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

Reserved on: 10.11.2025
Date of Decision: 17.03.2026
Judgment uploaded on: As per digital signature

\+ C.A.(COMM.IPD-PAT) 244/2022 & I.A. 10126/2022

GERON CORPORATION .....Appellant
Through: Mr. Sanjeev Kumar Tiwari & Mr. Shatadal Ghosh, Advocates.

versus

THE ASSISTANT CONTROLLER OF PATENTS AND DESIGNS .....Respondent
Through: Mr. Pratima N Lakra, CGSC with Ms. Kanchan Shakya, Mr. Shailendra Kumar Mishra, Mr. Priyam Sharma & Mr. Chanakya Kene, Advocates.

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CORAM:
HON'BLE MS. JUSTICE MANMEET PRITAM SINGH ARORA

J U D G M E N T

MANMEET PRITAM SINGH ARORA, J

C.A.(COMM.IPD-PAT) 244/2022

1. The present appeal has been filed under Section 117-A of the Patents Act, 1970 ['the Patents Act'], read with Section 151 of the Code of Civil Procedure, 1908 ['CPC'], against the order dated 31.12.2021 ['impugned order'] passed by the Controller/Respondent.

BRIEF FACTS

2. Brief facts necessary for deciding the present appeal are set out below:

3. The Appellant/Geron Corporation is inter alia a large-stage clinical biopharmaceutical company that is focused on the development and potential commercialisation of imetelstst, a first-in-class telomerase inhibitor.

4. On 26.05.2015, the Appellant's PCT application no. PCT/US2013/072302 titled 'DIAGNOSTIC MARKERS FOR TREATING CELL PROLIFERATIVE DISORDERS WITH TELOMERASE INHIBITORS' entered the national phase in India as Indian Patent Application No. 4506/DELNP/2015['Subject Patent Application']. Subject Patent Application claimed methods for the identification of individuals previously diagnosed with a cell proliferative disorder, that would show benefit when treated with a telomerase inhibitor compound, based on the average relative length of telomeres in cancer cells from said individuals.

5. A request for examination of Subject Patent Application was filed on 24.11.2016, and pursuant to examination, the First Examination Report ['FER'] was issued on 20.11.2019. The FER objected to the Patent Application on the following grounds:

a. Claims 1, 6-9, and 16 lacked novelty as required under Section 2(1)(j) of the Patents Act;
b. Claims 1-16 lacked inventive step as required under Section 2(1)(ja) of the Patents Act;
c. Claims 1-16 were not allowable under Section 3(i) of the Patents Act as the claims were directed towards a method of diagnosis.
d. Claims 1-16 were not allowable under Section 3(d) of the Patents Act, as the process had been disclosed in the prior art and was, hence, directed towards the mere use of known process.
e. Claims 1-16 were not allowable under Section 3(j) of the Patents

Act, as the said claims related to biological samples from the individual.

f. Claims 1-16 were indefinite, broad, vague and did not clearly define the scope of the invention and did not comply with the requirements of Section 10(4)(c) of the Patents Act.

6. Thereafter, the Appellant filed a detailed response to the FER on 08.06.2020. A hearing notice was issued on 05.02.2021 scheduling the hearing for 05.03.2021, wherein certain objections in the FER as regards to the lack of inventive step under Section 2(1)(j) and (ja) and lack of patentable subject matter under Section 3(d), (i), and (j), sufficiency of disclosure under Section 10 of the Patents Act were maintained.

7. The Appellant addressed all objections through detailed oral arguments, discussed possible claim amendments, and explained the technical advancement of the invention over the cited prior art. Pursuant to the oral hearing, the Appellant filed detailed written submissions along with the amended set of claims and relevant documents on 19.04.2021. The Appellant submitted 14 amended claims, of which only Claim 1 (as follows) is an independent claim:

> An in vitro screening method of selecting an individual diagnosed with or suspected of having cancer who will benefit from treatment with a telomerase inhibitor, the method comprising:
>
> a. determining relative telomere length by analysing the relative length of telomeric nucleic acids in cancer cells present in a biological sample from the individual; and
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> b. selecting an individual who will benefit from treatment with a telomerase inhibitor when the average relative telomere

length in the cancer cells present in a biological sample from the individual is determined to be in the 50th percentile or less of a relative telomere length range determined from a known standard, wherein the cancer is a solid tumor; and wherein: the known standard is a telomere length range established from naturally occurring tumors from individuals wherein cancer cells from the naturally occurring tumors are of the same type as the cancer cells present in the biological sample from the individual diagnosed with the cancer; or

the known standard comprises characterised cell lines.

8. However, subsequent to the filing of the written submissions, the Controller *vide* the impugned order refused to grant the patent in respect of the Subject Patent Application.

