



\$~2

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

+ **C.A.(COMM.IPD-PAT) 58/2024**

NATALJA EIKJE

.....Appellant

Through: Mr. Tarun Gandhi, Ms. Gauravi
Arora and Ms. Nanki Arneja, Advocates.

versus

JOINT CONTROLLER OF PATENTS AND DESIGNS

.....Respondent

Through: Mr. Ankur Mittal, CGSC with Ms.
Rabaica Jaiswal and Mr. Hrithik Saxena,
Advocates.

CORAM:

HON'BLE MS. JUSTICE JYOTI SINGH

ORDER

22.04.2026

%

1. This appeal is filed by the Appellant under Section 117A of the Patents Act, 1970 ('1970 Act') laying a challenge to order dated 15.04.2024 passed by the Respondent, whereby the patent application of the Appellant has been refused under Section 15 of the 1970 Act on the ground that claims 1-6 are not patentable under Section 3(i) of the 1970 Act.

2. To the extent necessary, facts of the case are that US Priority Application No. 61/595,050 was filed on 21.02.2012 and PCT International Application No. PCT/EE2013/000001 was filed on 21.02.2013. Indian Patent Application No. 7173/DELNP/2014 was filed as National Phase Application on 26.08.2014 out of PCT International Application by MC PROFESSIONAL OU, EIKJE, Natalja and SKREBOVA, Irina, as co-



applicants. Voluntary amendment of description and claims of instant application was filed on 13.04.2018 on Form-13. First Examination Report (FER) was issued on 26.02.2021, wherein Respondent raised objections related to lack of inventive step, lack of patentability etc., under Sections 2(1)(ja), 3(d), 3(i) and 3(k), to which reply was filed on 26.08.2021 along with amended set of claims. After hearing was concluded, Appellant filed post-hearing written submissions on 15.10.2023 along with amended set of claims. However, vide impugned order dated 15.04.2024, Respondent refused the grant of patent.

3. Learned counsel for the Appellant submits that Appellant is a Norwegian national with research experience of several years in the fields of dermatology, venereology, physiology, clinical physics, radiology, tomography, medical instrumentation, physiological biophysics and specializes in discovering and developing new approaches to cure skin cancer. Her research is focused on understanding the mechanisms behind carcinogenesis. Present invention relates to *'An in vitro method of comparative spectral pattern analysis of nucleic acids and proteins molecules sequentially expressed in benign, premalignant and malignant tumourous tissues for characterizing multistage epidermal carcinogenesis model and indicating the grade of neoplastic activity in cells on a biopsied skin tissue sample by FTIR microspectroscopy'* (claims 1-6) and *'an FTIR microspectrometer'* (claims 7-10) and *'a combination group of nucleic acids and proteins molecules with characteristic spectral parameters and with characteristic intra- and inter-molecular expression of DNA, RNA and proteins'* (claims 11-16). It is urged that the present application provides an optical method for characterization of carcinogenesis in skin tumourous



tissues based on FTIR microspectroscopy and more specifically, it provides an analytical method for simultaneous observation and further characterization of intramolecular and intermolecular interactions for nucleic acids and proteins commonly and specifically expressed in an IR spectrum of pathology, with respect to understanding molecular, cellular and tissue changes occurring during skin carcinogenesis.

4. Learned counsel *inter alia* raises two broad grounds challenging the impugned order. It is urged that a total of 16 claims were made by the Appellant and while there were no objections raised against claims 7-16, the entire set of claims have been rejected *in toto* on the ground that claims 1-6 are not patentable under Section 3(i). Assuming for the sake of argument, there was an objection *qua* claims 1-6, Respondent ought to have passed an order granting claims 7 to 16, which admittedly, do not fall within the purview of Section 3(i) and this is a sufficient ground for setting aside the impugned order and remanding the matter.

