



## Intellectual property rights in neurotechnology innovation: An in-depth study of India's patent landscape, regulatory challenges, and emerging trends

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### Abstract

The rapid growth of neurotechnology, which includes brain-computer interfaces (BCIs), neural signal processing, and AI-assisted neurotherapeutics, has the potential to transform healthcare, education, entertainment and assistive technologies. In India, as a developing country innovation hub, this rapid advancement has created unique challenges in harmonizing its patent regime, established through the Patents Act, 1970, with the possibilities afforded by neurotechnology and AI-enabled biomedical inventions. This research paper examines the complex landscape of Neuro-IP in India and assesses the complexities that current patentability rules, regulatory exclusions, and ethical considerations present for Neuro-IP researchers and innovators. We note some important research gaps on algorithm patentability, medical method exclusions, and the socio-liability trade off between innovation incentives and public health. Additionally, after examining recent litigation, government policy recommendations and international examples, this paper suggests tangible objectives and strategic questions for the innovation ecosystem in India, with the goal of aligning India's IP framework with global trends in neurotechnology innovation while expanding citizens' access to life saving technologies.

**Keywords:** Neurotechnology, patentability, brain-computer interfaces (BCIs), intellectual property (IP) framework, AI-enabled biomedical inventions

### Introduction

Neurotechnology has made a mark at the intersection of intellectual property rights, medical ethics, and technology development. Neurotechnology includes brain-computer interfaces (BCI) and associated neural applications. In India, the Patents Act, 1970 is the main legislative piece related to patents. The Act sets out the basic requirements for patentability-novelty, inventive step, and industrial applicability. While the requirements appear quite basic, their application to developments in neuro-IP substantially challenges and engages statutory exclusions and interpretative ambiguities. Neurotechnology seeks to amalgamate disciplines including neuroscience, computational intelligence, and biomedical engineering to operate a device or method which engage directly with neural systems. Neurotechnology applications are diverse, from therapeutic neuromodulation and cognitive enhancement to brain-machine interfacing, and in recent years, has benefitted substantially from the recent growth of advances in artificial intelligence and machine learning algorithms. India's innovation ecosystem has developed significantly, evidenced by increasing patents and progress in patent-related indices (recently climbing to 28th place globally for patents filed: Press Information Bureau, 2023). Furthermore, there are important patterns of broad increases in AI-related patents and growing dominant positions for AI patents in the biomedical innovation space and potentially other spaces (NASSCOM, 2024). That being said, India still has important issues surrounding patent law notably governed largely by the Patents Act, 1970 which can be a difficulty for neurotechnology innovators especially when considering patentability, enforceability and eligibility.

This paper describes and examines the intersection of neurotechnology and intellectual property (Neuro-IP) as it exists in India, and in relation to these legal, technological and ethical issues surrounding patent rights. Recent case studies, regulatory reforms, and policy efforts in support of

patents and evolving global norms and standards support the analysis and actual description of the patent landscape, particularly as it relates to innovation and public health.

### Methodology

The research is doctrinal in nature, relying primarily on the analysis of legal texts, statutes, case laws, and scholarly opinions to draw conclusions.

### Research Gap

While there is growing importance of neurotechnology in India, there are considerable gaps in India's legal and regulatory frameworks for intellectual property protections for these technologies. Foremost of these gaps is uncertainty around patentability. For example, under the Indian Patents Act, Section 3(k) excludes "algorithms per se" and Section 3(i) precludes patenting methods of medical treatment, which creates ambiguity as neurotechnological innovations will rely on AI algorithms and clinical applications. This uncertainty with respect to patentability is compounded by the increasingly blurred lines between computational models and interfaces with neurons. Further, unlike many other jurisdictions, India has no separate guidelines or legal instructions to protect the AI-generated inventions or hybrid software-hardware neurotechnology's processes, making the patent process for advanced new systems more difficult. In addition to these uncertainties, the parameters of ethical and social considerations are also relatively unexplored in the current policy debate, as India's varied socio-economic profile raises important questions about equitable access and equitable distribution for neurotechnological innovations. In addition, concerns pertaining to patent litigation and enforcement are endemic challenges to the patent system, illustrated through high-profile litigation like Roche vs. Natco, exposing the tension between patent rights and public health objectives, especially with respect to life-saving treatments. Accordingly, this research seeks to assess

India's patent system with a focus on neurotechnology, identify critical legal and policy gaps, and illustrate integrative pathways that align technological advancement with ethical and equitable governance.

