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Nanotechnology Patent Applications and Section 3(d) of Indian Patents Act, 1970: An Empirical Research

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Nanotechnology is an evolving branch of science. It is one of the most promising and radical new technological frontiers. Being a hybrid of chemistry and engineering, nanotechnology holds some peculiarities that cause special problems for the application of Patent Law. India looks forward to develop in every field of Science and Technology including nanotech, and aspires to hold Intellectual Property rights in it. In 2016, India ranked 3rd in the nanotechnology publications after China and USA. The patenting process in nanotechnology is there but yet to increase in favour of domestic applications at the Indian Patent Office coupled with the lack of Indian case law on the subject makes the discussion on the Indian patent regime and nanotechnology most pertinent. Indian Patent Law when applied to the field of nanotechnology raises a number of concerns and difficulties in terms of grant of patent. Therefore, it is necessary to carefully consider whether the Indian Patent System offers a favourable environment for the growth of nanotech industry by motivating patent protection in India. In this research paper, the authors have addressed one specific issue that is of the impact of Section 3(d) of the Indian Patent Act, 1970 on the nanotechnology patent applications in India. The authors propose an amendment in Section 3(d) of the Indian Patent Act, 1970 and some steps that the patent office could take to promote nanotechnology patenting in India and in turn aid the nanotechnology industry growth in India.

Keywords: Nanotechnology, Patent, Patent Applications, Nanotechnology Industry, Section 3(d) of Indian Patents Act, 1970

In the year 2007, India launched the national nanotechnology mission, which has promoted the technology in all possible sectors.[1] Given the future potential of nanotechnology, if further steps are taken in the right direction, it will be a great contributor to the Indian economy. One of the step in the right direction is that while addressing the important aspects of professional education, in the National Education Policy 2020 (NEP), it is stated that that India must take the lead in training professionals in cutting-edge fields that are rapidly gaining importance, such as artificial intelligence (AI), 3-D machining, big data analysis, and machine learning, as well as genomics, biotechnology, nanotechnology, and neuroscience, all of which have important applications in health, environment, and sustainable living and will be woven into undergraduate education to improve youth employability.[2] However, the resolve in NEP, financial investments in the Nanotechnology sector by Indian Government and instituting the National Nanoscience and Technology Mission (NSTM / Nano Mission) are just some initial milestones for growth of Nanotechnology industry in India. India must not ignore the importance of promoting patent protection in nanotechnology.

In 2021, India ranked 3rd in the nanotechnology publications after China and USA. Out of a total 202,000 scientific research papers considered, China's share was 42.45%, followed by USA with 11.50% and India with 9.43%.[3] The research publications in nanotechnology from India in comparison to the ratio of patents applied for in the field of nanotechnology that originate from India are very low. A comparison of the top 3 ranking countries (China, USA & India) in terms of their scientific research publications output in the field of nanotechnology (as shown in Table 1) with the statistics of applications under PCT (Patent Cooperation Treaty) of last seven years originating from China, USA and India (Table 2) confirm the fact stated earlier.

Some of the recent innovations in the field of nanotechnology listed by a UK based company 'IN-PART' which provides for industry-academia connect are: superior carbon fibres; a nanocarrier to improve targeted drug delivery; advances for transparent conductive thin films; frontier for droplets in droplets; the world's smallest (and most useful) hacky sacks; A spray-drying technique making noise

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Table 1 — Share % of top 3 ranking countries out of total publications in field of nanotechnology[4]

Country	2015	2016	2017	2018	2019	2020	2021
China	34.06	34.51	32	39.47	40	40.9	42.45
USA	16.65	16.25	13	14.75	13.5	12.8	11.50
India	7.55	8.05	7	8.45	8.5	9	9.43

Table 2 — Number of PCT filings in field of micro-structural and nano-technology in China, USA and India (2015-2021)[5]

