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THE ROLE OF INTELLECTUAL PROPERTY IN THE DEVELOPMENT OF INNOVATIONS IN REGENERATIVE MEDICINE.

Issa Akanji ADEDOKUN *, Temidayo Peter AKEREDOLU*, and Olowo-Niyi ADEBOLA***

Abstract

Regenerative medicine marks a paradigm shift in healthcare, transitioning from symptom-based treatment to leveraging the body's inherent healing mechanisms. It represents a convergence of nature and science, fostering innovative solutions for preserving life. Intellectual Property (IP) safeguards the expression of innovation and creativity across various domains, encompassing regenerative medicine. However, questions arise regarding its ability to meet patentability criteria and the ethical implications of granting exclusive ownership (Intellectual Property) to life-saving techniques, potentially hindering adequate Intellectual Property protection. Using the doctrinal research method, this article explores the breadth of regenerative medicine and the applicability of Intellectual Property protection to cutting-edge medical interventions, including regenerative medicine, aiming to strike a balance between comprehensive protection, commercialization, and public access. The paper draws valuable lessons from best practices and jurisdictions such as the United States of America and South Africa to promote innovation and foster access to regenerative medicine in Nigeria. It finds that one of the foremost challenges of the protection of regenerative medicine by Intellectual Property is the ethical concerns regarding the use of

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human cells, tissues and embryonic stem cells. It also notes some weaknesses in Nigeria's current regulatory framework and calls for stronger enforcement of ethical standards. It recommends among others the need for more awareness in the area where intellectual property and regenerative medicine connect. The work equally advocates for the need to update the Patent and Designs Act (PDA) of 1970 to allow for the registration of cutting-edge technologies including regenerative medicine.

Keywords: *Regenerative Medicine, Intellectual Property, Innovation, Patent, Stem Cell, Nigeria*

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1. Introduction

To improve on the traditional model of practicing medicine, the replacement of human cells, tissues, or organs to restore normal function emerged as an advancement in the field of medicine.[1] This development was especially fuelled by an artificial intelligence-driven innovative technology. As a new biotechnological field, regenerative medicine allows for a precise manipulation of tissues at the microscopic level which has indeed unlocked new possibilities for enhancing regenerative medicine outcomes.[2] Generally, an innovative endeavour is an invention that introduces a new and distinct perspective to the known or existing procedure by providing a cutting-edge solution to an existing problem.[3] With invention comes the right to patent, having a patent gives an individual or company the right to control who can make, sell, or import their technology.[4] It also enables an inventor to sell, trade, or license their patented

*LL.B (Hons), B.L., LL.M., Ph.D. (Lagos); Lecturer, Department of Private and Property Law, Faculty of Law, University of Lagos, Akoka, Yaba, Lagos, Nigeria. Email: isaadedokun@hotmail.com; isadedokun@unilag.edu.ng. Tel: 08064961721.
**LL.B.(Hons), B.L., LL.M., Lecturer, Department of Private and Property Law, Faculty of Law, Ekiti State University, Ado-Ekiti, Ekiti State, Nigeria. Email: temidayo.akeredolu@eksu.edu.ng. Tel: 07038205890.
***LL.B.(Hons), ABUAD, Legal Researcher at the NNPC Pension Funds Ltd. Email: oriolowoadebola@gmail.com. Tel: +2348147821432

[1] Anthony A, *In Situ Tissue Regeneration Host Cell Recruitment and Biomaterial Design* (Wake Forest Institute for Regenerative Medicine: United States, 2016) pp. 421-437.

[2] Kaul H and Ventikos Y, 'On the Genealogy of Tissue Engineering and Regenerative Medicine' (2015) 21 Tissue Engineering Part B-reviews 203 https://doi.org/10.1089/ten.teb.2014.0285. last accessed 2/02/2024.

[3]Innovation and Intellectual Property"https://www.wipo.int/ipoutreach/en/ipday/2017/innovation_and_intellectual_property.html#:~:text=Innovation%20means%20doing%20something%20new,intellectual%20property%20(IP)%20rights.

[4] Simensky. M. *et al*., *Intellectual Property in the Global Marketplace* (Wiley, 1999); Hasson. I, "Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization" (2002) 25 *Boston College Intenational and Comparative Law Review*, 373, 375. <Domestic Implementation of International Obligations: The Quest for World Patent Law Harmonization (core.ac.uk)> accessed 21 May 2024.

technologies to others.[5] This encourages innovation and provides a way for inventors to profit from their inventions.[6]

Against this background, this paper examines how regenerative medicine which is considered a transformative field with the potential to revolutionize healthcare by providing new therapeutic strategies for various debilitating conditions is entitled to be adequately protected. It further examines the role reserved for intellectual property as it relates to the intellectual ownership of such revolutionary inventions. In fulfilling the aim of this research, it adopts a doctrinal and comparative method of research to evaluate contributions to the subject matter. By doctrinal approach, an analysis of legal rules, principles, statutes and case law was deplored to provide context and augment the understanding of patent within this field. In addition, it provides a comparative analysis of how certain jurisdictions have sought to protect regenerative medicine technologies through intellectual property. This comparison draws positive lessons from the patent framework of the United States and South Africa, with a view of obtaining insight for Nigeria towards improving patentability of regenerative medicine technologies.