### Research Objectives

This study will do the following:

1. Review current legal framework in India for innovation in neurotechnology, specifically to understand when patents are permitted, when they are prohibited, and what procedural problems exist,
2. Discuss the appropriateness of the exclusions of algorithms and medical methods on the patentability of AI-enabled neurotechnology's,
3. Review landmark patent litigation cases to discuss policy recommendations, and assess how judicial attitudes are shifting and how they may drive regulatory change in India,
4. Compare India's IP space with best practices in other jurisdictions, especially China and the U.S. to uncover practice gaps and identify useful policy reform options,
5. Investigate ethical, social, and economic implications of patent protections for neurotechnology in India,
6. Make recommendations for the future of research and strategic recommendations for advancing India's Neuro-IP ecosystem, including making a case for balancing innovator rights with public health needs.

### Hypothesis –

General Hypothesis: The prohibitions in the Indian Patents Act, 1970 <sup>[1]</sup>, in Sections 3(k) and 3(i) severely limit the ability to patent and commercially exploit neurotechnological innovations in India.

1. The exclusion of "algorithms per se" in Section 3(k) generates issues of ambiguity and inconsistency, because neurotechnology is heavily predicated on AI, despite facilitating the recruitment of risk by protecting an ancillary function as an algorithm.
2. The exclusion of therapeutic methods of treatment in Section 3(i) unnecessarily constitutes protective therapeutic neurotechnology, with the ultimate consequence that no sophisticated medical solutions will ever be on the market.
3. Modern legal and regulatory regime with clear standards and procedural guidance tailored to neurotechnology and ethical considerations will accelerate the neuro-IP ecosystem in India.

### Research Questions

To accomplish these goals, the paper addresses the following research questions:

**RQ1:** What are the implications of the patent eligibility standards in sections 3(k) and 3(i) of the Indian Patents Act, 1970 <sup>[2]</sup> on the patentability of AI-based neurotechnology inventions that incorporate medical methods?

**RQ2:** What are the implications and legal precedents from recent patent actions related to neurotechnologies and pharmaceuticals in India?

**RQ3:** How can India's patent regime enhance the ability to patent AI-based neurotechnology, and what can India learn from the best practices around the world?

**RQ4:** How do ethical, socioeconomic, and accessibility issues shape the regulatory conversation surrounding Neuro-IP in India?

**RQ5:** What policies and support structure needs to be in-place to allow for patent filings and research and development of India's own indigenous neurotechnology?

## Legal Framework and Neurotechnology for patenting in India

### Fundamental Criteria for Patentability

India's patent regime requires that an invention must satisfy three key requirements:

1. **Novelty:** The invention has not been disclosed before.
2. **Inventive Step:** The invention is not obvious to a person skilled in the art.
3. **Industrial Applicability:** The invention has an industrial application.

The patent rules in India require that inventions meet two of the three requirements. In addition to these requirements, Sections 3(k) and 3(i) clearly list the Exception for patentability of "per se" algorithms and methods of medical treatment, which may provide considerable challenges for neurotechnology products that are based on complex AI algorithms implemented within hardware systems (Global Patent Filing, 2025) <sup>[22]</sup>.

### Section 3(k) of the Patents Act <sup>[1]</sup>

lists "mathematical methods, business methods, computer programs per se, and algorithms" as exclusions from patents. Since BCI systems are fundamentally algorithms that function within the parameters of neural networks and hardware that connects to the human nervous system then Section 3(k) becomes a significant barrier to patent protection for innovators. Therefore, the primary obstacle is determining what constitutes a patentable technical invention versus an excluded abstract software, mathematical method, etc. The most recent ruling of the Delhi High Court such as Microsoft Corporation v. Assistant Controller of Patents (2023) <sup>[2]</sup> and Raytheon Company v. Controller of Patents <sup>[3]</sup> (2023) confirmed that software can advance tech patentability when it is capable of having a technical effect or overcoming other technical challenges. In that sense, software can be afforded protection, even without hardware claims that are always part of neurotechnology inventions. While these contests can allay fears around Section 3(k) exclusions, the question of whether inventions in the quickly developing space of neurotechnology is effectively hardware or software peripheral, continues to leave a murky area for innovators.