5. With regard to rejection of claims 1-6 under Section 3(i) of the 1970 Act, it is urged that Respondent failed to appreciate the response to FER, wherein Appellant had brought forth that the present application provides an *in vitro* method of comparative special pattern analysis of nucleic acids and proteins, molecules for characterizing multistage epidermal carcinogenesis model, indicating the grade of neoplastic activity in cells by FTIR microspectroscopy, wherein analysis of said spectral pattern provides intermediate findings, which by themselves do not relate to method of detection. More specifically, present invention provides an analytical method for simultaneous observation and further characterization of intra- and inter-molecular interactions for nucleic acids and proteins expressed in



the Infrared (IR) spectrum of epidermal with respect to understanding molecular, cellular and tissue changes occurring during skin carcinogenesis. Hence, present application discloses *in vitro* method of comparative spectral pattern analysis for characterizing multistage epidermal carcinogenesis and indicating grade of neoplastic activity in cells on a biopsied skin tissue sample by FTIR microspectroscopy. The problem of common and specific characterization of carcinogenesis in human skin tumors by FTIR microspectroscopy remains unresolved in the prior art.

6. It is urged that for determining grant of patent, it must be seen whether claims defined a process for making a diagnosis for treatment and it is evident from the impugned order that Respondent has completely failed to technically comprehend the claimed invention and has incorrectly determined the metes and bounds thereof. Method claims 1-6 claims do not relate to a process of treatment or diagnosis but define an *in vitro* method of comparative spectral pattern analysis of nucleic acids and proteins molecules and therefore, claims 1-6 are not related to diagnosis for the treatment of humans and thus cannot be considered non-patentable under Section 3(i) of the 1970 Act. It is well settled that there are inherent differences in diagnostic methods and other methods such as screening. A test qualifying as diagnostic should inherently identify a disease or condition for potential treatment. Respondent has erroneously opined that an expert in medical field can analyze such spectral patterns of sequentially expressed nucleic acids and proteins for a systemic progression of the grade of activity of nucleic acids and proteins within one type of tumor in association with MM to be characteristic for malignant skin tumor progression in the same patient and clearly this view is unsupported in law as also scientific literature.



Respondent has also wrongly held that claims 1-6 contain method steps which are performed on patients, overlooking that the claims disclose an *in vitro* process.

7. Mr. Ankur Mittal, learned CGSC defends the impugned order *albeit* it is fairly not disputed that there was no objection with respect to claims 7-16. It is urged that reading of claims 1-6 reveals that Appellant is claiming a diagnostic process and the claims fall under the scope of Section 3(i) since the claimed method, which is an *in vitro* method of comparative spectral pattern analysis of nucleic acids and proteins molecules, sequentially expressed in benign, premalignant and malignant tumorous tissues for characterizing multistage epidermal carcinogenesis model and indicating the grade of neoplastic activity in cells, is a diagnostic process. The term ‘diagnosis’ means discovery of source of patient’s illness from the study of its symptoms and claimed invention is aimed at determining the degree of neoplastic activity in cells on a biopsied skin tissue. When the claims itself provide for characterization which enable an expert in the medical field to characterize the carcinogenesis and decide the tumor type, it is safe to assume that the method involves diagnosis of the nature of the disease or how the biopsied sample is working. On the other hand, if it was only screening as per the case of the Appellant, it would not have led to any characterization of multistage epidermal carcinogenesis model and indicate the grade of neoplastic activity in cells on a biopsied skin tissue.

8. It is further urged that use of FTIR microspectroscopy is merely the technique or tool employed to carry out the analysis and the choice of technology does not alter the nature of the outcome. Outcome of the claimed process is to determine or indicate a disease or its condition and is thus, a



diagnosis process. The method indicates the grade of neoplastic activity in cells i.e., determining progression and severity of cancer and objective is to distinguish between different stages of carcinogenesis and thereby provide a clear indication of how advanced the disease is, which is diagnosis in itself. The end result of the claimed method is a definitive medical determination regarding the presence, nature and stage of a disease, which is the core and essential function of diagnosis. Once a method enables such determination it necessarily assumes the character of a diagnostic method within the meaning of Section 3(i). Reliance is placed on the judgment of the Madras High Court in *Chinese University of Hong Kong and Another v. Assistant Controller of Patents & Designs, 2023 SCC OnLine Mad 6372*, wherein the Court laid down the test for determining whether a claimed process falls within the scope of a ‘diagnostic method’ under Section 3(i) and held that any process which leads to identification, detection or determination of a disease, its condition or progression would qualify as a diagnostic method.