Country of origin	2015	2016	2017	2018	2019	2020	2021
China	24	31	27	33	42	70	81
USA	116	117	147	141	126	148	141
India	5	3	4	3	2	7	5

in gene silencing; a fireproof nanomaterial bringing the heat; and more.[6] In India too there are various companies and start-ups that offer nanotechnology products such as: Adnano Technologies in Carbon nanomaterials; Dabur Pharma in Drug delivery; Mittal Enterprises in nanofluids; Nano sniff Technologies in microcantilever and microheater sensor technologies and Neo-Ecosystems in Nanocoatings.[7]

Need and Relevance of the Study

India looks forward to develop in every field of Science and Technology including nanotech, and aspires to hold Intellectual Property rights in it. Since 2015, India has ranked 3rd in the nanotechnology publications after China and USA (Table 1). The patenting process in nanotechnology is there but yet to increase in favour of domestic applications at the Indian Patent Office coupled with the lack of Indian case law on the subject makes the discussion on the Indian patent regime and nanotechnology most pertinent. Indian Patent Law when applied to the field of nanotechnology raises a number of concerns and difficulties in terms of grant of patent, which the authors have studied in a larger part of their research. The authors believe that it is necessary to carefully consider whether the Indian Patent System offers a favourable environment for the growth of nanotech industry by motivating patent protection in India. However, in this research paper, the authors have limited their discussion only to one but very important and specific issue that is of the impact of Section 3(d) on the nanotechnology patent applications in India.

Dr. Prabhuda Ganguli and Siddharth Jabade[8] talk about the evolving concept of the nanotechnology patent landscape etc. The design of a search strategy and the search for prior art in the field of nanotechnology are both included in the comprehensive patenting process and worldwide categorization system. The authors primarily focus on the following topics: institutionalised management of intellectual property rights, public perception of risk to health and ecosystems, patentability, and the steps that will be required to meet these and other similar challenges on the way to realising profits in nanotechnology. This book explains the techno-legal aspects of inventions related to nanotechnology in a straightforward and understandable manner for a varied readership that may not be familiar with the legal complexities of IPR. This will help with the innovations' efficient incorporation into businesses. The book explains many case studies and pictorial illustrations that cover topics including ideation and commercialization of IP-enabled nanotechnology. Authors have tried to cover almost everything in terms of nanotechnology and IPRs but failed to report the effective mechanism of patenting in nanotech science in India.

Indrani Barpujari[9] discusses the difficulties that patenting nanotechnology poses for national patent systems and potential solutions. In order to derive conclusions for India, it looks at the patent regimes and case laws of other nations, namely the United States. The study emphasises the paucity of Indian jurisprudence and the low amount of Nanotechnology patent applications and granted at the Indian Patent Office. The following are the challenges and issues with nanotechnology patents, according to the author:

(a) Broad Claims and Patents on Basic Inventions
(b) Multi-Disciplinary and Multi-Industry Applications
(c) Increased Upstream Patenting and Universities' Role
(d) Difficulties in Identifying nanotechnology Patents
(e) Difficulties in Meeting Patentability Criteria.

Further, in response to the challenges, the author has attempted to propose some approaches for India toward adjusting the Patent Regime for Nanotechnology in comparison to the EPO and USPTO. She also stated that the Patent Law should provide flexibility and exemptions to allow nanotechnology subject matter to meet patentability criteria.

Anuar HS *et. al.*[10] draw attention to the significance of nanotechnology in terms of patents, difficulties, and applications. It contains a thorough analysis of the body of literature that has been written about patent problems, difficulties, and nanotechnology applications. When a nano-based product or method is acknowledged as a workable patented product, that presents one of the hurdles. The application of nanotechnology has also

grown from a single nanoscale to sophisticated nanosystems. Numerous authorities from numerous nations have now been established to oversee nanotechnology patents (in products and services). The main focus of the various parties engaged in making sure that any issue that occurs can be quickly resolved should be issues related to nanopatenting.