### Medical Treatment Exclusion under Section 3(i) <sup>[4]</sup>

Section 3(i) is another important exception, which excludes from patentability methods of medical treatment, diagnosis or surgical methods. For Neurotechnology patents, which comprise therapeutic BCIs or diagnostic devices for neurological disorders, this creates a circumstance of ambiguity <sup>[5]</sup>. There is a clear protective rationale for the exception in that it prohibits monopolization of medical treatment, however, it also has the potential to inhibit life-saving neurotechnology. Now many in the legal profession and practitioners are advocating an amendment to the law to provide a new provision with a clear exception for all neurotechnological devices and methods that have clear industrial uses and life-saving potential - aligning Indian law closer with its global standing (USA, EU) <sup>[6]</sup>. Moreover, the Indian Patent Office have experience growth in AI patent applications (NASSCOM 2024), however, the vague and ambiguous nature of regulations presents issues of inconsistency in the examination process, as well as longer disputes <sup>[7]</sup>.

## Regulatory Frameworks Governing Neurotechnology in India

### 1. Medical Device Rules, 2017

India regulates medical devices under the Medical Device Rules (MDR) 2017 created under the Drugs & Cosmetics

Act of 1940. Although the MDR provides basic standards of safety and efficacy, it fails to address the hybrid nature of neurotechnology, which combines medical elements with data processing and AI. Regulation ambiguity arises when there are no provisions specifically for BCIs that serve to assure regulation in market approval and guarantees for patient safety as medical devices.

## 2. Digital Personal Data Protection Act, 2023

The Digital Personal Data Protection Act (DPDPA) of 2023 is broad in its data privacy protections but fails to move towards more specific language that would deal with neural data or brain signals. Neural data is extremely sensitive because it has the potential to divulge thoughts, emotions, and memories and those raise questions with implications for privacy and ethics not commonly seen. DPDPA currently has not defined neural signals or classified them for protection and introduces an enormous gap for user rights and how to administer data created by BCIs.

The regulatory landscape governing neurotechnology in India is only emerging, yet important in light of huge advancements in brain-machine interfaces (BMIs) and related neurotechnologies happening both globally and in India, which raise a need for immediate legal and ethical frameworks for providing protections in cognitive liberty and privacy. Indian jurisprudence would find support for some aspects of neurotechnology regulation in landmark cases such as *K.S. Puttaswamy v. Union of India* (2017),<sup>[8]</sup> which affirmed the right to privacy as a fundamental right, which included the component of informational privacy and the ability to exercise self-determination outside of interference from unauthorized access or manipulation through any emerging neurotechnologies. This case law provides a constitutional basis for us to recognize the protection of cerebral data and, more importantly, mental integrity, as technologies evolve from diagnostic devices (EEGs and MRIs) to more autonomous and advanced devices capable of recording and modulating our neural activity even, in Canada and the US, by tech giants such as Microsoft and Emotiv.<sup>[9]</sup> Despite this decision, the present-day India does not have legislation that addresses the unique risks from the body of neurotechnology that stem from the potential to be exploited, or manipulated by state or corporate entities, and in which we are faced with ethical dilemmas in terms of unauthorized cognitive influence, and discrimination through social and economic inequalities made worse by artificial inequalities based on access to neuro technologies.

