Patent Eligibility of Diagnostic Process in India: An Analysis of the Recent Trends

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***Abstract*—Innovations related to diagnostic procedures are outside the protection of patent law under section 3(i) of the Patent Act, 1970. The provision categorically devoid patent or claim to any invention which lays down the procedure for treating a human or an animal. But, in the light of the emerging advancements in the field like gene therapy, regenerative medicine and other progressive and sophisticated medical advancements, the line of difference between a procedure for diagnosis and the subject matter of such eligible inventions often becomes blurred. This article examines how the Indian patent laws provide for such patent exclusions and how such provisions are being interpreted by the Indian Patent Office and the courts. The recent judicial interpretations pertaining to different inventions for the grant of a patent containing diagnostic claims have rendered observations from the courts as to how there has to be interpretive clarity and procedural steadiness in terms of patent eligibility exclusions under the Indian law. In the light of such developments, the article devolves into an analysis of such recent decisions by various high courts, the rationale given by the Indian Patent Office in such patent applications. Through a doctrinal research through analysis of statutory provisions, Patent office practices, recent judgements, the article aspires and advocates for robust emulative and interpretative framework for evaluating and analysing diagnostic patent claims in India that reiterates to objectives of access to health care innovations and an extension of right to health of the public.**

***Index Terms*—innovation, diagnostic inventions, medical process claims, public health, right to health, health care inventions, access to health care, patent claims, Patentability**

I. INTRODUCTION

Advancements in the field of medicine and allied technologies have witnessed unparalleled advancements in recent decades. Inventions like wearable devices, robotic surgery, Nanomedicine, gene editing technologies, and regenerative medicine are among the few. These pioneering innovations in the field of medical innovations have changed the face of health care delivery systems across the world, rendering better healthcare services to the public.[1]Innovations are critical to public health and advancements in the field of medical innovations. But, legal recognition of such inventions and acquiring monopoly through patent remains contentious in India because of the restrictions on patentability of medical process inventions. Medical diagnostics are crucial in facilitating early detection and care for diseases and in enabling targeted treatment protocols to the medical professionals.

Diagnostic inventions within the parlance of research and innovation refer to the facilities including devices, tests, methods and platforms that are used to detect or identify diseases in human beings, animals and plants, monitor the conditions and status of health. They are crucial in the health care setup in aiding clinical decision-making. Advancements in the field of diagnostic innovations ensure accurate and affordable solutions within the health care framework. They include within its framework a

[1] Mahara, Gehendra; Tian, Cuihong; Xu, Xiaojia; Wang, Wei. *Revolutionising health care: Exploring the latest advances in medical sciences. Journal of Global Health*, 13(3) (2023): 03042. See also Mahara, Gehendra; Tian, Cuihong; Xu, Xiaojia; Zhu, Jianbo. *Breakthrough of glycobiology in the 21st century. Frontiers in Immunology*, 13(13) (2023): 1071360. See also Recent progress in the field of Artificial Organs. *Artificial Organs*, 45(4) (2021): 649.

wide assay of technologies including, artificial intelligence, physiological measurements, molecular signatures and even procedures like the angiography or a simple pregnancy detection kit.[2]

Diagnosis is crucial to clinical in medical and health care decision-making. Diagnostic inventions are inevitable to a functioning public health ecosystem because timely or early diagnosis can provide efficient health care management, and it would also enable less treatment cost when one has to deal with the disease at an advanced stage. The paramount and indispensable role of diagnosis in matters relating to public health policy and management was evident during the COVID-19 pandemic in protecting the population and handling extreme epidemic emergencies.The importance of diagnostic inventions was retreated during the COVID-19 pandemic in the form of different diagnostic tests, diagnostic text kits that could be used easily at the convenience of our home. Technological advancements in the area of medical diagnosis have been exponentially expanded. With the emergence of novice areas in diagnostics like genomics, artificial intelligence, biomarkers, etc.,. 'Medical diagnosis' as an area of research and market prospects has taken a huge leap in the emerging field of medical research and market.[3]

The sustainable development goals enshrine that for a country to achieve Universal Health Care would require efficient and affordable medical services to the people to avert ill health and to provide and enable the prevention, treatment, promotion, rehabilitation and services related to health.[4] thus medical and health care technology and their access have an inevitable role in enabling the right to health of citizens and are also linked to aspects of medical ethics and policy. Thus granting exclusive rights over medical and therapeutic invention can have an impact on the right to health of the public. Granting such monopoly rights to diagnostic processes can also make access to healthcare cost but also restrict the freedom of practice to be exercised by the medical practitioners.[5] Thus, the patent laws across the world therefore restrict diagnostic processes from the purview of patent protection meanwhile the products and apparatus used for such diagnosis are freely patentable. [6]

