

THE INTELLECTUAL PROPERTY CONUNDRUM: THE LEGAL IMPLICATIONS OF NANOTECHNOLOGY IN MEDICINE AND SUSTAINABLE ENERGY

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ABSTRACT

Nanotechnology and medicine are significantly interconnected, particularly through the augmentation of drug delivery systems, diagnostics, and treatments like gene therapy through the unique properties of nanoparticles. These advancements, while a necessity in the contemporary world and protected by intellectual property laws, insinuate the presence of vital challenges for sustainable energy and environmental health. Nanoparticles, once introduced, continue to persist in ecosystems, potentially leading to bioaccumulation and instigating the vicious cycle of nano-pollution. This study hypothesizes that the negative environmental impacts of nanotechnology in medicine undermine sustainable energy practices due to inadequate and fragmented regulatory frameworks and the blanket protection provided to such technology by patents. The paper employs a doctrinal method to critically evaluate existing legal frameworks, policies, and international standards, revealing gaps and inconsistencies that fail to address the environmental and energy implications of nanotechnology in medicine. Regulations from international bodies like ISO and regional initiatives such as the EU's REACH illustrate that the absence of cohesive, enforceable guidelines hampers the effective management of nanotechnology's risks and the inability of countries, particularly in developing and underdeveloped countries to govern their energy utilisation, leading to waste and pollution. In India, despite the recognition of nano-pollution, its vulnerable position as a developing country, the lack of a specific regulatory framework and patent protection providing a form of immunity has left it bereft of reaching global and regional standards. The paper examines legal implications collectively, emphasizing the urgent need for harmonized international standards that incorporate sustainability criteria to mitigate the environmental drawbacks of medical nanotechnology. The study focuses on ill impacts on the environment, wherein sustainable energy will continue to be overshadowed by the benefits of nanotechnology in medicine.

Keywords – *nanotechnology in medicine, sustainable energy, cycle of toxicity, regulation of nanoparticles, blanket patent protection.*

I. INTRODUCTION

Ralph Merkle once said, “Nanotechnology is an idea that most people simply didn’t believe”. The etymology of nanotechnology can be traced back to the Greek word “nano” which means “dwarf”. It later

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became a unit of measurement and its meaning transformed to “one billionth part.” Nanotechnology, became the study of nanoparticles, which are one billionth part in surface-area-to-volume ratio and this ratio is measured in nanoscale size.¹ Nanotechnology is the conversion of matter with at least one dimension sized from 1-100 nanometers. This scale is commonly known as the nanoscale and matter at this stage acquires special and unique properties including quantum abilities the most commonly used property is the surface area.² Nanotechnology operates so efficiently due to its high surface area which allows the absorption of significant quantities of medication and its efficient circulation in the bloodstream.³ The increased surface area also enhances the magnetic, optical and catalytic properties, which broadens the application in medical treatments.⁴ Polymeric nanoparticles and liposomal nanocarriers, known for their biocompatibility and biodegradability, are frequently employed in these systems to optimize drug delivery.⁵ Further, the advent of medical nanobots based on a bottom-up approach which are capable of self-replication, can unblock arteries, repair genetic defects, or even replace entire organs, has led to a transformation in the medical field.⁶ Presently, the replacement of DNA molecules is a technique developed to help genetic abnormalities and eradicate diseases at a molecular level and can be used in fertility treatments.⁷

In the modern world as we know it today, nanotechnology no longer remains an elusive idea but rather a field of study that spans various areas of study including chemistry, physics, biology, medicine, engineering and optics. In fact, fields such as molecular nanotechnology have developed which relates to the precise manipulation of atoms and molecules to fabricate a macroscale product.⁸ Nanotechnology has essentially defined fields such as molecular biology, semiconductor physics, energy storage and has created diverse applications in nanomedicine as previously mentioned, biomaterial energy production and microfabrication.

Nanotechnology is not a recent discovery, it has existed since 600-300 B.C. through pottery in

¹ Mahmoud Nasrollahzadeh, et. al., *An Introduction to Nanotechnology*, 28 INTERFACE. SCI & TECH 1 (2019).

² K. Eric Drexler, 1 *Engines of creation: the coming era of nanotechnology* (1986).

³ Elena Serrano, et.al, *Nanotechnology for Sustainable Energy*, 13 RENEW. & SUSTAINABLE ENERGY REV. 2373 (2009), <https://doi.org/10.1016/j.rser.2009.06.003>.

⁴ Abid Haleem et al., *Applications of Nanotechnology in Medical Field: A Brief Review*, 7 GLOB. HEALTH J. 70 (2023).

⁵ A.S. Klymchenko et al., *Dye-Loaded Nanoemulsions: Biomimetic Fluorescent Nanocarriers for Bioimaging and Nanomedicine*, 10 ADV. HEALTHC. MATER., (2021).

⁶ Mritunjai Singh et al., *Nanotechnology in Medicine and Antibacterial Effect of Silver Nanoparticles*, 3(3) DIGEST J. OF NANOMATERIALS & BIOSTRUCTURES 115 (2008).

⁷ A.M.A. Moshed et al., *The Application of Nanotechnology in medical sciences: new horizon of treatment*, 9 AM. J. BIOMED. SCI. 1, 14 (2017).

⁸ *Supra*, note 2.

Keeladi, India where materials such as carbon nanotubes were used, in Damascus steel in 900 B.C. where cementite nanowires were used and in Ninth century Mesopotamia where nanoparticles were used in glazes to produce gold and copper coloured effects which was emulated by Islamic ceramics later on.⁹

Nanotechnology is a field that was revolutionized by Richard Feynman in 1959 through his lecture in Caltech “There is Plenty of Room at the Bottom”.¹⁰ In 1974, Japanese researcher Norio Taniguchi first coined “nano-technology” to describe atomic-scale processes in thin-film deposition and ion-beam milling. Later, Eric Drexler independently adopted the term in his 1986 book *Engines of Creation*, proposing self-replicating molecular assemblers and popularizing the vision of molecular nanotechnology, thereby setting the future standards for molecular scale manufacturing. Nanotechnology developed through contributions to physics including the invention of a scanning tunnelling microscope in 1981 which is used to image surfaces at the atomic level developed by Gerd Binnig and Heinrich Rohrer for which they were awarded the Noble Prize in Physics in 1986. The discovery of Fullerenes in 1985 by Harry Kroto, Richard Smalley and Robert Kurl for which they were awarded the Nobel Prize in Chemistry in 1996. The application of Fullerenes was discovered in carbon nanotubes by Sumio Ijima in 1993. In present day, such Fullerenes are used to manufacture industrial grade carbon nanotubes which find their application in nanomedicine. The field was placed in the limelight through the pharmaceutical industry through drug delivery systems and medical treatments.

