

BIOTECHNOLOGY PATENTS: UNTANGLING THE DOUBLE HELIX OF INNOVATION, ETHICS AND LEGAL CHALLENGES

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ABSTRACT

This essay delves into the intricate intersection of biotechnology patents and the associated ethical and legal challenges, with a specific focus on the TRIPS agreement. It aims to unpack the consequences of patenting living organisms and biotechnological innovations, while critically assessing the patent laws in fostering innovation versus protecting ethical standards. The article explores the nuanced distinctions between discoveries and inventions with respect to the Indian Patents Act. Further, ethical debates surrounding gene patents, and the manipulation of life forms are scrutinized through various theoretical lenses, including the doctrine of product of nature, moral utility doctrine, property rights, and the sacredness of life. Furthermore, the article addresses two emerging challenges in the field of biotechnology which are: i) the potential patenting of de-extinct species and the ethical considerations involved in their revival and ii) the implications of the 2024 WIPO Treaty on Intellectual Property, Genetic Resources, and Associated Traditional Knowledge, highlighting its potential impact on the global patenting landscape while pointing out its inherent flaws, particularly in regard to non-disclosure penalties. The findings suggest that while biotechnology patents foster innovation and increase the incentive for research, they raise significant moral and legal concerns. The evolving legal landscape requires a delicate balance between protecting intellectual property and ensuring ethical responsibility, with the potential for ongoing legal reforms to address these complexities. The article ultimately calls for continuous evaluation of biotechnology patent laws to ensure alignment with both international standards and national interests.

I. INTRODUCTION

From converting ordinary crops into superfoods¹ to developing engineered immune cells that cure cancer,² creating biofuel and other sustainable material,³ and promising the creation of plants which can survive in ex-situ or unnatural environments, biotechnology is truly catapulting us into a new era of scientific marvels solving some of humanity's most pressing concerns meticulously.⁴ This interdisciplinary field leverages the strength of living beings and is poised to make advancements in health, innovation and sustainability across various industries like space, food, and agriculture.

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¹ Sarah Garland & Helen Anne Curry, *Turning Promise into Practice: Crop Biotechnology for Increasing Genetic Diversity and Climate Resilience*, PLOS BIOL. (2022).

² Sharon Reynolds, *Stealing Strategies from Cancerous T-Cells May Boost Immunotherapy*, NAT'L CANCER INST. (2024).

³ *Advanced Biofuel and Sustainability*, DEP'T OF BIOTECHNOLOGY, MINISTRY OF SCI. & TECH., <https://dbtindia.gov.in/scientific-directorates/advanced-biofuels-sustainability-ner/advanced-biofuels-sustainability>

⁴ Ntombikhona Koza, *Microorganisms in Plant Growth and Development: Roles in Abiotic Stress Tolerance and Secondary Metabolites Secretion*, NAT'L LIBR. MED. (2022).

The cruise of biotechnology has sailed all the way from solving the mystery of DNA by giving it a structural model, a “double helix model”⁵ to the use of a gene therapy Luxturna®⁶ for treating a rare inherited form of blindness: Leber congenital amaurosis.⁷ Recently, a news headline which captivated the attention of many was the accomplished feat of Moderna against Pfizer and BioNTech with the European Patent Authority maintaining the validity of Moderna’s patent⁸ which protects “specific alterations to mRNA molecules designed to lower its immunogenicity and identify the potential uses of the same.”⁹ With such developments taking place rapidly, it becomes important to understand the stance of biotechnological protection in the backdrop of Trade - Related Aspects of Intellectual Property Rights [“**TRIPS**”] agreement in India. The first step includes unfolding the very meaning of biotechnology which refers to the conduction of biological processes and manipulation of the genes of microorganisms for myriad purposes for instance manufacturing drugs, and antibiotics. The United Nations Convention on Biological Diversity, 1992 defines it as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses.”¹⁰ Further, a microorganism is defined as “any organism too small to be visible to the naked eye which include bacteria, some fungi, mycoplasmas, protozoa, rickettsia and viruses.”¹¹ This biotechnological protection is governed by the Indian Patents Act, 1970. The second step necessitates not only grasping the definitions and standards set forth by international agreements but also critically evaluating the broader implications of patenting life forms. As biotechnology continues to push the boundaries of what is possible, its patent protection remains dynamic and a crucial area of discourse.

