention in question is incapable of identifying the existence or non-existence of a disease / disorder condition and further, testing would be required for such purpose, it would be outside the purview of Section 3(i) of the Act. The same is also reiterated in Paragraph No. 94 of ***Sequenom Inc. & Anr.*** (*supra*), wherein the Court held that the patent office has itself been inconsistent by granting patents for some *in vitro* diagnostic-related processes while rejecting others.

26. The learned Counsel for the Appellant submitted that the detection methods claimed under the present invention differ significantly from diagnostic methods. Diagnostic methods require the skill as well as knowledge of the physician or surgeon to analyze and interpret symptoms, while in the case of detection, the result is not accompanied by a discussion.

27. The learned Counsel for the Appellant submitted that detection is viewed as an independent process directly obtained by the detection method, which does not require the skill and knowledge of a physician or surgeon.

28. The learned Counsel for the Appellant further submitted that Claim No. 5 of the present invention is directed to "a method for identifying an olfactory receptor in nematodes", which is a method is for use in deciding which nematodes to use in the cancer detection method and, therefore, is not related to the diagnostic method.

29. As per the Impugned Order, the object under the present invention claims a method for detecting and characterizing cancer type in human subject, which is not allowed under Section 3(i) of the Act.

30. Under Paragraph Nos. 100 and 101 of the decision in ***Sequenom Inc. & Anr.*** (*supra*), the Court held that since the extremely accurate test has 98.6% sensitivity and 99.8% specificity, it leads to conformity. It emphasized that when the language of Section 3(i) of the Act uses the word diagnostic, it would include both positive and negative diagnoses. Accordingly, since there is a tangible result achieved by the test which is being performed, it would defeat the purpose of Section 3(i) of the Act if a patent is granted. The application cannot be held to be patentable merely because the test does not confirm the presence of a particular medical condition. Although it was affirmed that it does eliminate the need for further examination in respect of that medical condition, it was held that "*While there can be no doubt that the subject invention could be a useful invention, the mere fact that it is an in vitro method would by itself be insufficient to make the invention patentable, so long as the purpose of the process is to diagnose a medical condition.*"

31. The term "diagnostic process" has been explained in Paragraph No. 79 of ***Natera Inc. and Anr.*** (*supra*), wherein the Court held that the manner in which the diagnosis is performed would not be patentable. The Court further observed that with the help of examples that the manner of checking blood pressure using different tools, the process of checking glucose levels, the manner of doing a swab test etc., would not be patentable.

32. In the same way, in the present invention, the method leads to the identification of cancer with high accuracy. Additionally, the Court in ***The Chinese University of Hong Kong*** (*supra*), stated that even screening test would qualify as "diagnostic" for purposes of Section 3(i) of the Act if it identifies the disease, disorder or condition *albeit* subject to confirmation by definitive tests. The relevant paragraph is reproduced hereunder:

> *"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 noninvasive prenatal testing (NIPT), reference may be made to the publication by Medline Plus titled "What is noninvasive prenatal testing (NIPT) and what disorders it can screen for" and the publication by the American Clinical Laboratory Association Screening v. Diagnostic:*
> *Understanding Noninvasive 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."*

33. Therefore, based on the discussion of the Complete Specification, it is inferred that the Complete Specification of the Subject Application provide that the process sought to be patented is not limited to just a screening process for diagnosing cancer before it happens, but it also is a general diagnosing method for cancer. Therefore, the invention claimed in Subject Application would fall under the Section 3(i) of the Act.

34. Further, Paragraph No. 50 of ***The Chinese University of Hong Kong*** (*supra*) also supports the above view. The relevant paragraph is reproduced hereunder:

> *"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 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 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."*

35. The Appellant argued that the diagnostic methods require the skill and knowledge of the physician or surgeon to analyze and interpret symptoms, while in the case of detection, the result is not accompanied by a discussion. This Court is of the view that it is immaterial who performs the method. In such a situation, it would be challenging if this section is kept limited to only methods practiced by medical practitioners as the application would be patentable even if the method would be completely autonomous.

36. Further, the Complete Specification of the Subject Application provides that the process sought to be patented is not limited to just

screening process for diagnosing cancer before it happens; but it also is a general diagnosing method for cancer. The Appellant's averment to the effect that specifications can expand or limit the scope of claims is not applicable in the present case because there is a contrast between the import of the specifications versus the import of the amended claims. Even assuming that the amended claims claim only screening, the claims cannot be read contrary to specifications. In ***The Chinese University of Hong Kong*** (*supra*), it was held that to proceed to examine the claims in the context of the specification, it is necessary to determine whether it specifies a process for making a diagnosis for treatment. Therefore, the contention of the Appellant that the determination diagnosing method should be on the basis of claims and not specification cannot be accepted.

37. The proposed amended Claim No. 1 read as "…*wherein the determination that the subject has cancer or cancer risk is used as supporting documentation for a preliminary screening or medical examination, and not as a definitive medical diagnosis…*". However, the Complete Specification shows that the screening claimed in amended Claim No. 1 results in highly accurate results in identification of the cancer. Therefore, the proposed claims cannot be allowed under Section 3(i) of the Act.

38. The proposed amended Claim No. 5 read as "*a method for identifying an olfactory receptor in nematodes for use in the detection method*." Further, the independent Claim No. 10 claims an *in vitro* method for identifying cancer types.

39. The independent Claim No. 10 would proceed/use the cancer detection method claimed in Claim Nos. 1 to 4. Therefore, if proposed

Claim Nos. 1 to 4 are not acceptable under Section 3(i) of the Act, the independent Claim No. 10 would also not be acceptable. As regards the independent Claim No. 5, the Impugned Order rightly held that the said method is a one of the preparatory steps of the claimed diagnostic method as mentioned in Claim No. 1, which decides the identification of nematodes that is to use in the cancer detection method and in isolation, it is of no use.

40. The Impugned Order rightly noted the steps involved in the Subject Application while providing reasons for the claimed method to be a diagnostic method. Accordingly, the Appeal is dismissed and the Impugned Order dated 29.08.2023 is upheld.

TEJAS KARIA, J

JANUARY 17, 2026
KC/N