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

% *Date of Decision: 12th May, 2026*

\+ C.A.(COMM.IPD-PAT) 32/2025

UNIVERSITY OF NORTH TEXAS & ANR. .....Appellants

Through: Ms. Vaishali Joshi, Mr. Vineet Rohilla and Mr. Ankush Verma, Advocates.

versus

ASSISTANT CONTROLELR OF PATENTS AND DESIGNS .....Respondent

Through: Ms. Nidhi Raman, CGSC with Mr. Arnav Mittal and Ms. Nikita Singh, Advocates.

CORAM:
HON'BLE MS. JUSTICE JYOTI SINGH

JUDGEMENT

JYOTI SINGH, J. (ORAL)

1. This appeal is filed on behalf of the Appellants under Section 117A(2) of the Patents Act, 1970 ('1970 Act') laying a challenge to impugned order dated 31.01.2025 as also for a direction to the Respondent to grant patent in respect of Indian Patent Application No. 202117006438.

2. For the sake of completeness, necessary facts as pleaded in the appeal are that subject application was filed on 29.07.2019 as a National Phase Application of PCT having PCT International Application No. PCT/IB2019/056456 claiming priority from US Patent Application No. 62/712,941 dated 31.07.2018. Subject application was filed before Indian Patent Office ('IPO') on 16.02.2021 for grant of patent for invention titled 'TECHNOLOGIES FOR RAPID DETECTION AND QUANTITATION

OF VOLATILE ORGANIC COMPOUNDS (VOCS) USING BREATH SAMPLES' and was allotted Indian Patent Application No. 202117006438. Request for Examination was filed by the Appellants on 04.07.2022 and First Examination Report ('FER') was issued on 18.04.2023 raising objections under Section 2(1)(ja) for lack of inventive step, non-patentability under Section 3(i), lack of clarity and conciseness and sufficiency of disclosure under Section 10(4) and (5) of 1970 Act. Detailed response was filed by the Appellants to the FER on 25.09.2023 with amended claims 1-19. Hearing was concluded on 21.10.2024, whereafter Appellants filed written submissions on 05.11.2024 along with amended claims 1-19. By order dated 31.01.2025, Respondent refused the subject application on the grounds that the claimed invention lacks inventive step, clarity and conciseness and there is insufficient disclosure as also that the invention was non-patentable under Section 3(i) of 1970 Act.

3. Learned counsel for the Appellants submits that present invention relates to breathalyser systems and devices designed to facilitate quantitative analysis of Tetrahydrocannabinol (THC) and other substances in the field using breath samples (para [0002] of the complete specifications). With rise in the consumption of marijuana due to legalization in some States, it has become necessary to properly quantitate Δ-9-THC, such that an accurate and rapid determination of whether a person is under the influence of marijuana can be achieved. Three cannabinoid compounds are currently analysed to determine cannabinoid concentrations in the blood: Δ-9-THC, 11- hydroxy-tetrahydocannabinol (11-0H-THC) and carboxy-tetrahydrocannabinol (THC-COOH). Currently, techniques for determining the presence of drugs, such as cannabinoids, require analysis via blood plasma, urine or oral fluid

samples. Most analytical techniques use gas chromatography coupled to mass spectrometry (GS/MS). This presents a problem of having to collect a sample and bring it back to the lab for further analysis. These techniques have a long analysis time, with most analyses taking more than 15 minutes to detect cannabinoids. Furthermore, detecting Δ-9-THC using GC/MS can also introduce another problem because the ionization source is electron ionization (EI).