1.1 Patent eligibility of diagnostic processes under the TRIPS Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) enshrines a minimum standard for protection of intellectual property amongst the member countries. The TRIPS agreement necessitates that the member countries make process and product patents available for inventors without discriminating any filed/s of technology as long as they are novel, have inventive steps and industrial applications.[7] But, TRIPS expressly allows the members to demonstrate diagnostic process inventions, though the exclusion is not mandatory it helps the member countries to alight their policy and legal aspirations in tune with the public health necessities.[8] This was in tune with the TIPS objectives which necessitated that the intellectual property enforcement shall be done in a "manner conducive to social and economic welfare"[9] and the members are free to adopt measures in the interest of their public health policies as long as they are not contrary to the agreement.[10] meanwhile the TRIPS agreement has not defined "diagnostic methods" it has left the interpretation open to the

[2] Mall P, Why India should become a global leader in high-quality, affordable TB diagnostics, *Indian Journal of Medical Research*, 135(5) (2012) 685-689

[3] Diagnostic Method Patents and Harms to Follow-On Innovation, 126 Harv. L. Rev. 1370 (Mar. 2013).

[4] World Health Organization, World Health Statistics 2017: Monitoring Health for the SDGs (Geneva 2017).

[5] Haroon Hasan Akhtar, *Undiagnosed: The Failure to Determine Patentability Standards for Diagnostic Tests*, 104 J. Pat. & Trademark Off. Soc'y 377 (July 2024).

[6] Lauren Matlock-Colangelo, *Broadly Unpatentable: How Broad Method Claims Have Limited Patentability of Diagnostic Inventions*, 119 Colum. L. Rev. 797 (Apr. 2019).

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 331 (1994).

[8] Id. art. 27(3a).

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, supra note 9, art. 7.

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights, supra note 9, art. 7.

member countries to fit in their socio-economic situation in line with other categories of medical processes.

1.2 International Trends in Patent Eligibility of Diagnostic Methods

The patent eligibility of medical process inventions differs substantially from country to country depending on the policy aspirations. Being included in the category of medical process inventions for patent eligibility, diagnostic method invention has been raising various policy ambiguities because of the extensive innovations in the field for the past two decades. Under the European Patent Convention[11], the perspective seems to have structured wherein patent protection is extended to in vitro diagnostic methods, meanwhile in vivo diagnostic methods which are performed on the human body remain outside the scope of patent eligibility.[12] the United States used to be popular in following a liberal approach in granting patents for medical processes but keeping the medical fraternity outside the scope of infringement. But the judiciary initiated trend of identifying patentability criteria for inventions seems to have taken a major concern over the grand of certain category of diagnostic process inventions which was reflected in the famously discussed cases of *Mayo v Prometheus*[13] which rejected patent for diagnostic process invention citing the 'application of natural law'. There are also challenges in maintaining faced by the patent office across the world with the diagnostic inventions becoming non-disaggregatible in separating the device, procedure or software components; this has been vastly noticed in AI enabled medical devices.

Across jurisdictions, the intention of the regulation seems to be surrounding the concept of protecting the devices and pharmaceutical and other manufactured substances through patent protection, meanwhile limiting the monopoly rights over the diagnostic procedure. This approach is driving the ensure the free access of clinicians over the diagnostic procedure that is inevitable in extending health care facilities.[14]

II. LEGAL FRAMEWORK IN INDIA

India's legal framework surrounding the patentability of medical and health care inventions has always stood out in terms of ensuring the monopoly assigned though patents are not on the coast of the public health of the citizens' access to health care inventions and technology. Medical inventions based on the patentability considerations under the Indian patent framework could be identified broadly under the following categories.

Table 1: A compilation of the classification of medical and health inventions as per the patent eligibility criteria under section 3 of the Patent Act, 1970

CATEGORY	STATUS OF PATENT ELIGIBILITY IN INDIA	REMARKS
Chemical compositions and pharmaceutical products	Patentable as long as section 3(d)[15], 3(e)[16] and 3(p)[17] are complied along with the patentability criteria	The category includes the active pharmaceutical ingredients, drug Formulations and compositions. The category also includes vaccines and biologists like peptides, proteins and antibodies. Chemicals used in sterilisation,

[11] Convention on the Grant of European Patents (European Patent Convention) art. 53(c), Oct. 5, 1973, 1065 U.N.T.S. 199.

