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Future Trends in Biotechnology Patents: Impact of Nano-Biomedicine and Artificial Intelligence on the Patent Landscape

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Abstract: The development of nano-biomedicine and artificial intelligence (AI) technologies are changing the biotechnology landscape and the global patent system. Both technologies are advancing innovation in sectors such as oncology, genetic diseases, and vaccinology, while posing new challenges in the intellectual property legal framework. This article analyzes the specific sectors most affected by these technologies, discusses regulatory efforts in specific jurisdictions, as well as highlights patent-related case studies of major companies. Additionally, an analysis of the risks and opportunities for collaboration between various parties is outlined to demonstrate the need for regulatory reform to support global innovation. The article also provides strategic recommendations for policymakers as well as long-term projections on the impact of this technology on the patent system in the next 20-30 years.

Keywords: Nano-biomedicine Innovation, AI-driven Patent Analysis, Convergence of Nanotechnology and AI

INTRODUCTION

Biotechnology continues to be one of the most dynamic fields in global innovation, as advances in the underlying technology have driven significant breakthroughs in medical treatments, research, and drug development. Nano-biomedicine, as a branch of biotechnology that integrates nanotechnology in medical applications, has introduced revolutionary new approaches, such as nanoparticle-based drug delivery, gene therapy, and biosensors for early diagnosis of diseases. These technologies enable more precise and personalized medicine by minimizing side effects and increasing therapeutic efficacy (Kumar et al., 2024). For example, the use of lipid nanoparticles in an mRNA vaccine for COVID-19 has proven the real impact of nano-biomedicine in accelerating the response to the global pandemic (Vase et al., 2024). In addition, artificial intelligence (AI) has become a major catalyst in the transformation of biotechnology, accelerating the analysis of genomic data, optimizing personalized therapy, and speeding up the discovery of new drugs. Machine learning algorithms used to analyze large datasets enable the identification of complex genetic patterns, which was previously difficult to do with conventional methods. AI also plays an

important role in modern vaccine design, such as antigen structure prediction using AI-based protein modeling technology (Chaaban et al., 2024). With AI, the drug discovery process that previously took years can now be accelerated to a matter of months. However, the complexity of these technologies often outstrips the limitations of the existing patent legal framework. The traditional patent system is designed for more linear and segmented innovations, while nano-biomedicine and AI are multidisciplinary and continue to evolve dynamically. For example, patents for nanoparticle-based drug delivery systems designed with AI algorithms often overlap with other patent categories, such as medical devices, pharmaceuticals, and software (Vora et al., 2023). These incompatibilities pose serious challenges in the validation of patent claims, which are often the subject of cross-jurisdictional legal disputes. Another issue is the lack of international harmonization in patent regulation. Although certain jurisdictions, such as the United States and the European Union, have begun to adapt their regulations for new technologies, many developing countries still face limitations in legal infrastructure and human resources to handle complex patent claims (Maskus, 2001). This not only creates inequities in access to patent protection, but also exacerbates inequalities in the distribution of innovative technologies across the globe. Exploitation of patents by large corporations is also a major concern. Multinational companies with vast resources often take advantage of loopholes in regulation to dominate the patent landscape, stifling innovation by smaller actors such as startups and academic institutions. For example, a litigation case regarding the patenting of lipid nanoparticles for mRNA vaccines shows how large actors can use their position to control access to critical technologies (Verma et al., 2023). This article aims to further explore the key sectors most affected by nano-biomedicine and AI technologies, and evaluate existing regulatory efforts in different jurisdictions. Additionally, this article identifies opportunities to create a more adaptive and inclusive patent system, focusing on regulatory reform, international collaboration, and recognition of multidisciplinary innovation's contribution to global progress.

