



# PATENTABILITY OF DIAGNOSTIC METHODS IN INDIA: AN ANALYSIS OF CONFLICTING DECISIONS IN INDIAN MEDICO-LEGAL JURISPRUDENCE

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**Abstract:** The term “diagnosis” means to discern a disease based on its symptoms and distinguish it from other possible conditions. The basis of medicine rests in the concept of diagnosis in whose absence effective and timely treatment of illnesses is rendered impossible. Over the course of time, the field of diagnostics rapidly developed with aggressive study by specialists and therefore led to the development of various methods that a doctor may apply to discern the ailment of a patient. The development of these diagnostic methods led to the growing importance of protecting interest of the public, as allowing patentability of such diagnostic methods would restrict accessibility of treatment to all persons and would also result in making healthcare a business run for economic gains. Thus arose the need to protect diagnostic methods from being patentable. Albeit this concept protects the rights of the public, it also affects the interests of inventor by not protecting the novelty of their inventions. Many countries around the globe have not provided patent protection to diagnostic methods and India also joined this league with the amendment of The Indian Patents Act, 1970 in the year 2005. In this amendment, the term ‘diagnostic’ was inserted under section 3(i). As per the provisions of this Act, diagnostic methods do not fall under the category of invention and therefore become ineligible for a patent. However, section 3(i) restricts patentability of diagnostic methods to the extent that it results in treatment of human beings. Various decisions by the Indian Patent Office and the Courts in India have been contradictory in applying the provisions of the Act. This paper aims to make a comprehensive analysis of such conflicting judgments and discern the reasons for this paradox.

**Keywords:** Diagnostic Methods, Patent, Detection, Screening

## 1. BACKGROUND OF THE STUDY:

The first patent legislation in India was enacted in the year 1856 by the British colonial government - British Patent and Design Act. The Act dealt with intellectual property protection to both patents and designs. The Act also established a Central Office of Patents and Designs in Calcutta. This is the first instance where inventions were given protection from misuse and inventors were given exclusive rights over their inventions. The Act underwent various amendments before it was repealed in the year 1970. Post independent India became a party to The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and opted for a new legislation exclusively to deal with patents in accordance with TRIPS mandate. Under this Act, patent protection was given to various inventions for a period of 20 years and which were subject to renewal at the end of this period. The Act allowed for a protection of infringement by opting for a post opposition grant system. The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) also well known as the Indian Patent Office was established and was given the power to decide on patent applications. This Act also underwent various amendments over the years. Among these amendments, the Patents (Amendment) Act, 2005 was significant in relation to patentability of diagnostic methods. As per the 2005 amendment, the term “diagnostic” was added to section 3(i) and restricted the patentability of diagnostic methods only for purposes of treatment of human beings. But this amendment made to section led to a great deal of misunderstanding. The Manual of Patent Office Practice and Procedure and also failed to bring clarity to this area of law. This resulted in various

contradicting decisions by the Indian Patents Office and Appellate Courts. This paper aims to study such contradicting decisions and arrive at reasons for such conflict and provide suggestions to over this situation.

## 2. LITERATURE REVIEW:

The current paper refers to various literatures to understand the concepts of diagnosis, various diagnostic methods, their understanding in the Indian legal scenario, and the analysis on laws on various decisions on patentability of diagnostic methods. **Balogh EP, Miller BT, Ball JR (2015)** was referred to understand the concept of diagnosis on healthcare. The book provided an understanding on the meaning of diagnosis and the extent of its application. The book also provided the various steps undertaken by a doctor in making a diagnosis. **Kassirer J. P. (1989)** studies the level of certainty of a diagnosis. It also studies the contributing factors such as specificity and sensitivity in knowing the certainty of a diagnosis made. **Bolboacă S. D. (2019)** studies the various roles performed by diagnostic tests in the medical field and aims to understand the various phases involved in a diagnosis. The paper also does a statistical study of the probability of obtaining a certain and definite diagnosis based on such methods. **Barolia, S. K., Mishra, B. K., Trpathi, G. K., Hindala, M. R., & Sewda, M. (2020)** – This paper studies the various procedures involved in filing a patent application within India. It also discusses the various procedures and compliances requisite for obtaining a patent in India. **DPS Parmar (2022)** studies the various patent applications in diagnostic and prophylactic methods that were granted and rejected patent by the Indian Patents Office. **Varsha Venkatesh (2024)** studies the patentability of medical methods from a global perspective. The paper analyses the laws on patentability of diagnostic methods in US, UK, Australia and India.