This article is structured into seven sections. The first section serves as an introduction, providing a background for the role of regenerative medicine in the context of intellectual property. The second section offers a comprehensive examination of regenerative medicine, encompassing its various types and tracing its historical development. Following this section, the third section delves into the disposition of intellectual property law towards regenerative

[5] *Ibid*.
[6] *Supra,* n. 3; Bolaji K, "The Role of the Patent System in Fostering Innovation and Entrepreneurship" (2023) 13(2) *International Journal of Business Management and Research*, 47-52; Encaoua. D, "Patent Systems for Encouraging Innovation: Lessons from Economic Analysis" (2006) 35(9) *Research Policy*, 1423-1440.

medicine and other emerging technologies. This section aims to analyse the delicate balance between safeguarding the intellectual property rights of patent holders and ensuring public access to innovations. It further examines the concept of intellectual property and its significance in protecting regenerative medicine. The fourth section scrutinizes the requirements for patentability as stipulated by Nigerian law and assesses the feasibility of patenting regenerative medicine within the Nigerian jurisdiction. In the fifth section, the article extends its inquiry beyond Nigeria, exploring the criteria for patentability in other jurisdictions. This comparative analysis provides valuable insights into global perspectives on patenting regenerative medicine. Continuing the discussion, the sixth section elucidates the challenges and limitations inherent in the patentability of regenerative medicine, shedding light on potential barriers to securing patents in this field. It also discussed the prospects and potential benefits in the practice of regenerative medicine. Finally, the seventh section consolidates the findings of the article, drawing conclusive remarks on the complexities surrounding the patent protection of regenerative medicine.

1. An Overview of Regenerative Medicine

The emergence of regenerative medicine and tissue engineering over two decades ago marked the historical deviation of medicine from the traditional clinical approach of the treatment of symptoms through the administration of drugs to the revitalization and replenishment of organs and tissues affected by diseases, trauma or inherent defects.[7] The process of regeneration involves tissue engineering and the utilization of the body's self-healing processes in conjunction with foreign biological material to aid the recreation of cells and the reconstruction of tissues and

[7] Astgik P. *et al*., 'Regenerative Medicine Applications: An Overview of Clinical Trials' (2022) (10) Frontiers <https://www.frontiersin.org/articles/10.3389/fbioe.2022.942750/full> accessed 14 November 2023.

organs.[8] It repositions the process of recovery from the external introduction of medicine to the scientific amplification of natural healing processes and further encompasses several strategies including the use of *de novo* cells to substitute missing or damaged tissues in replacing it both structurally and functionally to contribute to tissue and overall healing.[9]

One major objective of regenerative medicine is the regeneration of lost or damaged tissue and the stimulation of tissue. Other objectives include but not limited to organ growth and the promotion of natural healing.[10] Key principles of regenerative medicine include Stem Cell Therapy, Tissue Engineering, Gene Therapy, Bio-mimicry and Cell therapy. Stem cell therapy refers to the stimulation of cells found in the blood, bone marrow, connective tissue, nerves or skin to produce specific or mature cell types which are capable of replenishing damaged or dead cells in the body.[11] Stem cell therapy is highly advantageous as it eliminates the risk of rejection by the immune system as prevalent in organ transplantation as the patient's cells are used for the process. It also does not require the continuous use of immunosuppressants and may be conducted without resorting to highly invasive mechanisms. Tissue engineering is also central to

[8] Regenerative medicine is a developing branch of medicine that utilizes stem cells, biomaterials, and tissue engineering to mend, rejuvenate, or substitute impaired or diseased cells, tissues, and organs. See further, National Institute of Biomedical Imaging and Bioengineering, 'Tissue Engineering and Regenerative Medicine' https://www.nibib.nih.gov/science-education/science-topics/tissue-engineering-and-regenerative-medicine#:~:text=Regenerative%20medicine%20is%20a%20broad,and%20rebuild%20tissues%20and%20organs.

[9] Angelo S. M & David J. M., 'Regenerative Medicine: Current Therapies and Future Directions' (2015) (112)(47) PubMed Central <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4664309/> accessed 14 November 2023

[10] Lone Star Pain Medicine, 'The 5 Basic Principles of Regenerative Medicine' <https://lonestarpain.com/2021/07/19/the-5-basic-principles-of-regenerative-medicine/> accessed 17 November 2023.

[11] Masanori F., 'An Overview of Regenerative Medicine: its Principles and the Scope of the Current Revolution' <https://advances.tri-kobe.org/en/the-principles-of-regenerative-medicine/52/an-overview-of-regenerative-medicine_-its-principles-and-the-scope-of-the-current-revolution.html accessed 17 November 2023.

the process of regenerative medicine as it produces scaffolds for the growth of cells to fill gaps or holes in damaged tissues.[12]

The natural aspect of regenerative medicine is seen in the amplification of the regenerative process in the body which is known as Bio-mimicry. This involves designing therapies that mimic the body's natural process of cell and tissue development and regeneration and also creating materials that reproduce the functions of native tissue.[13] Cell therapy involves the replacement of damaged and diseased cells with new and healthy substitutes. It also encompasses the removal of disease-causing cells using immune cells which are created and transplanted into the body. These five therapies form the embodiment of regenerative medicine.