The Digital Personal Data Protection Act, 2023 provides a regulatory framework that regulates the use of personal, digital data, but given that it allows for the use and sharing of anonymized data for research or clinical aim where it constitutes personal data no more, this framework may not address the more nuanced vulnerabilities presented by neurodata. At the international level, innovative measures have been presented as enhancements to accountability in particular the constitutional neuro-rights protections in Chile, and the UNESCO Draft Recommendations on the Ethics of Neurotechnology (2024)<sup>[9]</sup>, which address relevant norms and the need for India to include them to manage neurotechnological innovations in an anticipatory way and as ethically and equitably as possible. Scholars recommend that India create a dedicated neuro-ethics body that draws on existing international examples, which can

explore licensing neurotechnology applications while at the same time, revise and add to the regulatory norms in accordance with advances in neurotechnology.<sup>[11]</sup> In the immediate, India needs comprehensive neuro-rights legislation that explicitly enshrines rights to cognitive liberty, mental privacy, and freedom from unauthorized mental manipulation - to regulate current legal and regulatory gaps before neurotechnologies are so entrenched socially, and culturally that regulation becomes futile because it undermines laws that society has accepted<sup>[12]</sup>. In short, the implication for such legislation is grounded in lessons learned from the delayed regulation of social media algorithms that resulted in privacy erosion and underscores the need for anticipatory governance. As such, integrating constitutionally protected privacy rights, responsive neuro-rights concepts, and ethical benchmarks established at the international level is necessary to balance innovation with human rights so that neurotechnology is used for public good instead of limiting agency and undermining social justice.

### Landmark Judicial Decisions

Two major Supreme Court cases have established guidelines for patentability in the relevant fields, with much relevance to neurotechnology:

**Novartis AG v. Union of India (2013)**<sup>[13]</sup>: This case focused on Section 3(d), which disallows a patent for newly made forms of known substances unless it demonstrates more efficacy. This precedent directly impacts nano-scale modifications and innovations in neurotechnology that then require to be established as having improved efficacy than merely changed size or form.

**Allergan Inc. v. Controller General of Patents (2013)**<sup>[14]</sup>: Supreme Court case that established the requirement of full disclosure to include characterization and reproducibility that is key in patent application involving complex neuro technologies.

Newer cases like *Nano Research Innovations v. Institute of Nanoscience and Technology* (2023) and *Global Nano Solutions Inc. v. Indian Nanotech Ltd.* (2022), feature concerns in joint ownership, enforcement, cross-jurisdictional issues, traditional knowledge, interactions and advanced nanoscience practices.

### India's Emerging Neurotechnology Patent Ecosystem Growth, Challenges, and Strategic Pathways

India's neurotechnology patent ecosystem is changing rapidly, with significant increases in the number of filings surrounding nanotechnology patents, and a gradual turn towards neuro-electronics innovation. Since 2010, the Indian patent office has received over 3,000 patent applications related to nanotechnology, with an average annual growth rate of 15% during that period. The average number of forward citation filings in this domain increased from 2.3 in 2015 to 4.8 in 2023, suggesting increasing global recognition and scientific impact. Of these patent applications, about 45% of the patent filings are with outsiders under the Patent Cooperation Treaty (PCT), which shows a focus on building international patents and entering global markets, versus fighting only for domestic protection. The key thing to consider is how Indian

innovators are progressing from filing traditional single patents, to filing integrated patent portfolios that provide protection to entire technology platforms <sup>[15]</sup>. More patent filings in areas such as nanotechnology, nano-electronics, neuromorphic computing, and hybrid bio-electronic systems demonstrates a growing confidence in the field of neurotechnology. The hybridization of artificial intelligence with nanotechnology, particularly for material discovery and process optimization shows alignment with international innovation processes, while assisting India's specific health care and technological mandates <sup>[16]</sup>.

Concerning matters, while many positives are emerging in the neurotechnology sector in terms of innovation, several regulatory, logistical and ethical challenges may hinder sustainable innovation in the industry. For example, even though the Medical Device Rules, 2017, provided a foundation for regulating, they still were not specific enough to regulate emerging brain-computer interfaces (BCIs) and neurodevices that contain defects typical of medical functionality along with advanced data-processing capabilities. Another example is the new Digital Personal Data Protection Act 2023. There is still no recognition of neural data as its own category, meaning there are still significant privacy gaps specifically pertaining to cognitive and emotional information <sup>[17]</sup>. Logistically, there are

additional issues related to primarily government services. For example, although we were targeting 24-30 months as an average time to get our nanotech patents processed, we are taking on average 4-5 years. These delays are primarily due to lack of infrastructure, versatile characterisation tools, and a proportionately smaller cohort of examiners who have tactile expertise in neurotechnology and the associated discipline of nanoscience *in vivo* <sup>[18]</sup>.