4. It is stated that currently three types of breathalysers are being used by local law enforcement officers in the field i.e., liquid chromatography coupled to mass spectrometry (LC/MS), high-field asymmetric waveform ion mobility (FAIMS) and liquid chromatography coupled to spectroscopy. Existing methodologies highlight various drawbacks. LC/MS is useful for quantitation but cannot be used in the field and requires several minutes to analyse the sample before the cannabinoids can be seen. In other cases *inter alia* either the required resolution or peak capacity to determine the concentration of Δ-9-THC is lacking or the time required to analyse a sample is in the range of 8-15 minutes. Present invention is technologically advanced with several features *inter alia* facilitating detection of cannabinoids and other substances in breath samples in the field and such systems can be used by lawful enforcement agencies to rapidly and accurately identify and detect marijuana in drivers on road.

5. It is urged that Section 2(1)(ja) of 1970 Act defines 'inventive step' as a feature of invention that involves technical advancement as compared to existing knowledge or having economic significance or both and requires that the claimed invention should not be obvious to a person skilled in the art. In the decision in ***Agriboard International LLC v. Deputy Controller of***

Patents and Designs, 2022 SCC OnLine Del 940, this Court has given a framework for assessing an inventive step in view of cited documents and directed that the Controller must consider three elements: (a) invention disclosed in the prior art; (b) invention disclosed in the application under consideration; and (c) manner in which subject invention would be obvious to a person skilled in the art. However, without any analysis on the three elements, Respondent has arrived at a conclusion that the claimed invention lacks inventive step. Division Benches of this Court in ***F. Hoffmann-La Roche Ltd. & Anr. v. Cipla Ltd., 2015 SCC OnLine Del 13619*** has laid down a five-step test to determine obviousness/lack of inventive step and also held that while conducting an enquiry into obviousness, hindsight approach is impermissible and legal conclusion must be reached on the basis of facts gleaned from the prior art and should not include knowledge gleaned from patent disclosure. This position of law was reiterated in and ***Tapas Chatterjee v. Assistant Controller of Patents and Designs and Another, 2025 SCC OnLine Del 6369.*** It is urged that the teachings in prior art documents have to be considered as a whole and teachings away from patent claim are treated as non-obvious. To enquire into obviousness, two-fold enquiry is required to be conducted i.e., motivation to select and motivation to modify. None of these steps have been followed by the Respondent before arriving at the impugned decision and on this ground, the order deserves to be set aside.

6. It is argued that Respondent failed to appreciate the technical aspect of present invention and although an attempt was made to identify the key technical features, the identification was as follows, which was incorrect:-

*"**Key technical features:***

- *A system for analyzing a breath sample*
  - *A sampling chamber*
  - *An inlet coupled to the sampling chamber*
- *A molecule collector disposed within the sampling chamber"*

7. Had the Respondent correctly identified the technical features in claim 1 of claimed invention as also differentiating features with the prior arts, as pointed out by the Appellants in response to FER and written submissions, the decision would have been otherwise. Respondent has clearly failed to identify the person skilled in the art, which is a failure to follow Step-1 of ***F. Hoffmann (supra)*** and has also failed to decide whether the differences pointed out in the cited documents and claimed invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out a hindsight approach. On internal page 24 of the impugned order, Respondent has referred to the differences between D1 and claimed invention but without any comparison and analysis, Respondent has directly reached the conclusion at page 26 that claim 1 lacks inventive step, as follows:-

> *"The system described in Claim 1 lacks inventive steps over D1 as it also involves collecting a breath sample, conditioning it, and detecting VOCs using a sensor. The use of a heating element and a THz spectrometer does not provide a technical advance over the SERS-based detection system described in D1."*

