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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 13.03.2025

CORAM:

THE HONOURABLE MR. JUSTICE SENTHILKUMAR RAMAMOORTHY

C.M.A.(PT)No.40 of 2024

University of Washington
4545 Roosevelt
Way NE, Suite 400, Seattle,
Washington 98105-4721,
United States of America. .. Appellant

Vs.

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

Prayer : Civil Miscellaneous Appeal (Patent) file under Section 117 of the Patents Act, 1970 (as amended by the Tribunals Reforms Act, 2021) praying to set aside the order passed by the Assistant Controller of Patents & Designs dated 26.04.2021 in relation to the Patent Application No.201747006075 and direct the Respondent to grant the patent and publish the grant in the journal

https://www.mhc.tn.gov.in/judis (Uploaded on: 17/03/2025 12:38:11 pm)

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For Appellant : Ms.Vindhya S.Mani
for Lakshmi Kumaran and Sridharan
Attorneys

For Respondent : Mr.A.R.Sakthivel, SPC
Dr,Bhanumathi R. Controller

JUDGMENT

This appeal is directed against the order dated 24.06.2021 rejecting application No.201747006075 for grant of patent for an invention titled "METHODS OF DETERMINING TISSUES AND/OR CELL TYPES GIVING RISE TO CELL-FREE DNA AND METHODS OF IDENTIFYING A DISEASE OR DISORDER USING SAME".

2. The appellant filed the above-mentioned application and requested the respondent to examine the same and issue a report. Pursuant thereto, First Examination Report dated 16.12.2020 was issued. In such report, objections were raised *inter alia* on grounds of lack of novelty and inventive step and on the ground of non-patentability under Sections 3(d), 3(i) and 3(k). The appellant responded thereto on 15.10.2020 and submitted amended claims and amended complete specification. Pursuant to hearing notice dated 16.04.2021, a hearing was

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held on 18.05.2021. After the hearing, the appellant filed written submissions dated 01.06.2021 and enclosed amended claims 1 to 59, which were the claims considered and rejected under the impugned order.

3. Learned counsel for the appellant submitted that the claimed invention was eventually rejected solely with reference to Section 3(i) of the Patents Act. She further submits that the respondent erroneously concluded that the instant method finds application in diagnostics and thereby attracts Section 3(i) of the Act. According to learned counsel, the claimed invention does not per se disclose pathology inasmuch as the disease, disorder or condition cannot be diagnosed entirely on the basis of claimed invention.

4. These contentions are refuted by the respondent. By referring to independent claim 1, it is submitted that the said claim *ex facie* pertains to detection of the presence of tumour-derived cell-free DNA (cf DNA) in a biological sample. Consequently, it is contended that the claimed invention is self evidently a method of diagnosing cancer.

5. The operative portion of the order is as under:

"Objection 5:

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Applicant agent's arguments have been considered but not found persuasive in view of above claims, Claims 1-58 on record states "An in vitro method of detecting the presence of tumor-derived cell free DNA (cfDNA) in a biological sample, the method comprising: determining a sequence associated with at least a portion of a plurality of cfDNA fragments isolated from the biological sample"

The instant method finds application in diagnostics and thereby still attracts section 3(i) of Act. The amended claims are not patentable u/s 3(1) of the Patents Act, 1970.

Section 3(i) of Patent Act 1970 states: 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 amended claims it appears that the amended claims are drawn to a method of prognosis or detection or diagnosis (complete specification). In view of this, section 3(i) objection holds good. The amended claims on record 1 to 58 are not eligible for patent grant

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as per the Section 3(i) of the Patents Act."

6. It is evident from the above extract that after setting out a part of independent claim 1, a conclusion was drawn that the method finds application in diagnostics and therefore falls within the scope of Section 3(i) of the Patents Act. In the *Chinese University of Hong Kong v. The Assistant Controller of Patents, 2023:MHC:4616, and The Chinese University of Hong Kong and another v. the Assistant Controller of Patents, 2023:MHC:4617*, I interpreted Section 3(i) and concluded that it applies to claimed inventions which would per se disclose pathology to a person skilled in the art. Put differently, not every claimed invention that is relevant for diagnosis would fall within the ambit of Section 3(i) of the Patents Act. Since the operative portion of the impugned order does not contain a discussion on these aspects before recording conclusions, reconsideration is necessary.

7. Therefore, the impugned order dated 24.06.2021 is set aside and the matter is remanded for reconsideration on the following terms:

(i) In order to preclude the possibility of pre-determination and to avoid embarrassment to all concerned, an officer other than the officer

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who issued the impugned order shall undertake reconsideration.

(ii) After providing a reasonable opportunity to the appellant, a reasoned order shall be issued within four months from the date of receipt of a copy of this order after taking note of the observations made herein.

(iii) For the avoidance of doubt, it is made clear, however, that no observations have been made on the merits of the patent application.

8. CMA(PT) No.40 of 2023 is disposed of on the above terms. There shall be no order as to costs.

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Index : Yes/No

Internet : Yes/No

Neutral Citation : Yes/No

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To

The Assistant Controller of Patents and Designs
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G.S.T.Road, Guindy, Chennai-600 032.

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SENTHILKUMAR RAMAMOORTHY J.

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