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# PATENT PROTECTION FOR NUCLEAR-MEDICINE INNOVATIONS UNDER THE SHANTI ACT, 2025: FROM ABSOLUTE EXCLUSION TO CONDITIONAL PATENTABILITY

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## ABSTRACT

Historically, atomic energy-related inventions were excluded from patent protection via an absolute statutory provision in the Indian patent regime. Nuclear technology's strategic importance and the need to ensure the maintenance of government control over aspects related to national security constituted the background of this tough policy stance. Granting conditional patent protection to inventions related to peaceful use of nuclear energy and radiation, provided there is statutory protection, the SHANTI Act, 2025 marks a dramatic change in this context. This article addresses the issue of this change and its possible impact on advancements in nuclear medicine.

The article reviews the existing legal system prior to the adoption of the SHANTI Act, analyzes changes introduced to the system with respect to intellectual property protection and control over nuclear technologies. Specifically, it focuses on patentability of inventions in the field of radiation treatment, nuclear imaging in medicine, application of radiopharmaceuticals, and other technologies developed on the basis of nuclear science but intended for peaceful medical purposes. It takes into consideration the limits imposed on the inventions connected with sensitive activities and inventions that have significance for national security.

The balance between patent protection, invention, public health interests, and security concerns is analysed through the doctrinal and comparative approach. The article argues that in case the invention meets all the criteria for patentability and has peaceful medical purposes, the mere usage of nuclear technology does not make it automatically ineligible for patent protection. A special approach taking into account their technological character, peaceful use, security sensitivity, and importance for public health is needed to address the issues of patents in nuclear-medicine inventions.

**Keywords:** SHANTI Act; Nuclear Medicine; Patent Protection; Conditional Patentability; Public Health; Nuclear Security.

## **Introduction**

Because of its strategic value, national security implications and threats to public safety, nuclear technology has always been characterized by extremely rigorous regulation in India. Similarly, the field of intellectual property was also subjected to such an approach to regulation. The desire of the State to control strategically valuable nuclear technologies was expressed in the previous legislation that did not provide any patent protection for ideas related to atomic energy. This approach leaves very limited opportunities for the patent system to recognize any nuclear science advances, including those that have applicability in other industries.

A significant change from such an approach was made by means of enactment of the SHANTI Act, 2025<sup>1</sup>. The Act introduces a new nexus between nuclear regulation and intellectual property laws through substitution of the previous absolute exclusion for a regime of conditional patentability of some peaceful uses of nuclear energy and radiation technologies. Such a change is especially important in relation to nuclear medicine that includes application of nuclear and radiation technologies in medical imaging, cancer therapy, radiopharmaceuticals and other medical advances.

The key legal challenge raised by such conditional patentability is the question of how to differentiate between nuclear inventions that should remain subject to protection due to national security reasons and legitimate civilian inventions. Unconditional patentability may contradict the necessity to control nuclear technology and prevent mis disclosure of information, even though it can promote nuclear medicine research, investment and commercialisation.

Addressing this challenge in relation to nuclear medicine inventions, this essay will explore the transition from absolute exclusion to conditional patentability in the context of SHANTI legislation. It will consider the relevant requirements for peaceful nuclear technologies, changes introduced by the new regime, and pre-SHANTI legal regime. It will also discuss the need to balance nuclear security, public health, and patent protection. This essay argues that the nuclear-medicine innovations should not be dismissed simply because of utilization of radiation or nuclear technology. On the contrary, while ensuring appropriate protections for strategically valuable technologies, it should be evaluated separately with respect to its civilian

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<sup>1</sup> Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India Act, No. 39 of 2025, India Code (2025)

purpose and technological and security sensitivity.

### **The Pre-SHANTI Legal Regime: The Exclusion of Nuclear Inventions from Patent Protection**

Before the introduction of the SHANTI Act, 2025, India had a particularly strict legal system for regulating the patentability of inventions related to the use of atomic energy technology.