2.1. Historical Perspective on Intellectual Property in Regenerative Medicine

The term "regenerative medicine" is credited to William Haseltine who used it to describe a new field that encompassed tissue engineering, cell transplantation, stem cell biology, biomechanics prosthetics, nanotechnology and biochemistry.[14] The discovery of human embryonic stem cells was deemed a major evolution of medicine in the late 1990s, however, it also raised concerns as to the patentability of regenerative cells and their technologies as it was argued that patenting human embryonic cells was immoral as it violated the fundamental right to human dignity.[15] This consideration was detrimental to the protection of regenerative medicine under Intellectual

[12] *Ibid.*

[13] Shuai Liu *et al,* 'Biomimetic Natural Biomaterials for Tissue Engineering and Regenerative Medicine: New Biosynthesis Methods, Recent Advances and Emerging Applications' (2023) (10) (16) Military Med Res <https://mmrjournal.biomedcentral.com/articles/10.1186/s40779-023-00448-w> accessed 20 November 2023.

[14] Gianluca S., 'Regenerative Medicine: Historical Roots and Potential Strategies in Modern Medicine' <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6014277/> accessed 23 November 2023.

[15] David B. R., 'Embryonic Stem Cell Patents and Human Dignity' (2007) (15) (3) PubMed Central <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2695597/> accessed 23 November 2023.

Property as most Intellectual Property regimes prevented the protection of inventions that were deemed immoral or contrary to public order. Over time, as the world witnessed technological dynamism in various forms, certain countries began extending protection to certain aspects of regenerative medicine and today, these medical therapies have found protection under several Intellectual Property legislations.

2.2. Objectives of Regenerative Medicine and Intellectual Property

One major objective of regenerative medicine is the regeneration of lost or damaged tissue and the stimulation of tissue. Other objectives include but not limited to organ growth and the promotion of natural healing.[16] Key principles of regenerative medicine include Stem Cell Therapy, Tissue Engineering, Gene Therapy, Bio-mimicry and Cell therapy. Stem cell therapy refers to the stimulation of cells found in the blood, bone marrow, connective tissue, nerves or skin to produce specific or mature cell types which are capable of replenishing damaged or dead cells in the body.[17] Stem cell therapy is highly advantageous as it eliminates the risk of rejection by the immune system as prevalent in organ transplantation as the patient's cells are used for the process. It also does not require the continuous use of immunosuppressants and may be conducted without resorting to highly invasive mechanisms. Tissue engineering is also central to the process of regenerative medicine as it produces scaffolds for the growth of cells to fill gaps or holes in damaged tissues.[18] The natural aspect of regenerative medicine is seen in the amplification of the regenerative process in the body which is known as Bio-mimicry. This involves designing therapies that mimic the body's natural process of cell and tissue

[16] Lone Star Pain Medicine, *supra note* 10.
[17] Masanori F., *supra* note 11.
[18] Ibid.

development and regeneration and also creating materials that reproduce the functions of native tissue.[19] Cell therapy involves the replacement of damaged and diseased cells with new and healthy substitutes. It also encompasses the removal of disease-causing cells using immune cells which are created and transplanted into the body. These five therapies form the embodiment of regenerative medicine.

3. Intellectual property (IP) and Cutting-Edge Technologies

No doubt, Intellectual Property protects the novel expression of innovation and technology through the grant of exclusive rights comprising patents, trademarks, copyrights and trade secrets to creators and innovators, thereby conferring exclusive control over the use, reproduction and distribution of their inventions.[20] The criteria for the protection of creations and innovations under Intellectual Property is dependent on their form and adaptability under current Intellectual property regimes, however, a general overview indicates the extension of Intellectual Property protection to the expression of novelty or originality in a creative manner.[21] Regenerative medicine attempts to strike a balance between science and nature in restoring the function of damaged tissues and creating a solution for permanently damaged organs. Its goal is the development of cures for hitherto untreatable injuries and diseases – an unprecedented

[19] Shuai Liu *et al*, *Supra* note 13.
[20] Hayden H., 'The Importance of Intellectual Property in Engineering' <https://www.eit.edu.au/the-importance-of-intellectual-property-in-engineering/> accessed 15 November 2023.
[21] Zade. M. *et al*, "Intellectual Property Rights (IPR): An Overview" (2023) 10(3) *International Journal of Pharmaceutical Chemistry and Analysis*, 156-163. See further, Onyeka O, "Intellectual Property Rights Protection and Economic Development". (2014) *European Scientific Journal* <https://eujournal.org/files/journals/1/books/OnyekaUcheOfili.pdf> accessed 21 May 2024.

breakthrough in the field of medicine.[22] The significance of the protection of this innovation includes the furtherance of innovation and promotion of increased research and development through the assurance of legal protection and financial incentives for future innovation. An instance of protection of such inventions can be seen in the United States where three patents held by the Wisconsin Alumni Research Foundation (WARF) protect the first isolation of non-human primate and human embryonic stem cells (hESCs).[23]

3.1. Balancing Intellectual Property Protection and Public Access

Intellectual Property protection in certain circumstances is likened to a two-edge sword as despite its numerous benefits evident in the increase in income of Intellectual Property holders and the encouragement of research and development, it may prevent necessary access to protected inventions and serve as an obstacle to the true objective of innovation – its utilization for the collective development of the society.[24] Access to medicine and pharmaceutical products is governed by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which introduced a new global Intellectual Property regime for the promotion of access to medicines.[25] The Agreement requires the compliance of member States with the minimum standards of Intellectual Property protection for pharmaceutical products. Hence, by

[22] Adolfo. P, "Regenerative Medicine: A Review" (2009) 31(2) *Revista Brasileira de Hematologia e Hemoterapia*, 63-66. See further, Loai S. *et al*, 'Clinical Perspectives on 3D Bioprinting Paradigms for Regenerative Medicine' (2019) 1(1) *Regenerative Medicine Frontiers*; Gaskon I., 'Stem Cell Therapy and Rejuvenation, and Their Impact on Society' (2023) 10(6) Bioengineering 694.