[12] Enlarged Board of Appeal of the European Patent Office, Decision G 1/24 (2025).

[13] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

[14] Asher Hodes, Diagnostic Patent Subject Matter, *Berkeley Technology Law Journal,* 26(1) (2011) 225

[15] Patents Act, No. 39 of 1970, § 3(d) (India).

[16] Id § 3(e)

[17] § 3(p), supra note 16.

		cleaning tissues, etc.
Medical Devices	Patentable as long as the applicable criteria are complied with and the invention does not come under the purview of section 3(f)[18]	Includes a wide array of instruments used in diagnostics, surgical tools and other clinical equipment, implants, patient monitoring equipment, medical imaging equipment, drug delivery devices and other assistive devices like mobility aids. These are inclusive of categories that come under machines, apparatus, or manufacturers and articles and devices.
Medical Processes	Not eligible for patent under section 3(i)[19] of the Patent Act, 1790	Blanket restriction on all kinds of medical procedures, either as independent or dependent claims.
Health care management systems and software	Could attract section 3(k)[20], but granted patent as long as a new and novel device is accompanied.	The majority of the AI enabled medical devices fall under the category, also including health care data management services, software-enabled medical devices etc.
Biotech inventions related to medicine and health care	Paintable as long as does not involve aspects relating to section 3(j)[21], 3(p)[22] etc.	Vaccines, enzymes etc.

Section 3(i)[23] of the Patent Act, 1970 excludes from patent eligibility medical process inventions in India which have been interpreted to cover diagnostic methods and procedures. In case of medical diagnostic process innovations in general, will be accompanied by a device, agents, etc. Which would require regulatory approval under the Drugs and Cosmetics Act, 1940[24]. When the innovation is an independent clinical method of procedure for diagnosis, then it could only be applied by an expert or a clinician wherein the regulatory pathway used for devices will not be triggered. In such cases, the governance and approval completely rely on ethics, institutional oversight and the standards laid down by several organisations which regulate medical practice, hospitals, and diagnostic centers in the country. For research relating to such procedures, the institutional ethic commute procedures as mandated under the Indian Council for Medical Research's National Ethical Guidelines[25] have to be followed.

The innovations in the field of medical diagnostics have enabled faster, affordable, ease of use and more precision to the health care industry. For the legal and regulatory parlance in India, the innovations in the

[18] § 3(f), supra note 16.
[19] § 3(i), supra note 16.
[20] § 3(k), supra note 16.
[21] § 3(j), supra note 16.
[22] § 3(p), supra note 16.
[23] § 3(i), supra note 16.
[24] Drugs and Cosmetics Act, No. 23 of 1940, § 3(b)(i) (India).
[25] Indian Council of Medical Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).

field of diagnosis could be classified broadly into those come under the purview of the Medical Device Rules 2017[26] under the Drugs and Cosmetics Act, 1940[27] which provides for prior approval of the statutory authority for commercial use including the and distribution and import of such devices and substances within the country. Meanwhile diagnostic methods are purely clinical and often do not require regulations and permissions as in the case of devices, They are often classified under "good clinical diagnostic practises," which are approved by the experts and professional associations.

In addition to the patentability criteria Section 3(i) if the Patent Act excludes from patent eligibility "any process for the medical, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for the similar treatment of animals to render them free of disease or to increase their economic value or that of their products". The provisions create a significant limitation under the Indian patent law pertaining to inventions or claims involving medical processes. The exclusion stems from the ethical and public health concerns relating to patient care and avoiding monopolisation of treatment procedures and autonomy of health care professionals.Thus, the various tending fields of diagnostic inventions, in reference to the Indian patent regime could be classified with reference to their patent eligibility as follows

Table 2: depicting major filed of inventions in diagnosis categorised into patentable and non patentable inventions under the patent law in india

PATENTABLE DIAGNOSTIC INVENTIONS	NON-PATENTABLE DIAGNOSTIC INVENTIONS
Diagnostic Compositions like compounds used in detention of diseases, reagents, biomarkers etc.	Examination procedures performed and human beings and animals
Diagnostic devices, apparatus and diagnostic kits	Disease detection procedures performed on living organisms or *in vitro*
Software and AI based Diagnostics as long as they are not abstract algorithms	When the compositions or devices do not demonstrate enhanced efficacy as required under section 3(d), 3(e) and 3(f).
Process of manufacturing the diagnostic devices and compositions	