SUBMISSIONS BY THE PARTIES

Submissions by the Appellant

9. Learned counsel for the Appellant has made the following submissions:

9.1. It is stated that the hearing notice dated 04.02.2021 had specified objections under section 2(1)(j), 3(d), 3(i) and 10(4). The impugned order stated that the objections under section 3(j) and 10(4) had been met; however, it failed to give any finding whether the Appellant met the objections under section 2(1)(j) and 3(d).

9.2. Claim 1 of the invention is directed towards an in vitro screening method for selecting an individual who has already been diagnosed with cancer or is suspected of having cancer. The Controller's claim that the invention is a diagnostic method, is incorrect. The Controller has disregarded its own Manual of Patent Office Practice and Procedure and Guidelines for

Examination of Biotechnology Applications for Patent, March 2013 published by the Office of Controller General of Patents, Designs & Trademarks ['Guidelines'], which defines diagnosis as '*Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests'*. However, Claim 1 is directed to an individual, who has already been diagnosed or is suspected of having cancer. The method of Claim 1 does not and cannot ascertain or identify the disease the individual is suffering from, i.e., whether the individual is suffering from cancer and if so, then what is the nature of the cancer.

Reliance by the Controller on the Guidelines to reject the invention under section 3(i) is incorrect as the Guidelines themselves state that they do not constitute rule-making, and, hence, lack the force of law.

9.3. Considering that the invention pertains to the measurement of the relative length of the telomere and is not a diagnostic, the telomere length cannot be considered a diagnostic marker.

9.4. Under Section 138(4) of the Patents Act, the title and specification of a PCT application are adopted as such at the national phase, with no scope for amendment at that stage; the title reflects the US patent regime, not Indian law. The Controller's own practice contradicts its stand, as it has granted patents with diagnostic titles.

9.5. The Controller's argument for a restrictive interpretation of 'diagnosis' is unsustainable; the term must be given its plain and ordinary meaning as recognised in law and by the Controller's own materials. The Supreme Court has held that where statutory words are clear and unambiguous, Courts must give effect to their plain meaning, and the Controller has failed to show any alternative meaning of 'diagnosis'.

9.6. The Controller's claim that the invention amounts to a method of treating cancer is incorrect and based on an improper reliance on the original PCT Claims 2 and 3. Such reliance is contrary to settled law, as patentability must be examined on the claims as they stand in the national phase, not on originally filed PCT claims reflecting a different (US) patent regime. By relying on the original PCT claims, the Controller failed to examine the amended claims and effectively ignored them without authority.

9.7. The Controller's statement that changes in preamble or drafting do not alter claim scope shows a de facto rejection of the amended claims, in violation of principles of natural justice.

9.8. The Controller's contention that the claimed invention is barred under section 3(i) of the Patents Act, as substantiated by prior art D1, is also incorrect. The Controller has submitted that *'D1 discloses monitoring a patient for adverse event related to telomerase inhibition therapy, involving testing a biological sample from the patient for average/median telomere length'*. This submission clearly conceded that D1 is only directed towards monitoring the patient for adverse events after the administration of the telomerase inhibition therapy, and therefore, is not relevant to the claimed invention, which is a screen and hence is conducted prior to the actual treatment of the patient.

9.9. Subject Patent Application at issue in this appeal has been granted in multiple jurisdictions across the world, including in Europe, the US, Japan, etc. The grant of the application in Europe is pertinent because the EPC has a similar bar to patentability as section 3(i) of the Patents Act, namely 53(c).

9.10. The Controller's argument on the basis of the cost factors for the public at large, especially for Indians, where a large portion of the Indian public is

not insured or is not able to access higher-cost private healthcare, is also misplaced, given that healthcare requirements are met.

9.11. The claimed invention, which is the subject of this appeal, is merely a screen and, as claimed, does not render the subject free of cancer.

9.12. Reliance is being placed upon the judgment of Madras High Court in **Chinese University of Hong Kong v. Assistant Controller of Patents & Designs**[1].

Submissions by the Controller

10. In response, the learned counsel for the Controller has made the following submissions:

10.1. It is stated that the Controller has correctly characterised the claimed invention as a diagnostic method related to the medical treatment of a cancer patient, as the same is apparent from the following:

a. First, the claimed method is performed on a biological sample of the subject patient.
b. Second, the method is diagnosing the telomere length in the cells of the subject patient; here, telomere length is a diagnostic marker.
c. Third, the assessment of telomere length is being done for the purpose of telomerase inhibition therapy of the subject patient, which will be done on those patients who have short telomeres.
d. Fourth, the title of the invention also indicated the same 'DIAGNOSTIC MARKERS FOR TREATING CELL PROLIFERATIVE DISORDERS WITH TELOMERASE INHIBITORS'.
e. Fifth, the short telomere length in a subject is indicative of higher

[1] 2023 SCC OnLine Mad 6372 [CMA (PT) No. 14/2023 and CMP No. 16669/2023]

telomerase activity, which needs to be treated with telomerase inhibitors.

f. Sixth, Section 3(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.