8. The conclusion is thus cryptic and unreasoned on as to how the use of a heating element and a THz spectrometer does not provide a technical advancement over the SERS-based detection system described in D1, when both the features are not disclosed in D1. The only similarity that exists between the two is that both analyse breath samples, which was not enough

to refuse the application. Detailed submissions were filed to show how the teachings of D1 cannot be obvious to a person skilled in the art to lead to the claimed invention but none of these points have been considered and the only reasoning given is that fundamental elements of the system are similar in the prior art. Similarly, with respect to D2, Respondent has failed to point out relevant disclosure or analysis and has simply jumped to a conclusion that the system described in claim 1 lacks inventive step over D2 as it also involves collecting a breath sample, conditioning it and detecting VOCs using a sensor and mere use of heating element and a THz spectrometer is not a technical advance. This Court in ***Best Agrolife Limited v. Deputy Controller of Patents and Another, 2022 SCC OnLine Del 1982*** and ***Otsuka Pharmaceutical Co. Ltd. v. Controller of Patents, 2022 SCC OnLine Del 4982*** has highlighted the importance and mandate of passing reasoned and speaking orders but contrary thereto, the application has been refused by a cryptic, non-speaking and unreasoned order as also without following the five-step test in ***F. Hoffmann (supra)*** and ***Tapas Chatterjee (supra).***

9. It is argued that Appellants filed a detailed response to the FER on 25.09.2023 bringing forth the stark differences between D1 and D2, however, these have not been considered in the impugned order. Respondent has also erred in refusing the application on ground of lack of clarity and sufficient disclosure overlooking that the disclosure provided in the complete specification fully and particularly describes the present invention and its method. Illustratively, Respondent has observed that the material composition, structure and mechanism of adhesion to VOCs are not explicitly explained when the phrase ‘molecule collector’ is used. In a

similar vein, the 'heating element' is referred to but its precise configuration and interaction with the molecule collector is not explained. Paragraphs [0027] and [0028] along with Figure 1 and 2 of the complete specifications of the subject application clearly describe the structure and material composition of the 'molecule collector' and further, the term 'heating element' can be clearly visualized from paragraph [0028] with Figure 1 of complete specification, which states that *'the sampling device 110 may also include or be coupled to a heating element 118 configured to introduce heath within the sampling chamber 110. For example, the heating element 118 may include a power source coupled to the molecule collector 116 and configured to apply a voltage to the molecule collector 116. Applying voltage to the molecule collector 116 may heat up the molecule collector, thereby introducing heat within the sampling chamber 110'.* It is thus clear that the heating element is getting heated by application of voltage which increases the temperature of sampling chamber and heats the molecule collector. A complete chain of interaction between heating element and molecule chamber has been described in the complete specification, which has not been considered by the Respondent.

10. It is argued that the order suffers from several other errors such as in internal page 27 of the order Respondent has observed that although the analysis device that consists of THz spectrometer is detailed, it is unclear how the excitation source and detector work and the claims do not explain how the detector detects target VOCs based on excitation characteristics or how the excitation signal is introduced. The observation completely glosses over paragraph [0032] of the complete specification which describes working of the spectroscope and line 18 whereof states that *'In an aspect,*

the excitation source 320 may be a THz laser device and the excitation signal 324 may be a THz laser signal. In aspects, the one or more characteristics associated with the excitation of at least the portion of the VOCs may include at least one of the absorbance characteristics and a fluorescent emission characteristic, which may be utilized to identify the one or more target VOCs present within the breath sample 102, as described in more detail below. In an aspect, the THz spectrometer components (e.g., the excitation source 320 and the detector 322) may operate under control of, or in coordination with, a computing device, such as a computing device that includes the one or more processors 122, the memory 130, and the one or more I/O devices 126'. Therefore, the description clearly and sufficiently discloses the functioning of the analysis device.

11. As for the objection of non-patentability under Section 3(i) of 1970 Act, it is argued that Respondent has neither analysed the claims nor applied any test for making an assessment whether claimed invention falls within the ambit of 'diagnostic method'. The entire purpose of subject invention is analysis of breath samples to detect certain VOCs and 'Summary' in the complete specifications brings forth that present application claims systems and apparatuses and the methods providing techniques for improved on-site quantification of cannabinoids and other substances from breath samples are disclosed (paragraph [0009] of the complete specifications). The preamble to claim 14, which the Respondent has explicitly objected under Section 3(i), clearly states *'A method for analysing a breath sample, the method comprising: ....'* . There is no discussion in the specification about existence of any disease or disorder let alone claiming a method for diagnosis and impugned order is a result of non-application of mind by the Respondent.