[23] U.S. Patent Nos: 5,843,780; 6,200,806; 7,029,913; Golden. J, "WARF's Stem Cell Patents and Tensions between Public and Private Sector Approaches to Research" (2010) 38(2) *Journal of Law, Medicine and Ethics*, 314–331.

[24] Talkmore Chided, 'The Role of Intellectual Property Rights' Protection in Advancing Development in South Africa' (2022) (26) https://www.ajol.info/index.php/ldd/article/view/245744/232489. accessed 15 November 2023.

[25] Motari. M *et al*, 'The Role of IPRS on Access to Medicines in the WHO Region: 25 years after the TRIPS Agreement' (2021) (21) 21(1) *BMC Public Health*, 490. Available at: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y> accessed 15 November 2023.

virtue of Article 27(1) of the agreement, patent should be made available for any inventive product or process in the pharmaceutical field as long as they are new, involve an inventive step, and are capable of industrial application.

It also creates flexibility to maneuver the limited accessibility to pharmaceutical products by implementing compulsory licenses, restricting the scope of patentability and the definition of invention. For instance, before the introduction of Article 31bis, Article 31(f) of the TRIPS Agreement stated that compulsory licenses could only be issued predominantly for the supply of the domestic market, thereby restricting the ability of countries to produce generic medicines for export to other countries, particularly those lacking manufacturing capacity, which hindered access to affordable medications in resource-constrained settings.

However, Article 31bis of the TRIPS Agreement, which took effect in January 2017, amended Article 31(f) to address concerns regarding access to affordable medicines in least developed countries (LDCs) lacking manufacturing capacity.[26] This amendment allows countries producing generic medicines under compulsory licensing to export these medicines to such nations, thereby facilitating access to essential medications.

By enabling the transfer of pharmaceutical products from countries with manufacturing capabilities to those without, Article 31bis aims to bridge the gap in healthcare accessibility and promote public health in disadvantaged regions. This provision underscores the importance of balancing intellectual property rights with the imperative of ensuring access to life-saving treatments, particularly in economically vulnerable communities.

[26]*Ibid.*

Another notable exception which allows for flexibility is the Bolar exception.[27] It permits the use of a patented invention to obtain regulatory approval, thereby increasing access to generic medicines by allowing the sale of medicines as soon as it comes off-patent without needing to wait years for regulatory approval.[28] Also, the Agreement permits parallel importation[29] which allows the importing of protected medicines from any country where they can be purchased cheaper than locally.[30]

These developments have been met with resistance by Intellectual Property Rights (IPR) holders and the exceptions have been criticized as being counter-intuitive as they may result in the over-dependence on expensive patented versions of drugs in the long-term.[31] It is against this background that this article seeks to examine the balance between the protection of regenerative medicine and its access to members of the public on an equitable basis.

Intellectual Property offers creators and innovators legal protection for their ideas, creations and ingenuity in addition to enabling them to secure the financial benefits of their works.[32] This results in the legal and financial recognition of innovation which encourages the growth and

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[27] The Bolar exemption allows manufacturers of generic drugs benefit from patent law exemptions in certain circumstances; *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc.* 733 F.2d 858 (1984).

[28] WTO, WIPO, and WHO, Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade (WTO, WHO and WIPO, 2nd ed, 2020), 73, 229.

[29] Tenni B. *et al*, "What is the Impact of Intellectual Property Rules on Access to Medicines? A Systematic Review' (2022) (18)(40) BMC <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-022-00826-4> accessed 16 November 2023; Article 6 of TRIPS Agreement.

[30] Abass. M, "Parrallel Importation as a Policy Option to Reduce Price of Patented Health Technologies" (2021) 17(4) *Journal of Generic Medicines*, 214-219.

[31] Carlos M. C, "Trips Agreement and Access to Drugs in Developing Countries" <https://sur.conectas.org/en/trips-agreement-access-drugs-developing-countries/> accessed 22 November 2023.

[32] Virtouosi Legal, 'The Impact of IP Law on Innovation and Creativity' <https://www.virtuosolegal.com/faq/the-impact-of-ip-law-on-innovation-and-creativity/#:~:text=Intellectual%20property%20(IP)%20law%20plays,benefit%20financially%20from%20their%20work.> accessed 20 November 2023.

development of evolution in the innovative space. The extension of Intellectual Property protection to regenerative medicine therapies could spur further research into its field and possibly change the trajectory of medicine through the legal protection of new technologies like regenerative medicine.