Indeed, according to Section 20(1) of the Atomic Energy Act, 1962<sup>2</sup>, Section 4 of the Patents Act, 1970<sup>3</sup> explicitly provided for the prohibition on granting patents for inventions relating to atomic energy. Thus, it constituted a particular statutory bar in contrast to common exceptions stated in Section 3 of the Patents Act since it was dictated by the importance of nuclear technology and the need of the State to control it. Hence, the exception was related to the broader legal regulation of the activity rather than the military one<sup>4</sup>.

The ban in question was mainly stipulated by Section 20 of the Atomic Energy Act of 1962. It covered inventions related to the creation, development, and application of atomic energy and certain nuclear materials. As a result, irrespective of whether inventions met the general criteria of novelty, inventive step, and industrial application, they did not get patented once they fell within the scope of nuclear energy operations. Consequently, such legal regime implied a special regime oriented mostly on state control and strategic considerations, putting nuclear inventions outside the regular patentability system.

Moreover, the Central Government had considerable control over the nuclear-related patent applications before the implementation of the SHANTI Act. If an application was considered to involve an idea falling within the prohibited atomic-energy area, its government examination could be conducted. Inquiries regarding the application of the restriction can also be addressed to the Central Government by the Controller of Patents. Such a procedure ensured that the national interest and governmental policy were taken into consideration when patenting the nuclear-related ideas.

Patent exclusion affected private innovations and commercialization considerably. The

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<sup>2</sup> Atomic Energy Act, No. 33 of 1962, § 20(1), India Code (1962)

<sup>3</sup> Patents Act, No. 39 of 1970, § 4, India Code (1970).

<sup>4</sup> Kartik Sharma, 'Peace' on the Nuclear Front? Analysing the Upheaval in the Nuclear Energy Patents Regime Through SHANTI Act, SpicyIP (Dec. 31, 2025), <https://spicyip.com/2025/12/peace-on-the-nuclear-frontanalysing-the-upheaval-in-the-nuclear-energy-patents-regime-through-shanti-act.html>.

impossibility of obtaining patents could diminish the usual incentives associated with investments in nuclear-related R&D because patents provide innovators with the exclusive rights in exchange for disclosing them. Particularly, it was important in case of civilian applications of nuclear technology beyond the traditional use in the nuclear energy production industry. The examples of radiation therapy, nuclear medical imaging, and other medical uses prove that nuclear technology can have significant commercial and public health impacts that differ from strategic uses<sup>5</sup>.

Thus, the patent system and nuclear technology were quite separate from each other under the previous regime. The sensitivity of atomic energy and the necessity to protect national security interests justified the exception, but its frequent usage raised concerns over civilian technologies having peaceful applications. Technologies in the nuclear area could experience serious obstacles to patentability due to the lack of clear division between strategically sensitive nuclear breakthroughs and useful civilian inventions. It is especially relevant to the medical sphere because nuclear and radiation technologies could assist in diagnostics and treatment<sup>6</sup>.

In conclusion, concerning intellectual property, the previous regime can be regarded as an exclusionary system based not only on the purpose or use of inventions but rather on the nature of technology. The patent ownership and private utilization of nuclear inventions were limited due to the interaction of Section 4 of the Patents Act and Section 20 of the Atomic Energy Act. Given the above, it is necessary to consider the significance of the SHANTI Act, 2025 and its revaluation of whether all nuclear inventions should be exempt from patent protection or whether civilian peaceful inventions should be considered on a different basis of conditional patentability<sup>7</sup>.

### **The SHANTI Act, 2025: From Absolute Exclusion to Conditional Patentability**

The policy towards the patentability of intellectual property rights for nuclear innovations in India has seen a fundamental transformation following the enactment of the Sustainable

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<sup>5</sup> Vikrant Rana, The SHANTI Act, 2025 and the Transformation of Nuclear IP Law in India, APAA e-Newsletter, Issue No. 52 (Apr. 2026), <https://apaaonline.org/article/the-shanti-act-2025-and-the-transformation-of-nuclear-ip-law-in-india/>.