In view thereof, the claimed method falls within the scope of non-patentable subject matter under section 3(i) of the Patents Act.

10.2. This contention is further substantiated by the fact that the prior art D1 discloses monitoring a patient for an adverse event related to telomerase inhibition therapy, involving testing a biological sample from the patient for average/median telomere length.

10.3. A plain reading of the ground (P) of the appeal itself sufficiently indicates that the invention is directed to the diagnosis of certain parameters based on which the treatment of cancer patients is to be carried out.

10.4. The word 'diagnosis' cannot be given a restrictive meaning as is sought to be given, for a process by which a disease is identified. 'Diagnosis' is also necessary at various stages of a disease.

10.5. The exclusion of diagnostic tests and methods under TRIPS was introduced to address cost concerns and ensure public access, particularly in India, where a large segment of the population lacks insurance or access to expensive private healthcare. Any interpretation as urged by the Appellant would run completely contrary to this underlying intent.

10.6. Reliance is being placed upon the judgments of **Chinese University of**

Hong Kong v. Controller of Patents & Designs[2], **Natera Inc. & Anr. v. Assistant Controller of Patents and Designs**[3], and **Sequenom Inc & Anr. v. The Controller of Patents**[4]**.**

ANALYSIS

11. I have heard counsel for the parties and perused material on record.

12. This Court shall first examine the analysis made by the Controller in the impugned order. The relevant parts of the impugned order are as follows:

> "**Analysis:**
>
> The description nowhere discloses any "in vitro screening method". At para [0183] "Stained slides were **screened** under IN Cell Analyzer 2000 (GE Corp.) to collect the fluorescent signal intensity and fluorescent signal area of DAPI (nuclei) and Cy3 (telomere)." There is only mention of screen word. "in vitro" word has been used at para [0031] and [0064] which is not related to presently claimed method but related with some other facts related to the technical field. As analysed above in para 5, **when subject matter of the claims are same, the scope of the claim will remain same regardless of its preamble or way of drafting the claim by disguising to look different in scope of invention.**
>
> **9. NON-PATENTABILITY UNDER SECTION 3(i) of the Patents 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*." The argument of the applicant's learned agent is: "The claims are defining an in vitro technique of screening an individual already diagnosed with the disease and thus the screening method cannot be construed as method of treatment or diagnosis". The argument of the learned agent is not persuasive because the method presently claimed is firstly performed on a biological sample obtained from suspected as well as diagnosed cancer patient. Secondly, the claimed method is encompassed as method of treating cancer (see original PCT claims 2 and 3). This is also substantiated by the fact that the prior art D1 discloses

[2] 2023 SCC OnLine Mad 8616 [CMA (PT) No. 1/2023 and W.P. No. 7666/2023]
[3] 2025: DHC:8937
[4] 2025: DHC:8926

monitoring a patient for an adverse event related to telomerase inhibition therapy, involving testing a biological sample from the patient for **average/median telomere length**.

Guidelines for Examination of Biotechnology Applications for Patent defines- "**Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests."** While, the said guideline further makes it clear through an illustrative example:

ILLUSTRATIVE EXAMPLE:

Claim: A method of monitoring drug response in a patient suffering from cancer treated with a combination of Gemcitabine and P1446A, comprising detection of a gene signature with at least two drug response markers, wherein the said drug response markers are selected from the group consisting of P21, REV3L, FGF5, PTK7, POLH, P27 and SSTR2.

Analysis: The subject-matter of claim is directed to method of diagnosis of human beings or animals, which are statutorily barred from the patentability under Section 3 (i) of the Patents Act. Hence, the subject-matter of claim is not patentable.

This is clear to a skilled person from above example that the determining relative telomere length by analysing the relative length of telomeric nucleic acids are done on biological sample from the subject. Present application is also based on the similar detection of telomere length from the sample of the subject for estimating a telomerase inhibitor drug response. The presently amended claims 1-14 neither change the subject matter and scope of the claims nor intended purpose of the diagnosis and treatment of the cancer in human subject. Amended claims 1-14 are clearly indicating method of diagnosis and its implication in the method of treatment for cancer in a suspected or diagnosed cancer patient.

Based on the above analysis and findings, I am convinced that present claims 1-14 are directed to a non-patentable subject matter as defined u/s 3(i) of the Patents Act, being diagnostic method related to cancer in human subjects and has direct application in method of treating cancer in a patient. Since claims define nonpatentable subject matter, therefore, other patentability criteria u/s 2(1)(j) and 3(d) have not been assessed further.

