

Nano-tech and Indian Regulatory Regime: A Review

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Abstract

Nano-technology is still a niche field in the realm of science and technology, however its potential in terms of increased efficacy and effectiveness cannot and should not be taken away. In a world driven by advancements in innovation and technology, like any other scientific advancement nano-tech brings into the light question about use and abuse and therefore it becomes imperative to ask ourselves that whether or not we are fully equipped to control its abuse and protect the bona-fide usage of the technology. To keep a vigil and curb the abuse it is needed that we regulate the field. These regulations serve us in order to keep up with the ever-evolving fields of science & technology but in order to keep up with the pace of evolution the regulatory regime has to have a robust framework and a foresight because of certain limitations of law. Hence this paper becomes important as we analyze the Indian approach for governing the field of nanotechnology, as we discuss the lacunae and scope of improvement in the current approach of the Indian government and policymakers viz-a-viz existence of a gap in terms of robust framework governing and regulating this emerging field.

Keywords: India, Nano-technology, Regulatory Regime, Science and technology.

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INTRODUCTION

Technology and law both are meant to serve a single purpose, to ensure development and wellbeing of society and at the same point of time both are used to keep a vigil on each other i.e. law is used to keep in check abuse of technology and technology is used to increase the efficacy and efficiency of law. However, as the matter of concern before us in this paper is review of the Indian regulatory regime concerning the field of nano-technology, we will be focusing on first part of the preposition i.e. law being used to keep in check abuse of technology and protect the bona-fide usage at the same point of time [1].

Nanotechnology, happens to be an emerging field of science which includes technology involving particles at a nano scale. These technologies are used in pharmaceuticals, food packaging, bio-technology, neurosciences etc. These technological innovations and scientific leaps are a moot point with respect to the potential ethical and regulatory issues as unlike every other advancement the basic elements used in these tend to pose certain threats to users. Certain issues that crop up

with usage of new technology might include but are not limited to environmental impact, public trust, transparency in terms of information, potential risks, etc.

Due to its promising nature and ability to revolutionize a lot of industries such as information technology, medicine, energetic, astronautics, food etc. and provide novel solutions to the issues such as environment degradation, drinking water and sanitation it has gained traction amongst the general public and therefore as a result it got major push from governments and received major investments public and private players boosting the further research and developmental works in this field.

The investments and policy initiatives were not limited to the global north, i.e., the developed society but also the developing society took it up as a task and opportunity to carry out developmental works. In this line the government of India started to invest in the field of nanotechnologies in the year 2001 [2]. Post this decision since 2002 the field became a distinct area of research. Simultaneously, an

initiative i.e. Nano Science and Technology Initiative was started by Department of Science and Technology which is the most funded initiative with 170 USD which was followed by allocation of 193 billion rupees under 2007–2012 under eleventh five-year plan of government of India and it kept on increasing in the subsequent period.

Nano-tech: Progress and Concerns

Although, the research in this field has increased manifold the governmental approach to the regulation of nanotechnology has been largely a lackluster kind of response. For example, it was in 2006 that National Institute of Pharmaceutical Education and Research announced development of guidelines for nano-tech based drugs [3]. Later in 2010, Nano mission announced creation of a regulatory board along with an expert supervising environmental and health issues. Both of these entities did not end up as a pioneering body. However, post 2010, in 2011 guidelines recommending the safe handling of the particles came into effect and became the first concrete step in the field of nanotechnology in India.

The overall performance of this sector can be understood in terms of the quantity and quality of literature produced. An increase in the number of publications shows that post year 2000 there was constant increase in the literature published and also prove increased collaborations between academia and institutions. However, the major concern remains in terms of filing of patents within and outside the country even after presence of governmental policies to focus on innovation.

Hence, it becomes important to find out the shortcomings of the system and to find out we have to identify certain factors such as funding, commercialization, risk regulation, benefit distribution etc. As far as funding is concerned, there is a mixed response from the stakeholders as some from the scholarship appreciate how it is getting comparatively more funding than the other fields of research however, in comparison to the other countries it remains a meagre amount so far. To add into

this, private investments lacks in India leading to another set of issues.

The second issue is with respect to capacity building in terms of expertise and infrastructure in India. This also gets to see a mix response largely tilting towards on the critical side of it where in it has been claimed that although there remains no dearth with respect to the brilliantly minded scholars but at the present moment India lacks the sufficient infrastructure to regulate and contain the risk posed by this technology specially in terms with intellectual property regime. Thirdly, the commercialization or its lack under Indian situations is debated upon by the parties as it is claimed that there is no convergence or meeting of minds of the research and manufacturing along with a missing link with respect to investors. In this regard the researchers and the companies end up playing a blame game leading us to a precarious situation.