<sup>6</sup> Smriti Yadav & Madhura Sureshkumar, The SHANTI Act, 2025 Changes the Dynamics of Atomic Energy Related Inventions in India, Mondaq (June 30, 2026), <https://www.mondaq.com/india/patent/1809200/theshanti-act-2025-changes-the-dynamics-of-atomic-energy-related-inventions-in-india>.

<sup>7</sup> Id

Harnessing and Advancement of Nuclear Energy for Transforming India Act, 2025 (SHANTI Act). The former legal regime included a statutory prohibition on patent protection for inventions related to atomic energy that was mainly embodied in Section 4 of the Patents Act, 1970 read with Section 20 of the Atomic Energy Act, 1962. Thus, by creating the framework that would make nuclear innovations patentable in certain conditions, the SHANTI Act switches from exclusionary policy to conditional patentability<sup>8</sup>.

The amendment of Section 4 of the Patents Act of 1970 is the main intellectual property law change. It should be noted that all inventions related to nuclear energy are no longer prohibited according to the amended clause. Instead, the terms of the Patents Act and special conditions set forth in Section 38 of the SHANTI Act<sup>9</sup> apply to patent protection of nuclear innovations. Consequently, the section becomes the key provision that decides whether an innovation related to nuclear technology can get a patent. Therefore, the innovation should meet both general criteria of patentability and one of the allowed categories under the SHANTI framework.

Under Section 38(1), the Central Government has the right to grant a patent for inventions that it considers to be suitable for peaceful use of radiation and nuclear energy. It is particularly noteworthy since the inclusion of this criterion means that the intended purpose of an invention should be considered a relevant factor in deciding whether the patent application can be granted. Nevertheless, there is an uncertainty in the concept of "peaceful uses" that complicates the differentiation between strategically important and civil nuclear technologies. Such difference provides the grounds for patent protection of innovations in the field of peaceful uses of nuclear science, for instance, inventions related to nuclear medicine.

However, switching to conditional patentability is not an example of deregulation of nuclear intellectual property. The innovations related to activities listed in Section 3(5) of the SHANTI Act<sup>10</sup>, as well as innovations that are considered to be sensitive and/or having the implications for the national security, still remain excluded under Section 38. Consequently, despite the fact that nuclear industry as a whole became more liberalized and open to participation of private companies, the strategically important activities are still controlled by the state. Therefore, the new regime seeks to differentiate between nuclear innovations that can be patentable and the

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<sup>8</sup> Id

<sup>9</sup> Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India Act, No. 39 of 2025, § 38 (2025)

<sup>10</sup> Sustainable Harnessing and Advancement of Nuclear Energy for Transforming India Act, No. 39 of 2025, § 3(5) (2025)

innovations whose exploitation can be detrimental for the strategic purposes.

Furthermore, the role of the Central Government in evaluation of the security aspects of nuclear inventions remains unchanged in the SHANTI framework. The governmental evaluation of applications in accordance with the applicable regulatory framework may consist of the analysis whether an invention belongs to the sensitive and restricted categories. It represents a big difference from the ordinary patent examination that is mainly focused on patentability criteria such as industrial applicability, inventive step, and originality. Those criteria work together with additional evaluation of national security and regulatory issues according to the SHANTI framework<sup>11</sup>.

The former absolute exclusion could hinder potentially useful nuclear innovations from getting traditional patent protection. Consequently, the reform becomes especially important for the civil innovation. The new framework increases the potential for patent protection of innovations in the areas of peaceful use of nuclear energy and radiation, for instance, innovations related to medical imaging, radiation-based therapy, and other applications in healthcare sector. Despite preserving the restrictions on strategically important technologies, such developments can help to stimulate research, investments, technology transfer, and commercialization.

Moreover, the new framework faces administrative challenges. In order to prevent the exclusion of legitimate inventions from the patent protection, the concepts like "peaceful uses," "sensitive inventions," and "national-security implications" should be interpreted in a uniform manner. While inadequate control could jeopardize the legitimate security interests, excessive administrative discretion could replicate some problems inherent in the former regime. Consequently, clear examination standards, transparent decision-making of the government, and proper differentiation between civil applications and strategically limited nuclear activities will be needed for the effectiveness of the SHANTI framework<sup>12</sup>.