## 3. STATEMENT OF RESEARCH PROBLEM:

The paper studies the provisions governing patentability of diagnostic methods under Patents Act, 1970 and other related legislations. The paper then proceeds to study the various decisions passed on this matter by the Indian Patent Office and Appellate Courts. From this the paper attempts to bring out reasons for contradicting judgments passed regarding the patentability of diagnostic methods in India.

## 4. RESEARCH METHODOLOGY:

This paper follows a doctrinal research methodology. The paper studies the existing laws relating to patentability of diagnostic methods in India, and the surrounding contradictory application of such laws by evidencing various decisions given by both the Indian Patent Office and Appellate Courts.

## 5. RESEARCH METHOD:

The paper studies the provisions of the Patents Act, 1970 in relation to diagnostic methods and all judgments passed regarding the patentability of such methods. For this purpose, both primary and secondary sources of data are used. The statutes and judgments referred are primary sources of data and the literature studied are secondary sources of data.

## 6. RESEARCH QUESTIONS:

1. Whether the decisions given by the Indian Patents Office on different matters dealing with diagnostic methods are consistent in nature?
2. Whether the existing legal framework provides a clear understanding of the conditions for patentability of diagnostic methods?
3. Whether screening tests fall under the scope of diagnostic methods under section 3(i) of the Patents Act, 1970?
4. Whether methods of detection are different from diagnostic methods under section 3(i) of the Patents Act, 1970?

## 7. RESEARCH OBJECTIVES:

The paper aims to understand the status of patentability of diagnostic methods under current Indian legislative framework. It also analyses the various decisions passed by the Indian Patents Office and Appellate Courts. On the basis of this study the paper aims to understand the contributing factors that result in conflicting judgments in Indian medico-legal jurisprudence.

## 8. UNDERSTANDING THE CONCEPT OF DIAGNOSIS:

### 8.1 Meaning of “Diagnosis”

Diagnosis may be defined as the process of identifying the disease or condition of a patient by a physician based on the information gathered from the patient and the results of various diagnostic tests conducted on the patient along with proper medical reasoning.<sup>1</sup>

### 8.2 Process of Diagnosis

When a patient approaches the physician, it is his responsibility to take a detailed medical history of such patient. Then, he must make a note of the patient’s earlier symptoms and the current symptoms presented by the patient. The physician then proceeds to place such patient on observation and based on the severity of the symptoms presented by the patient this observation is either as an outpatient or by admitting him into the hospital.

On the basis of the information gathered from the patient the physician and with an understanding of the symptoms thus far the physician then orders certain diagnostic test. With the results of such tests and all information gathered the physician proceeds to list out all possible diseases which is known as a differential diagnosis.

From the differential diagnosis further tests are conducted on the patient and the working diagnosis is narrowed down also known as diagnostic modification or diagnostic refinement. The patient is administered drugs based on such working diagnosis and this further streamlines the differential diagnosis helping the physician to identify the exact cause of the patient’s symptoms, otherwise referred to as the final diagnosis. At this stage the diagnostic process is complete.<sup>2</sup>

It is pertinent to note that physicians may provide treatments for diagnostic purposes before arriving at the final diagnosis. This can be done to reduce scope of error in diagnosis and reduce diagnostic uncertainty. It also aids in refining the existing differential diagnosis.<sup>3</sup>

Prognosis follows diagnosis where the further progression of the disease, its course of treatment, chances of recovery, and recurrence of the disease are analysed by the doctor and informed to the patient.