However, there are two sides to every coin and while there is no denying the advantages of nanotechnology, the disadvantage in the usage of nanotechnology lies in the toxic nature of the materials used. Since nanoparticles have nanoscale properties, they allow them to permeate biological membranes and accumulate in organs leading to bioaccumulation.¹¹ These risks necessitate thorough investigation and regulation to ensure that the benefits of nanotechnology do not come at the expense of safety and environmental sustainability. However, due to the constant fluctuation of the development of nanotechnology, it is very difficult to formulate a legal framework that does not completely become obsolete.¹² The absence of a clear regulatory framework exacerbates the dangers, as the unique behaviour of nanoparticles is not addressed by

⁹ Samer Bayda et al., *The History of Nanoscience and Nanotechnology: From Chemical–Physical Applications to Nanomedicine*, 10 BIOMOLECULES 11 (2020), <https://doi.org/10.3390/biom10010011>

¹⁰ *Supra*, note 4.

¹¹ A. Surendiran et al., *Novel Applications of Nanotechnology in Medicine*, 130 INDIAN J. MED. RES. 689, 701 (2009).

¹² Bowman, D.M. & Hodge, G.A., *A small matter of regulation: an international review of nanotechnology regulation*, 8 COLUM. SCI. & TECH. L. REV. 1(2007).

any form of traditional, medical or environmental laws.

For instance, in India, there are multiple regulatory frameworks set up for nanotechnology but either there is an abject lack of enforceability or such frameworks remain in a nascent stage and pose challenges that India is not equipped to handle.¹³ For example, India has policies such as the Nano Mission which was launched in India in 2007 to boost research and development in the field of nanotechnology.¹⁴ Prior to this, in 2001 the Department of Science and Technology had launched the Nano Science and Technology Initiative to empower research in agriculture, healthcare services and the fertilizer industry.¹⁵ These initiatives merely encourage research in the field of nanotechnology and do not serve as guidelines for the safe usage and handling of toxic nanomaterials especially at an industrial level. However, recently, the Draft Guidelines for Safe Handling of Nanomaterials in Research Laboratories and Industries was released by the Department of Science and Technology as a part of national Programme on Nano Science and Technology, erstwhile Nano Mission.¹⁶ These guidelines are a welcome step forward but they require enforceability as well in the form of regulations.

This paper is structured into two interconnected parts. Part I explores the fundamentals of nanotechnology, its applications in medicine and sustainable energy, and its integration across various fields. It also examines the socio-ethical and legal implications arising from these intersections. Part II focuses on the intellectual property [“IP”] complexities of nanotechnology. This section further compares nanotechnology with biotechnology, highlighting the similarities and differences in their patentability, commercialization, and regulatory challenges. These two parts are intricately linked by their critical assessment of how existing legal mechanisms inadvertently provide a form of immunity to these harmful effects, often failing to hold industries accountable. By weaving these discussions together, the paper presents a comprehensive analysis of the need for more robust legal oversight and reform in the governance of nanotechnology.

II. USAGES OF NANOTECHNOLOGY

A. Nanotechnology in Medicine and Healthcare as Nanomedicine

¹³ Bhatia, P. and Chugh, *A multilevel governance framework for regulation of nanomedicine in India*. 6(4) NANOTECHNOLOGY REVIEWS, 373-382 (2017).

¹⁴ Dep’t of Sci. & Tech., Gov’t of India, Nat’l Programme on Nano Sci. & Tech. (Earlier Nano Mission), <https://dst.gov.in/scientific-programmes/mission-nano-science-and-technology-nano-mission>

¹⁵ *Id.*

¹⁶ Centre for Knowledge Management of Nanoscience & Technology, Dept. of Sci. & Tech., Govt. of India, Guidelines and Best Practices for Safe Handling of Nanomaterials in Research Laboratories and Industries (Draft Guidelines), <https://dst.gov.in/sites/default/files/Draft-Guidelines%20.pdf>

Nanotechnology is relevant in the contemporary medical as a distinct area of study. Historically, nanotechnology has been used in medicine in drug delivery and diagnostics. Nanoparticles have been used in chemotherapy due to their precision and effectiveness. The invention of “nanoflares” has led to an increased detection in cancer cells through light signals, and smart pills to monitor patient conditions.¹⁷ However, such developments are being callously used despite phenomena such as bioaccumulation.¹⁸ Nanoparticles due to their size and high surface reactivity bypass biological barriers and evade the immune system, allowing them to persist and accumulate within biological tissues over time. This persistence leads to bioaccumulation, where nanoparticles build up in organs like the liver, kidneys and even bones, quite akin to the deposit of radioactive materials which causes effects spanning generations.¹⁹ One key distinction is that there is no definitive evidence that bioaccumulation of nanoparticles leads to genetic issues.²⁰ However, given that the widespread use of nanotechnology is relatively recent, it would be premature to draw conclusions, and making assumptions may not be prudent. Nanoparticles, such as silver nanoparticles used for their antibacterial properties, can persist in biological systems due to their ability to bypass immune defences and accumulate in tissues.²¹ Though conclusive evidence of genetic damage from bioaccumulation is lacking, the persistence and interaction of nanoparticles with cells present potential risks. Nanotechnology has become so deeply ingrained in medicine leading to the formation of a distinct field known as nanomedicine offering such significant advantages that, finding a suitable and less harmful alternative with similar properties to nanomaterials is extremely challenging. Therefore, we stand on the precipice of carefully managing use of nanomaterials to ensure that only necessary amounts are employed without causing further complications caused by potential toxicity.²²

B. Nanotechnology In Sustainable Energy Practices

Nanotechnology has found a primary use in the intersection of sustainable energy practices. In the field of sustainable energy, nanotechnology has been used in environmental remediation, but it is a paradoxical notion where something that benefits the environment seems to cause it so much harm. Nanoparticles are used in the water purification process, where nanoparticles, like Nano

¹⁷ Damilola E. Babatunde et al., *Environmental and Societal Impact of Nanotechnology*, 1 DEPT. OF CHEM. ENG., COVENANT UNIV., OTA, NIGERIA (DEC. 2019).