METHOD

This research uses a qualitative-descriptive approach to analyze the impact of nano-biomedicine and artificial intelligence (AI) technologies on the global patent system. The main focus of the research is to understand how the existing patent system is adapting to the complexities of new technologies, identify the key challenges faced, and explore opportunities for regulatory reform. In this context, the research utilizes secondary data, case study analysis, and mapping of regulatory trends across different jurisdictions. Primary data collection was done through reliable sources such as reports from the World Intellectual Property Organization (WIPO), the European Patent Office (EPO), and the United States Patent and Trademark Office (USPTO). These reports provide up-to-date data on global patent trends, including the number of patent applications filed in the nano-biomedicine and AI categories, as well as analysis on the challenges faced by innovators in the patent system across jurisdictions. In addition, the study makes use of academic literature from highly reputed journals that address related issues such as patent exploitation, regulatory harmonization, and the contribution of AI in innovation. To provide an in-depth overview, this research also utilizes a case study approach. The study includes analysis of cases involving major companies such as Pfizer, Moderna, and Google DeepMind. For instance, Pfizer's patent conflict over lipid nanoparticle (LNP) technology used in mRNA vaccine delivery was one of the case studies analyzed in detail. The case provides insights into how overlapping patent claims create legal disputes across jurisdictions and demonstrates the need for international regulatory harmonization. Other case studies, such as Moderna's use of AI algorithms in vaccine design, illustrate how new technologies are challenging the boundaries of the traditional patent system. Google DeepMind, with its AlphaFold algorithm for protein

structure prediction, serves as a relevant example of the challenges in validating patent claims for innovations generated by AI.

The research also maps regulatory trends across different jurisdictions to understand how countries are adapting to new technologies. For instance, the EPO has introduced new guidelines that emphasize the importance of human contribution in AI-based patent claims. On the other hand, the United States through the "AI Inventorship Act" has started exploring the possibility of recognizing the role of AI in innovation. The analysis also covers developing countries such as Indonesia, which still face limitations in legal infrastructure and human resources to handle complex patent claims. The data collected was analyzed thematically to identify key patterns, including patent exploitation by large companies, challenges in international regulatory harmonization, and potential for cross-sector collaboration. This analysis helps shed light on the dynamics affecting the patent system in the era of nano-biomedicine and AI technologies. In this process, the research also identifies strategic steps that can be taken to create a more inclusive and adaptive patent system.

However, the study has limitations, including reliance on secondary data that may not cover all aspects of regulatory dynamics and patent litigation. The case study approach, while providing in-depth insights, may not fully reflect global trends. Therefore, further research involving interviews with innovators or surveys of stakeholders may provide additional perspectives. Overall, this methodology is designed to provide a comprehensive and relevant analysis of how the patent system can evolve to meet the challenges and opportunities presented by nano-biomedicine and AI technologies. With this approach, this research aims to make a significant contribution to the academic and policy discussions on patent system reform in an era of advanced technological innovation.

RESULTS AND DISCUSSION

Nano-biomedicine and artificial intelligence (AI) have brought significant impact in various biotechnology sectors, especially in terms of improving the effectiveness and efficiency of medical therapies. The key sectors most affected include oncology, genetic diseases and vaccinology. Each sector shows how the integration of these technologies can address complex medical challenges while opening up new opportunities for innovation.

Oncology is the sector most affected by developments in nano-biomedicine and AI. Nano-biomedicine has enabled more targeted drug delivery to tumors using nanoparticles specifically designed to target cancer cells. With this capability, side effects on healthy tissues can be minimized, while therapeutic efficacy is increased. One example of this application is the lipid nanoparticle (LNP) technology patented by Pfizer for use in cancer treatment. This patent shows great potential in delivering more precise cancer therapy, especially in combination with modern immunotherapy (Cheng et al., 2024). In addition, AI plays an important role in this sector by predicting a patient's response to a particular therapy based on the analysis of large genomic data. AI enables the mapping of a patient's molecular profile to determine the most effective therapy, an approach known as precision oncology (Hachache et al., 2024).