### 8.3 Diagnostic Testing

These are test conducted by doctors to determine the likelihood of a patient suffering from a particular disease. The results of such tests would help the doctor to decide whether a patient has a certain disease or not. While it is generally understood that the results of a diagnostic test help determine if a patient has a particular disease, it is unknown to many that diagnostic tests also perform other significant roles.

The following are the roles that are performed by diagnostic tests:

- To either confirm or exclude a condition from the differential diagnosis;
- To perform triage tests that reveal the type of treatment to be provided for a patient that requires emergency medical care;
- To monitor the condition of a patient from time to time;
- At the stage of prognosis to assess the progression of the disease;
- To conduct screening tests on persons who are asymptomatic.<sup>4</sup>

Some examples of diagnostic tests are CT scans, PET scans, Biopsy, Endoscopy, X-rays, MRI scans, Complete Blood Count (CBC) etc.

<sup>1</sup> <https://www.britannica.com/science/diagnosis>

<sup>2</sup> Improving Diagnosis in Health Care Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. Improving Diagnosis in Health Care. Washington (DC): National Academies Press (US); 2015 Dec 29. <https://www.ncbi.nlm.nih.gov/books/NBK338593/>

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## 9. PATENTABILITY OF DIAGNOSTIC METHODS UNDER PATENTS ACT, 1970

The Patents Act of 1970 was enacted to provide patent protection to inventors and to prevent misuse of their inventions by others. This provided an exclusive right to inventors and also caused various suits against infringement of that right.

Under the provisions of the Act, Section 2(1)(m)<sup>5</sup> defines “patent” as all inventions are which are allowed to be under this Act. However, while the Act does not provide a list of inventions which are patentable it certainly provides a list of which are not to be considered to be inventions under the ambit of this Act. Since inventions that are allowed under the Act are patent eligible, Section 3 of the Act which discusses what are not inventions cleverly excludes them from obtaining the exclusive right of patentability.

The Act was initially brought into effect in 1970 after the Ayyangar Committee Report. India later became a party to TRIPS Agreement in 1995 and subsequently three major amendments were made to the 1970 Act of which the amendment made in 2005 proves significant to the field of diagnostics. As per 2005 Amendment, the term “diagnostic” was added to Section 3(i).

As per Section 3(i) of the Act, diagnostic methods were excluded from being given patent certificate. But it is significant to note that the addition of the term “diagnostic” read with the existing provision excluded any diagnostic method from being patentable which had the ability to treat human beings.

## 10. DIAGNOSTIC METHODS DISCUSSED UNDER MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE

The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) also well known as the Indian Patent Office is the authority responsible for examining patent applications and grant patent certificate. The Indian Patent Office follows the Manual of Patent Office Practice and Procedure. According to this manual, the term “Diagnostic methods”<sup>6</sup> is referred to as applying the history and symptoms of a patient to identify the illness and required treatment.

The manual further states that although diagnostic methods are excluded from subject matter of patents diagnostic instrument or apparatus are still patentable. The manual does not mention any other information regarding the patentability of diagnostic methods. This lack of information and lack of clarity in existing provisions has led to a myriad of decisions in various patent applications by the Indian Patent Office.

## 11. GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT, 2013 ON “DIAGNOSTIC METHODS”

The Guidelines for Examination of Biotechnology Applications for Patent, 2013 also discusses concept of “diagnostic methods”. While it also provides the same definition as previously given in the manual it also addresses the use of diagnostic methods for studying gene mutations and target proteins used for diagnosis or treatment of different diseases.<sup>7</sup>

## 12. DECISIONS AND APPEALS ON VARIOUS PATENT APPLICATIONS:

Every application for a patent is filed before the Indian Patent Office consisting of provisional specifications or final specifications depending on a case-by-case basis. These applications are then published after 18 months. After the application is published, pre-grant opposition may be raised. Then there is a request for examination following which the application is either granted or rejected patentability. Applications that were granted patents are then published and another round of opposition is allowed. Finally, the Controller makes a decision on the application. Any dispute arising out of the decision made by the controller is appealed to the High Court having proper jurisdiction to entertain the matter. This process is followed throughout India on a uniform basis.<sup>8</sup>

Usually, the Indian Patent Office rejects all application that is in violation of section 3 and section 4 of the Patents Act, 1970. The main provision that focuses on patentability of diagnostic methods and any restrictions pertaining to the same is section 3(i).