4. Patentability Requirements in Nigeria

The Patent and Designs Act (PDA) of 1970 governs the process of patent registration in Nigeria and establishes criteria for patent eligibility. This provision outlines three primary conditions for patentability: novelty, inventive step, and industrial applicability.[33] However, certain matters are not patentable under the Act. Plants or animal varieties, or essentially biological processes for the production of plants or animals are not patentable.[34] Inventions the publication of which will be contrary to public order and morality are also excluded,[35] so also are principles of a scientific nature.[36] To understand how stem cells are governed by this section, it is crucial to understand their origins. Stem cells primarily exist in two forms: embryonic stem cells and adult stem cells.[37]

Embryonic stem cells, which are self-replicating, originate from human embryos or fetal tissue. These cells are obtained from the blastocyst stage of pregnancy, during which the embryo has the highest potential for implantation. Recent advancements have also allowed for the extraction of stem cells from umbilical cord blood and the amniotic cell lining, which are biological waste

[33] Section 1(1) of the Act.
[34] Section 1(4)(a) of the Act.
[35] Section 1(4)(b) of the Act.
[36] Section 1(5) of the Act.
[37] El Barky. A, 'Stem Cells, Classifications and their Clinical Applications' (2017) 1(1) *Am J Pharmacol Ther.* 001-007.

products after childbirth.[38] Adult stem cells are primarily sourced from bone marrow, adipose tissue (fat), and blood.[39] As the sources of these stem cells are biological, stem cell research therapy and regenerative medicines becomes a debatable issue and fall under the exception provided in section 1(4) of the Act.

Furthermore, the Patent and Designs Act (PDA) does not delineate the criteria for determining what constitutes stem cells contrary to public order or morality, and how such terms should be assessed in the context of patent applications. This lack of criteria under the law presents a significant challenge in a diverse country like Nigeria, characterized by its multi-ethnic, multi-cultural, and multi-religious makeup. The measure for assessing morality varies among ethnic groups, tribes and religions, thereby necessitating the need for a clear parameter.

Nevertheless, when considering the process for patent grant under the PDA, there is a possibility that a Patent grant in such subject matter may subsist if not challenged. Section 4(4) of the Patents and Designs Act 1970 stipulates that patents in Nigeria are granted without guarantee of their validity. The Registrar does not assess if the application meets patentability requirements but only ensures that all necessary documents are submitted. If formal requirements are met, the registrar issues the patent certificate.[40]

Consequently, receiving a patent certificate in Nigeria does not automatically validate the patent. Its validity can be contested in court, and if challenged, the burden of proving its validity lies

[38] *Ibid*.
[39] *Ibid*.
[40] Section 4 of the Act.

with the patentee.[41] Section 9 of the Act empowers the court, upon request, to examine whether a patented invention meets the criteria for patentability, if the description conforms to clarity and completeness requirements, and if there were prior applications or patents for the same invention.[42] If the court determines that the patent fails the validity test outlined in sections 1 or 3(2) of the Act, it will declare the patent null and void.

5. Patentability Criteria for Regenerative Medicine Technologies: Practices in Selected Jurisdictions

5.1.The United States of America

In the United States of America, the legal framework patentability criteria is the United States Patent Act. Section 101 of the United States Patent Act stipulates the eligibility requirement for patent protection as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patient therefore, subject to the conditions and requirements of this title.

The section further provides that the subject matter of protection must not be a judicial exception. These judicial exceptions were outlined in the case of *Diamond v Diehr*,[43] the Supreme Court outlined three exceptions to patentability requirements to include: laws of nature, physical phenomena and abstract ideas. In the case of *Association for Molecular Pathology v*

[41] Section 9 of the Act.
[42] Section 3(2) of the Act.
[43] 480 U S 175 (1981)

Myriad Genetics, Inc.,[44] the court highlighted the importance of these exclusions by holding that the grant of patent would prevent access to these tools and therefore inhibit the varying possibilities of the expression of innovation.[45]

Stem cells form the core of regenerative medicine as they can be used to form specific cells that can regenerate and repair damaged and diseased tissues.[46] The earlier position on the patentability of stem cells is found in the Leahy-Smith America Invents Act provides that "Notwithstanding any other provision of law, no patient may issue on a claim directed to or encompassing a human organism". However, in the landmark case of *Diamond v Chakrabarty,*[47] the Supreme Court affirmed the decision of the Court of Customs and Patent Appeals to grant a patient for a bacterium capable of breaking down crude oil. The court concurred that a live, human-made micro-organism is patentable subject matter and constitutes a "manufacture" or "composition of matter" within the statute. The decision of the court was to the effect that genetically modified organisms could be protected. Minimally manipulated human cells and tissue-based products are protected by 21 CFR 1271 and Section 361 of the Public Health Services (PHS) Act which is described as a pathway for the approval of innovations in biologics while other forms of regenerative medicine therapies are protected under Section 351 of the PHS Act and the FDA regulation 21.

5.2. South Africa

[44] 569 U S 576

[45] Nicholas A Z, 'Stem Cells: Intellectual Property Issues in Regenerative Medicine' (2013) (22) (1) *PubMed Central* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3883125/> accessed 21 November 2023.

[46] Mayo C, 'Stem Cells: What they are and what They Do' <https://www.mayoclinic.org/tests-procedures/bone-marrow-transplant/in-depth/stem-cells/art-20048117#:~:text=Generate%20healthy%20cells%20to%20replace,damaged%20or%20affected%20by%20disease> accessed22 November 2023.

[47] 447 U.S 303 (1980).

The concept of regenerative medicine albeit its emergence over twenty years ago remains a growing technology in its developmental stages. In Africa, the evolution of regenerative medicine is limited to a few countries, one of which is South Africa.[48] In the absence of a specific framework for the protection of regenerative medicine therapies, reliance is placed on the definition of medicine under the Medicines and Related Substances Act.[49] The Act defines medicine to include *"... any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in ... (ii) restoring, correcting or modifying any somatic or psychic (sis) or organic function in humans...*"

The foregoing provisions serve as authority for the legality of regenerative medicine in South Africa.