Genetic diseases are also a sector that is greatly affected by nano-biomedicine and AI technologies. In this context, nano-biomedicine has opened up opportunities for high-precision gene editing, using technologies such as CRISPR combined with nanoparticle-based delivery systems. With this method, gene editing can be performed more safely and efficiently, enabling the treatment of previously incurable genetic diseases. AI, on the other hand, is used to analyze genomic data and identify genetic mutations that are potential targets

for therapy. Companies like Moderna have utilized AI in the design of mRNA-based gene therapies, which increases the efficiency and precision of developing these therapies. Their patent covers an AI algorithm used to predict the optimal molecular structure, ensuring that the resulting mRNA can work effectively in target cells (Zhang et al., 2023).

Vaccinology is another sector undergoing a major transformation with the integration of nano-biomedicine and AI. In vaccine development, nano-biomedicine plays an important role in improving vaccine stability, efficacy and distribution, especially in mRNA-based vaccines. This technology enables packaging of mRNA into lipid nanoparticles that protect the genetic material during transportation into the body, ensuring efficient delivery to target cells. AI also makes significant contributions to vaccine design by predicting the structure of the most immunogenic antigens. For example, the mRNA vaccine for COVID-19 developed by Moderna and Pfizer-BioNTech utilizes a combination of nano-biomedicine and AI. In this process, AI was used to analyze genetic data from the SARS-CoV-2 virus and predict the spike proteins that the vaccine targets. This combination resulted in a vaccine that was not only effective but also developed in a fraction of the time of conventional methods (Kaushik et al., 2023).

The combined impact of nano-biomedicine and AI across these three sectors shows how technology integration can revolutionize biotechnology. In addition to improving clinical outcomes, these technologies also accelerate the development of new therapies, reduce research costs, and increase access to treatment worldwide. However, regulatory challenges and international harmonization remain issues that must be addressed to maximize the potential of these technologies (da Silva, 2024).

Patent Regulations in Several Countries

Patent regulation plays an important role in supporting technological innovation, including nano-biomedicine and artificial intelligence (AI). However, the multidisciplinary nature and complexity of these technologies pose significant challenges in the legal system. Some jurisdictions have tried to adapt their regulations to keep up with these advancements, but different approaches between countries create additional challenges for global innovators.

Regulatory Adaptation in the United States

The United States has tried to address this challenge by proposing legislation such as the “AI Inventorship Act,” which aims to recognize the contribution of AI in the innovation process. Landmark cases such as Thaler v. Commissioner of Patents exemplify how courts have confronted the issue of whether AI can be considered an “inventor.” In this case, the court rejected the claim that AI can be recognized as an inventor under existing patent law, asserting that the legal definition of inventor is still limited to humans (Thaler v. Commissioner of Patents, 2021). Despite efforts to develop more inclusive regulations, the implementation of laws such as the “AI Inventorship Act” faces major challenges. One major obstacle is ensuring that the legal system can distinguish between human and AI contributions to innovation. For example, AI algorithms designed to predict protein structures might generate innovations autonomously without direct human intervention, but the question of who should hold the rights to such innovations remains an unresolved debate (Bonadio & McDonagh, 2020).

Approach in the European Union

The European Union has also taken steps to adapt their patent system. The European Patent Office (EPO) introduced new guidelines for the assessment of AI-based patents, which

highlight the importance of human contribution in the innovation process. These guidelines stipulate that patent claims involving AI must clearly demonstrate the role of humans in the design or operation of the algorithm. However, this approach has faced criticism for being too restrictive and not reflecting the reality where AI often plays an autonomous role in innovation (Arkoudas et al., 2012). Furthermore, the difference in approach between the European Union and the United States creates uncertainty for innovators operating in the global market. For example, patents recognized in the European Union may not meet the legal requirements in the United States, which may hinder the launch of products based on AI or nano-biomedicine technologies in various international markets (Engler, 2022). International regulatory harmonization is an urgent need to ensure that technological innovations can be protected and utilized globally.