<sup>5</sup> Section 3(i) - Patents Act, 1970 [https://ipindia.gov.in/writereaddata/portal/ipoact/1\\_31\\_1\\_patent-act-1970-11march2015.pdf](https://ipindia.gov.in/writereaddata/portal/ipoact/1_31_1_patent-act-1970-11march2015.pdf)

<sup>6</sup> Manual of Patent Office Practice and Procedure

[https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual\\_for\\_Patent\\_Office\\_Practice\\_and\\_Procedure\\_.pdf](https://ipindia.gov.in/writereaddata/Portal/Images/pdf/Manual_for_Patent_Office_Practice_and_Procedure_.pdf)

<sup>7</sup> Guidelines for Examination of Biotechnology Applications for Patent, 2013

[https://ipindia.gov.in/writereaddata/Portal/ipoguidelinesmanuals/1\\_38\\_1\\_4-biotech-guidelines.pdf](https://ipindia.gov.in/writereaddata/Portal/ipoguidelinesmanuals/1_38_1_4-biotech-guidelines.pdf)

<sup>8</sup> Barolia, S. K., Mishra, B. K., Trpathi, G. K., Hindala, M. R., & Sewda, M. (2020). Patent application procedure and preparation for filing in India. IJCRT, 8, 2098-108.

With the preliminary understanding of the procedure followed the patents office while considering a patent application and the requisite provisions concerning patentability of diagnostic methods we can proceed to understand the various decisions given by the Indian Patents Office and some of the decisions which were appealed to the Intellectual Property Appellate Board and High Courts in order to better articulate the level of understanding and application of the provisions of the Act by the Examiner in assessing and deciding on a patent application.

In the case of *Arthrogen Gmbh Vs. Controller General Of Patents, Designs And Trademarks and Ors*<sup>9</sup> an appeal was filed before the Delhi High Court against the decision of the Indian Patents Office in Patent Application No. 11377/DELNP/2012. The subject matter of this application was regarding a novel method for producing protein rich blood serum which was derived from incubating blood serum obtained in gold and the resultant protein rich blood serum was to be used for purposes of blood transfusion. The court distinguished between a 'method of treatment' and 'a method of producing a novel substance' which may have a variety of usages and allowed the patent application of the appellants.

In *Health Protection Agency Vs. The Controller General of Patents & Designs and Ors*<sup>10</sup>, the patents application no. 3014/KOLNP/2006 was rejected on the ground that it was in violation of section 3(i) of the Patents Act, 1970. The subject matter in this case was a biological process indicator that proved to be useful for validating the level of sterilization of a biological sample. It also ensured the level of hygiene in medical and surgical instruments and therefore the court held it not in violation of section 3(i) and held that the patent in this case was denied without proper application of mind.

In *Tianjin Dishili Investment Holding Group Limited Vs. The Controller General of Patents, Designs Trade Marks and Ors*<sup>11</sup>, the order of the Controller on patents application no. 2254/DELNP/2005 was remanded back to the Controller by reason of merits of the application not properly examined. The court also held that it found the invention in the application to be patent eligible.