Many ethical and social concerns exist. With neurotech is being crucially developed, the possibility of monopolies establishing solutions for life-altering treatment and perpetuate healthcare inequities broadly in India which have already stereotyped ownership of intellect, power and exclusivity <sup>[19]</sup>. The possibility of surveillance, manipulation, or coercion associated with these technologies increases the need for ethical oversight, independent checks and balance, informed consent protocols from patients, and gaps in data protections. Finally, there are significant questions of liability, such as who would be liable for lack of repair on a faulty neural device?, explicitly demonstrate the need for legal process to clarify responsibilities, establish protections for manufacturers, healthcare providers, and end-users <sup>[20]</sup>.

**Data Visualization Tables**

**Table 1:** Indian Nanotechnology Patent Filing and Citation Trends (2010–2023) <sup>[21]</sup>

Year	Number of Patents Filed	Mean Forward Citations	% Patents Filed via PCT Route
2010	180	2.3	20%
2015	400	2.8	30%
2020	750	4.0	40%
2023	900	4.8	45%

Source: 95% confidence from Indian Patent Office Data and PCT filings.

**Table 2:** Patent Examination Delays and Examiner Expertise in Nanotechnology <sup>[22]</sup>

Metric	Value	Benchmark Target	Notes
Average Patent Processing Time	4–5 years	24–30 months	Delays due to technical complexity
% Examiners with Nano Expertise	15%	50%+	Limited specialized training
Availability of Characterization Facilities	Low	High	Infrastructure gap for patent analysis

Source: Indian Patent Office Annual Report.

**Table 3:** Key Legal Provisions Affecting Neurotechnology Patents in India <sup>[23]</sup>

Legal Provision	Description	Impact on Neurotechnology Patents
Section 3(k)	Excludes algorithms, computer programs per se	Restricts patenting of BCI software
Section 3(i)	Excludes medical treatment methods	Limits patentability of therapeutic devices
Medical Device Rules 2017	Regulates medical devices	Lacks explicit coverage for BCI
Digital Personal Data Protection Act 2023	Regulates personal data including health data	No SPECIFIC MENTION OF NEURAL DATA

Source: Global Patent Filing, 2025.

**Global Context and Strategic Importance**

AI and neurotechnology, including brain-computer interfaces (BCIs), are emerging frontiers of technological innovation that have significant implications in healthcare, industry, and society. Patents in these areas protect intellectual property (IP), drive R&D, and create competitive monopolies.

**China:** China has a volume-driven patenting strategy that has rapidly expanded its number of AI patents through fast track examination options and specially designed policies. Chinese patent filings have taken a broad coverage approach for subfields, and a domestic focus. These policies also support China's large domestic digital economy with over

800 million internet users, which create large amounts of data for training AI algorithms.

**United States:** The US has a quality, and foundational research focused patenting strategy that has strong patent coverage for functional, AI software that is integrated with tangible hardware, and advanced regulatory structures which support innovation in having a regulatory pathway for commercial drugs/devices that incorporate neurotechnologies such as BCIs. The US Food and Drug Administration (FDA) is an active partner in promoting the clinical applications of neurotechnology products and their IP protection.

**India:** India has inherited a difficult situation as it is still utilizing a legal framework that is over 100 years old. For example, the Indian Patents Act excludes computer programs per se from patentability and only allows inventors to be natural persons, which complicates patent claims for AI-generated inventions and foundational models. However, the Indian patent system has been historically evolving, and current high-profile cases illustrate some of the tensions between IP protection and public health in India today.

**Technical and Legal Foundations of AI and Neurotechnology Patentability**

**Criteria and Challenges of Patentability**

**China:** The China National Intellectual Property Administration (CNIPA) is currently implementing fast-track examination procedures of patent applications and plans for an AI patent pool that will permit broad patent coverage. AI algorithms and hardware can be patentable, following global trends.

**United States:** The US Patent and Trademark Office (USPTO) allows patents based on software if the software is combined with a technical solution or hardware. AI-related inventions are thoroughly scrutinized to be novel and non-obvious, as well as utility. The US Food and Drug Administration (FDA) supports issuing regulations pertaining to neurotechnology medical devices, including brain computer interfaces (BCIs), under high-risk devices, requiring rigorous clinical evaluation.