Challenges in Developing Countries

Developing countries face greater challenges in adapting their patent regulations to new technologies. The lack of trained human resources, adequate legal infrastructure, and funding for research makes it difficult for these countries to compete at the global level. For example, Indonesia, despite having great potential in biotechnology research, still faces significant obstacles in assessing patent claims involving nano-biomedicine and AI. The complexity of these technologies often outstrips the technical and legal capacity of the national patent evaluation system (Santosa, n.d.). This unpreparedness may hamper foreign investment and local innovation in developing countries. Moreover, reliance on multinational companies to provide these technologies may exacerbate inequalities in access to advanced technologies. Developing countries also face the risk of patent exploitation by more powerful actors, where large companies may monopolize intellectual property rights over technologies that should be more widely accessible (Naoaj, 2023).

The Need for International Harmonization

These challenges point to the urgent need for harmonization of patent regulations at the international level. Organizations like WIPO can play an important role in drafting a legal framework that can be adopted globally. This harmonization should include guidance on how patent claims involving AI and nano-biomedicine should be evaluated, as well as mechanisms to resolve disputes across jurisdictions. For example, initiatives such as the Patent Cooperation Treaty (PCT), designed to facilitate patent registration in multiple countries, could be expanded to include specific guidelines for new technologies. Additionally, training for patent evaluators in developing countries needs to be improved to ensure that they can understand and assess complex patent claims with accuracy and efficiency (Orr and Bottomley, 2020).

Impact of Regulation on Innovation

Inadequate or inconsistent regulations can adversely affect innovation. Legal uncertainty can make innovators hesitant to apply for patents, while overly strict regulations can hinder technological development. Conversely, adaptive and inclusive regulations can encourage collaboration between the public and private sectors, as well as between developed and developing countries. By creating a more harmonized legal framework, the global patent system can support the development of nano-biomedicine and AI technologies in a more sustainable manner (Zhou & Gattinger, 2024). This discussion on regulation highlights that

while some jurisdictions have made significant progress, more needs to be done to create a legal system that truly supports multidisciplinary innovation. International harmonization, capacity building in developing countries, and recognition of AI's contribution in the innovation process are important steps towards a more inclusive patent system future.

Legal Complexities and Challenges in Large Corporate Patent Cases

Several patent cases filed by major companies show how the complexity of new technologies, such as nano-biomedicine and AI, creates significant legal challenges. These cases illustrate the dynamics of cross-jurisdictional patent disputes, claim validation issues, as well as the implications of evolving technologies to the patent system.

Pfizer Case: Lipid Nanoparticle Patent Conflict

Pfizer is facing one of the most high-profile patent cases in the history of mRNA vaccine development. Their patent for lipid nanoparticles (LNPs) used in the delivery of COVID-19 mRNA vaccines is the subject of a legal dispute with another company that claims to have developed similar technology earlier. The LNP technology is a key element in ensuring the stability and efficiency of mRNA vaccines during delivery into the body, and as such, this patent has immense strategic value (Cheng et al., 2024). This conflict created international arbitration as the LNP patents filed by Pfizer were deemed to infringe on the intellectual property rights of other biotechnology companies, such as Arbutus Biopharma. Arbutus claimed that some elements of Pfizer's LNP technology were based on innovations that they had patented earlier. This case highlights how complex technological overlaps can trigger costly and prolonged litigation. Moreover, this dispute reveals the need for a more transparent and consistent patent system to handle patent claims in the field of nano-biomedicine (Madar et al., 2024).

Moderna Case: AI Algorithm-Based Patents

Moderna, one of the pioneers in mRNA vaccine technology, is also facing legal challenges regarding their patent claims. Moderna filed a patent for mRNA technology designed using an AI algorithm they developed to predict the optimal RNA structure in COVID-19 vaccines. This algorithm enables faster and more precise vaccine design, accelerating the response to global pandemics (Lenarczyk et al., 2024). However, this patent faced challenges from various parties, including small biotech companies and academic research institutions. Some claim that Moderna's patent claims are too broad, covering technology that should be considered public domain or the result of collaborative research. This lawsuit not only demonstrates the risk of patent overlap but also highlights the issue of the right to innovation involving AI algorithms. Is the contribution of AI in the design of this vaccine enough to grant exclusive rights to Moderna, or should most of its claims be shared with other parties? This case remains an intense legal debate and underscores the need to clarify the rules on AI-based patents (Jalilian et al., 2023).