12. Ms. Nidhi Raman, learned CGSC arguing for the Respondent submits that subject application was prosecuted in accordance with provisions of 1970 Act and is a speaking and detailed order and conclusions have been arrived at after carefully considering the specifications and claims of the claimed invention, FER, hearing submissions, both oral and written and other records. The claimed invention lacks inventive step in view of prior arts D1-D2. D1 discloses a system for collecting, conditioning and detecting analytes (drugs) from breath using a spectroscopic sensor (SERS). Mere substitution of SERS with THz spectrometer or addition of heating element, which are standard and known components, does not provide technical advancement. Similarly, D2 discloses a system for sensing analytes in breath using a nanoparticle sensor and fundamentally mirrors the claimed invention i.e., collecting breath, conditioning it and detecting VOCs. Respondent has reasoned that use of heating element and THz spectrometer cannot be a technical advancement over nanoparticle-based detection system described in D2.

13. It is further argued that Appellants' challenge to objection under Section 2(1)(ja) of 1970 Act is primarily based on the assertion that D2 does not disclose a heating element for releasing analytes. The assertion is factually incorrect and inconsistent with their own admission during prosecution that *'Also, D2 at paragraph [0285] discloses: '...An embodiment that aids in increasing sensitivity is shown in FIG. 53... Once the analyte is captured, it is 'flushed out' from the concentrator via some mechanism such as a heater 421'.* Once the heating element is removed as a differentiator, the only difference is use of THz spectrometer in subject application and nanoparticle-based sensor in D2 or SERS sensor in D1. THz

spectroscopy is already a known technique and replacement of one sensor with another is a routine optimization. Hence, there is no technical advancement in the claimed invention.

14. It is urged that the argument of the Appellants that the invention is not a diagnostic method is untenable. Figure 6 of subject application is titled *'graph illustrating observed VOCs for a breath sample of a person suffering from seasonal allergies'* and paragraph [0008] highlights the need for improved detection of *'synthetic opioid overdoses'* in civilians and military personnel. Identifying a drug overdose is a critical medical diagnosis required for immediate therapeutic intervention.

15. On insufficiency of disclosure under Section 10(4) of 1970 Act, Ms. Raman urges that Respondent has provided precise reasoning regarding lack of structural definition for critical claim elements. The order notes that while specification mentions the collector 'can cling' to VOCs, it is not explained what materials, configurations or mechanisms are used to accomplish this and moreover, the nature and extent of innovation is difficult to comprehend due to unclear wordings in the claim, more particularly, claim 1. Similarly, there is lack of clarity and detail for heating element where precise configuration and interaction with the molecule collector is not explained. Many such issues have been raised in the order and it cannot be argued by the Appellants that the impugned order is non-speaking or suffers from non-application of mind.

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

17. The subject application relates to techniques for rapid detection and quantitation of volatile organic compounds (VOCs) using breath samples. In

the FER, objections were raised under Section 2(1)(ja) for lack of inventive step, non-patentability under Section 3(i), lack of clarity and conciseness and sufficiency of disclosure under Section 10(4) and (5) of 1970 Act. Responding to the objections in the FER, Appellants amended the claims deleting claim 20 and resultantly, claims 1-19 were under consideration for grant of patent.

18. The first contention of the Appellants is that the impugned order is unreasoned and non-speaking and the five-step test laid down in ***F. Hoffmann (supra)*** and reiterated in ***Tapas Chatterjee (supra)*** was not followed by the Respondent. For sake of reference, the five steps are as follows:-

> Step No. 1 - To identify an ordinary person skilled in the art;
>
> Step No. 2 - To identify the inventive concept embodied in the patent;
>
> Step No. 3 - To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date;
>
> Step No. 4 - To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications; and
>
> Step No. 5 - To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art and rule out hindsight approach.