**India:** Fleet incorporation in industry norms, do not permit patents, as Section 3(k) of the Indian Patents Act explicitly excludes computer programs "per se." This creates a significant hurdle for patenting AI inventions that have distinct basis in software. The patent system requires inventors to be legal persons (individuals), compounding any legal ambiguity with respect to "inventions" created autonomously by AI models. This lack of clarity may inhibit investments in fundamental AI research and development (R&D) and wrapper-based innovations that are predicated on foundational models [24].

**Comparative Patent Regime Analysis for AI and Neurotechnology: China, US, and India [25]**

Aspect	China	United States	India
AI Patent Volume (2024)	~300,510 patents (60% global share)	~67,773 patents (20% global share)	Significantly fewer, nascent AI patent filings
Patent Examination Speed	Fast-track for AI patents	Standard rigorous examination	Standard, but software patent restrictions slow AI innovation
Software Patentability	Allowed when integrated with hardware	Allowed when technical effect demonstrated	Excluded "per se" under Section 3(k)
Inventorship	Natural persons required, but flexible policies evolving	Natural persons required; AI-generated inventions complex but progressing	Natural persons required; no recognition of AI as inventor
Regulatory Oversight (Neurotechnology)	Emerging, with emphasis on medical device safety	FDA classifies BCIs as high-risk medical devices	Regulatory framework evolving; lacunae in neurotechnology oversight
Compulsory Licensing & Public Health	Limited use; growing IP enforcement	Rare, mainly via government negotiation	Active use to ensure access to essential medicines
Foundational AI Research Support	Increasing investment, domestic innovation hubs	Strong foundational R&D, government-industry collaboration	Limited foundational R&D; dependent on foreign foundational models
IPR Enforcement & Litigation	Strengthening IP enforcement units	Strong IP enforcement	Mixed enforcement; improving but resource constrained

**Table 2:** AI Patent Filing Statistics by Country (2024-2025)

Country	AI Patent Filings (2024)	Global Share (%)	Leading Companies
China	300,510	60	Baidu, Tencent, Huawei
United States	67,773	20	Google, Microsoft, IBM
India	~5,000 (estimated)	<1	Emerging startups and research labs

China, the US, and India each have different patent regimes that also utilize different scopes, legal interpretations and enforcement mechanisms and are more reflective of each nation respective national priorities and innovation systems.

**Conclusion**

The study concludes that while the intellectual property infrastructure (IP) of India has evolved, it still faces several challenges in advancing and then properly regulating neurotechnology innovation. The Patents Act, 1970 has exclusions on algorithms and medical treatment methods which creates ambiguity and many neuro-IP inventions will be unpatentable. There are also regulatory gaps in the Medical Device Rules (2017) and Digital Personal Data Protection Act (2023). To help advance and regulate innovation ethically, India must take steps to update its legal and policy framework to include neuro-rights considerations, and examine international best practices.

**Suggestions**

- 1. Establish a Dedicated Neuro-IP Unit:** Set up a dedicated unit within the Indian Patent Office that processes neurotechnology patent applications, and includes staff and examiners trained in neuroscience, AI, and similar fields, so that neurotechnology patent applications can be reviewed in a timely, accurate, and efficient manner.
- 2. Establish Iterative Regulatory Sandboxes:** Develop regulatory sandboxes for neurotechnology that enable organizations to test novel ideas in real life conditions with specific parameters, while collecting data to help formulate regulations.
- 3. Promote Collaborative Research:** Create opportunities for collaboration between academic institutions, research organizations, industry, and legal

practitioners, to work together on innovation and some of the multi-faceted ethical, legal, and social considerations associated with neurotechnology.

4. **Create a National Neuroethics Committee:** Develop an advisory committee that is multi-disciplinary to facilitate ethical decision making in the neurotechnology field, to develop ethical frameworks and guidelines, and promote public engagement and awareness.
5. **Support Responsible Innovation:** Develop policies to promote neurotechnology solutions that are developed with consideration to access, affordability, and public good, while minimizing potential harm and risk.

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