Consequently, the absolute exclusion of patent protection gives way to conditional patentability under the SHANTI Act. Under the new framework, it is possible to examine the inventions that belong to harmless civil application while still keeping the necessary restrictions for strategic and national-security reasons, in contrast to treating the nuclear nature of invention as an

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<sup>11</sup> Id

<sup>12</sup> Id

automatic reason for exclusion from the patent protection. Thus, this change creates the legal grounds for examining whether the innovations in the field of nuclear medicine can receive adequate patent protection in India<sup>13</sup>.

### **Patentability of Nuclear-Medicine Innovations under the SHANTI Framework**

An interesting opportunity in terms of protecting innovations in civilian use of nuclear energy and radiation is presented by the SHANTI Act, 2025. The inventions regarding nuclear energy under the Patents Act and Section 38 of the SHANTI Act are now eligible for patent protection according to the amended Section 4 of the Patents Act, 1970. Under the powers given by Section 38(1), the Central Government may grant patents for the inventions it finds fit for peaceful use of nuclear energy and radiation. Being crucial for the use of medical technology for diagnosis and treatment via use of radioactive substances and radiation, such a change is especially important for nuclear medicine.

One of the most obvious areas in which distinction between strategic nuclear technology and peaceful uses becomes relevant is nuclear medicine. The inventions involving technologies such as radiation therapy devices and nuclear medical imaging would be considered for patents, as the SHANTI framework states medical use of nuclear technologies among the acceptable peaceful uses. All other developments of medical use of radiation and radioactivity for diagnosis, treatment, and pharmaceutical use would also fall under the area of civilian uses provided they meet the requirements of patentability and legal criteria<sup>14</sup>.

However, not all inventions in the area of nuclear medicine would become eligible for patenting just because of the introduction of patent protection for those technologies. The invention needs to satisfy the legal criteria of patentability in accordance with Indian law, including novelty, inventive step, and industrial applicability. Furthermore, the invention should fall under the category of Section 38 allowing for peaceful uses of nuclear energy. As a consequence, the inventions in the area of nuclear medicine need to be evaluated from two aspects – the first one being if it is patentable in accordance with the regular patent law, and the second one being if

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<sup>13</sup> Lokendra Sharma, Shanti Act Advances Reform, Streamlines and Dilutes Liability, Takshashila Issue Brief No. 2026-02, Version 1.0 (Jan. 2026), The Takshashila Institution, <https://takshashila.org.in/content/publications/20260116-Shanti-Act-Advances-Reform-Streamlines-and-Dilutes-Liability.html>.

<sup>14</sup> Id

it falls under the SHANTI framework<sup>15</sup>.

Thus, the appropriateness of use may be dependent largely upon the medical aspect of the technology. Technologies utilizing radiation to treat cancer and diagnostic imaging are recognized as the example of peaceful uses of nuclear energy and radiation. It would mean that a wide range of healthcare technologies would become covered by the SHANTI framework. Thus, under the security screening provisions of the SHANTI Act, further improvement of radiation delivery systems, imaging technologies, and other nuclear medicine equipment may be transformed from the area of statutory exclusion to the patent system<sup>16</sup>.

However, there are numerous limitations on the statutory permission. Technologies deemed to be sensitive or having some consequences for national security, as well as inventions related to the activities listed in Section 3(5), are excluded from the section. The Central Government has the authority to review the application if the legislative requirements are not met and to order rejection of the patent by the Controller. Thus, when a technology includes some security and strategic aspects due to the underlying nuclear technology, materials, and processes used in it, even a technology of civilian use in medicine may be required to be reviewed. It means that the challenge lies in distinguishing true civilian medical inventions from those which technological aspects may raise some security or strategic concerns.