The Case of Google DeepMind: Protein Structure Prediction

Google DeepMind, known for its AI innovations in general technology, has begun to venture into the biotechnology sector by developing algorithms for protein structure prediction. This technology, known as AlphaFold, enables modeling of protein structures with an unprecedented level of accuracy, opening up huge opportunities for new drug

research. However, their patent claims face challenges in validation as the AlphaFold algorithm is constantly evolving through automated learning. This process creates problems in defining patent boundaries, as innovations generated by AI do not always fit into traditional patent categories (Bohrer & Bargmann, 2024).

One of the key challenges is how to identify the human contribution in the initial design of AlphaFold compared to the innovation "generated" by the algorithm itself. Should patents be granted for the initial algorithm or for the specific results produced by the algorithm? This complexity sparked a discussion on whether AI algorithms like AlphaFold can be considered "inventors," which is currently not recognized in most jurisdictions (Bohrer & Bargmann, 2024).

Impact of Litigation on Innovation

These cases show that patent litigation not only affects large companies but also has implications for the innovation ecosystem as a whole. Protracted legal disputes can hamper the development of new technologies as they create legal uncertainty for innovators. Moreover, this kind of litigation often involves enormous costs, which can deter smaller companies or academic institutions from participating in patent filings or further technology development (Bohrer & Bargmann, 2024).

Furthermore, these cases highlight the risks of large company dominance in the global patent landscape. With vast resources, companies such as Pfizer, Moderna, and Google DeepMind have an advantage in securing patents for advanced technologies. However, this dominance can also create monopolies that hinder equitable access to these technologies, especially in developing countries (Prabhala, 2022).

The Need for Regulatory Reform

The patent litigation in these cases underscores the urgent need to reform the global patent system to make it more adaptive to new technologies. Clearer regulations on AI contributions, international harmonization in patent definitions, and strengthening of international arbitration mechanisms can help reduce conflicts and accelerate the adoption of new technologies in the global market. With this approach, the patent system can better support innovation without compromising the principles of fairness and inclusiveness.

Challenges and Opportunities in Nano-Biomedicine and AI Innovation

In the nano-biomedicine and artificial intelligence (AI) innovation landscape, there are significant challenges and opportunities that affect how these technologies are adopted and developed. Key challenges include patent exploitation by large corporations and unequal access to innovative technologies. However, on the other hand, opportunities for collaboration between stakeholders also offer avenues to create a more inclusive and sustainable innovation ecosystem.

Patent Exploitation by Large Companies

One of the main risks in the development of nano-biomedicine and AI technologies is patent exploitation by large corporations. With abundant resources, multinational corporations have the ability to secure patents on advanced technologies, even for innovations that often involve contributions from multiple parties, including academia and small research institutions. The dominance of large corporations in the patent landscape

creates monopolies that can stifle innovation by smaller actors, such as universities and startups, which are often the main source of revolutionary ideas (Rikap & Lundvall, 2021). For example, in the vaccinology sector, large companies such as Pfizer and Moderna have extensive patent portfolios for mRNA technology. While these technologies are largely developed based on basic research by academic institutions, patents are often monopolized by large companies. This makes access to such technologies limited for developing countries that may not be able to afford high royalties (Stewart, 2000). Without effective regulation, this risk of exploitation could exacerbate global inequalities in the distribution of advanced technologies, which are critical to public health needs.

Risk of Innovation Imbalance

Patent exploitation also has the potential to create an innovation imbalance. Large companies tend to focus on technologies that provide quick financial returns, while basic research or innovations for rare diseases and developing countries are often overlooked. In the nano-biomedicine sector, for example, most patents filed by large companies focus on the treatment of non-communicable diseases common in developed countries, such as cancer or diabetes. In contrast, research on tropical diseases more relevant for developing countries, such as malaria or tuberculosis, receives much less attention (Padma et al., 2022). Furthermore, regulatory uncertainty often creates additional barriers for startups and universities looking to file patents for their technologies. Complicated and expensive patent filing processes are often prohibitive, especially for smaller institutions that lack the financial capacity to compete with larger companies. This creates the risk that innovations from small actors may be absorbed by large companies without adequate recognition, harming the innovation system as a whole (Athreye et al., 2021).