19. In ***Tapas Chatterjee (supra)***, Division Bench held that the five steps have to be followed sequentially while examining the aspect of obviousness

and existence of inventive step. In the present case, Respondent has not followed the first step of identifying an ordinary person skilled in the art and this is enough to vitiate the impugned order. In fact, Appellants have pointed out that even the second step of identifying the inventive concept embodied in the invention has also not been followed and a grave error has occurred in identifying the key features, noted above. Insofar as Steps 3-5 are concerned, while the impugned order makes a reference to similarities and differences in the prior arts D1 and D2 and the claimed invention, there is no analysis on whether the differences brought forth by the Appellants between the cited prior arts and the claimed invention would constitute steps which would have been obvious to an ordinary person skilled in the art so as to rule out hindsight approach. Impugned order reflects that at internal pages 24 and 25, Respondent has referred to D1 and D2 but without carrying out further exercise as required in law, reached a conclusion that since D1 discloses a system for collecting a sample from exhaled breath and detecting the presence of analytes such as drugs substances and the system described in claim 1 also involves collecting a breath sample, conditioning it and detecting VOCs using a sensor, mere use of heating element and THz spectrometer does not constitute technical advancement. In response to the FER, Appellants had brought forth how cited portions of D1 and D2, individually or in combination, failed to disclose each and every element of amended claim. For sake of reference, relevant paragraphs are extracted hereunder:-

> *"We respectfully submit that the cited portions of D1 and D2, individually or in combination, fail to disclose each and every element of amended claim 1. For example, the cited portions of D1 and D2 do not disclose "an analysis device comprising a Terahertz (THz) spectrometer that includes*

an excitation source and a detector, wherein the analysis device is configured to: introduce, via the excitation source, an excitation signal within the sampling chamber subsequent to the release of at the least a portion of the VOCs from the molecule collector; identify, via the detector, one or more target VOCs from among the VOCs present in the sampling chamber subsequent to release of at least the portion of the VOCs from the molecule collector, wherein the one or more target VOCs are identified based on one or more characteristics associated with excitation of at least the portion of the VOCs released from the molecule collector in response to the excitation signal; and generate an output representative of the one or more target VOCs," as recited in amended claim 1.

In the FER, the Office indicates that "D1 discloses systems and methods for collecting a sample from exhaled breath of a subject, and for detecting the presence or determining the quantitative amount of analytes in the breath sample. The analytes are for instance drug substances in the exhaled breath. More particularly, the invention relates to such portable systems using Surface Enhanced Raman spectroscopy in a sensor for detecting the analytes from the exhaled breath (see para[0001])." Thus, the cited portions of D1 specifically indicate that the invention uses Surface Enhanced Raman spectroscopy, not Terahertz (THz) spectroscopy. D1 is silent regarding an analysis device that includes a THz spectrometer including an excitation source and a detector. Therefore, D1 does not disclose "an analysis device comprising a Terahertz (THz) spectrometer that includes an excitation source and a detector, wherein the analysis device is configured to: introduce, via the excitation source, an excitation signal within the sampling chamber subsequent to the release of at the least a portion of the VOCs from the molecule collector; identify, via the detector, one or more target VOCs from among the VOCs present in the sampling chamber subsequent to release of at least the portion of the VOCs from the molecule collector, wherein the one or more target VOCs are identified based on one or more characteristics associated with excitation of at least the portion of the VOCs released from the molecule collector in response to the excitation signal; and generate an output representative of the one or more target VOCs," as recited in amended claim 1.