The requirement of pre-disclosure notice is another limiting factor. Before disclosing any invention in the area of nuclear energy to third parties, the applicant should inform the Central Government about it. Such legislation may have some practical implications for publication of research results, collaboration, investment, and transfer of technologies by researchers, universities, hospitals, and businesses operating in the area of nuclear medicine. Therefore, when disclosing research results that later may become the basis for filing a patent application, academic researchers should consider the security aspects of the invention<sup>17</sup>.

Thus, the SHANTI framework provides the model where patent eligibility is promoted for peaceful medical purposes but where the aspects of national security are not overruled. Patentability of nuclear-medicine inventions should be evaluated considering their technological contribution, civilian medical application, compliance with general patentability

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<sup>15</sup> Id

<sup>16</sup> Id

<sup>17</sup> Id

requirements, and sensitivity under the SHANTI framework, not just due to involvement of nuclear energy or radiation. Such approach would allow for maintaining governmental control over technologies requiring strategic security while promoting research in nuclear medicine and private investments<sup>18</sup>.

### **Balancing Patent Protection, Public Health and Nuclear Security**

The adoption of conditional patentability in the SHANTI Act of 2025 requires balancing of three different interests: nuclear security, public health and intellectual property. Patents give inventors exclusive rights on qualified inventions, which in turn can stimulate investment, research and development. Thus, patent protection can help in making advancements in nuclear medicine with regard to better therapeutic and diagnostic technologies. Yet, there are some security and safety risks connected to the use of nuclear technologies, which require governmental supervision<sup>19</sup>.

One of the arguments in favour of stimulating more innovations in civilian uses of nuclear technology is the aspect of public health. There is an increasing demand for nuclear technology in healthcare purposes, like cancer therapy and medical diagnosis. The system of laws and legislation, which entirely excludes such technologies from the sphere of patents, may negatively affect the incentives for research and technology development. However, exclusive rights provided by patent protection may affect the cost and availability of essential technologies in the sphere of healthcare. Thus, the SHANTI framework should ensure that protection of intellectual property does not operate independently of the broader goal of ensuring public health.

When the use of nuclear-medicine technologies is crucial for diagnostic or therapeutic purposes, the connection between public health and intellectual property is particularly important. Innovations are rewarded through patent rights, but their use should be consistent with the patent law process that considers public interests. Thus, instead of being considered an uncontrolled commercial monopoly, the presence of patent protection should be regarded as the encouragement of technological development. Some regulations related to licensing, access and public interests may become important in some situations in order to provide continuous

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<sup>18</sup> Id

<sup>19</sup> Mansi Tirthani, SHANTI Act 2025: India's Nuclear Needs and Right to Life, IMPRI (2025), <https://www.impriindia.com/insights/policy-update/shanti-act-2025-indias-nuclear-needs-and-right-to-life/>

availability of proprietary nuclear-medicine technologies.<sup>20</sup>

However, the aspects of nuclear security impose additional limitations that make the inventions in the sphere of nuclear medicine different from regular pharmaceutical or medical technologies. In the SHANTI framework, there are limitations on inventions that are sensitive or have national security implications and also activities reserved under the legislation. Thus, when the revelation of technical information may lead to strategic risks, governmental supervision is required. This helps to prevent technologies that are still sensitive from being freely revealed or commercialized as a result of the expansion of patent protection for civilian nuclear uses.

The broader framework of the regulation in the sphere of nuclear industry also explains the need for such protection measures. The purpose of the SHANTI framework is to provide governmental control over the sensitive nuclear activities while promoting increasing involvement and technological development. This provides the regulatory balance that allows encouraging civilian innovations and at the same time keeping the authority of the state to control the activities associated with the risks of safety, security or strategic issues. Thus, the new paradigm for intellectual property law is limited patent protection considering nuclear security issues rather than complete exclusion or unlimited patentability<sup>21</sup>.