10. The Applicant submitted the amended claims 1-14 on 19 April, 2021 along with the written submissions to the hearing. The amended claims 1-14

> do not meet the requirements of patentability in view of the above analysis and findings, the requirements of objections of hearing notice u/s 3(i) is not met, and hence, I refuse this patent application **4506/DELNP/2015** for the grant of a patent."

13. From the above extracted analysis made by the Controller in the impugned order and the submissions advanced by the counsel of both parties, it is clear that the Subject Patent Application has been refused because the subject matter claimed therein falls under Section 3(i) of the Patents Act for being a diagnostic method for the treatment of cancer patients.

14. Therefore, the issue arising before this Court for consideration in this matter is the patentability of an in vitro cancer patient/suspected cancer patient screening method for telomerase inhibitor therapy under Section 3(i) of the Patents Act.

Exclusion of Diagnostic Method Under Section 3(i) of the Patents Act

15. Before analysing the subject matter of the present appeal, this Court shall first analyse the legal position of exclusion of a diagnostic method for treatment under Section 3(i) of the Patents Act.

16. Section 3 of the Patents Act lists different categories of subject matters that are not eligible for patent protection in India. Section 3(i) of the Patents Act excludes treatment methods from patentability. The said section is extracted below for clarity:

> "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;"

17. In 2019, the office of the Controller General of Patents, Designs and

Trademarks issued a **Manual of Patent Office Practice and Procedure** version 3.0, 26.11.2019 [hereinafter 'the Manual']. This Manual gives guidance to patent offices for the applicability of Section 3(i) of the Patents Act. Relevant Section 09.03.05.08 of the **Chapter- 9: Examination & Grant,** is as follows:

> "Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention. **This provision excludes the following from patentability:**
>
> a) Medicinal methods: for example a process of administering medicines orally, or through injectables, or topically or through a dermal patch.
> b) Surgical methods: for example a stitch-free incision for cataract removal.
> c) Curative methods: for example a method of cleaning plaque from teeth.
> d) Prophylactic methods: for example a method of vaccination.
> e) **Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic.**"
>
> [Emphasis Supplied]

18. Further, an illustration of the diagnostic method falling under Section 3(i) of the Patents Act is given in the Biotechnology Guidelines. The same has also been relied upon by the Controller in the impugned order. However, it is argued by the Appellant that the reliance made by the Controller on the Biotechnology Guidelines is incorrect since it lacks force of law.

19. This Court has considered the argument of the Appellant. However, this Court is of the considered opinion that the Guidelines are established to ensure uniformity and consistency among examiners and controllers of the Patent Office in practices in the examination of patent applications in the relevant field. The role of Guidelines is not rule-making; however, they play a

significant role in the examination process for patent applications at the patent office. Thus, reliance of the Controller on the Guidelines cannot be said to be erroneous unless the relevant portion of the Guidelines relied on by the Controller is proved to be wrong or is inconsistent with the Patents Act. In the present case, the Appellant has failed to show the same. Therefore, reliance by the Controller on the Guideline, which they are bound to do in appropriate cases, cannot be held against them. While saying this, this Court also accepts that such Guidelines are to be timely updated to incorporate legal and technological developments. Otherwise, the gap between judicial positions on specific subject matter and patent office practices widens and may lead to errors in examination. The said provision of the Guideline relied on by the Controller is as follows:

> "**ILLUSTRATIVE EXAMPLE:**
>
> Claim: **A method of monitoring drug response in a patient suffering from cancer treated with a combination of Gemcitabine and P1446A, comprising detection of a gene signature with at least two drug response markers, wherein the said drug response markers are selected from the group consisting of P21, REV3L, FGF5, PTK7, POLH, P27 and SSTR2. Analysis: The subject-matter of claim is directed to method of diagnosis of human beings or animals, which are statutorily barred from the patentability under Section 3 (i) of the Patents Act. Hence, the subject-matter of claim is not patentable.**"
>
> [Emphasis Supplied]

20. The scope of Section 3(i) of the Patents Act has also been clarified by various High Courts. In **Chinese University of Hong Kong v. Assistant Controller of Patents & Designs** (supra) wherein the High Court of Madras has examined the exclusion of the diagnostic method under Section 3(i) of the Patents Act in detail. The relevant paragraphs of the said decision read as follows:

"26. 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.

27. 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."*

28. 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

29. 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."

30. 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."*

31. 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.

……

46. 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.

47. 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).