Diagnostic method inventions are procedures or processes that are developed to detect, identify or determine the presence , intensity, characteristics of a medical condition, disease in humans or animals.For diagnostic inventions to be patentable India must satisfy the requirements of novelty[28] inventive step[29] and industrial application[30]. Though looking from an analytical perspective, the law seems settled on the category of diagnostic inventions being patent eligible and not eligible. But, the situation often gets complex because of the complexity and advancement of innovations in the field. Like the software and AI enabled diagnosis which enables diagnosis through data-enabled solutions facilitating decision support models, image analysis pipelines, etc.[31] There are also facilities that enable sample collection, data standards and quality assurance and results in National essential diagnostic frameworks.[32] The diagnostic tools and devices come under the

[26] Medical Devices Rules, 2017, Gazette of India, Notif. No. G.S.R. 78(E) (India, Jan. 31, 2017).
[27] Supra note 24

[28] § 2(1)(l) supra note 16
[29] § 2(1)(ja) supra note 16
[30] § 2(1)(ta) supra note 16
[31] Vijay S. et al., *Introducing a National Essential Diagnostics List in India*, 99 Bull. World Health Org. 236 (2021).
[32] Gupta P. et al., *A Comprehensive Roadmap for MedTech Innovations' Uptake into the Public Health Care System in India*, 5 Frontiers Dig. Health 1268010 (2023).

framework for "medical devices" for regulatory framework within the Indian legal system.

III. RECENT JUDICIAL ENGAGEMENTS CONCERNING PATENT ELIGIBILITY

The Indian High Courts recently have been coming across the decisions of the Indian Patent Office rejecting applications for diagnostic processes citing section 3(i) of the Patent Act. In the case of *Chinese University of Hong Kong v Assistant Controller of Patents* [33] the Delhi High Court considered if the invasive paternal testing procedures or *in vitro* diagnostic procedures would come under the preview of section 3(i) of the Patent Act, 1970 since the invention was denied patent citing it as diagnostic invention by the Indian Patent Office. The court took a stand that for the scope of diagnostic method inventions for patent eligibility in India whether the innovation is in vitro or in vivo process is immaterial and what is pertinent is the objective and scope of the invention and how far it is pertinent in the expert diagnostic decision-making. The invention in question in the matter was related to genomic analysis of a fetus based on a sample that was obtained from the mother. The court granted patent in this case, unlike the Indian patent office because the seeded claims were about determining the 'fetal fraction' from a maternal sample and court heard that that does not constitute diagnostic process sparse and is only a step before diagnosis. Thus, the process was considered to be technical and did not reveal any pathology results or clinical diagnoses and could hence become patentable. But in the case of *Sequenom Inc. v. Controller of Patents & Designs* while deciding over the grant of patent for "Methylation-based enrichment of fetal nucleic acid from maternal sample useful for non-invasive prenatal diagnosis." The Delhi High Court upheld the decision of the patent office and held that diagnostic procedures which have the potential to identify foetal abnormalities would fall within the purview of section 3(i).[34] in the case of *Kymab Limited vs. Assistant Controller of Patents*[35] a patent was sought for the " Animal Models and Therapeutic Molecules" which claimed in the application the procedure for producing antibodies in reference to desired antigen by immunizing a transgenic mouse or a non-human mammal which has segments of genes of human immunoglobulin.

Meanwhile, in the case of *Sugen Inc. v Assistant Controller of Patents*[36] the Madras High Court decided on the patent eligibility of in vitro diagnostic procedures that could detect specific conditions or biomarkers related to cancer diagnosis. The court took a stand the scope of patentability exclusion for diagnostic processes in India is limited to those procedures which help in 'identifying the pathology for treatment'. And upheld the denial of patent by the Indian Patent Office. In the case of *Natera Inc. & Anr v. Assistant Controller of Patents*[37] the invention in hand involved in the diagnostic process to identify the nature of cancer in the lungs or its stage of progression using biomarkers. The High Court upheld the decision of the Indian patent office. But deviating from this trend in the case of *EMD Millipore v Controller*[38] *of Patents* the Delhi High Court granted patent for a bio molecule detection procedure based on IR spectroscopy thus narrowing down the scope of diagnostic procedures within the purview of section 3(i).