Another issue caused by nuclear technology lies in the possibility of the overlapping of dual-use technologies with civilian medical technologies. Technical skills, materials and procedures that can be used for other purposes may become part of the technology intended for legitimate medical purposes. Thus, only the stated purpose of the invention should not be considered the criterion of peaceful medical innovation. The technological features, intended use, possible application and security issues should be taken into account. This is particularly important when the patent specification implies disclosure of technical information, which can be used elsewhere<sup>22</sup>.

Thus, the SHANTI framework requires the finely balanced approach towards the use of administrative discretion. While the lack of sufficient control may put under risk real national security concerns, excessive restrictions may deter private investments and scientific

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<sup>20</sup> Id.

<sup>21</sup> Pragati Kumar, Analysing “Supplier Liability” Under SHANTI Bill 2025: A Case Study on Small Modular Reactors, 3 *Beyond Briefs L. Rev.*, no. 2, art. 9 (2026)

<sup>22</sup> Id.

cooperation in the sphere of nuclear medicine. Clear criteria for determination of whether the innovation is a peaceful use, if it belongs to the list of sensitive inventions and if the disclosure may cause security issues will provide researchers and patent applicants with certainty. Moreover, transparent procedure will add the confidence to the patent system and reduce the chance of the equal treatment of similar technologies<sup>23</sup>.

The establishment of the reasonable balance between innovation and regulation should be the final goal. Technologies posing really strategic or security risks should continue to be subject to appropriate limitations, but the inventions in the sphere of nuclear medicine serving civilian healthcare purposes should be able to receive patent protection when the patentability criteria are met. With this strategy, the obligations of the state to protect public health, nuclear safety and national security would not be harmed, and the SHANTI Act would promote innovation and investments in the sphere of nuclear medicine<sup>24</sup>.

### **Comparative Approaches and the Indian Regulatory Framework**

It is necessary to take into consideration the SHANTI Act, 2025 in the perspective of the general process of international cooperation and nuclear control. Being a strategic area, nuclear technology has always been controlled by the state in India. The SHANTI Act introduces private involvement in the civil nuclear sector with at the same time imposing certain restrictions. It gives a great framework for considering how India should facilitate intellectual property protection and technological innovations in the global nuclear architecture<sup>25</sup>.

International cooperation played an important role in the growth of India's civil nuclear industry. The incorporation of India into international civil nuclear cooperation has been made possible through the India-US Civil Nuclear Agreement and international participation. By providing more opportunities for private enterprises to take part in the tasks performed earlier by the public sector, the SHANTI Act brings significant changes into the domestic regulatory framework. As a result, new possibilities for the cooperation in technology, investments and technology transfer including the technologies which may be used for peaceful purposes, such

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<sup>23</sup> Id.

<sup>24</sup> Vishal Manve, Workforce Not Policy - Is the Biggest Obstacle to India's Nuclear Energy Ambitions, ORF America (Mar. 5, 2026), <https://doi.org/10.7916/1RBM-4T56>.

<sup>25</sup> D. P. Srivastava, India-US Cooperation in the Energy Sector, Hoover Institution, Stanford University (June 2026), [https://hoover-s3-website.s3.us-west-2.amazonaws.com/s3fs-public/research/docs/Srivastava\\_USIndiaCooperation\\_web-260618.pdf](https://hoover-s3-website.s3.us-west-2.amazonaws.com/s3fs-public/research/docs/Srivastava_USIndiaCooperation_web-260618.pdf).

as medicine, may occur due to these changes.<sup>26</sup>

Another example of the changing regulatory framework is the development of small modular reactors (SMRs). The development of emerging nuclear technologies is related to SMRs; thus, there is a need for regulatory frameworks capable to handle innovative approaches to design, deployment, ownership and supervision for safety. The changing strategy of India aims to provide support for technological innovation but maintain governmental regulation of the activities which are strategic for the state. The regulation of SMRs demonstrates the general problem of supporting innovation in the sector subjected to increased requirements of safety and security although SMRs are primarily concerned with nuclear power generation rather than with nuclear medicine<sup>27</sup>.