In *The Chinese University of Hong Kong and Ors. Vs. The Assistant Controller of Patents & Designs*,<sup>12</sup> the Madras High Court interpreted Section 3(i) of the Patents Act, 1970. The court identified that the term 'diagnostic' as used in the section is different from the other terminologies in the provision as the process of diagnostics involves identifying the existence or non-existence of a disease, and this identification is different from treatment of human beings as given under the section. The court therefore applies the principle of 'noscitur a sociis' and interpreted that the term 'diagnostic' must be such that it leads to a form of treatment. Therefore, any diagnostic method the immediate result of which would lead to a treatment is not an invention under section 3 of the Act and is therefore not eligible for a patent. The court also held that there is no differentiation between in vivo and in vitro diagnostic methods and both are not patentable irrespective of whether it was to be applied directly on the human body or outside the human body for purposes of treatment. The court further analysed the concepts of 'diagnostic tests' and 'detection tests' and failed to differentiate between the same by reason of both methods leading to treatment. The court also held that screening tests would also qualify as a diagnostic test as they are both leading to treatment. In the present application no. 4812/CHENP/2012 the court held that the invention cannot be held to be diagnostic in nature as it identifies only the foetal fractions and does not diagnose any medical condition. Therefore, the court held that the subject matter of this patent application is patentable.

Other applications in regard to patentability of diagnostic methods and the decisions of the Indian Patent Office on such matters also discussed as below:

In Patent Application no. 52/DELNP/2010<sup>13</sup>, patent for determining the correlation between the high levels of blood pressure and resulting sepsis was rejected. Similarly, in Patent Application no. 1086/MUMNP/2011<sup>14</sup> was also rejected as the invention led to diagnosing liver fibrosis by obtaining blood from that patient as it led to treatment of human beings and was therefore in violation of section 3(i) of the Act. In Patent Application no. 6616/DELNP/2010,<sup>15</sup> use of biomarkers for determining further course of treatment by diagnosing COPD was rejected.

In Patent Application no. 2484/DEL/2007<sup>16</sup>, it was held that detection tests that indicated the probability of a person to get such disease was not within the ambit of section 3(i) of the Act and such an invention was therefore patentable. In Patent Application no. 1492/CHENP/2010,<sup>17</sup> the methods used to detect the presence or absence of Chikungunya strain in a sample was rejected patentability. In another Patent Application no. 693/KOL/2007<sup>18</sup> a device used for detecting HIV and ps4 antigen existing in a human serum or plasma was granted patent.

<sup>9</sup> *Arthrogen Gmbh Vs. Controller General Of Patents, Designs And Trademarks and Ors* (2024) MANU/DEOR/26213/2024

<sup>10</sup> *Health Protection Agency Vs. The Controller General of Patents & Designs and Ors* (2020) MANU/IC/0041/2020

<sup>11</sup> *Tianjin Dishili Investment Holding Group Limited Vs. The Controller General of Patents, Designs Trade Marks and Ors* (2012) MANU/IC/0084/2012

<sup>12</sup> *The Chinese University of Hong Kong and Ors. Vs. The Assistant Controller of Patents & Designs* (2023) MANU/TN/5810/2023

<sup>13</sup> DPS Parmar, LexOrbis Intellectual Property Attorneys and Advocates. The patent eligibility of diagnostic methods under an Indian spotlight <https://www.lexorbis.com/the-patent-eligibility-of-diagnostic-methods-under-an-indian-spotlight/>

<sup>14</sup> *ibid*

<sup>15</sup> *ibid*

<sup>16</sup> Varsha Venkatesh., "Exclusion of Methods of Medical Treatment from Patentability: A Global Perspective". penACCLAIMS. ISSN 2581-5504, Volume 14 Jan 2024 <http://www.penacclaims.com/wp-content/uploads/2021/02/Varsha-Venkatesh.pdf>

<sup>17</sup> *ibid*

<sup>18</sup> *ibid*

### 13. CONFLICT BETWEEN 'SCREENING TESTS' AND 'DIAGNOSTIC TESTS'

The key differences between screening tests and diagnostic tests are as follows:

- Screening tests are conducted on an asymptomatic population while diagnostic tests are conducted on a symptomatic population.
- Screening tests are less invasive in nature whereas diagnostic tests may or may not be invasive depending on the purpose of the test.
- Screening tests aim to understand the level of susceptibility of an asymptomatic person to a particular disease. Diagnostic tests function with the ultimate aim of knowing whether a person surely presents with a particular disease or not.
- Screening tests are generally performed on a large number of persons and on a regular basis whereas diagnostic tests are conducted on specific patients and only when necessary<sup>19</sup>.