In the FER, the Office indicates that "D2 discloses apparatus comprises a fluid collecting device configured to receive a sample of breath; a conditioning device coupled to the fluid collecting device and configured to receive the sample of breath and condition the sample with respect to at least one of temperature, flow rate, pressure, humidity, and concentration; and a sensing device coupled to the conditioning device and configured to receive the conditioned sample, wherein the sensing device includes a nanoparticle-based sensor and further whereby the analyte interacts with

the sensing device to cause a change that is sensed by the sensing device and wherein the change comprises information useful in characterizing the analyte. Preferably, the apparatus is hand-held and characterizing the analyte is useful for health monitoring (see abstract).” Thus, the cited portions of D2 specifically indicate that characterization of an analyte is based on a change associated with analyte interaction with a nanoparticle-based sensor. D2 is silent regarding an analysis device that includes a THz spectrometer including an excitation source and a detector. Therefore, D2 also does not disclose “an analysis device comprising a Terahertz (THz) spectrometer that includes an excitation source and a detector, wherein the analysis device is configured to: introduce, via the excitation source, an excitation signal within the sampling chamber subsequent to the release of at the least a portion of the VOCs from the molecule collector; identify, via the detector, one or more target VOCs from among the VOCs present in the sampling chamber subsequent to release of at least the portion of the VOCs from the molecule collector, wherein the one or more target VOCs are identified based on one or more characteristics associated with excitation of at least the portion of the VOCs released from the molecule collector in response to the excitation signal; and generate an output representative of the one or more target VOCs,” as recited in amended claim 1.

Consequently, the cited portions of D1-D2, individually or in combination, fail to disclose, teach, or suggest at least the above-cited features of amended claim 1. Hence, amended claim 1 has inventive step in view of D1-D2. Amended claim 14 recites similar features and has inventive step in view of D1-D2 for similar reasons. Amended claims 2-13 and 15-19 depend from amended claims 1 and 14, respectively, and have inventive step at least by virtue of depending from independent claims having inventive step.

At least for the above reasons, we respectfully submit that the amended claims 1-19 constitute an invention as defined under Section 2(1)(j) of the Patents Act, 1970 (“the Act”).

In view of the above, reconsideration and withdrawal of this objection is respectfully requested.”

20. None of these points have been mentioned leave alone analyzation by the Respondent and similar is the position on comparison of independent claim 1 on cited prior art D2, which discloses a system for sensing analytes in a fluid including breath, using a nanoparticle-based sensor. All that is stated in the order is that independent claims do not demonstrate a technical

advance inasmuch as use of a heating element and a THz spectrometer is not a non-obvious improvement over existing technologies. In ***Agriboard (supra)***, this Court held that while adjudicating the subject application for lack of inventive step, it is imperative to consider three elements: (a) invention disclosed in the prior art; (b) invention disclosed in the application under consideration; and (c) manner in which subject invention would be obvious to a person skilled in the art. There is not even a bare minimum discussion in the impugned order on the three elements and their impact on determination of inventive step. As rightly flagged by the Appellants, without such analysis, rejection of the patent application under Section 2(1)(ja) of 1970 Act is contrary to the provision itself and essentially borders on hindsight approach, which has been seriously condemned by the Division Bench in ***F. Hoffmann (supra)***. Pertinently, Appellants had flagged and highlighted what in their perception were material and stark differences between the claims of the claimed invention and prior arts D1 and D2 but none have been analysed and allegedly, even the key technical features have been wrongly incorporated in the impugned order and construed, making a difference to the ultimate conclusion. Even today, Respondent is unable to contest this point and therefore, the matter does require a fresh consideration.