In light of the discussed case laws[11], Nikolas J Uhlir[12] states that the Patent Office faces substantial difficulties while examining nanotech applications. Because nanotech inventions typically exhibit unusual and highly size-dependent properties, strong incentives exist that encourage nanotech applicants during the examination process to define the invention over the prior art. The author has given a solution to the existing problem of examining nanotech applications in the article. According to the author, when it comes to nanotech applications, the Patent Office has a lot of challenges, because nanotech inventions often have novel and size-dependent qualities, there are substantial incentives for nanotech applicants to leverage these properties during the examination process to distinguish their invention from the prior art. This method, combined with the scarcity of nanotech prior art and applicants' proclivity to function as their lexicographers, forces examiners to establish inherency arguments with insufficient evidence. Arguments that the examiner failed to fulfil the evidentiary burden required to demonstrate a plausible theory of inherency are quite likely to be made against these assertions of inherency. Double patenting, both malicious and innocent, is also possible as a result of this activity. However, this problem can be mitigated by:

(a) Increasing the relative amount of prior art available to the examiner by increasing the duty of disclosure on nanotech applicants;

(b) Adopting a rule imposing standardized metrics for nanotechnology applications; or

(c) Judicially reaffirming that the Patent Office can meet its burden of establishing a viable theory of inherency for all products, including nanotechnology, by showing a substantial structural similarity between them.

In the article, Molenda[13] reviews case law[14] and makes the case that nanotech inventors should serve as their lexicographers and define essential terms in their patent specifications. He also discusses how the law may affect nanotech patents and how to understand language in patent claims. When applying for a patent for a nanotechnology invention, the applicant must carefully evaluate the terminology that will be used to describe the invention. The language employed in the claims will establish the patent's scope in any subsequent licencing and litigation proceedings.

Mark A Lemly[15] explores whether patenting nanotechnology will be a success or if it will just be the fad of the future. Watching nanotechnology patents is advised. Mark has noted a few traits that would make them fundamentally distinct from patents in any other business over the previous 80 years. If and how the law must intervene to adapt the rules of patent law to the requirements of this emerging industry will depend on how the market reacts to these characteristics. We shall also gain a more comprehensive understanding of the function of patents in enabling technology. Although the author has particularly discussed how to address the patent system's existing issues, the improvements are broader and do not address nanotechnology-specific issues.

Nanotechnology is a natural experiment that can show us whether we have learned anything about how to licence and enforce patents without limiting innovation since the days of the Wright brothers, or whether the lack of early patent protection for the enabling technologies of the last century was merely a series of fortunate circumstances. Dennis Fernandez[16] focused on the American patent system, which is undergoing its most significant revision since the enactment of the Patent Act of 1952, and many of the changes are relevant to nanotechnology. To better comprehend the current state of IP in nanotechnology, this overview examines basic IP definitions, recent IP advances, and sophisticated protection measures.

Michael Costello-Caulkins[17] discusses the legality of nanotechnology patents in light of several case studies from the United States and European Patent Applications. The author has identified several parallels and differences in patent procedures as well as the interpretation of patentability requirements in both jurisdictions. The author also validates the forecast that US nanopatent applications will be granted at a faster rate than European applications. Therefore, the prior art references will be of greater quality if the EPO gives more examiners and time to each application. In light of this, nanotechnology companies can anticipate a different level of service from the USPTO compared to the EPO, as well as

different patent scopes when applications are eventually granted patents.

Abhishek K Mishra *et. al.*[18] discuss and examine the various obstacles that patenting nanotechnology poses for India's patent laws as well as potential solutions. Nanotechnology exacerbates issues that may conflict with the preservation of intellectual property rights and non-commercial legal rules (which include environmental laws). In the lack of compatible patent law provisions, nanotechnology will face difficult challenges in terms of satisfying invention, inventive step, industrial capability, and eligibility of subject matter under Section 3 of the Indian Patents Act 1970. The authors specifically point out towards clause (d) of Section 3 as being one of the important challenges. However, there is no practical data in support of the contentions.

When dealing with nanotechnology patenting as a topic of discussion, Anupriya Shyam[19] pointed out several issues about patentability requirements. The purpose of granting intellectual property rights, she continued, is to promote more innovation, which will ultimately benefit the broader public. As a result, the law must not obstruct progress. Therefore, existing patent rules must be appropriately changed to incorporate the special needs of this sector for nanotechnology to advance. The Patent Office should give the problem of novelty assessment, prior art search, and institutional competence the highest priority. This article too lacks any supportive data or specific suggestions.