Collaboration Opportunities and Inclusive Patent System

While the challenges are significant, the opportunity to create an inclusive innovation ecosystem remains open. Collaboration between academia, government, and the private sector can be a solution to address the imbalance in access to technology and the exploitation of patents by large companies. This cooperation can not only improve efficiency in technology development, but also ensure that the benefits of innovation are widely shared. One example of a successful collaborative initiative is COVAX, a global program designed to ensure equitable distribution of COVID-19 vaccines, including in developing countries. Through collaboration between international organizations, governments, and pharmaceutical companies, COVAX successfully facilitated access to nano-biomedicine and AI-based mRNA vaccines, although challenges remain in the scale of distribution (Budish et al., 2022). Models like COVAX show that global partnerships can be an effective way to address inequalities in the distribution of advanced technologies. Collaboration can also be encouraged through incentive policies, such as the sharing of intellectual property rights for publicly funded research. For example, governments can regulate that patents resulting from research funded by public funds should include open access clauses or profit sharing with developing countries. This approach can encourage cross-sector collaboration while ensuring that innovation does not only benefit large companies but also provides benefits to society as a whole (Huang et al., 2024).

Open Technology and Co-Innovation

Another opportunity that can be explored is the open technology approach. In this system, researchers and companies share data and knowledge to accelerate innovation without being restricted by proprietary patents. This model has proven successful in some cases, such as in the development of open-source software in the field of information technology. A similar approach can be applied in nano-biomedicine and AI development, especially for basic research that lays the foundation for commercial applications. For example, projects such as the "Open COVID Pledge" launched during the pandemic allow researchers to share patents and data free of charge for a certain period to support the rapid and efficient development of solutions. This approach could be adopted more widely to ensure that new technologies are accessible to all, especially in global health emergencies (Contreras, 2021).

Potential Impact of Collaboration

Effective collaboration can have a significant positive impact on the global innovation landscape. By encouraging broader participation from various actors, an inclusive patent system can increase the speed and efficiency of technology development, while ensuring that the benefits of innovation are felt equally. Moreover, cross-sector collaboration can help overcome regulatory barriers and ensure that new technologies can be adopted quickly across different jurisdictions. By encouraging partnerships between large companies, universities, and governments, the opportunity to create a fair and inclusive patent system becomes more real. This initiative will not only encourage innovation but also create a more sustainable ecosystem, where nano-biomedicine and AI technologies can be optimally utilized for global benefit (Holgersson et al., 2018).

Patent System Reform for Nano-Biomedicine and AI Technology

The existing patent system faces great challenges in dealing with the complexities of nano-biomedicine and artificial intelligence (AI) technologies. These technological developments not only change the way innovation is carried out but also affect the way intellectual property rights should be protected. To ensure that the patent system remains relevant and supports global innovation, comprehensive and strategic reforms are required. These reforms should include international harmonization of regulations, enhancement of patent evaluation capacity in developing countries, and recognition of the contribution of AI in the innovation process.

Harmonization of International Regulations

One of the key strategic steps in the patent system reform is the harmonization of regulations at the international level. Currently, significant differences in regulatory approaches across different jurisdictions create barriers for global innovators. For instance, the United States has started recognizing the role of AI in innovation through laws such as the "AI Inventorship Act," while the European Union still focuses on the contribution of humans in the innovation process (Kretschmer et al., 2022). This discrepancy creates uncertainty for companies looking to launch new technologies in the global market, which may ultimately hinder the adoption of advanced technologies. International harmonization can be achieved through collaboration between organizations such as the World Intellectual Property Organization (WIPO) and regional patent bodies such as the European Patent Office (EPO)

and the United States Patent and Trademark Office (USPTO). A global framework that establishes guidelines for the evaluation of AI and nano-biomedicine-based patent claims can help reduce conflicts between jurisdictions. This harmonization will also ensure that patents granted in one country can be recognized in another without significant barriers, thereby accelerating the process of commercialization of innovations (Miyamoto, 2019).