6. Challenges and Prospects of the Practice of Regenerative Medicine in Nigeria

There are several significant obstacles confronting the implementation of regenerative medicine. Some of these obstacles stems from the insufficiency of proper facilities and funding to legal and ethical issues. In Nigeria, the challenges are even more pronounced as Regenerative medicine is still at its early stages and therefore faces several challenges, particularly in relation to intellectual property protection. The practice further offers some prospects and potentials. This section shall first discuss the prospects and potentials of regenerative medicine before delving into its challenges.

6.1. Regenerative Medicines: its Prospects and Potentials in Nigeria.

[48]Viden, I.M *et al*, 'Regenerative Medicines: A New Regulatory Paradigm for South Africa' (2022) (196) Elsevier <https://www.sciencedirect.com/science/article/pii/S0300908422000505> accessed 20 November 2023.
[49] No. 101 of 1965.

In Nigeria, there have been efforts to promote the adoption of regenerative medicine, despite the obstacles faced. Multiple Universities and research institutions in the nation, including the University of Lagos, the University of Ibadan, and the Nigerian Institute of Medical Research, have implemented stem cell research programs and are investigating the potential uses of regenerative medicine in the treatment of different diseases and conditions.[50]Regenerative medicine has also demonstrated potential in Nigeria specifically for the treatment of sickle cell disease.[51] In 2018, Nigerian researchers achieved a noteworthy accomplishment in the field of regenerative medicine by effectively treating a patient with sickle cell disease through the application of stem cell treatment.[52] Regenerative medicine in Nigeria also emphasizes the treatment of injuries and wounds.[53] Scientists are investigating the utilization of biomaterials and tissue engineering methods to create sophisticated wound dressings and skin grafts that can accelerate healing and facilitate the growth of new tissue.[54]Indeed, there have been some advancements in the field of regenerative medicine in Nigeria, this field is still in its nascent phase, necessitating greater investment, research, and collaboration to fully exploit its promise. Collaborations between Nigerian universities and international research groups have the potential to offer vital resources and expertise to promote the progress of regenerative medicine in the country.

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[50] Oluwole S *et al*, 'Stem Cell Research and Regenerative Medicine in Nigeria: Prospects and Challenges' (2018) 13 *African Journal of Biotechnology* 1.

[51] Sickle cell disease is a hereditary affliction that impacts a substantial proportion of the Nigerian population.

[52] Scientists have been exploring the possibilities of stem cell treatment as a potential remedy for this ailment. See, Bakare A, 'Nigerian Doctor Overcomes Challenges to Treat Sickle Cell Patient with Stem Cell Therapy' (PUNCH, 12 September 2018) <https://punchng.com/nigerian-doctor-overcomes-challenges-to-treat-sickle-cell-patient-with-stem-cell-therapy/> accessed 20 May 2024.

[53] *Ibid.*

[54] Agbedia C and Oshegbo G, 'The Challenges of Stem Cell Research in Nigeria' (2013) 2 *International Journal of Advanced Nursing Studies, p.6.*

6.2. Challenges and Limitations of Intellectual Property Protection in Regenerative Medicine

Despite the highlighted prospects of regenerative medicine above, some of the notable challenges of the practice of regenerative medicine and its limitations as regards Intellectual Property Protection in Nigeria are discussed with specific details as follows:

6.2.1. Inadequate Funding and Resources

A significant challenge worthy of examination is lack of funding and infrastructure for advancement of regenerative medicine. Research in Regenerative medicine, which involves advanced technologies such as stem cell manipulation, gene editing, and tissue engineering, is costly.[55] The lack of adequate funding and infrastructure thus limits the scope and scale of research projects.[56] The University of Lagos, which has been conducting stem cell research, has cited funding constraints as a major obstacle to advancing their regenerative medicine programs. An immediate past Vice-Chancellor, Professor Oluwatoyin Ogundipe once lamented on lack of access to fund the regenerative medicine project when he stated that *"Limited funding has hampered our ability to acquire state-of-the-art equipment and sustain long-term research projects.*[57] In addition, a significant number of healthcare facilities in the country suffer from a shortage of essential equipment and adequately trained workers to carry out sophisticated research and therapy in this field. For instance, a Nigerian doctor, Dr. Oluwole Akinkugbe, who had successfully treated a sickle cell patient using stem cell therapy, highlighted the challenges

[55] Obaro M 'Medical Biotechnology and Biomimetics: Prospects and Challenges in Sub-Saharan Africa' (2021) *Biomimetics and Bionic Applications with Clinical Applications* 19-27.
[56] *Ibid*.
[57] 'University of Lagos Highlights Funding Constraints in Stem Cell Research' (University of Lagos, 15 March 2021) <https://unilag.edu.ng/news/university-of-lagos-highlights-funding-constraints-in-stem-cell-research/> accessed 20 May 2024

of finding trained personnel and specialized facilities in Nigeria relying on international collaborations by traveling abroad to receive the necessary training and access specialized equipment.[58]

6.2.2. Access and Affordability

Another problem bedeviling the potential use of regenerative medicine is the access and affordability issue. The expense of regenerative medicine therapies can be excessively high for several Nigerians, as these treatments are frequently not included in health insurance policies.[59]

For example, in 2018, a Nigerian family had to crowdfund over $100,000 to cover the cost of stem cell therapy for their child with sickle cell disease in India due to the lack of affordable options in Nigeria. The family's story was widely reported in Nigerian media, highlighting the financial barriers to accessing regenerative medicine therapies in the country.[60] If stem cell therapies become commercially available, there are concerns about equitable access and affordability, especially in resource-limited settings like Nigeria.[61] This paper thus raises questions about the fairness of distributing costs and benefits, given the country's economic inequalities and fragile healthcare system.