……

Screening and Diagnosis

49. In medical literature, a distinction is often drawn between screening and diagnosis. Such distinction is typically made on the basis that asymptomatic persons are screened, persons at risk of any disease, disorder or condition are put through preliminary tests for early diagnosis and symptomatic persons are put through diagnostic tests. This raises the question whether such screening of asymptomatic persons would qualify as diagnostic for purposes of Section 3(i). In my view, if a screening test is capable of identifying the existence or nonexistence of a disease, disorder or condition and/or the site, extent, severity or other aspects thereof for treatment of human beings, irrespective of whether the person concerned is symptomatic or asymptomatic, such screening test would qualify as a diagnostic test. In other words, the label used for the test - be it screening or anything else - is not determinative.

50. Medical literature also makes the distinction between screening and

diagnosis on the basis that diagnostic tests are required to confirm the results of screening tests. Even in the specific context of noninvasive prenatal testing (NIPT), reference may be made to the publication by Medline Plus titled "*What is non-invasive prenatal testing (NIPT) and what disorders it can screen for"* and the publication by the American Clinical Laboratory Association "*Screening* v. *Diagnostic : Understanding Non-invasive Prenatal Screening*". Adopting this approach, in my view, is also not in consonance with the meaning of "diagnostic" in Section 3(i), i.e. capable of uncovering the pathology. Put differently, if the screening test identifies the disease, disorder or condition albeit subject to confirmation by definitive tests, it would still qualify as "diagnostic" for purposes of Section 3(i) because the provision does not use the qualifier "definitive".

51. What is determinative, therefore, of whether a test is diagnostic is to ask the question whether the test is inherently and *per se* capable of identifying the disease, disorder or condition for treatment of the person. It bears repetition that such capability of the test should, in turn, be determined by assuming that person(s) skilled in the art, including a medical doctor, examine the results. If the person(s) skilled in the art would not be in a position to diagnose the disease, disorder or condition, as the case may be, on the basis of the process because the process is not designed to diagnose diseases, disorders or conditions, such process, whether labelled as screening or anything else, would not qualify as diagnostic for purposes of Section 3(i). In order to clarify, I provide one illustration in the context of non-invasive prenatal testing. It is conceivable that a novel and inventive process to isolate the cell free foetal DNA from the biological sample may be invented. This process cannot *per se* uncover pathology and, therefore, would not qualify as "diagnostic" as per the principle formulated above. I recognise that the line of demarcation between diagnostic and nondiagnostic 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."

[Emphasis Supplied]

21. A Co-ordinate Bench of this Court has recently clarified the exclusion

of diagnostic method under Section 3(i) of the Patents Act in **Natera Inc. & Anr. v. Assistant Controller of Patents and Designs** (supra). Relevant paragraphs from the said judgment read as follows:

> "79. Thus, in view of the above discussion, the salient points for interpretation of Section 3(i) of the Patents Act may be summarised as under:
> ……
>
> (ii) A perusal of the various terminologies used in Section 3(i) of the Act shows that the exclusions are meant for processes which are employed by medical practitioners, paramedical personnel, nurses, etc. The interpretation of key terms in Section 3(i) of the Patents Act in the context of other provisions of the Patents Act would be as under:
> ……
>
> (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 monopolise 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.**"
>
> [Emphasis Supplied]

22. The same Bench in **Sequenom Inc & Anr. v. The Controller of Patents** clarified further that the bar of Section 3(i) of the Patents Act would also apply to diagnostic methods that though do not confirm pathology but influence the medical practitioner's treatment decision. Which is as follows:

> "102. In the opinion of this Court, when the language of the Section 3(i) of the Act uses the word diagnostic, the same would include positive and negative diagnosis. The persons who are eliminated from undergoing further confirmation tests in respect of any medical condition, genetic abnormality etc., shows that there is a tangible result achieved by the method/ test which is being performed. **It would defeat the purpose of Section 3(i) of the Act,**

if a test is held to be patentable merely because the test does not confirm the presence of a particular medical condition, although it does eliminate the need for further examination in respect of that medical condition.

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

[Emphasis Supplied]

23. Further, a limited reference to the Article 53 (c) of European Patent Convention ['EPC'] is made to take note of the international practice as it is relevant for the present appeal and was duly taken into consideration by Co-ordinate Bench of this Court in **Natera Inc. & Anr. v. Assistant Controller of Patents and Designs** (supra) and **Sequenom Inc & Anr. v. The Controller of Patents** (supra). According to EPC, in vitro diagnostic methods are permissible subject matter for patent grant. The relevant provision of EPC is reproduced hereunder for clarity:

"Article 53
Exceptions to patentability
European patents shall not be granted in respect of:
.....
(c) methods for treatment of the human or animal body by surgery or therapy and **diagnostic methods practised on the human or animal body**; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

24. Guidelines for Examination in the European Patent Office, April 2025 edition by the European Patent Office ['EPO'] further clarifies the diagnostic

method as follows:

> "**4.2.1.3 Diagnostic methods**
>
> Diagnostic methods likewise do not cover all methods related to diagnosis. To determine whether a claim is directed to a diagnostic method within the meaning of **Art. 53(c)** and so excluded from patentability, it must first be established whether it includes all of the necessary phases (**G 1/04**).
> The claim must include method steps relating to **all** of the following phases:
>
> (i)the **examination phase**, involving the collection of data
> (ii)the **comparison** of the data with standard values
> (iii)the **finding of any significant deviation**, i.e. a symptom, during the comparison
> (iv)the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary **decision phase** (diagnosis for curative purposes in the strict sense)."