¹⁸ A. Sharma et al., *Toxicity with Waste-Generated Ionizing Radiations: Blunders Behind the Scenes*, FREE RADICAL BIOLOGY AND ENVIRONMENTAL TOXICITY 305 (Cham: Springer Int'l Publ'g 2022).

¹⁹ Christian Franke et al., *The Assessment of Bioaccumulation*, 29 CHEMOSPHERE 1501 (1994).

²⁰ GUPTA, P.K., NANOTOXICOLOGY IN NANOBIO-MEDICINE, 111-123 (Springer, 2023).

²¹ Mritunjai Singh et al., *Nanotechnology in Medicine and Antibacterial Effect of Silver Nanoparticles*, 3(3) DIGEST J. OF NANOMATERIALS & BIOSTRUCTURES 115 (2008).

²² *Supra*, note 9.

Zero-Valent Iron [“NZVI”], are utilized to remove contaminants from groundwater and wastewater. These particles target and neutralize toxic substances, providing an efficient method for environmental restoration.²³ Nanoparticles, especially quantum dots and nanowires, are used to improve the efficiency of solar panels. These materials enhance the light absorption capabilities of photovoltaic cells, contributing to the development of more efficient and affordable solar energy systems.²⁴ This advancement could significantly boost the adoption of solar energy, making it a more viable and sustainable option for the future. However, the waste accumulated from making something environment-friendly is highly toxic and one of the main causes of a new kind of pollution known as nano-pollution.²⁵ Nanoparticles, due to their properties such as size and reactivity, can easily disperse into the air, water, and soil during production, use, or disposal.²⁶ These particles have the potential to accumulate in ecosystems, leading to unknown ecological consequences. Studies highlight that such accumulation could disrupt soil health, water quality, and marine ecosystems, affecting both plant and animal life.²⁷

Therefore, nanotechnology has massive implications for the environment and contributes to pollution as well. However, despite its contribution to such pollution, it also helps maintain sustainability, thus acting as a double-edged sword.

III. SOCIO-ETHICAL IMPLICATIONS OF SUSTAINABLE ENERGY THROUGH THE USE OF NANOTECHNOLOGY IN MEDICINE AND HEALTHCARE

The benefits of nanotechnology in nanomedicine and sustainable energy are widespread; however, these advantages must be taken with a pinch of salt. While without the considerable benefits, modern medicine as we know it would not exist, there are varying problems as well which includes the perpetuation of a vicious cycle caused by nanotechnology for which there are no existing policy and legal framework available. Nanotechnology resources are available primarily in third-world countries and are used industriously by first-world nations.²⁸ There is a transient corporate interest created that leans heavily in favour of first-world countries and perpetuates what is now called

²³ Matthew A. et. al., *Green Chemistry and the Health Implications of Nanoparticles*, 8(5) GREEN CHEM., 417, 432 (2006).

²⁴ *Supra*, note 1.

²⁵ Lisa Pokrajac et al., *Nanotechnology for a Sustainable Future: Addressing Global Challenges with the International Network4Sustainable Nanotechnology*, 15 ACS NANO 18608 (2021).

²⁶ Amoabediny, G.H., Naderi, A et. al., *Guidelines for safe handling, use and disposal of nanoparticles*, 170(1) J. PHYS. CONF. SER 012037 (2009).

²⁷ Bundschuh, et. al., *Nanoparticles in the environment: where do we come from, where do we go to?*, 30 ENV. SCI. EUR, 1-17(2018.).

²⁸ Invernizzi, N. and Foladori, G., *Nanotechnology and the developing world: Will nanotechnology overcome poverty or widen disparities*, 2 NANOTECH. L. & BUS. 294 (2005).

economic slavery.²⁹ Third-world countries are extremely reliant on first-world nations to fulfil their economic necessities and fall prey to this economic colonization.³⁰ Hence, there is a quid pro quo created where first-world countries are dependent on third-world countries for resources, and first world countries in return, provide economic relief. The dependency favours the first world by far because of the economic disparity and the clear exploitation of the resources of third world countries to satisfy the interests of the first world nations.³¹ The prime example of this is the mining industry in the Democratic Republic of Congo [**“DRC”**], which shows a clear pattern of economic colonialism, where first-world countries exploit local resources for their technological advancements.³² This mirrors earlier colonial practices where third-world countries were systematically stripped of their resources to benefit industrial powers.

In the case of cobalt, a critical material for batteries and electronics, up to 70% of the global supply is sourced from the DRC.³³ This dynamic creates a dependence of third-world countries on first-world nations, perpetuating a cycle of economic subjugation.³⁴ Similarly, the rise of the nanoparticle industry is expected to follow this pattern due to similarities between cobalt and raw materials used in nanotechnology. Many raw materials for nanotechnology are found in developing regions, but the profits and technological advancements disproportionately favour developed countries, creating an economic slavery as these countries remain dependent on selling their resources with little return investment in their infrastructure or communities.

The nanomaterials obtained through extreme environmental damage are further used to remediate the environment. Furthermore, nanoparticles are used significantly by the medical industry as compared to other industries. Hence, it creates a cycle where toxic materials are obtained to save lives, and the very same materials also take lives. This is evidenced by the nanomaterials that are mined in Mozambique and the suffering of the miners from various diseases due to the toxicity of these particles.³⁵

²⁹ Fabio Salamanca-Buentello et al., *Nanotechnology and the Developing World*, 2 PLOS MED. e97 (2005).

³⁰ Ikechukwu C. Ezema, et. al., *Initiatives and strategies for development of nanotechnology in nations: a lesson for Africa and other least developed countries*, 9 NANOSCALE RES. LETT. 133 (2014).

³¹ Priyom Bose, *Nanomedicine: Advantages and Disadvantages*, AZONANO (Mar. 12, 2024), <https://www.azonano.com/article.aspx?ArticleID=6707>.

³² Jennifer Wu & Janet Wong, *Child Labour in Cobalt Mining: A Holistic View on the Complexity of the Issue and a Reality Check on the Effectiveness of Engagement*, J.P. MORGAN ASSET MANAGEMENT (2024).

³³ Debasmita Patra, et. al., *Nanoscience and Nanotechnology: Ethical, Legal, Social and Environmental Issues*, 96 CURRENT SCI. 651-657 (2009).

³⁴ Barzel, Y., *An economic analysis of slavery* 20(1) J.L. &ECON 87-110 (1977).