6.6.3. Legal Issues

[58] Bakare A, '*Supra* note 52.
[59] Okebukola P and Siyanbola W, 'Engagement of Nigerians in the Science of Stem Cell Research and Applications' (2012) 4 *African Journal of Medicine and Medical Sciences* 71.
[60] 'Nigerian Family Crowdfunds $100,000 for Child's Stem Cell Therapy in India' (Vanguard, 3 December 2018) <https://www.vanguardngr.com/2018/12/nigerian-family-crowdfunds-100000-for-childs-stem-cell-therapy-in-india/> accessed 20 May 2024.
[61] Caulfield T, Ogbogu U and Isasi R, 'Stem cell research and commercialization: The Role of International Guidelines' (2009) 18(2) *Stem Cells and Development* 177.

Research emphasizes the importance of obtaining informed consent from patients/donors before conducting any stem cell research or procedures.[62] This is a fundamental legal requirement to respect the autonomy and self-determination of individuals. The National Health Act 2014 mandates that research on living persons can only be conducted with their written consent after being informed about the objectives and potential effects.[63] For minors, consent must be obtained from parents/guardians.[64]However, ensuring truly informed consent can be challenging, especially when dealing with complex scientific procedures and desperate patients hoping for cures.

6.2.4 Ethical Issues

One of the foremost challenges of the protection of regenerative medicine by Intellectual Property is the ethical concerns regarding the use of human cells, tissues and embryonic stem cells.[65] These are considered integral pillars of human life and the grant of patents for processes involving the revitalization of these organs may be considered highly unethical and viewed as the commercialization of human body parts.[66] For example, on the issue of embryo destruction, the crux of the ethical debate revolves around the moral status of the human embryo and whether it should be accorded the same rights and protections as a born human being. Those who believe

[62] Isasi R, Knoppers BM, Andrews PW and Rossant J, 'Ethical Governance of Biological and Biomedical Research: Canadian legal pragmatism and the novel issue of stem cells' (2004) 5(4) *EMBO reports* 350.
[63] Ibid.
[64] Department of Health and Social Care, 'The NHS Constitution for England' (2021) <https://www.gov.uk/government/publications/the-nhs-constitution-for-england> accessed 20 May 2024.
[65] Mastroianni AC and Kahn JP, 'Risk and Responsibility: Ethics, Grimes v Kennedy Krieger Institute, and Public Health Research involving Children' (2001) 91(7) *American Journal of Public Health* 1079.
[66] Nima B. *et al,* 'Commercialization and Regulation of Regenerative Medicine Products: Promises, Advances and Challenges' (2022) (153) *Pub Med Central* https://pubmed.ncbi.nlm.nih.gov/36076549/> accessed 23 November 2023.

that life begins at conception would view the destruction of embryos for research as unethical and a violation of the embryo's right to life.

Another ethical issue relates to consent and autonomy. Ensuring truly informed consent is not only a legal requirement but also an ethical imperative to respect the autonomy and self-determination of individuals involved in stem cell research. Participants must be able to make voluntary decisions free from coercion, undue influence, or exploitation, which can be challenging in cases of vulnerable populations or those desperately seeking cures.[67]

6.6.5. Ownership and Patent Rights

Striking a balance between protecting the rights of the Intellectual Property Rights holders in regenerative medicine and making its therapies available to the public is yet another challenge affecting its wholesome protection under Intellectual property. Importantly, determining the particular element of the regenerative therapies that is eligible for patent protection and identifying and separating its complex elements in making patent claims appear daunting. As stem cell research advances and leads to potential commercial applications, issues around ownership rights and patenting of stem cell lines, therapies, and technologies may arise. Clear legal frameworks would therefore be needed to govern these aspects and ensure fair access and distribution of benefits.[68]

6.6.6. Regulatory and Oversight Concerns

One major challenge is the inadequate legal and regulatory framework for protection of regenerative medicine technologies. Nigeria’s Patent and Designs Act 1970 (as amended) has not

[67] Mastroianni AC and Kahn JP, *Supra note* 65.
[68] Dresser R, 'Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation' (2010) 38(2) *The Journal of Law, Medicine & Ethics* 332.

kept pace with the rapid advancements in biotechnology and regenerative medicine.[69] The legislation lacks specific provisions to address the complexities of modern biotechnological inventions. Even when patents are granted, enforcement of intellectual property rights in Nigeria is weak. There is a high prevalence of intellectual property infringement with limited recourse for patent holders to effectively enforce their rights through the legal system.[70] Effective regulation and oversight mechanisms are thus crucial to prevent unethical practices, ensure compliance with guidelines, and maintain public trust in stem cell research.[71] These legal and ethical issues underscore the complexities and sensitivities surrounding stem cell research. Balancing scientific progress with ethical considerations and developing robust legal frameworks are necessary to harness the potential benefits of stem cell research while safeguarding human rights and dignity.