25. From the Patents Act, Manual, Guidelines and judgments cited above, the principles relevant for adjudicating the present appeal concerning the exclusion of diagnostic methods under Section 3(i) of the Patents Act are as follows:

I. The word 'diagnostic' in Section 3(i) must be construed as diagnosis for treatment of human beings, and not every test that is merely useful or relevant to medicine.

II. The diagnostics may/may not reveal a medical condition. However, the deciding factor is whether it is contributing to the decision-making by the medical practitioner for treatment.

III. Section 3(i) does not distinguish between in vivo and in vitro diagnosis, and, therefore, in vitro diagnostic processes can also be patent-ineligible.

IV. Patent eligibility under Section 3(i) must be determined by examining the claims in the context of the complete specification, not by isolated phrases or drafting labels.

V. The test is whether the claimed process is inherently capable of enabling a diagnosis for treatment, assuming a person skilled in the art [including a medical doctor] assesses the claim and its results.

VI. A diagnosis need not be definitive to attract Section 3(i). If a process supports a diagnosis for treatment, even if subject to confirmation, it can still be excluded.

VII. The distinction between 'screening' and 'diagnosis' is not determinative, and screening tests can be 'diagnostic' if they identify a disease/condition [or its aspects] for treatment.

VIII. Processes employed by medical practitioners/paramedical staff/nurses are the principal target of Section 3(i) exclusions, reflecting a policy against monopolising treatment methods.

IX. The 'manner or process of diagnosis' is not patentable, such as processes for checking blood pressure, performing swab tests, or checking glucose levels.

X. Diagnostic products, tools and devices may be patentable, provided they meet patentability requirements.

XI. The Guidelines indicate that biomarker-based monitoring of drug response in a patient is considered a diagnostic method and is, therefore, barred under Section 3(i) of the Patents Act.

XII. The EPO practice shows four [4] stages as constituents of the diagnostic method practised on the human/animal body, i.e., examination phase,

comparison with standard values, finding of any significant deviation and decision phase.

26. Now, in light of the principles laid above, this Court shall examine the claims and complete specification of the Subject Patent Application to enquire if the same falls within the exclusion of diagnostic methods under Section 3(i) of the Patents Act.

27. The latest amended claim set of the Subject Patent Application comprises fourteen [14] Claims, of which Claim 1 is the only independent claim, and Claims 2-14 are dependent. The independent Claim 1 of the Subject Patent Application is as follows:

> "1. **An in vitro screening method of selecting an individual diagnosed with or suspected of having cancer who will benefit from treatment with a telomerase inhibitor**, the method comprising:
>
> a. determining relative telomere length by analysing the relative length of telomeric nucleic acids in cancer cells present in a biological sample from the individual; and
>
> b. selecting an individual who will benefit from treatment with a telomerase inhibitor when the average relative telomere length in the cancer cells present in a biological sample from the individual is determined to be in the 50th percentile or less of a relative telomere length range determined from a known standard, wherein the cancer is a solid tumor; and wherein: the known standard is a telomere length range established from naturally occurring tumors from individuals wherein cancer cells from the naturally occurring tumors are of the same type as the cancer cells present in the biological sample from the individual diagnosed with the cancer; or the known standard comprises characterised cell lines."
>
> [Emphasis Supplied]

28. The afore-extracted Claim 1 of the Subject Patent Application covers an in vitro screening method of selecting an individual diagnosed with or

suspected of having cancer who will benefit from treatment with a telomerase inhibitor. This method primarily involves two [2] major steps, which are:

i. Determining relative telomere length by analysing the relative length of telomeric nucleic acids in cancer cells present in a biological sample from the individual.

ii. Selecting the individual for benefit from telomerase inhibitor treatment [decision/selection step]. Selecting the individual who will benefit from treatment when the measured average relative telomere length in the cancer cells is ≤ 50th percentile of a reference telomere-length range [known standard], where the standard is either:

   a. a range established from naturally occurring tumors of the same cancer type, or

   b. characterised cell lines.