³⁵ Gavin Hilson et al., *Formalizing Artisanal and Small-Scale Mining in Mozambique: Concerns, Priorities, and Challenges*, IGC (June 2021), F-19016-MOZ-1, <https://www.theigc.org/sites/default/files/2021/06/Hilson-et-al-June-2021-Final-report.pdf>.

Mozambique is a primal example of economic exploitation as it has attracted significant international investment including a USD 150 million loan from the US International Development and Finance Corporation to support Balama.³⁶ Mozambique has an exceptionally large and high grade graphite reserves with mines such as the Balama mine which has around 110 million tons of graphite ore reserves and produces 350,000 tonnes of graphite concentrate annually.³⁷ The graphite concentrate is used as a raw material which is used to produce carbon black nanoparticles. Mozambique is a sought-after mining destination, largely due to the ease of mining due to the presence of open pit mining sites.³⁸

Therefore, the presence of optimal conditions has led to Mozambique having a “flourishing” artisanal and small-scale mining operations [“**ASM**”] sector, which serves as a crucial source of income for many. While ASM is legally recognized, there is a scourge of non-compliance with the compulsory mining license regulations, leading to parallel illegal markets, with unlicensed miners known as *garimpeiros*.³⁹ Nanomaterials are usually in the form of carbon black or titanium dioxide nanoparticles. Mozambique, due to its abundant graphite reserves, is well-positioned as a supplier of carbon black nanoparticles.⁴⁰ However, the sector is largely informal, leading to a dearth of investment needed to legitimise the ventures in ASM.⁴¹ Due to the lack of such appropriate safeguards, miners are at considerable risk, as prolonged exposure to toxic chemicals such as methylates and bioaccumulates can lead to severe health complications.⁴²

Although nanotechnology serves as a valuable economic opportunity for these miners, the lack of protective policies and regulatory enforcement has resulted in hazardous working conditions that contribute to premature mortality. The example of Mozambique is merely part of a larger problem prevalent in other developing countries including India as well. While India may not be as prevalent in terms of mining raw materials for nanoparticles, this is mainly due to a lack of data. In India, the data for ASM which is the primary form of acquiring raw materials for nanotechnology is

³⁶ Wilder Alejandro Sanchez, *Protests Shutter Mozambique's Balama Graphite Mine*, SITUATION REPORTS, (Dec. 30, 2024) <https://www.geopoliticalmonitor.com/protests-shutter-mozambiques-balama-graphite-mine/>.

³⁷ Amilia Stone, *Mozambique's Graphite Boom*, DIRECTORSTALK (Mar. 27, 2025), <https://directorstalk.net/mozambiques-graphite-boom>.

³⁸ *Id.*

³⁹ Estacio Valoi, *Mozambique | Southern Africa's Mining Scars, Part 3*, ZAM (Sept. 4, 2023), <https://www.zammagazine.com/investigations/1679-mozambique-southern-africa-s-mining-scars-part-3>

⁴⁰ Chemicals & Raw Materials, *Nanotechnology Industries Association*, <https://nanotechia.org/sectors/chemicals-raw-materials>

⁴¹ *Infra*, note 43.

⁴² *Supra*, note 24.

collected under the Indian Mines Act, 1952 and Minerals (Regulation and Development) Act 1957.⁴³ The Indian Bureau of Mines working under the MMRD Act, 1957 does not maintain a record for 'Minor Minerals' including minerals like carbon or titanium oxide which is mainly used for nanomaterials.⁴⁴ However, the mining of nanomaterials is not particularly prevalent in India due to a lack of such minerals being naturally available. Informality is also widespread within ASM in India, with many operations lacking formal licenses and legal protections, exposing miners to significant health and safety risks from toxic exposures including chemical bioaccumulation.⁴⁵

IV. CHALLENGES IN THE REGULATORY SECTOR FOR NANOTECHNOLOGY

A. In Medicine and Healthcare as Nanomedicine

Nanotechnology has significant implications for health, particularly through its applications within the human body. It is commonly presumed that products consumed by the general public must adhere to rigorous standards, with policies in place to ensure such compliance. The medical industry, known for its stringent enforcement of standards, operates at a higher level of accountability due to its direct impact on human health. However, it is startling to realize that nanotechnology lacks uniform standards despite being an integral part of a sector that remains operational even in global emergencies.⁴⁶ The use of unethically sourced materials in this context raises serious concerns.

It is not to say that international efforts have not been made for the regulation of nanotechnology; the issue arises in the inadequacy of such protections. The ISO has developed technical guidelines such as ISO/TR 13121⁴⁷ for risk evaluation of nanomaterials and ISO 29701⁴⁸ for measuring nanoparticle toxicity. These standards promote safety in manufacturing and medical applications but have not been fully adopted globally, leading to variations in implementation and effectiveness.⁴⁹ However, these standards regulate the technical aspects of nanotechnology, but

⁴³ *Artisanal and Small-scale Mining in India*, DELVE DATABASE REPORT (1997-98 data), <https://www.delvedatabase.org/uploads/resources/Artisanal-and-Small-scale-Mining-in-India.pdf>.

⁴⁴ KUNTALA LAHIRI-DUTT & JAMES MCQUILKEN, *Debe State Of The Artisanal And Small-Scale Mining Sector-India*, in *State Of The Artisanal And Small-Scale Mining Sector*, 60-74 (World Bank Group ed., vol. 1, 2019).

⁴⁵ Deb, M., et al., *Artisanal and small scale mining in India: selected studies and an overview of the issues*, 22 INT'L J. MINING, RECLAMATION & ENV 194 (2008).

⁴⁶ Snir, R., *Trends in global nanotechnology regulation: The public-private interplay*, 17 VAND. J. ENT. & TECH. L., 107 (2014).

⁴⁷ ISO, ISO/TR 13121:2011 Nanotechnologies-Nanomaterial Risk Evaluation (Technical Report, 2011), <https://www.iso.org/standard/52976.html>.

⁴⁸ ISO, ISO 29701:2010 Nanotechnologies- Endotoxin Test on Nanomaterial Samples for In Vitro Systems-Limulus Amebocyte Lysate (LAL) Test, (International Standard, Sept. 2010) <https://www.iso.org/standard/45640.html>.