6.6.7. Public Awareness and Acceptance

The low level of public awareness is another major challenge facing regenerative medicine in Nigeria. Many Nigerians are unaware of what regenerative medicine entails, including its potential benefits and applications.[72] In some parts of Nigeria, there have been instances of resistance to stem cell therapies due to cultural beliefs or misconceptions about the use of stem cells. A study conducted by some researchers at the University of Ibadan highlighted this issue. The research acknowledged the need for public education and awareness campaigns to address

[69] Aishatu A, 'Patenting in Biotechnology: An Analysis of the Three Tests of Patentability under the Nigerian Patent Law' (2024) 11(1) *Nnamdi Azikwe University Journal of Commercial and Property Law* 24-35.
[70] Oluyinka A, 'Intellectual Property Rights Protection in Nigeria: Issues and Perspectives' (2022) 13(1) *Journal of Information and Knowledge Management* 1-9.
[71] World Medical Association, 'World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects' (2013) 310(20) *JAMA* 2191.
[72] Clara A, and Oshegbo G, 'The Challenges of Stem Cell Research in Nigeria' (2013) 2(2) *International Journal of Advanced Nursing Studies* 52.

these concerns.[73] Public awareness on the significance of intellectual property in fostering innovation and ensuring the availability of cutting-edge treatments is also low. This lack of knowledge hinders public support for policies that protect regenerative medicine technologies through intellectual property.[74]

The issues analysed above form some of the crux of the challenges of the protection of regenerative medicine under the umbrella of Intellectual Property.

7. Conclusion and Recommendations

The article interrogated the extents that intellectual property covers in the field of regenerative medicine. The initial reluctance of regulators and human rights proponents in accepting that intellectual property rights could be gotten over some processes they considered highly degrading to the inalienable dignity of man as a natural being. It further examined the progress that has been made in the field so far after the initial kick back in several jurisdictions of the World. The fact that the protection of intellectual property rights would broadly widen the field of regenerative medicine was made in very lucid terms. The research as part of its findings, found that the use of regenerative medicine has the ability of revolutionizing medicine and inspiring treatments to illnesses currently deemed untreatable. Therefore, there is strong incentive to take positive legal steps towards promoting the development of innovations in regenerative medicine. To do this, there is a need to adopt a robust legal framework, implement national policies for innovations, and to empower relevant agencies to supervise this new

[73] Olufunmilayo I. O *et al*, 'Public Perceptions and Attitudes towards Stem Cell Research and Therapy in Nigeria' (2020) 15(3) *BMC Medical Ethics* 42.
[74]Clara A, and Oshegbo G, *supra* note 72.

technology. Given the issues canvassed in this work, the following specific recommendations are proffered:

a. Provision of a Robust Legal Framework

Intellectual property rights are guaranteed by their various legal frameworks covering copyright, trademark and patent. The current legal framework on patent which seeks to regulate innovations and new technologies have been discussed above highlighting the gaps in the law. To encourage continued research and development of regenerative practices and technologies, the regulatory framework should be wide enough to protect the inventor. These regulatory framework would also guide on the ethical issues requiring strict compliance and frequent updates as this innovation progresses. Specially, there is the need to update the Nigeria's Patent and Designs Act 1970 (as amended) to allow for the registration of cutting-edge technologies including regenerative medicine.

b. Adopt National Policies to encourage Innovation

The National Science, Technology and Innovation Policy (NSTIP) 2022 contains the Health Research & Innovation (Pharmaceutical Research, Natural Medicine and Products) section which encourages research and development in alternative and molecular medicine,[75] as well as ethics and standards in its development. There is a need to have better implementation plans that would ensure the facilitation of research and development of regenerative medicine. In addition, there is a further need to strengthen the enforcement of the patent law, develop a national intellectual property strategy for regenerative medicine, and enhance international partnerships to leverage expertise,

[75] National Science, Technology and Innovation Policy 2022, 3.12.4, para 5, pg 13.

technologies, and best practices in regenerative medicine and IP protection. A lot more could be done in that field, more landmark discoveries made, more patents registered and more persons motivated to delve into that area which holds great benefits for potential patent holders and scholars.

c. Promotion of Public Awareness

The public should be made aware of the improvements in the regulatory framework and the implementation plan for the policies of innovation and development. The purpose of this is to encourage further research into regenerative medicine as they are aware of the incentives such as the protected rights to their inventions. More importantly, public awareness of the nature, risks and benefits of regenerative medicine would help debunk the mystery surrounding these types of medical practices and technologies.

d. Collaboration of Agencies to support Regenerative Medicine

There is need for sister agencies to collaborate to support regenerative medicine. The Nigerian Copyright Commission is the agency that currently regulates copyright in Nigeria and their efforts have ensured that the copyright framework is up to date through the Nigerian Copyright Act 2022. Similar agencies with internal specific committees are required to ensure a rigorous protection of patent right for regenerative technologies. This practice has been adopted in various countries committed to the progress of innovation, for example, the United States of America has the Food and Drug Administration with internal committees such as the Cellular, Tissue and Gene Therapies Advisory Committee. The European Union and Australia also have similar regulators such as the Committee for Advanced Therapies in the European Medicines Agency and the Advisory

Committee on Biologicals in the Therapeutic Goods Administration respectively. In Nigeria, the National Committee on the Research and Application of Stem Cell Transplantation Technology would need to collaborate with the National Office for Technology Acquisition and Promotion (NOTAP) to regulate, protect and encourage research into regenerative medicine. The cheering news is that the NOTAP is currently mandated to assist in the patenting of all inventions and innovations carried out by government funded research institutes and others in the private sector and should be extended to cover all possible ethical and medical practices that may arise.