⁵ Ashish Swarup, Shishir, Shruti & Anchal, *Biotechnology in the Realm of History*, J. Pharm. Bioallied Sci., NAT’L LIBR. MED. 3(3) (2011).

⁶ *Luxturna (Voretigene Neparvovec)*, EUR. MEDICINES AGENCY, SCI. MED. HEALTH (2024), <https://www.ema.europa.eu/en/medicines/human/EPAR/luxturna#:~:text=Luxturna%20consists%20of%20a%20virus,the%20progression%20of%20the%20disease>.

⁷ *Leber Congenital Amaurosis*, UNIV. OF CAL., S.F., [https://www.ucsfhealth.org/conditions/leber-congenital-amaurosis-lca#:~:text=Leber%20congenital%20amaurosis%20\(LCA\)%20is,out%20of%20every%20100%2C000%20babies](https://www.ucsfhealth.org/conditions/leber-congenital-amaurosis-lca#:~:text=Leber%20congenital%20amaurosis%20(LCA)%20is,out%20of%20every%20100%2C000%20babies).

⁸ *Moderna Wins COVID Shot Patent Case Against Pfizer-BioNTech in Europe*, REUTERS (MAY 17, 2024), <https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-wins-case-patent-dispute-with-pfizer-biontech-over-covid-shot-ft-reports-2024-05-17/>.

⁹ Ian Johnston & Oliver Barnes, *Moderna Wins Covid Jab Patent Dispute Over Pfizer and BioNTech*, FINANCIAL TIMES (2024), <https://www.ft.com/content/50c5078c-c9f0-4b35-b916-3475b641c773>.

¹⁰ *Technology and Innovation to Improve Our Quality of Life*, REPSOL (Sept. 11, 2023), <https://www.repsol.com/en/energy-and-the-future/technology-and-innovation/biotechnology/index.cshtml#:~:text=Thanks%20to%20recent%20developments%20and,vaccines%2C%20among%20many%20other%20examples>.

¹¹ J. LAW & E.A. MARTIN, CONCISE MEDICAL DICTIONARY (Oxford Univ. Press, 2010).

Part I of the essay explores the eligibility of biotechnological inventions, especially living organisms for patent protection under the Indian Patents Act. Part II delves into the various theoretical frameworks addressing the ethical dilemmas associated with patenting biotechnological inventions. Subsequent sections examine two contemporary challenges in the realm of biotechnological patents: the revival of extinct species and the implications of the latest World Intellectual Property Organization [“WIPO”] treaty, which, despite appearing commendable, reveals underlying arbitrariness.

II. NATURE’S FINDS, HUMAN MINDS: DISCOVERIES VS. INVENTIONS

Firstly, there has been a deep contention on whether discoveries should be considered patentable and what is the underlying distinction between discoveries and inventions. As per the Indian stance, according to Section 2 (1)(j)¹² read with Section 3 of the Indian Patents Act, 2005¹³, only those “inventions” are patentable which satisfy the three tests of: novelty, non-obviousness and utility while being new products or processes or developing an inventive step capable of industrial application. However, the international treaties and agreements, including the TRIPS agreement, do not define what exactly inventions and discoveries are. But as observed in India, anything which is created including non-natural living beings comes under the purview of the former whereas the latter constitutes something which already existed before but was not known to humankind. The rationale behind this distinction is evident from Section 3(d) that the sole discovery of a new form of a substance which does not amplify its known efficacy can’t be termed as an invention and thus made patentable. However, there exists ambiguity related to the concept of efficacy and the process of proving its enhancement. Back in 2006, the Mashelkar Committee set up under the Ministry of Health and Family Welfare, was tasked with the responsibility of analyzing whether excluding micro-organisms from the subject matter of patents would violate the TRIPS agreement.¹⁴ After its reports being revised in 2009 on grounds of technical inaccuracy, the committee submitted in the context of Article 27.3,¹⁵ with respect to the latter issue, that such exclusion would indeed violate the TRIPS agreement and further stated, “micro-organisms involving human intervention and utility are patentable subject matter under the TRIPS Agreement, provided they meet the prescribed patentability criteria.”¹⁶

¹² The Patents (Amendment) Act, No. 15 of 2005, India Code (2005) §2(1)(j).