29. For further clarification regarding the steps of the screening method claimed in the Subject Patent Application, relevant paragraphs from the detailed description of the Complete Specification of the Subject Patent Application are extracted below:

> "*IV. Methods of the Invention*
>
> [0080] In some aspects, methods for selecting an individual diagnosed with or suspected of having cancer who will benefit from treatment with a telomerase inhibitor are provided herein. These methods are based on determining the average relative length of telomeres in cancer cells present in a biological sample from the individual. **If the average telomere length in cancer cells present in a biological sample from the individual is determined to be in the 50th percentile or less of a relative telomere length range determined from one or more known standards, then the individual diagnosed with or suspected of having cancer will benefit from treatment with a telomerase inhibitor (such as any of the telomerase inhibitors provided herein).** In other aspects, the telomerase inhibitor compounds disclosed herein can be used for the treatment and/or prevention

of a cell proliferative disorder (such as cancer) when the average relative telomere length in cancer cells present in a biological sample from the individual is determined to be in the 50th percentile or less of a relative telomere length range determined from one or more known standards.

……

B. *Methods for selecting individuals who will benefit from telomerase inhibitor treatment*

[0095] Provided herein are methods for selecting an individual diagnosed with or suspected of having cancer that will benefit from treatment with a telomerase inhibitor. Telomere length is determined by analysing the length of telomeric nucleotides in cancer cells present in a biological sample from the individual. By "benefit" it is meant that there is a positive or beneficial difference in the severity or occurrence of at least one clinical or biological score (such as, but not limited to, progression free survival), value, or measure used to evaluate such individuals in those who have been treated with the telomerase inhibitor compounds of the present invention as compared to those that have not.

1. Obtaining biological samples

[0096] Biological samples from individuals diagnosed with or suspected of having a cell proliferative disorder (such as cancer) can be obtained in various ways. For example, a biological sample can be obtained from a solid tumor, which may be a subcutaneously accessible tumor or from any other type of cancerous solid tumor accessible to biopsy or surgical removal. The biological sample may be obtained by any method known in the art including, but not limited to, needle or core biopsy or fine needle aspiration. Additionally, the biological sample may be fixed, paraffin embedded, fresh, or frozen before telomere length is determined. In some embodiments, the biological sample is formalin fixed and then embedded in paraffin. In some embodiments, the individual has or is suspected of having a blood-home cancer *(i.e.,* a hematological cancer, such as, but not limited to, leukemia, lymphoma, etc.). In this case, a biological sample may be obtained from the individual's blood.

2. Measuring telomere length in biological samples

……

[0116] The PCR methods described herein may also be used to measure

an individual's reaction to treatment with a telomerase inhibitor (such as any of the telomerase inhibitors disclosed herein). The rate at which the relative telomere length shortens in solid tumors over the treatment time is measured to determine the reaction of the individual to the telomerase inhibitor.

3. Selecting an individual diagnosed with or suspected of having cancer who will benefit from treatment with a telomerase inhibitor

[0124] In some aspects, provided herein are **methods for selecting an individual diagnosed with or suspected of having cancer who will benefit from treatment with a telomerase inhibitor, the method comprising: determining relative telomere length by analysing the relative length of telomeric nucleic acids in cancer cells present in a biological sample from the individual; and selecting an individual who will benefit from treatment with a telomerase inhibitor when the average relative telomere length in the cancer cells present in a biological sample from the individual is determined to be in the 50th percentile or less of a relative telomere length range determined from one or more known standards. In some embodiments, the telomerase inhibitor comprises an oligonucleotide. In some embodiments, the telomerase inhibitor is imetelstat. In another embodiment, the cancer is small cell lung cancer, breast cancer, prostate cancer, or a hematological cancer. In still other embodiments, the individual is a human**."

[Emphasis Supplied]

30. The above paragraphs, extracted from the detailed description of the complete specification of the Subject Patent Application, describe the two-step method claimed in the Subject Patent Application. The method is used to select individuals to determine whether they will benefit from telomerase inhibitor treatment. According to the said method, if the telomere length in the identified cell is ≤ the 50th percentile, the individual will benefit from treatment.

31. It is also pertinent to note that the Controller in the impugned order has taken note of the original PCT Claims to understand the nature and scope of

the claims of the Subject Patent Application. The Controller, on perusal of Claim 1, Claim 2 and Claim 3 of the original PCT application, concluded that the scope of the invention is for the diagnosis and treatment of Cancer. Pertinently, the said finding of the Controller is not disputed by the Appellant.

The Controller has thereafter examined the corresponding voluntary amended claims dated 24.11.2016, and concluded that the expression 'in vitro screening method' has been inserted by amendment to disguise the method of diagnosis and treatment to appear as an 'in vitro screening method'.

Lastly, the Controller takes note of the amended claims filed in the post hearing written submissions and after comparing it with corresponding claims of the PCT application concludes that the change in the language of the amended claims does not affect the substance of the subject matter covered in the claims of the Subject Patent Application, which in his opinion is a diagnostic method for treatment of cancer. This analysis has been set out in detail by the Controller at paragraphs '6 to 8' of the impugned order, and in the considered opinion of this Court, the said analysis of the Controller is correct and merits no interference.