⁴⁹ Ekpo Kelechukwu, *Nanotechnology: Regulatory Outlook on Nanomaterials and Nanomedicines in United States, Europe and India*, 7 APP. CLIN. RES., CLIN. TRIALS & REGUL. AFF 225 (2020).

they do not provide any guidelines as to the measures to be taken when these guidelines are not followed. Another issue that arises is the fact that these guidelines do not have a mandatory adherence, thereby creating a fragmented framework that does not work effectively or ensure any safety standards.

All of these nations do not consider nanotechnology an important research field, even after the groundbreaking research of silver nanoparticles in antimicrobial applications. Silver nanoparticles were underwritten despite their unique physicochemical properties due to safety and scalability concerns.⁵⁰ But their impact was undeniable, now silver nanoparticles are incorporated in medical devices, wound dressings and even consumer goods for antimicrobial protection that may be sold over-the-counter. Therefore, nanotechnology in India needs to be considered as a serious avenue for research, which leads to exceptional avenues for commercialisation.

The only nation that has recognised the problem is Brazil which has formulated the Nanotechnology Act which integrates environmental policies with medical technology development.⁵¹ It requires all medical nanotechnologies to undergo environmental impact assessments which thereby provides some form of regulation in the present context.⁵²

B. In Sustainable Energy Practices

Nanotechnology sits at the intersection of various sectors such as chemistry, pharmaceuticals, environmental science, and engineering. Often, regulatory policies belong to distinct fields, creating gaps when nanotechnology crosses these boundaries. For instance, medical devices using nanotechnology might fall under pharmaceutical regulations, while the energy impacts of these devices are governed by environmental laws, leading to inconsistencies and enforcement challenges. For instance, the EU's Cosmetics Regulation and Medical Devices Regulation,⁵³ both address the use of nanoparticles but primarily focus on consumer safety without a comprehensive view of environmental or sustainable energy impacts. This narrow focus overlooks how the lifecycle of medical nanomaterials affects broader sustainability efforts. Even in the USA, the EPA's classification of nanoparticles as chemicals often excludes their medical applications from

⁵⁰ *Supra*, note 13.

⁵¹ W. ENGELMANN, ET AL., *Nanotechnological Regulations in Brazil*, in *Nanomaterials: Ecotoxicity, Safety, and Public Perception* 369 (M. Rai & J. Biswas eds., Springer 2018).

⁵² Debasmita Patra, et. al., *Nanoscience and Nanotechnology: Ethical, Legal, Social and Environmental Issues*, 96 CURRENT SCI. 651-657 (2009).

⁵³ Regulation (EC) No 1223/2009 of the European Parliament and of the Council, on Cosmetic Products, 2009 O.J. (L 342) 59, <https://eur-lex.europa.eu/eli/reg/2009/1223/oj/eng>.

its purview, leaving the FDA to handle safety concerns that do not address environmental or energy sustainability. The lack of coordination between these agencies results in regulatory loopholes. The main reason for a standard not being set is the fact that nanotechnology is a developing field, and hence, present regulations become obsolete as soon as they become applicable. The absence of any standards has led to nanoparticles being clubbed together with other bulk materials of similar properties.⁵⁴ For example, while the EU's REACH regulation⁵⁵ and the US EPA⁵⁶ address chemical substances, they often fall short when applied to the nanoscale, which has distinct toxicological profiles due to altered surface area and reactivity.⁵⁷ The EU's REACH directive requires the registration of chemical substances, including nanomaterials, but its primary focus remains on consumer and occupational safety, not energy sustainability or environmental longevity. Standards in the present scenario pertain to the unavailability of standardized international methodology for toxicity testing or lifecycle assessment specific to nanoparticles.

The European Union, despite the lack of a comprehensive framework, does have a proactive approach through the **European Strategy for Nanotechnology**,⁵⁸ emphasizing the importance of aligning innovation with health, safety, and sustainability. However, enforcement remains a challenge as directives such as REACH do not adequately cover the environmental implications of medical nanoparticles, particularly in sustainable energy contexts. EU member states have been encouraged to develop their own nanomaterial registries, but without a harmonized framework, variations persist, affecting cross-border management and regulatory coherence.

Similarly, the only cohesive attempt in the USA is through California's Proposition 65 lists toxic substances,⁵⁹ including some nanoparticles, but this list is limited to known carcinogens and does not consider energy or ecological sustainability comprehensively. It only lists what constitutes as toxic but does not prescribe any penalty for failure in compliance.

⁵⁴ Lisa Pokrajac et al., *Nanotechnology for a Sustainable Future: Addressing Global Challenges with the International Network4Sustainable Nanotechnology*, 15 ACS Nano 18608 (2021).

⁵⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council, Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2006 O.J. (L 396) 1, <https://echa.europa.eu/regulations/reach/understanding-reach..>

⁵⁶ U.S. Env'tl. Prot. Agency, *About the TSCA Chemical Substance Inventory*, <https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory> (last visited June 8, 2025).

⁵⁷ M.V. Starynskyi & O.D. Pogrebnjak, *The Current State of Legal Regulation of the Use of Nanotechnology in the Medical Field and Prospects for Its Development*, LVIV UNIV. OF BUS. & L. (2021).

⁵⁸ Publications Office of the European Union, *A European Strategy for Nanotechnology*, <https://op.europa.eu/en/publication-detail/-/publication/3c40c558-7076-4cef-9343-4b1fbc09fe0d/>

⁵⁹ Office of Environmental Health Hazard Assessment, *The Proposition 65 List*, <https://oehha.ca.gov/proposition-65/proposition-65-list>.

Similar to ISO, India has the Bureau of Indian Standards, but it faces the same issues as ISO in the sense that these guidelines are not mandatory, and the lack of enforcement mechanisms means they have limited influence on how industries incorporate sustainability and safety measures in nanotechnology use.⁶⁰

In India, similar problems as in the EU and the USA persist. There is no unified policy and the closest to regulating this technology is the Drugs and Cosmetics Act, 1940 which governs medical applications,⁶¹ but it does not differentiate between nanomaterials and their conventional counterparts, leading to gaps in safety and sustainability assessments.⁶² As nanotechnology develops applications that intersect with sustainable energy, like energy-efficient batteries or medical devices powered by nanotechnology, there is a pressing need for India to integrate energy sustainability criteria into its regulatory policies.