¹³ *Id.* at §3.

¹⁴ Aditi Nadkarni & Gowree Golhale, *Revised Mashelkar Committee Report on Patent Law Issues Accepted by the Government*, PHARMA & HEALTHCARE UPDATE, NISHITH DESAI UPDATES (2009).

¹⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing World Trade Organization, Annex 1C, 1869 U.N.T.S. 299.

¹⁶ *Supra* note 5.

This debate of differentiating between discoveries and inventions is pertinently controversial in the field of biotechnology where one aspect of the subject matter relates to living beings. It is an accepted fact that something which is found in nature, a discovery, becomes an invention with human intervention or aptitude altering its traits and features. Biotechnology's involvement in manipulating and altering living organisms to meet various industrial demands raises questions regarding the status of its products. Given the changing matrix of patentable subject matter, living beings which form a part of the common culture or common heritage under international law are starting to become eligible for patents highlighting the antique philosophy of the US Supreme Court, "anything under the sun made by man to be patentable".

III. ANALYZING THE MORAL DILEMMAS IN BIOTECH PATENTS: A GENETIC TUG OF WAR

Tracing the roots of biotechnological patents, the doctrine of product of nature earlier formed the rational grounds specifically in the US when the issue for patenting a natural object was contended but it later came into limelight when the honorable US Supreme court in the landmark case of *Diamond v. Chakrabarty* affirmed the decision of the court of customs and patent appeals, which had overturned the board of patent appeals and interferences, which had affirmed the rejection of the patent by the examiner at the USPTO.¹⁷ It stated that it constitutes a "composition of matter" and is thus covered under the subject matter of patents.¹⁸ Chakrabarty had altered the bacteria by inserting plasmid (new DNA rings) making it capable of breaking down crude oil. Such cases evoked strong opinions from almost every category of sceptics while triggering an elementary traditional response which is the center of the objection: A gene can't be patented! The doctrine of product of nature, as the name suggests, is a legal principle which states that anything which is a product of nature or a natural phenomenon can't be patented because it is not an invention but a discovery.¹⁹ The product of nature doctrine established its initial foundation in *Ex parte Latimer*.²⁰ The patentee attempted to acquire both the end product and the manufacturing method for extracting Australian pine needle cellular tissue fibres into flexible filaments. The Commissioner explained in his opinion that the extraction method did not change the fibre because it kept its original structure and composition intact. The Commissioner illustrated this principle by comparing the situation to identifying tree characteristics or qualities in a forest which

¹⁷ *Diamond v. Chakrabarty*, 477 U.S. 303 (1980).

¹⁸ *IJLSI, Patenting: Product of Nature*, INT'L J. LEGAL SCI. & INNOVATION (June 27, 2019), <https://ijlsi.com/patenting-product-of-nature/>.

¹⁹ Krishna Ravi Srinivas, *Patents and Products of Nature Doctrine*, in A GUIDE TO PHARMACEUTICAL PATENTS, Vol. 2, Carlos M. Correa ed., Ch. 1, at 1-16 (South Ctr., 2008).