32. Thus, applying the principles elucidated from the Patents Act, Manual, Guidelines, judgments to the claims and detailed description of the complete specification of the Subject Patent Application, the following can be inferred:

i. The claimed method is an in vitro screening method used to select individuals eligible for telomerase inhibitor therapy for the cure or prevention of cancer. The decision of whether the individual is given the said treatment is made based on the result of the claimed method.

ii. An illustration of this method in lay language is that, if a patient who is suffering from, or suspected of having, cancer visits a medical

practitioner, the patient's biological sample containing the patient's cancer cells will be tested for telomere length analysis. If it falls within the claimed range [for example, at or below the 50th percentile of a known standard range], that patient will be selected for telomerase inhibitor treatment to prevent or treat cancer.

iii. This method involves the collection and examination of a sample from the selected patient, then comparison of the patient/suspected patient's telomerase length with standard telomerase length, identifying the deviation and deciding whether the patient/suspected patient receives the telomerase inhibitor therapy.

iv. The screening label of the method is insufficient to distinguish it from a diagnostic method, since it forms part of treatment decision-making. [**Re: Chinese University of Hong Kong v. Assistant Controller of Patents & Designs** (supra)].

v. The method, even though it does not reveal cancer, since the finding is the factor for deciding the treatment for the patient, will fall under the diagnostic method [**Sequenom Inc & Anr. v. The Controller of Patents** (supra)**]**.

vi. This method, even though it is an in vitro method since it forms part of the treatment, and also since Section 3(i) of the Patents Act does not distinguish between in vivo and in vitro diagnostic processes, squarely falls within the exclusion of treatment methods under said provision.

vii. Granting a patent to this subject matter will result in monopolising a medical practitioner's medical decision-making practice of measuring telomere length, and applying a threshold rule [≤50th percentile] to select patients for telomerase inhibitor therapy. Such a monopolisation

is in violation of Section 3(i) of the Patents Act. **[Re: Natera Inc. & Anr. v Assistant Controller of Patents and Designs** (supra)].

viii. Exclusion of similar subject matter is also illustrated in the Guidelines, where drug response is monitored post-treatment, whereas here it is monitored before treatment. In effect, both methods clearly fall under the treatment methods used by medical practitioners.

ix. Dependent Claims 2-14 do not change the nature of the subject matter claimed in Claim 1; instead, they further narrow the scope.

33. From the above inferences, it could be concluded that the subject matter claimed in the Subject Patent Application, though drafted as an 'in vitro screening method', is in substance a method for selecting cancer patients/suspected cancer patients who will benefit from treatment with a telomerase inhibitor, based on the determination of telomere length and application of a percentile threshold. The claims, even though they do not reveal the medical condition, are an essential part of the medical practitioner's decision-making in prescribing a telomerase-inhibition treatment. Therefore, this Court is of the opinion that the subject matter covered in the claims of the Subject Patent Application, when read along with the detailed description provided therein, covers a diagnostic process that forms the basis of the treatment of human beings. In view of Section 3(i) of the Patents Act, as clarified in the Manual, the Guidelines, and various decisions, the claimed methods are not patentable.

34. The Appellant's reliance on the grant of a patent in the USA and Europe for a similar grant in India also does not stand any merit. It is now well settled that a mere grant in foreign jurisdictions would not lead to grant of the patent in India, as the examination of the Subject Patent Application is governed by

the provisions of the Patents Act and since the Subject Patent Application has been held to be barred under section 3(i) of the Patents Act, the application has been rightly rejected.

35. The Appellant has relied upon the judgment of the **Chinese University of Hong Kong v. Assistant Controller of Patents & Designs** (supra), to rely upon the analysis of law on section 3(i) of the Patents Act. However, this Court notes that the same analysis of law is also set out in **Chinese University of Hong Kong v. Controller of Patents & Designs**[5], and has already been referred to above. The laws settled in these judgments do not persuade this Court to hold that the Appellant's Subject Patent Application has been incorrectly rejected.

36. Accordingly, for the reasons discussed above, there is no error or infirmity in the finding of the Controller that the Subject Patent Application cannot be granted in terms of Section 3(i) of the Patents Act.

37. Accordingly, the present appeal is dismissed.

38. Pending application stands disposed of.

39. The Registry is directed to supply a copy of the present order to the office of the Controller General of Patents, Designs & Trade Marks of India on the e-mail- llc-ipo@gov.in.

MANMEET PRITAM SINGH ARORA
(JUDGE)

MARCH 17, 2026/aa/fv

[5] 2023 SCC OnLine Mad 8616 [CMA (PT) No. 1/2023 and W.P. No. 7666/2023]