Further the recent issue involving the case of *Hirotsu Bioscience Inc. V Assistant Controller of Patents*[39] the Delhi High Court upheld the decision of the patent office and rejected a patent for a nematode-based cancer detection process using the warm which could identify the presence of cancerous cells in urine

[33] The Chinese University of Hong Kong v. Assistant Controller of Patents & Designs, Misc. Pet. No. 94/2013 (Delhi High Ct. Aug. 8, 2013).
[34] Sequenom Inc. v. Controller of Patents & Designs, 2025 SCC OnLine Del 7890 (India Oct. 9, 2025).
[35] Kymab Ltd. v. Assistant Controller of Patents & Designs, 2024 SCC OnLine Mad 4567 (India Sep. 26, 2024).
[36] Sugen Inc. v. Assistant Controller of Patents & Designs, 2015 PTC 417 (Del.).
[37] Natera, Inc. v. Union of India, 2025 SCC OnLine Del 4567 (India).
[38] EMD Millipore Corp. v. Assistant Controller of Patents & Designs, 2025 SCC OnLine Del 7891 (India Oct. 9, 2025).
[39] Hirotsu Bioscience Inc. v. Assistant Controller of Patents & Designs, 2023 SCC OnLine Del 5684 (India).

based on smell. The inventors claimed the process of cancer detection by observing the nematode and identification of car-specific receptors through worm mutants. The technique was to be noninvasive, claimed to be 100 percent efficient in identifying over 28 different types of gastrointestinal-based cancers even during stage 0. The applicants claimed that it's an in vitro process and focuses on "detection" and not "diagnostic process" and hence cannot come under section 3(i). Court held that the invention could identify the presence of a disease and could guide in the treatment which brings it under the ambit of section 3(i).

Table 3 : The decisions of various High Courts in matters pertaining to patent eligibility of medical procedures

s	CASE	JUDGMENT
1	Hirotsu Bioscience Inc. V Assistant Controller of Patents[40]	Decision of IPO upheld
2	Natera Inc. & Anr v. Assistant Controller of Patents [41]	Patent was granted
3	Sequenom Inc. v. Controller of Patents & Designs[42]	Decision of IPO upheld
4	EMD Millipore Corp. v. Assistant Controller of Patents & Designs[43]	Patent was granted
5	The Chinese University of Hong Kong v Assistant Controller of Patents [44]	Patent was granted

IV. CONCLUSION

Rampant advancement in the field of technology seems to be posing challenges to the patent office and the courts in coming to a conclusion regarding the category and extent of diagnostic procedures that should be included under section 3(i) of the Patent Act, 1970. The objective of the exclusion being made to enable diagnostic procedures freely accessible to clinicians without being worried about patent infringement seems universal and the countries seem to have upheld the importance of such patent exclusion.[45] This makes it necessary to have stinger guidelines in identifying such inventions which are to be kept outside the purview of patenting. Such a situation will have a far more drastic consequence considering the linkage of the exclusion in enabling access to diagnostic technologies to the citizens at an affordable price and are crucial during public health crisis, the exclusion also has a nexus with under Article 21 of the constitution of India. Further, they can also have an impact on physicians' autonomy and freedom. Besides many of the recent inventions in the field related to biomarkers, procedures with linkages to natural phenomena, scientific discoveries, and biological facts characteristics of use of naturally existing substances, etc., a regime which is inclusive of grant of patents to such inventions would lead to monopolization of natural laws. The examination inconsistency can also lead to an increase in number of litigations and risk of evergreening through process claim drafting

India seems to be following the international trend, but the different opinions of the High Court and the absence of specific patent office manual have made the process tedious in identifying the boundaries of diagnostic process inventions in India. This is also important considering the fact that exclusion of patents for diagnostic procedures arises out of the legislation and ambiguity in the decision-making can lead to undermining the statutory intent. It can also lead to situations of applicants inducing in practices to bypass the patent eligibility exclusion, this weakens the implementation of the law,

[40] Id 39
[41] Supra note 37
[42] Supra note 34
[43] Supra note 38
[44] Supra not 33

[45] Gregory N. Mandel, *The Non-Obvious Problem: How the Indeterminate Non-Obviousness Standard Produces Excessive Patent Grants*, 42 U.C. Davis L. Rev. 57 (2008).