Research Gaps

Can an atomic or molecular structure be patented? How can you prevent a gadget the size of an atom or molecule from being stolen? How will changing patent laws impact the reach of nanotechnology patents? In order to utilise the advancements in nanotechnology effectively and efficiently, these and other intellectual property issues must be resolved.

Patent Applicability, Balancing Innovative Freedom and Restrictive Intellectual Property, Academic Publication as Premature Disclosure, Technology Transfer Procedures, IP Rights (Public and Private Funded Research), and Intellectual Property Litigation are some of the current problems and challenges in nanotechnology intellectual property.

In India, patenting activity in nanotechnology is there but very low comparable to the number of quality research publications from Indian authors. The authors believe that the Indian Patent Office should significantly improve its support for home applications as a result. Additionally, there isn't any Indian case law on the topic, therefore the debate of the Indian patent system and nanotechnology is premature yet important.[9] The authors throughout their larger part of research did identify various issues relating to nanotechnology patenting in India, including filing of broad claims, interpretation of novelty and inventive step in nanotech patent applications, limitations of prior art in the field, knowledge and experience of the patent examiners in dealing with nanotechnology patent applications. However, for the purposes of this research paper, the authors focus on the unique situation of the patent law in India and have dealt only with the practical challenges due to Section 3(d) of the Indian Patent Act, 1970.

Research Objective

- To analyze Section 3(d) of the Indian Patent Act, 1970 with regard to nanotechnology patent applications in India.

Research Question

- How is Section 3(d) of the Indian Patent Act, 1970 interpreted in the case of nanotechnology patent applications in India?

Research Methodology

Doctrinal research methodology was used to lay the ground work of understanding thoroughly the patentability criteria, conducting literature review and narrowing down to the research gaps. Further doctrinal research also supports the conceptual analysis of Section 3(d) of the Indian Patent Act, 1970 in light of nanotechnological inventions.

Further, empirical methodology is primarily used by the authors to collect data from various legal and science experts from the field of nanotechnology in India, especially the persons who have experience with nanotechnology as a subject matter. The various experts from India include inventors, patent examiners and other authorities from patent offices, law practitioners, patent agents, scientists, researchers, academicians, research and development officials from well-known organizations, patent analysts and research scholars.

For the purpose of this research paper, the authors have taken relevant data from a larger set of survey, which was a 16-item questionnaire, that was created

in the Google Forms and sent through email and/or WhatsApp. Informed consent was obtained for the sole purpose of utilizing the data for research purposes. Sensitive personal data of the Respondents has not been disclosed for privacy reasons.

Because the respondents were difficult to identify unless through personal or professional familiarity, and there was no available database such as a standard register, the snowball sampling technique was adopted for most type of respondents except for collecting the data from patent agents for which the national patent agent register was referred. The limited practice and knowledge about the subject matter of nanotechnology is one of the reasons that mainly the snowball sampling technique was used.

The survey was given to 939 possible respondents, and 136 legitimate questionnaires were returned to the researcher, resulting in a 14.37 percent return rate. The low return rate could be because of the sensitivity and confidentiality of the discussed subject matter, or time constraints or not having enough experience in the field of nanotechnology patents.

Conceptual Analysis of Section 3(d) with Regard to Nanotechnology

Section 3 falls under the Chapter II titled "Inventions not patentable" of the Indian Patents Act, 1970, which means it deals with prohibited subject matter for patent grant. Clause (a) to (p) of Section 3 lists various things which are not inventions within the meaning of the Act for one or other reason. Though in a few clauses the reasons for not deeming it to be invention are apparent, a few clauses are silent on the reasoning. For example, the reasoning provided in clause (a) for "an invention which is frivolous or which claims anything obviously contrary to well established natural laws" and clause (b) for "an invention the primary or intended use …could be contrary to public order or morality…" is quite clear. On the other hand, clause (h) which deems "a method of agriculture or horticulture" as not being an invention capable of being patented provides no reason at all. Some authors of Intellectual Property books in India have tried to provide a better understanding to Section 3 of the Indian Patents Act, 1970.