This balance is additionally provided by the SHANTI Act which differentiates between activities regulated by the state and activities which become accessible for everybody. While maintaining some nuclear activities exclusively for the State, the act aims to simplify the regulatory framework and involve private organizations. Since the patent protection cannot be considered separately from the regulation of the underlying technologies, it is significant to this issue. Even though the invention possesses technological value, the possibility of its patent protection may be restricted if it is legally excluded or it is sensitive activity<sup>28</sup>.

Comparing with that, the evolving Indian approach is a reflection of the general principle of nuclear regulation: it is possible to advance civilian technologies without lifting the regulatory restrictions over the activities which are sensitive from the perspective of safety and security. The significance of the SHANTI Act consists in the fact that this principle becomes increasingly used in connection with intellectual property issues. India moves away from the general exclusion of nuclear-related inventions to the differentiated approach according to which strategic activities remain subject to state restrictions but peaceful applications may enjoy more legal protection.

Therefore, in the changing regulatory framework of India there are three interrelated aspects which should be taken into consideration: international technology cooperation, nuclear control and intellectual property protection. The increased involvement of foreign and private

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<sup>26</sup> Id.

<sup>27</sup> R. Srikanth, Small Modular Reactors in India's Energy Transition, 9 Nat'l Sec. 409 (2026), <https://doi.org/10.32381/NS.2026.09.03.4410>.

<sup>28</sup> Id.

organizations helps in improving access to financing, research resources and modern technologies; however, it requires the implementation of the effective safety, security and technology transfer regulations. This balance becomes increasingly important in connection with the growing civil nuclear industry of India since the technology developed in international cooperation may include both information which is restricted in security terms and intellectual property<sup>29</sup>.

This regulatory balance is especially important in nuclear medicine. After the introduction of the SHANTI reforms, increased scientific cooperation and private financing can become advantageous for the technology using radiation, nuclear imaging and other peaceful applications. However, the patentability of this technology must continue to be in line with the general regulatory framework which covers radiation safety, nuclear materials and sensitive technological information. Therefore, it is necessary to ensure in the evolving approach that proper security restrictions will be preserved but nuclear-medicine technologies won't be equated with strategic nuclear technologies just because they involve nuclear physics<sup>30</sup>.

In the end, the comparative and regulatory analysis shows that the problem of India is not only the improvement of patent protection but also the creation of an integrated interface between the nuclear control and intellectual property law. This approach is provided in the SHANTI Act which allows increased civilian involvement but preserves restrictions for strategic operations. Thus, in the future, the regulatory framework of India should provide enough guarantees for the researchers, medical institutions and private innovators while ensuring that the patent protection won't pose threat for nuclear safety, national security and international obligations of India<sup>31</sup>.

### **Towards a Coherent Framework for Nuclear-Medicine Patent Protection in India**

The groundwork for India's transition from a total prohibition of inventions related to nuclear technology to conditional patentability has been established through the SHANTI Act, 2025. However, the development of a reliable and accurate system that will determine what kinds of inventions are eligible for patents will be critical for this transition. Specifically, it should be

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<sup>29</sup> Id.

<sup>30</sup> Id.

<sup>31</sup> V. V. Sankarshanan & Uday Shankar, *Stabilising SHANTI: Delegated Legislation and Accountability in Indian Nuclear Regulation*, J. Energy & Nat. Res. L. (Sept. 4, 2026), <https://doi.org/10.1080/02646811.2026.2720026>.

possible to distinguish between the developments in the field of nuclear medicine that have legitimate and legal civilian medical purposes and the ones involving prohibited activities or having national security concerns. As such, it will be important to foster innovation while retaining the legal protection of nuclear technology<sup>32</sup>.

First, the phrase "peaceful uses of nuclear energy and radiation" mentioned in Section 38 must be clarified. Despite the fact that the SHANTI Act does not provide a specific definition of peaceful use, this term remains eligible for patents. Therefore, legislative or administrative guidelines related to the field of nuclear medicine should acknowledge legitimate civilian uses of this term, including radiation-based therapy, nuclear medical imaging, and other healthcare technologies. In addition, standards for determination of technologies having strategic or security implications should be set. Patent seekers working in this field will feel more comfortable with such guidelines.