The next issue that arises is the regulation of risk, and unlike its western counterparts, this was not a point of debate in India for a really long time and only emerged as the research in the field progressed [4]. This issue came to light with creation of genetically modified organisms as it posed a significant threat and although there was still not much of a hue and cry around it but industry experts accepted the lack of regulation in terms of safety and to deal with it measures should be implemented by governmental agencies. This debate also leads up to a point where in the necessity a whole new regulatory regime or amending the old laws becomes a question.

Last but not the least the public concern moves towards distribution of benefits, where in economic and developmental aspects are debated upon. This debate has usually not seen much of a difference in terms of opinion however although most of the industries have opted for a top-down approach in terms of trickling down the benefit but as in India the field is led by government therefore there are certain initiatives which exist and are funded by the government to have a better inclusivity

so as to provide benefits to masses specially the lowest strata of the society.

ANALYSIS

The study of Indian setup becomes necessary in order to analyze the aftermath of India missing out on the 1970's micro-electronic wave which provided for a head start to countries like China and South Korea i.e. the main competitors of India at global level. While the field is progressing there remains a want of professionals to cater to the needs and India being rich in terms of manpower is expected to deliver when asked [5].

The Indian setups' biggest drawback is its lack of focus on the ethical concern surrounding the premises of the field of nanotechnology as some of these are going to adversely impact the environment and human lifestyle. As we witness the advancements like never before a threat of warfare involving these advancements lingers over all of us while the other successful missions such as Indian Space Mission and Nuclear Mission are overshadowing the field with their successes.

The lack of concern is apparent as we can still see insecticides with nano-particles and appliances like washing machine using silver nano particles are still readily available in the market in spite of the risk associated with them. What's more worrisome for all of us is these practices being carried out post the acceptance of health hazard caused by size and nature of these particles [6].

Research competency and skills remain a positive for Indian setup because of the skillful manpower involved. The government has certainly come far from the original position and we see certain institutional setups for the promotion of the field of nanotechnology which has been spread across the nation which is complemented by public participation. In terms of guarding intellectual property, we can see the slight increase in the number of patents specifically in the arenas the developmental challenges which also included upcoming innovative products which are manufactured using new state of the art processes to tackle the larger issues.

As we barely peruse the literature available it can easily be identified that the Indian program is more of a public driven program and the industry participation remains weaker in comparison to the other nations. In addition to this there is an absence in terms of link between the research and the value chain as the patent regime has somehow restricted the patenting to only public institutions and as there is a lack of expertise in terms of these public institutions the horizon can be broadened keeping in mind involvement of the private organizations [7].

Furthermore, lack of institutional expertise in sense of increasing scalability of research and development, risk assessment and mitigation create another loophole in the system. As noted earlier this is public driven initiative when we talk about Indian setup yet we find that there happens to be no or less encouragement to the indigenous advancements in this field hence lack of support is apparent defect of the nanotechnology framework in India [8].

We have seen that only umbrella structure has been formed so far by the government agencies and there exists a doubt about extending and molding the same as per industry specific needs to strengthen the sectoral regulatory framework involving nano technology in order to incorporate its nitty-gritties. Along with it there is another apparent defect with respect to having a foresight as the decade old laws are not compatible with the current advancements and the needs of this sector [9]. While we need to focus on these there has to be some focus on public awareness about the field of nanotechnology and available facilities, which can only and only be created by the government

CONCLUSION

In contrast with the foreign counterparts there is an apparent consensus in favor of the technology given its potential however the larger scope of ethical and risk mitigation still remains unaddressed at large. Given it is a government led field the prerogative of establishing a robust legal framework, institutional support and capacity building while focusing on the scholarship and

safeguarding the intellectual property rests with the government. It is also on the government to address the public concerns surrounding the aforementioned issues and to build consensus around the same. However, a lot of work in the field such as translating scientific research into products and responsibly dealing with potential risks remain as an obstacle and hence to solve the issues legislative renovation has to be carried out by the government at large. Therefore, the government must take this opportunity to address the approach which has largely been top-down approach and shift it towards bottom-up approach so as to cater to developmental challenges. There are huge issues that we face in terms of development as a whole and if nanotech is introduced to those sectors then it can significantly add value to Indian products while also helping us to meet other larger societal concerns. While we address these issues we must have to balance out the interests in a manner that over regulating doesn't become an obstacle in the further development while under regulation also remains a matter of concern for public safety as if such balance is not made out any unwelcomed incident will cause us the opportunity to become a leader in this field and will surely push it away from our reach.

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