Understanding the nature of Section 3, it can be said that anything that falls within the limits of Section 3, will not be considered to be an invention and therefore it is a non-patentable subject matter, and thus does not meet the patenting criteria. As a result, if a patent application falls under any of the clauses in this Section 3, it cannot be considered for grant of patent.

Section 3 (d) of the Indian Patents Act, 1970 does not consider patentable "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

Although Section 3(d) is a crucial instrument for preventing patent evergreening, it might seriously impede the development of nanotechnology. In particular, under Section 3(d) of the Indian Patents Act, 1970, nanotechnology would face challenges in proving its eligibility as subject matter and achieving the requirements of novelty and inventive step.

There are various definitions available of the term 'nanotechnology' and a lack of a clear definition of the term 'nanotechnology' does present ambiguity to some extent. However, the authors for the purpose of this paper wish to rely on the understanding provided by the United States Government in following terms: "Nanotechnology is science, engineering, and technology conducted at the nanoscale, which is about 1 to 100 nanometres. Nanoscience and nanotechnology are the study and application of extremely small things and can be used across all other science fields, such as chemistry, biology, physics, materials science, and engineering. One nanometre is a billionth of a meter".[20] Thus, for example the measure of one inch consists of 25,400,000 nanometres.

The uniqueness of nanotechnology is mostly attributable to the shrinkage of size. The pharmaceutical industry is expected to gain the most from research supported by nanotechnology. The explanation appended to Section 3(d) makes changes in "particle size" as a non-patentable subject matter,

thus even if there is an invention of a nano-particle, which is an R&D outcome, of considerable size reduction of a known product, providing various benefits for the industry, it still could be rejected under Section 3(d).

The size of the nanoparticles used in drug delivery techniques, which varies depending on the substance, has a significant impact on their accuracy. As an illustration, due to their smaller size, nanoparticles have shown to be more efficient, water-soluble, target-specific, and stable drug delivery strategies than the well-known conventional routes. For many years, pharmaceutical researchers have used nanoparticles to lessen the toxicity and side effects of their medications. This raises questions about the use of the word "efficacy" in Section 3(d).

In many circumstances, nanomaterials are made up of a mix of different particles or technologies, or nanoparticles of an existing substance, with no variation in character or industrial applicability. Thus, the invention may fail to meet Section 3 (d) standard, especially the "efficacy" criteria. In India, there is a lack of criteria for determining efficacy and qualifying the enhancement of efficacy. Thus Section 3(d), due to lack of clarity of meaning of 'efficacy', could become a tool which may be misused for preventing grant of patents. In *Novartis* v *Union of India*[21], efficacy was interpreted to mean only therapeutic efficacy for the purpose of that case. The opportunity to define the contours of the term 'efficacy' was lost.

Section 3(d) emphasizes that a novel form of a known material is patentable only if the new form differs significantly in its qualities concerning 'efficacy.' As a result, patentability requires not simply a minor improvement in efficacy, but a significant improvement. The essential point here is not whether it may be defined as an innovation or simply a finding of something already possessed by the patent's subject matter, but whether the newly invented substance or product has improved in efficacy.

Empirical Research, Outcomes and Analysis

The demographic profile of the respondents was selected based on the following criteria:

a) Educational Background
b) Professional Background
c) Awareness of Nanotechnology as subject matter
d) Experience in dealing with nanotechnology patents
e) Practice of filing nanotechnology patent applications in India