Second, the creation of a specialized procedure for examination of patent applications related to nuclear technology is necessary. Such applications should comply with the requirements of novelty, inventive step, and industrial applicability; however, additional examination may be needed due to the possible influence on nuclear security. Such collaboration should take place between the appropriate nuclear regulatory agencies and the patent authority. This will ensure that applications with sensitive technologies undergo governmental assessment without unnecessary delays<sup>33</sup>.

Third, open and rational decision-making should complement the exercise of governmental discretion. The SHANTI Act allows government actions in case when invention is considered sensitive or has ramifications for national security. However, unlimited discretion may cause concern for the patent applicants, since the meaning of these terms is not entirely defined. Even with maintaining necessary secrecy of really sensitive nuclear technologies, the use of written justifications, uniform classification standards, and adequate procedures for examination will provide more procedural certainty<sup>34</sup>.

Moreover, the requirement of pre-disclosure must be reasonably applied. Inventors of potentially nuclear-related technology will need to consult the government prior to disclosing

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<sup>32</sup> Id.

<sup>33</sup> Id.

<sup>34</sup> Id.

their inventions to investors, partners, and other third parties. While this is necessary to avoid early disclosure of confidential data, this could discourage investment and collaboration in research. Therefore, to prevent unnecessary delays in nuclear-medicine research, the framework should establish explicit deadlines and procedures for governmental clearance.

Furthermore, it should be possible to keep regulatory approval and patent protection separate. It must be understood that obtaining patent of a nuclear-medicine invention does not authorize production, possession, use, or commercial use of radioactive materials or nuclear technologies. While the appropriate nuclear and medical regulatory framework should oversee safety, licensing, and operations, patent protection should be independent from this process as an intellectual property right. This separation will help to avoid using patent law as an unnecessary barrier to legitimate innovation or replacement of nuclear regulation<sup>35</sup>.

Finally, India should adopt a reasonable and technology-specific approach to nuclear medicine patent protection. While technologies associated with strategic fuel cycle or other reserved nuclear operations should not be viewed in the same way as civilian medical advancements, in case of security concerns, the government should be able to restrict inventions. Such an approach will provide more coherent basis for making decisions, considering peaceful intention, technological characteristics, security sensitivity, public health significance, and usual patentability requirements<sup>36</sup>.

Thus, a coherent system of nuclear-medicine patents should strike the balance between national security, innovation, access, and regulatory certainty. While the SHANTI Act has put an end to the previous blanket exclusion, the transition to the new conditional system will not be complete until there are precise guidelines and reliable procedures behind it. Therefore, India should make use of the new framework in order to promote research and investments in civilian nuclear medicine and to preserve strict regulations for strategically important technologies. With this approach, conditional patentability will become a valuable and reliable tool for fostering nuclear-medical innovation in India, rather than only a possibility of a law.

## Conclusion

Thus, by introducing conditional patentability for certain peaceful uses of nuclear energy and

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<sup>35</sup> Id.

<sup>36</sup> Id.

radiation into the law in place of the earlier absolute non-patentability, the SHANTI Act of 2025 is a significant departure from India's current stance on nuclear patents. This is particularly true regarding nuclear medicine in those developments in medical imaging, treatment using radiation, radiopharmaceuticals, and other related technologies can help both science and medicine.

Still, patentability must go hand in hand with the country's security measures and safety regarding nuclear energy. In case when the use of the invention has a justified application in civilian and medical fields, its patentability must not be refused solely due to the involvement of nuclear or radioactive technologies. On the contrary, a balanced policy should be followed that will separate strategic technologies from peaceful innovations.

In consequence, the SHANTI scheme provides the opportunity to facilitate nuclear medicine research, investments, and technical development under regulatory restrictions. This balance should be achieved through reasonable government oversight, objective patent evaluation process, and criteria for the peaceful use of technology. Ultimately, a unique solution could improve the country's public health, innovation, and intellectual property protection without undermining its justified nuclear security concerns.