Capacity Building for Patent Evaluation in Developing Countries

Developing countries often face major challenges in dealing with complex patent claims. Lack of trained human resources and adequate legal infrastructure are major obstacles. This not only hampers the ability of these countries to compete at the global level but also opens up opportunities for exploitation by multinational companies that monopolize advanced technologies (Olubiyi et al., 2022). Improving patent evaluation capacity in developing countries requires investments in training patent evaluators and modernizing patent administration systems. For instance, training programs organized by WIPO can help developing countries understand the complexities of nano-biomedicine and AI technologies, so that they can evaluate patent claims more accurately and efficiently. Moreover, digitizing the patent filing and evaluation process can increase transparency and speed up claim turnaround time, which will ultimately encourage more local innovation.

Recognizing AI's Contribution to the Innovation Process

One of the most controversial issues in the modern patent system is the recognition of AI's contribution to innovation. Currently, most jurisdictions do not recognize AI as an "inventor," even though AI algorithms often play a major role in producing innovative results. Cases such as Thaler v. Commissioner of Patents show that traditional legal systems still hold on to the concept that only humans can be recognized as inventors (Nguyen & Quan, 2023). However, with the increasing use of AI in biotechnology research, there is an urgent need to update the legal definition of "inventor." One approach that could be considered is a hybrid system, where patents could be granted to humans who develop or operate AI, but with explicit recognition that AI plays a significant role in the innovation process. This approach would not only improve legal clarity but also encourage wider use of AI in research and development (Mariani & Dwivedi, 2024).

Supporting Inclusive Innovation

Patent system reform should also be designed to support inclusive innovation. Currently, most patents for advanced technologies are controlled by large companies, while smaller actors such as universities and startups often do not have equal access to the patent system. To address this issue, reforms should include measures such as the reduction of patent filing fees for startups and academic institutions, as well as the establishment of funding programs to support local innovation in developing countries (Ziakis et al., 2022). Additionally, reforms should ensure that the patent system supports cross-sector collaboration. Partnerships between the public and private sectors can foster the development of technologies that are more inclusive and beneficial to society at large. For example, initiatives such as COVAX show that collaboration between governments, pharmaceutical companies, and international organizations can help address inequalities in access to innovative technologies, such as nano-biomedicine-based mRNA vaccines (Budish et al., 2022).

Projections for the Next 20-30 Years

In the next 20-30 years, nano-biomedicine and AI are expected to continue to drive major transformations in biotechnology. These technologies will not only improve efficiency and precision in medical treatments but also pave the way for new solutions in diagnosis, gene therapy, and vaccine development. However, this transformation will also create new challenges in the patent system, including the need to address technological overlaps and redefine the concept of "invention" in the context of AI (de Rassenfosse et al., 2022). With the right strategic measures, the patent landscape can become more adaptive and inclusive. International regulatory harmonization, recognition of AI contributions, and support for innovation in developing countries will be key to ensuring that the benefits of these technologies can be felt globally. Reforming the patent system will not only encourage sustainable innovation but also create a more equitable and inclusive technology ecosystem, where all actors, from large corporations to small startups, can participate and thrive (Schot & Steinmueller, 2018)**.**

CONCLUSIONS

Patent system reform is needed to accommodate the complexity of nano-biomedicine and AI technologies. Strategic steps include international regulatory harmonization, enhancement of patent evaluation capacity in developing countries, and recognition of AI's contribution to innovation. In the long term, the patent system should be designed to support inclusive innovation, allowing all actors, from large corporations to small startups, to participate in the global biotechnology landscape. Projections for the next 20-30 years show that nano-biomedicine and AI will continue to drive transformation in biotechnology, creating new challenges and opportunities. With the right strategic measures, the patent landscape can become more adaptive, inclusive, and supportive of sustainable innovation worldwide.

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