The authors managed to get 14 respondents who were scientists. The responses from the scientists/ inventors have been collected from the topmost and renowned organizations like Tata Technologies (Research & Development), JSW Group, Fertin Pharmaceuticals (Research & Development), Lupin Pharmaceuticals (Research & Development), Symbiosis Centre for Nanoscience and Nanotechnology, Institute of Nano Science and Technology, Defence Research & Development Organization, and IIT Bombay. Further the 55 respondents in the category of "Patent Agents/Attorneys" are from: Top law firms in India such as Lakshmi kumaran and Sridharan, Fox Mandal & Associates, S. S. Rana & Co.; Top IP Law firms such as Anand and Anand, IP Dome, Khurana & Khurana, Gopakumar Nair Associates, Remfry & Sagar, K & S Partners and Stratjuris Law Partners; Boutique IP services and consultancy firms; and individually practicing patent agents. Further the category of "Advocates (IP) / Law Counsel / Legal Manager" consists of respondents who are individual IP Advocates, In-house IP Counsels or IP Managers from Corporates. Also, responses from Judges, Academicians and Ph.D. Scholars having patent related experience were collected. Last but not the least the patent examiners and other authorities from patent office were also contacted to gather their experience in examination of nanotechnology patent applications.

However, the authors have relied on the data collected from 118 expert respondents out of the 136 (Fig. 1), due to their experience in dealing with nanotechnology patents. The selected 118 have carried out one or more of the following functions and therefore are well versed in the subject matter:

1. Researched nanotechnology patents
2. Invented nanotechnology-related inventions
3. Prepared Search report for nanotechnology inventions
4. Filed nanotechnology patent applications
5. Examined nanotechnology patents as Patent Examiner
6. Provided consultation regarding nanotechnology patent
7. Decided nanotechnology patent cases (opposition/ infringement/validity)

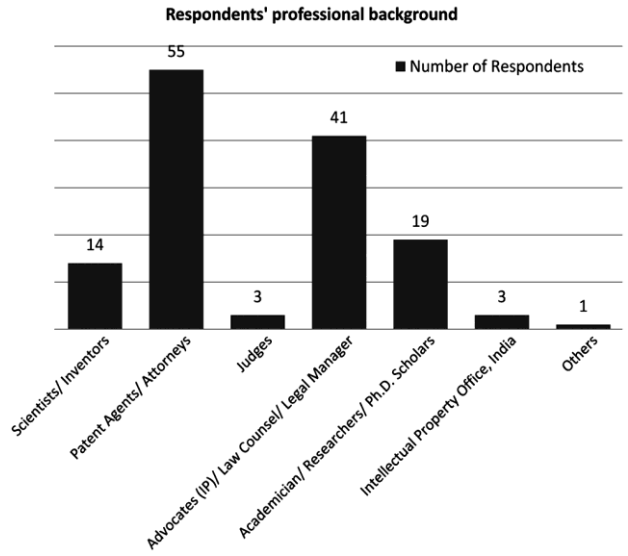

Fig. 1 — Respondents professional background

Table 3 — Patentability requirement under the Indian Patents Act, 1970 that poses a maximum challenge with respect to the grant of nanotechnology patent applications in India

Multiple options provided to respondents	Number of respondents who selected the option
Novelty	73
Inventive Step (including non-obviousness)	89
Capable of Industrial Application	7
Section 3 (b)	65
Section 3 (d)	95
Any other	04

One of the most important questions posed to the expert respondents was: Which patentability requirement under the Indian Patent Act, 1970 poses a maximum challenge with respect to the grant of Nanotechnology Patent applications in India? The respondents could select multiple choices in answer as there could be more than one challenge and it would be difficult to choose which one poses the maximum challenge, though the question was framed in a way to gauge the same as seen in Table 3.

Following is the analysis of the responses in regard to the criteria that pose a maximum challenge to nanotechnology patent applications (Fig. 2):

(i) Maximum responses (95) have pointed out Section 3(d) of Patents Act, 1970 as a challenge. Since Section 3(d) is identified by maximum respondents, it can be stated that Section 3(d), which is a unique provision introduced by Indian Patent Law, poses a maximum challenge to nanotechnology patent applications.