V. NANOTECHNOLOGY IN MEDICINE AND SUSTAINABLE ENERGY PRACTICES AND ITS CORRELATION TO INTELLECTUAL PROPERTY RIGHTS

Regarding the utilisation of nanotechnology in medicine and sustainable energy, the most obvious legal inter-relation concerns intellectual property rights, specifically patents. Despite its wide range of impacts, nanotechnology has a vast market and monetary investment. The production of nanotechnology is a form of intellectual property, and as such, the industry is built upon meeting the requisite bottom line. Nanotechnology was forecasted to reach \$1 trillion by 2015; however, this goal was overachieved by the year 2004.⁶³ Various governments across the world anticipated the revolutionary nature of nanotechnology and invested billions of dollars. The USA, during the Bush Administration, enacted the Nanotechnology Research and Development Act (the Nanotechnology Act)⁶⁴ which authorised billions of dollars of federal spending dedicated to nanotechnology. This development led to an increase in nanotechnology patents. The USPTO, in the year 2002, issued 526 nanotechnology patents.⁶⁵ This led to the development of the 'patent thicket' which refers to overlapping patent rights with minimum change in specifications in order

⁶⁰ Bureau of Indian Standards, *Reforms in BIS*, <https://static.pib.gov.in/WriteReadData/specificdocs/documents/2021/apr/doc202141341.pdf>

⁶¹ Drugs and Cosmetics Act, 1940, Act No. 23, Acts of Parliament, 1940 (India), https://www.indiacode.nic.in/bitstream/123456789/6800/1/drug_and_cosmetic_act_1940.pdf.

⁶² Damilola E. Babatunde et al., *Environmental and Societal Impact of Nanotechnology*, 1 DEPT. OF CHEM. ENG., COVENANT UNIV., OTA, NIGERIA (DEC. 2019).

⁶³ Terry K. Tullis, *Intellectual Property Issues Around Nanotechnology*, 1 NANOTECHNOL. REV. 189, 205 (2012).

⁶⁴ 21st Century Nanotechnology Research and Development Act, Pub. L. No. 108-153, 117 Stat. 1923 (2003), <https://www.congress.gov/bill/108th-congress/senate-bill/189..>

⁶⁵ Terry K. Tullis, *Application of the Government License Defense to Federally Funded Nanotechnology Research: The Case for a Limited Patent Compulsory Licensing Regime*, 53 UCLA L. REV. 279 (2005).

to cauterize the rush of persons who aim to secure such rights.⁶⁶ The challenges of nanotechnology patents can be summed up as the lack of legal clarity. Nanotechnology is a multidisciplinary and cross-sectoral field and does not conform to traditional patent laws. The requisites of patents include novelty and non-obviousness, this which in the traditional definition may not qualify as patentable and may be obsolete for classifying nanomaterials.⁶⁷ This is because nanotechnology evolves by modifying materials at a nanoscale and there is a grey area as to whether simply reducing something to the nanoscale counts as a new invention or whether it will be step taken for the evergreening of patents. Further, nanotechnology can lead to a ‘dense web of overlapping rights’ which makes it harder for inventors to design around existing patents. If we include the American system in this metric, the Nanotechnology Act merely provides for the regulation of spending on research of nanotechnology and not the nanotechnology patents’ regulation. Further, the traditional patent laws such as the US Patent Act⁶⁸ or Indian Patents Act⁶⁹ does not contain provisions tailored for nanotechnology.

The patent industry operates on the exclusivity of a piece of technology, which allows for exclusive licensing. This technology is imperative to medicine and sustainable energy usage; however, exclusive licensing limits the technology that can be made available, which is vital, especially when it comes to an individual’s life or the environment they live in.⁷⁰ While this author does not negate the disadvantages of nanotechnology, there is certainly a minimum requisite of nanotechnology that conditionally includes patent technology to improve a person’s quality of life. The alarming patent immunity granted to nanotechnology might lead to “nanotechnology anticommons”, a situation where, due to the exclusivity of patents, there is a lack of innovation leading to underutilisation and a lack of further research into an otherwise less explored field.⁷¹

Furthermore, nanotechnology in the USA is funded by the federal government. Hence, it can be inferred that the licensing regime for the same should not be exclusive to the bourgeoisie. Nanotechnology plays an irreplaceable role in facilities such as drinking water or sanitation; therefore, it follows that such commodities cannot be a hindrance to human life. In the USA, the

⁶⁶ Albert P. Halluin & Lorelei P. Westin, *Nanotechnology: The Importance of Intellectual Property Rights in an Emerging Technology*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 220 (2004).

⁶⁷ *The Patent Dilemma: Issues in Nanotechnology Innovation*, GLOBAL PATENT FILING (Sept. 13, 2024), <https://www.globalpatentfiling.com/blog/The-Patent-Dilemma-Issues-in-Nanotechnology-Innovation>.

⁶⁸ Patent Act of 1952, Pub. L. No. 82-593, ch. 950, 66 Stat. 792 (July 19, 1952) (codified as amended at 35 U.S.C. §§ 1–376 (2020)).

⁶⁹ The Patents Act, No. 39 of 1970, Acts of Parliament, (India).

⁷⁰ *Supra*, note 45.

⁷¹ *Id.*

Bayh-Dole Act allows for the limited grant of compulsory licenses if the patent is based on federally funded research.⁷²

It can also be argued that such non-exclusive licensing will fall under the spectrum of fair use and may lead to a more equitable usage of nanotechnology. In the USA, since nanotechnology is funded by the federal government, there is an implication of public investment, which should not detriment the society at large.⁷³ Nanotechnology plays a critical role in access to portable water and sanitation, due to which these technologies must be equitable and not obstructed by exclusive ownership.⁷⁴ Therefore, if exclusive licenses hinder access to nanotechnology, then the government can allow broader use through non-exclusive licensing to ensure benefit to the society. This concept is not confined to America; it may also be utilized in India, where similar difficulties exist. The implementation of compulsory licensing is at the heart of these issues. There has only been one accepted case of compulsory licensing in India, *Bayer v. Natco*,⁷⁵ which dealt with access limits to life-saving cancer treatments. Natco was granted a compulsory license to manufacture and sell a generic version of Bayer's cancer drug, Nexavar at a price lower than what Bayer sold the product for. The royalty rate was set to initially 6% of the net sales, later increased to 7% by the appellate court.⁷⁶ However, the decision is heavily contested because the Patents Act of 1970 requires the payment of specific compulsory royalties,⁷⁷ which in the instance of Bayer, is argued that despite a dramatic lowering of prices, the royalty ends up influencing the end pricing which may not always ensure the most affordable pricing to patients. The judgement, ironically, intended to achieve fair access to life-saving medicine. The same case applies to nanotechnology, where issuing a compulsory license may be ineffective because it will not provide equitable access and will only exacerbate the existing economic disparities.