9. Heard learned counsels for the parties and examined their submissions.

10. The instant patent application relates to ‘*An in vitro method of comparative spectral pattern analysis of nucleic acids and proteins molecules sequentially expressed in benign, premalignant and malignant tumourous tissues for characterizing multistage epidermal carcinogenesis model and indicating the grade of neoplastic activity in cells on a biopsied skin tissue sample by FTIR microspectroscopy*’ (claims 1-6) and ‘*an FTIR microspectrometer*’ (claims 7-10) and ‘*a combination group of nucleic acids and proteins molecules with characteristic spectral parameters and with characteristic intra- and inter-molecular expression of DNA, RNA and*



proteins’ (claims 11-16).

11. It is an undisputed position that when the FER was issued, no objections were raised against claims 7-16. Despite this, the Respondent has refused the subject application in entirety, which cannot be countenanced in law and to this extent, Appellant is right that the impugned order stands vitiated and the patent application deserves to be considered afresh.

12. Insofar as claims 1-6 are concerned, grant of patent has been refused on ground of non-patentability under Section 3(i) of the 1970 Act. Learned CGSC defends the order by urging that diagnosis means determination of the source and nature of the disease from a study of its symptoms and claims 1-6 relate to a process method involving spectral analysis of nucleic acids and proteins derived from tissue samples, which are sequentially expressed across benign, premalignant and malignant conditions. The method is not confined to observing or recording molecular characteristics but is specifically designed to interpret such data in a manner that yields medically significant conclusions and indicates the grade of neoplastic activity in cells i.e., determines the progression and severity of cancer. The claims are thus not patentable under Section 3(i) which was introduced by the legislature to exclude from patentability, methods which relate to medical, therapeutic and diagnostic treatment of human beings.

13. Counsel for the Appellant, on the other hand, urges that claims 1-6 fall outside the scope of Section 3(i) as they have no relation to diagnostic method and are strictly confined to an *in vitro* method of comparative spectral pattern analysis of nucleic acids and proteins molecules sequentially expressed in tumorous issues for characterizing a multistage epidermal carcinogenesis model and indicate the grade of neoplastic activity in cells on



a biopsied skin tissue sample by FTIR microspectroscopy, wherein the *in vitro* method is not a method of diagnosis of an ailment associated with a human being and/or animal.

14. On examination of the impugned order, I find merit in the stand of the Appellant that the patent application deserves to be considered again. One of the blatant and apparent error in the impugned order is the understanding and perception of the Respondent that the claimed method is diagnosis performed on patient, whereas claims 1-6 are strictly confined to an *in vitro* method, which means studies, experiments or diagnostic tests performed outside a living organism in a controlled laboratory environment and involve using components of an organism such as cells, tissues or molecules isolated from their normal biological surroundings, for instance, in test tubes, petri dishes etc.

15. Further, Appellant has brought forth that a test qualifying as diagnostic should inherently identify a disease or a condition for potential treatment, whereas the claimed invention includes no method for identifying the disease. The analysis of spectral patterns provides intermediate findings which have no relation to detective methods and more specifically, the present invention provides an analytical method for simultaneous observation and further characterization of intra-molecular and inter-molecular interactions for nucleic acids and proteins expressed in the IR spectrum of epidermis with respect to understanding molecular, cellular and tissue changes during skin carcinogenesis. None of these issues have been considered in the impugned order and Respondent has proceeded by treating the claimed invention as one relating to diagnosis performed on patients. Therefore, in my view the impugned order is untenable in law.



16. Accordingly, without entering into the merits of the case, the impugned order dated 15.04.2024 is quashed and set aside and the matter is remanded back to the Respondent for re-consideration of patent application no. 7173/DELNP/2014 in accordance with law. Decision will be taken by the Respondent within three months from today, after granting an opportunity of hearing to the Appellant. It is made clear that the decision will be taken on the basis of existing material on record of the Respondent and uninfluenced by the observations in this order as also the impugned order.

17. Appeal stands disposed of in the aforesaid terms.

JYOTI SINGH, J

APRIL 22, 2026/RW/AK