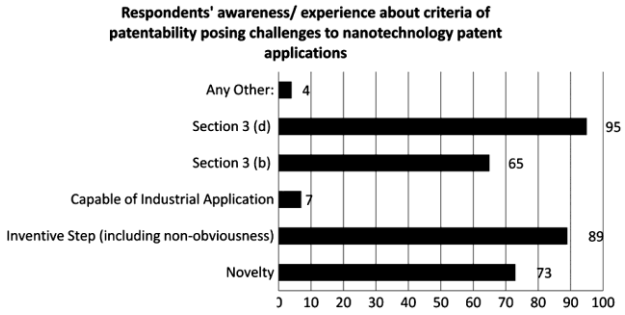

Fig. 2 — Respondents awareness / experience regarding the patentability requirement under Indian Patents Act, 1970 that poses maximum challenge to nanotechnology patent applications in India

(ii) The next bigger challenge identified in the responses (89) is the fulfillment of the requirement of 'Inventive Step'.

(iii) The third most selected challenge in the responses (73) was that of the criteria of 'Novelty'.

(iv) Interestingly 69 responses identified Section 3 (b) of the Patent Act, 1970 as a challenge too.

(v) Merely 7 responses pointed out the criteria of 'Capable of Industrial Applicability' as a challenge

(vi) 4 respondents also selected the option 'Any other'. Unfortunately, 2 of the respondents out of the 4 did not specify the said other challenge. 1 of the respondents out of the 4, who is an expert respondent from the renowned Law firm Lakshmi Kumaran and Sridharan, besides selecting other given options in the list also ticked on 'any other' option and pointed out other possible challenges that may be posed by Section 3 (e)[22] and Section 10[23] of Patents Act, 1970. The last respondent out of the 4, who is an academician teaching IP law, did not select any of the given options but tried to explain in his own words that "It's more about interdisciplinary spanning of the invention and 'Substantial Utility' method or approach adopted by India. So, novelty can be considered as a challenge to certain extent and in given contexts".

In one of the items of survey, a statement was provided and followed up with a question. The respondents were informed that our research shows that the nanomaterial could be a mix of many particles or technologies or a nanoparticle of an existing material, and patents for nanostructures, with little difference in character and industrial application, and it could fail to meet the efficacy standard set forth in

Section 3(d) of the Indian Patent Act, 1970. Upon that statement, they were asked: Do you think Section 3(d) of the Indian Patent Act, 1970 limits the scope of Nanotechnology patenting in India?

Out of the 118 respondents, 91 respondents selected the option 'Yes', 12 respondents selected the option 'No' and 15 respondents selected the option 'Not Sure'.

With the help of the above-mentioned question researcher primarily intended to focus more specifically on the respondent's experience and/or opinion towards Section 3 (d) of the Patent Act, 1970 (Fig. 3). Interestingly, 77 percent of respondents agreed that Section 3 (d) of the Patent Act, 1970 limits the scope of nanotechnology patenting in India.

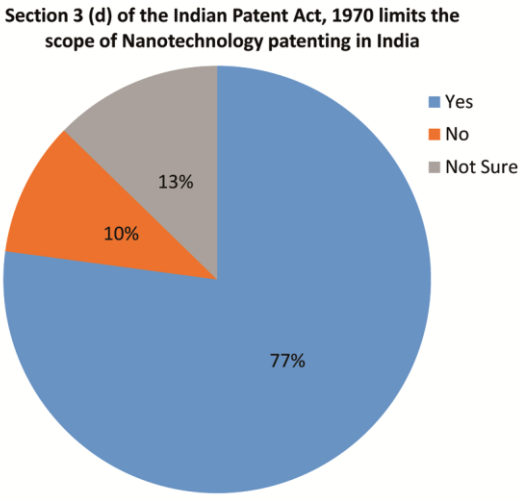

Fig. 3 — Respondents opinion on Section 3(d) of the Patent Act, 1970 limiting the scope of Nanotechnology Patenting in India

However, 10 percent of the respondent chose a negative answer and 13 percent gave their opinion that they are 'Not Sure' about it.

The researcher towards the end of the questionnaire had given an option to the respondents to provide any suggestions/opinions if they wished to. Some of the recommendations, suggestions, and comments though not directly specific to Section 3(d) have been found by the authors to be worth mentioning. The comments have further been categorised to portray the distinction between the views of patent practitioners' and inventors' perspectives (as shown in Table 4).