In addition to this, the defence of fair dealing only exists in copyright and will not be applicable to

⁷² Milken Institute, *The Bayh-Dole Act of 1980: Frequently Asked Questions*, <https://milkeninstitute.org/sites/default/files/reports-pdf/Bayh-Dole-FAQ.pdf>; Rice Univ. Off. of Tech. Transfer, *Bayh-Dole Act*, Rice Univ., Office of Technology Transfer (n.d.), <https://research.rice.edu/ott/bayh-dole-act>.

⁷³ M. Fasteau & I. Fletcher, *Nanotechnology: Is America Losing the Future?*, in INDUSTRIAL POLICY FOR THE UNITED STATES: WINNING THE COMPETITION FOR GOOD JOBS AND HIGH-VALUE INDUSTRIES 554 (Cambridge Univ. Press 2024).

⁷⁴ Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576 (2003).

⁷⁵ Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), <http://www.ipab.tn.nic.in/045-2013.htm> (last visited on June 8, 2025).

⁷⁶ World Intellectual Property Organization, Intellectual Property Appellate Board, Chennai, India [2013]: Bayer Corporation v. Natco Pharma Ltd. & Ors., OA/35/2012/PT/MUM, WIPO Lex (n.d.), <https://www.wipo.int/wipolex/en/text/585865>.

⁷⁷ The Patents Act, 1970, Act No. 39, Acts of Parliament, 1970 (India).

patents.⁷⁸ Fair Dealing as an exception in Indian copyright law that allows for the use of copyright material without obtaining prior license on the fulfilment of certain conditions unique to copyright. This can be adapted to the patent context as well. In the context of patent law, all uses outside the scope of compulsory license or a license make an argument for equitable access through fair dealing.⁷⁹ While, it may be argued that fair dealing as an exception when compulsory licensing exists may create redundancy, compulsory licenses do not account for end users ending up paying the price of up scaled royalties to the licensee which may in itself be a redundancy. It is thereby proposed that the laws regarding such payment of royalty must be made clear to ensure equity and a fair dealing exception may be created in certain situations where the problem may not entirely revolve around royalty.⁸⁰

In India, it is a challenge for accurate calculation of the registered patents since there is no classification for nanotechnology. Hence, it is a particular impossibility in India since our intellectual property regime seems to cut across a clear line as to what category an intellectual property can be placed into, but leaves many lacunae as to what emerging technologies can be placed into. Nonetheless, even in the US, several forms of intellectual property remain distinct, in spite of a unified intellectual property code. The approach to reform patent immunity for nanotechnology is entirely corrective. The aim is not to discourage innovation or affect the bottom line, but rather to draw a tightrope between the two through the course of consistently amended regulations to keep up with the demand and innovation that nanotechnology fosters.

VI. NANOTECHNOLOGY AND BIOTECHNOLOGY: THE DIVIDE IN INTELLECTUAL PROPERTY RIGHTS GRANTED FOR MEDICINE AND SUSTAINABLE ENERGY

Nanotechnology today is yesterday's biotechnology. The 'patent thicket' today is akin to the 'patent land rush' for biotechnology in the late 1980s.⁸¹ The fear of the anticommons stems from the biotechnology anticommons, although the situations were quite different. Anticommons is a situation where the number of inputs on a particular research increases and the innovator faces a patent thicket and is threatened by the possibility that a useful innovation is not developed due to lack of agreement with the patent holders. This is referred to as the tragedy of anticommons. This primarily occurs when too many patent holders have exclusion rights over a common resource,

⁷⁸ *Supra*, note 45.

⁷⁹ Rochelle Cooper Dreyfuss, *Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm*, 31 CARDOZO L. REV. 1437, 1437 (2010).

⁸⁰ Mark A. Lemley, *Patenting Nanotechnology*, 58 STAN. L. REV. 601, 606 (2005).

⁸¹ Raj Bawa, *Nanotechnology Patenting in the US*, 1 NANOTECHNOLOGY L. & BUS. J., 17, 36 (2004); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

the resource becomes underutilized.⁸²

Biotechnology was a revolutionary idea in the 1980s, promising to bring technology that could put current technology to shame. Despite the initial enthusiasm surrounding biotechnology, the field did not live up to its potential. It is contended that this is due to the biotechnology anticommons, where multiple biotechnology patents overlapped, preventing commercialization.⁸³ When the market for biotechnology patents opened up, it was due to the case of *Diamond v. Chakrabarty*,⁸⁴ where a genetically modified microorganism was given a patent. Further, the Bayh-Dole Act⁸⁵ led to government-funded research being approved hastily despite certain patents overlapping, as the USPTO was dealing with such a subject matter for the first time and was not equipped to deal with the ‘patent land rush.’⁸⁶

As a result, the universities facilitating the biotechnology research were eager to recover their capital despite the patents not being completely fleshed out and entered into a “reach through license agreement” which granted patents during upstream stages for a downstream discovery. This essentially means that future discoveries could be patented.⁸⁷ This mechanism is analogous to the provisional registration of patents under the Patents Act, 1970. However, because there is no assurance of discovery beyond the contractual obligations, and since such licensing agreements operate in a legally ambiguous area, they have been applied more liberally.⁸⁸ Notably, even provisional registration requires a complete patent registration to be submitted within one year, yet no specific regulations govern these agreements. Therefore, since multiple universities needed to be contractually obligated, there were demands for unreasonable royalties or demands from the patent holders for the development of a product in a downstream discovery which due to the overlapping similarities, lead to a stall on future innovation and by proxy leading to the slow development of the biotechnology field. This also engendered many researchers developing a fear

⁸² Gastón Llanes & Stefano Trento, *Anticommons and Optimal Patent Policy in a Model of Sequential Innovation*, Working Paper No. 09-148 (2009).

⁸³ MICHAEL A. HELLER & REBECCA S. EISENBERG, *Can patents deter innovation? The anticommons in biomedical research, in perspectives on property law* 159, 162-64 (Robert C. Ellickson et al. eds, 3d ed. 2002) (originally published in 280 Science 698 (1998)).

⁸⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980)

⁸⁵ The Bayh-Dole Act, 35 U.S.C. 200-12 (2000 & Supp. 2002).