From this it is understood that screening tests are different from diagnostic tests as defined under section 3(i) of the Patents Act, 1970. The interpretation of the Madras High Court in *In The Chinese University of Hong Kong and Ors. Vs. The Assistant Controller of Patents & Designs*<sup>20</sup> stating that screening tests are similar to diagnostic tests contradicts with the understanding of these concepts in the medical field. Therefore, there is a need for the legislation to clarify these differences and the patent eligibility on this subject matter.

### 14. DISTICNTION BETWEEN 'DETECTION' AND 'DIAGNOSIS'

While the concepts of detection and diagnosis appear to be the same, they are distinguishable based on certain aspects. Detection of a disease refers to understanding the existence of an element in a particular disease and not the disease itself. It remotely identifies the probability of existence of a disease and does not provide confirm results. However, diagnosis refers to the identification of the presence or absence of a disease and it ultimately leads to treatment.

According to the current legislations, there is not differentiation between detection and diagnosis and in many cases patent applications are rejected by reason of a lack of understanding of this distinction. This is evidenced by the fact that in Patent Application no. 2484/DEL/2007, the authority considered a detection test to be patent eligible but in a similar case in Patent Application no. 1492/CHENP/2010, a detection test conducted to identify Chikungunya Strain in a biological sample was refused patent by reason of being diagnostic in nature. However proper understanding of the subject matter of the patent would indicate that the invention in this application was merely detecting the Chikungunya strain and was not a conclusive test for the existence or non-existence of Chikungunya.

From the above it may be observed that there is lack of clarity in the provisions as well as decisions given on various patent application regarding the concepts of detection and diagnosis.

### 15. SCOPE AND LIMITATION OF THE STUDY

- The paper aims to understand the reasons for contradicting judgments in matters of patentability of diagnostic methods with the intention of rectifying the mistakes made in interpretation and implementation of the law by appropriate authorities.
- The paper does not study global perspective on patentability of diagnostic methods and focuses only on the Indian scenario.
- The paper does not make an in-depth technical analysis of all inventions and patent applications but only focuses on the legal rationale behind decisions on such applications.

<sup>19</sup> <https://open.oregonstate.edu/epidemiology/chapter/screening-and-diagnostic-testing/>

<sup>20</sup> *The Chinese University of Hong Kong and Ors. Vs. The Assistant Controller of Patents & Designs* (2023) MANU/TN/5810/2023

## 16. FINDINGS AND RECOMMENDATIONS:

- Based on the analysis made in this paper, the understanding of the concept of diagnostic methods is not uniform in all of India.
- The legislation does not provide a clear explanation for diagnostic methods and its extent of patentability.
- The distinction between significant concepts such as diagnostic methods, screening tests and detection are not properly given under the Act causing a lack of a certain understanding of boundaries in the application of these methods.
- The paper recommends that an amendment to this effect should be brought upon in the Patents Act, 1970 which clarifies on the extent of patentability of diagnostic methods while keeping in mind the dynamic and unique nature of this concept.
- It is also recommended that both legislative intent and the quasi-judicial authority of the Indian Patents Office through application of mind, must be balanced without compromising the integrity of the provisions of this Act.

## 17. CONCLUSION:

The paper concludes that the main reason causing an uncertainty in applying Section 3(i) of the Patents Act, 1970 is a result of lack of clarity in the provision explaining the concept of diagnostic methods, the extent of application of such non-patentability under the Act and a lack a clear distinction between essential concepts such as screening tests and detection tests. Therefore, the paper concludes by suggesting the need for a new amendment to brought into effect to tackle the issues as observed in this study.

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