Conclusion

The doctrinal research has clearly brought out the two aspects in Section 3(d), 'particle size' and 'efficacy' which pose an apparent challenge to nanotechnology inventions. In the Indian patent regime, there is a lack of a standard for determining efficacy and quantifying efficacy enhancement.

The responses collected from the expert respondents through empirical research revealed various practical aspects of patenting nanotechnology inventions. Also, the majority of expert respondents have identified Section 3(d) as a major barrier, thus it can be concluded that Section 3(d), a unique clause adopted by Indian Patent Law, is the greatest obstacle to nanotechnology patent applications in India.

The authors suggest an amendment in the Section 3 clause (d) as mentioned below and adoption of specific guidelines to be made applicable when dealing with nanotechnological patent applications for better clarity to the stakeholders and the patent

Table 4 — Patent practitioners perspectives *vis-à-vis* inventor's perspective as gathered during survey

Patent practitioners perspectives	Inventors perspectives
With in-depth analysis and understanding of the nanotechnology subject matter, criteria of patentability can be fulfilled	Although policymakers must consider an efficient system that can strike a balance between harmonizing with the rest of the world while maintaining the fundamental protection that inventors deserve, nanotechnology inventors must keep up with legal changes and be actively involved from the conception of their invention to the filing of a patent in order to ensure proper protection of their IP rights under the new law.
Nanotechnology subject matter may pose some challenges concerning the conceptualization of law.	Dealing with nanotechnology demands a balanced legal approach: strict control or overregulation may ruin the structure of nanotechnology, preventing the economic gains that this technology may give, while under-regulation of these elements may pose significant concerns. Existing IP regulations must be modified and interpreted in light of recent nanoscale technical developments if favourable results are to be achieved.
A middle-ground approach can be exercised while applying the test of patentability also case-specific approach can be adopted	Rather than rejecting patent applications under patent law, the nanotechnology sector should be supported by issuing patents and establishing a highly controlled regime.
The scope of the patentability criterion and Section 3(d) of the patent laws should be clarified through nanotechnology guidelines or rules.	The law should be favourable to inventors. According to research, there is no motivation or incentive for hard labour.

examiners who are dealing with nanotechnology patent applications.

The proposed amendment to Section 3 clause (d) of the Indian Patent Act, 1970, should be made by adding a proviso to the existing 'Explanation' proviso of Section 3 (d). The newly added proviso to the Explanation in Section 3(d) will read as:

"Provided that, while considering any nanotechnology patent application, the words 'particle size' from the above explanation shall be deemed to be excluded"

The newly added proviso will essentially provide that in case of nanotechnology patent applications, the words "particle size" provided in the explanation of Section 3(d) shall not matter and thus such nanotechnology inventions that are based on reduction of particle size will not be excluded from being capable of patenting simply due to reduction in particle size.

For nanotechnology patent applications, there are no universally accepted worldwide rules. However, new nanotechnology advances that change the functionality make it difficult to apply a common set of evaluation metrics to various nanotechnology inventions with various applications. The case-by-case evaluation approach will make it difficult and a time-consuming process and therefore will not serve as an appropriate means when dealing with nanoscale patent applications. Therefore, the authors propose adoption of "Guidelines for Examination of Nanotechnology Applications for Patent in India" which shall become useful for Indian Patent Office and patent applicants. These guidelines can be reviewed, adopted and implemented in collaboration with National Nano Science and Technology Mission (Nano Mission) of the Department of Science and Technology, Government of India.

It is proposed that the said guidelines shall provide for a standard definition of the term 'Nanotechnology' which is in conjunction with the definitions accepted by several developed nations and that definition shall also have the quality that it presents least challenges for the patentability of unique products and processes that are a result of the advancements in the nanotechnology field of innovation. Further the guidelines should also provide for more clarity and an inclusive meaning of the term 'efficacy' which will at least have a persuasive meaning, if not the law of the land. The proposed guidelines, are discussed in more detail by the authors in their larger research study (yet unpublished)and can be adopted by the Indian Patent Office after furthering an opportunity to various stakeholders to provide further inputs, if any.

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