⁸⁶ John M Olin Centre for Law, Economics and Business, *Estopping the Madness at the PTO: Improving Patent Administration Through Prosecution History Estoppel*, 116 HARV. L. REV. 2164, 2165 (2003).

⁸⁷ *Supra*, note 45.

⁸⁸ Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1087 (2003)

of exploitation at the hands of licensees, thereby causing an impediment in the channelling of funds for research, causing a bottleneck in development.⁸⁹

The similarity between the nature of products and the development of nanotechnology and biotechnology presumes the same fate for nanotechnology; however, there is some hope. Nanotechnology breeds on the cross-pollination of patents.⁹⁰ The concept of a singular patent for a singular nanotechnology product is not possible in any nation. In the USA, although there are certain nanotechnology patents, they largely depend on other processes to support nanotechnology. However, in India, problems of a larger magnitude persist. Nanotechnology in India is a developing area; therefore, one cannot find a generous number of patents containing the word 'nano.'⁹¹ In fact, there is no base or registry to understand whether a patent involves nanotechnology, except for a manual checking of patents. Further, nanotechnology patents are not as far and wide as biotechnology patents.⁹²

This lack of development ties back to the initial challenges discussed. India, being a developing country, is looked at as a provider of raw materials rather than as a producer of cutting-edge nanotechnology products. Moreover, the government does not particularly sponsor a lot of research in this field, further undermining its development.⁹³ State-sponsored research institutes do not have any incentive to research nanotechnology since the expense incurred even in the course of large-scale production does not justify the cost of initial investment.⁹⁴ There is also a dearth of investors and capitalists who are willing to risk investment in a rather 'developing' field. Biotechnology was proven useful; however, for nanotechnology; first, it requires such pioneering equipment to conduct research, and second, it serves only a niche clientele that does not require large-scale production due to the long-lasting nature of such products. Lastly, a fear of this new technology, especially when already existing technologies operate at the requisite intervals, has led to a stunted growth of nanotechnology in India.⁹⁵

⁸⁹ Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH 321, 350 (2004).

⁹⁰ M. Fakruddin et al., *Prospects and Applications of Nanobiotechnology: A Medical Perspective*, 10 J. NANOBIO TECHNOLOGY 31 (2012).

⁹¹ Beumer, K. & Bhattacharya, S., *Emerging technologies in India: developments, debates and silences about nanotechnology*. 40(5) SCI & PUB. POL'Y, 628-643 (2013).

⁹² A. Kumar, *Nanotechnology Development in India: An Overview* (Research & Info. Sys. for Dev. Countries 2014) (India).

⁹³ A. Kumar & P. N. Desai, *Mapping the Indian Nanotechnology Innovation System*, 11 WORLD J. SCI. TECH. & SUSTAINABLE DEV. 53 (2014).

⁹⁴ *Supra*, note 64.

⁹⁵ Liu, X, et. al., *Trends for Nanotechnology Development in China, Russia, and India*, 11 J. NANOPARTICLE. RES. 1845 (2009).

Although there is no current evolution of nanotechnology, the same stasis should not be presumed for the future. Nanotechnology experienced a boom in its usage as lipid nanoparticles in mRNA vaccines that were used during COVID-19.⁹⁶ Initially, the lipid nanoparticles were developed as a specialized delivery system for nucleic acid, which did not have much scope for development beyond niche research settings; however, it became instrumental for vaccine development. Further quantum dots that use semiconductor nanoparticles did not find initial success in commercial production; however, once it was used in display systems like monitors and televisions, they became the most requested form of conventional nanotechnology in use in a consumer market.⁹⁷ Therefore, this usage of nanotechnology highlights that nanotechnology can be commercialised and is a viable research prospect.

VII. RECOMMENDATIONS

To effectively govern the intersection of nanotechnology, medicine, and sustainable energy, a coordinated approach to intellectual property regulation is essential. Countries, particularly developing ones like India, must develop a unified national nanotechnology regulation that addresses the existing lacuna and the grey areas in the current nanotechnology regulations.

A crucial step in this direction is the establishment of a distinct classification or tagging system within national patent offices to identify and track nanotechnology-related patents. This would help prevent overlaps and clarify the scope of intellectual property claims. Further, patent filings should include mandatory disclosures detailing the environmental impact and lifecycle of the nanomaterials involved, thereby aligning intellectual property protection with sustainability goals. To avoid monopolistic control and foster innovation, governments should encourage open innovation models such as patent pooling and collaborative licensing, reducing the risk of a '*nanotechnology anticommons*.' In addition, the existing provisional and reach-through licensing framework needs reform, with stricter timelines, clearer disclosure standards, fair dealing exceptions and public-interest review mechanisms. Patent incentives, such as expedited processing or fiscal benefits, should be directly linked to public welfare outcomes, including contributions to clean energy or equitable healthcare access. A central oversight authority composed of representatives from environmental, medical, and intellectual property sectors could ensure coherence in regulation and enforcement. Finally, global cooperation through platforms like the

⁹⁶ Wilson, B. & Geetha, K.M., *Lipid Nanoparticles in the Development of mRNA Vaccines for COVID-19*, 74 JOURNAL OF DRUG DELIVERY SCIENCE AND TECHNOLOGY, 103553 (2022).

⁹⁷ Schoenmaker, L., et. al., *mRNA-lipid Nanoparticle COVID-19 Vaccines: Structure and Stability*, 601 INTL J. PHARMACEUTICS, 120586 (2021).

WTO, WIPO, and ISO is vital to harmonize standards, promote equitable access to nanotech innovation, and prevent legal fragmentation across jurisdictions. Together, these measures can create a regulatory environment that fosters responsible innovation while safeguarding public and environmental interests.

VIII. CONCLUSION

Nanotechnology is a transformative field that has much potential for growth, yet it is unregulated, and the opacity of the intellectual property regime poses many legal and environmental challenges. The erratic behaviour of nanoparticles makes regulation difficult; however, the absence of a coordinated global approach has created regulatory blind spots in developing countries, especially which compromise public health and equitable access to technology. The commercial viability of nanotechnology is undeniable; however, the harm caused by nanoparticles to the environment is also undeniable. It is irresponsible to compromise a promise of a future utopia by denying the reality of the dystopian world we currently reside in. History in the form of the stagnation of biotechnology growth must not repeat itself, leading to monopolistic control and ecological harm. To ensure that development does not happen at the cost of the environment or nanotechnology reigns unchecked due to the unfettered power granted by intellectual property, there must be reform.