21. On the aspect of Section 10(4) of 1970 Act, both parties have made rival submissions but Court finds merit in the contention of the Appellants that Respondent has not dealt with the objection in the manner required by law. The Bombay High Court in ***JFE Steel Corporation v. The Controller of Patents & Designs, 2026:BHC-OS:4866*** held that *"Having gone through the Impugned Order, I find merit in the aforesaid submission. A plain*

reading of the order makes it clear that the rejection is founded entirely on an alleged failure to meet the requirement of sufficiency of disclosure under Section 10 of the Patents Act, 1970. The Order does not contain any independent analysis or reasoning on the substantive statutory requirements of patentability, namely novelty and inventive step. Thus, in the absence of any findings on the aspect of lack of novelty or inventive step, the Impugned Order would have to be set aside." It is stated in the impugned order that material composition, structure and mechanism of adhesion to VOCs are not explicitly explained when the phrase 'molecule collector' is used and in a similar vein, 'heating element' is referred, but its precise configuration and interaction with molecule collector is not explained. Illustratively, Appellants submitted that the complete specification sufficiently discloses the claimed invention. The impugned order does not even mention or discuss as to what more disclosure was required by the Appellants. It is also argued that paragraphs [0027] and [0028] along with Figures 1 and 2 of complete specification clearly describe the structure and material composition of molecule collector and the term 'heating element' is not just self-explanatory but can be clearly visualised from reading of paragraph [0028] with Figure 1 of complete specification, which states that *'the sampling device 110 may also include or be coupled to a heating element 118 configured to introduce heath within the sampling chamber 110. For example, the heating element 118 may include a power source coupled to the molecule collector 116 and configured to apply a voltage to the molecule collector 116. Applying voltage to the molecule collector 116 may heat up the molecule collector, thereby introducing heat within the sampling chamber 110'* and hence, there is no ambiguity in the claim or lack of

sufficient disclosure. Similar submissions were brought forth with respect to other objections under Section 10(4) and were explained by the Appellants but there is no analysis in the impugned order.

22. On the aspect of non-patentability under Section 3(i) of 1970 Act, Respondent has observed that the technique outlined in claim 14 is a diagnostic method since it focuses on a diagnostic procedure for examining breath samples to identify and measure VOCs. This conclusion has been drawn glossing over the explanation given by the Respondent to support the plea that the claimed invention has been wrongly categorized as a 'diagnostic method'. Appellants relied on the judgment of the Madras High Court in the ***Chinese University of Hong Kong and Another v. Assistant Controller of Patents & Designs, 2023 SCC OnLine Mad 6372,*** where the Court observed that: *'23. The odd one out, as indicated above, is 'diagnostic'. Diagnosis, in the context of medical science, is a method of identifying the existence or non-existence of a disease or disorder or condition and/or the site, extent, severity or other aspects thereof ... '* and pointed out that nowhere in the complete specification is there a discussion about existing of any disease or disorder let alone a method for diagnosis and that the subject application is targeted towards detection of cannabinoids in breath sample of a person who is suspected to be driving under the influence of marijuana (DUIM). The 'Summary' of the complete specifications provides that the present application claims systems, apparatuses and methods providing techniques for improved on-site quantification of cannabinoids and other substances from breath samples. In fact, the Preamble to claim 14 clearly states *'A method for analysing a breath sample, the method comprising:....'*. Appellants rightly contend that

Respondent has neither analysed the claims nor applied any test for making an assessment whether the claimed invention falls within the ambit of 'diagnostic method' so as to be categorized the claimed invention non-patentable under Section 3(i) of 1970 Act. In my considered view, the fallacies brought forth by the Appellants in the impugned order warrant remand of the matter for fresh consideration by the Respondent.

23. For all the aforesaid reasons, impugned order dated 31.01.2025 is quashed and set aside, without expressing any opinion on the merits of the case and is remanded to the Respondent for considering Indian Patent Application bearing No. 202117006438, afresh. The decision will be taken within a period of four months from today, after granting opportunity of hearing to the Appellants as also considering response to the FER and written submissions filed by the Appellants. Needless to state, the order will be a detailed, speaking and a reasoned order and the decision will be taken uninfluenced by the observations in this order or the impugned order.

24. Appeal is partially allowed in the aforesaid terms and disposed of.

JYOTI SINGH, J

MAY 12, 2026/RW