²⁰ *Ex parte Latimer*, 1889 DEC. COMM'R PAT. 123.

does not qualify as patentable invention just like discovering new earth gems would not establish patent ownership rights for all similar gems. It was determined that extracted fibre counts as a natural product similar to wheat harvested by reapers. The interpretation of this doctrine had undergone a major change in the case of *Merck & Co. v. Olin Mathieson Chemical Corp.* where it was stated that according to the Act's language, there is no restriction on granting patents for natural products when they demonstrate both new and useful composition of matter status and fulfil patent requirements.²¹ Later, it was agreed that in case a natural product undergoes human intervention with it being altered or manipulated in such a way that the new product is substantially different from the original one, the doctrine will not be able to act as a shield of prevention for patents. Another set of arguments is based on the genes becoming fungible meaning "freely exchangeable or replaceable for one another of like nature or kind", so considering a living being as inanimate should be discouraged.²² The concept of sacred which constitutes two aspects: respect for life and protection of human spirit²³ is up in arms with its own explanation stating if patenting human genes chips away the essence of sacredness from life then it is immoral.²⁴ Another view states that in order to decide whether a gene patent is moral or not, one should take a look at the purpose for which the research was done.²⁵ So if the research objective was against public morality and welfare, the patent should not be permitted but this stance does not find a solid place in the embedded debate because it is quite difficult to interpret what exactly does the public policy and welfare include, thanks to its dynamic nature. It is important to note that Article 27 of the TRIPS agreement states that patents are available in all fields of technology but the member countries can refuse to grant patents in cases where "it is necessary to protect public order or morality, including the need to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."²⁶

Contrary to the above opinions is the theory of property rights propounded by John Locke which acknowledges the divine providence and natural creation of organisms. However, at the same time it affirms that labour is the best way to appropriate nature for use and once labour is infused to

²¹ *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4th Cir. 1958).

²² Himangshu Rathee, *Patentability of Human Genes: Scaling an Indian Perspective*, MANUPATRA (2015) https://docs.manupatra.in/newsline/articles/Upload/4CF9BD16-CD9B-4358-9F66-D2411B49322B.2-b_IPR.pdf.

²³ M. Somerville, *Making Health, Not War - Musings on Global Disparities in Health and Human Rights: A Critical Commentary by Solomon R. Benatar*, 88 AM. J. PUB. HEALTH 295 (1998).

²⁴ JOHANNA GIBSON, *PATENTING LIVES: LIFE PATENTS, CULTURE & DEV.*, 34-37 (Routledge, Sept. 28, 2008).

²⁵ S. Thambisetty, *Understanding Morality as a Ground for Exclusion from Patentability Under European Law*, 6 EU BIO SCI. J., ASIAN INT. BIOETHICS 46-52 (2002); see also TRIPS, Art. 27(2).

²⁶ *Supra* note 6.

create something out of the gifts of nature, it is only logical to provide the person with exclusive rights over the results.²⁷ So, if Locke were to judge the matter of the patent application by LG Life Sciences Ltd. in 2014, he would have probably granted the patent to the gene family - LBFL₃₁₃ which in reality was rejected by the court.²⁸ In this case, the human gene described in the invention had shown differential expression between pancreatic cancer tissues and normal pancreatic tissues along with additional malignant neoplasms. Due to the involvement of labor to manipulate the tissues, Locke would have not resisted to grant a patent in this case.

Another point of discord is the utilitarian theory which in this case is at odds with the moral utility doctrine. While the utilitarian theory by Jeremy Bentham argues that every society should function to achieve “maximum happiness of maximum members”, it is clear that biotechnology techniques have myriad benefits which include medical advancement, gene therapy to cure diseases, better food production in the field of agriculture and many more. However, the moral utility doctrine brings us back to the base question: Isn't patenting living organisms morally flawed as it corrupts the intrinsic values for instance dignity, sustenance and self-preservation attached to life?²⁹ Critics argue that patenting in biotechnology, for instance, human genes is a form of “modern slavery” as it constitutes dismemberment of people for commercial profits.³⁰ However, it is important to ensure that the lines of demarcation between patents and legal ownership are not blurred. Moreover, patent rights don't confer any kind of ownership to the applicant which means that a person might have a patent right over a car brand without owning one.³¹ This is what Pilar Ossorio, Associate Professor of Law and Bioethics at Wisconsin Law School also tries to justify by saying, “A human gene patent cannot be identified with legal ownership of human bodies, not simply because human gene patents confer no rights over naturally occurring genes, but because patent rights confer none of the positive rights to possess and use in which ownership typically consists.”³² It is also affirmed that those who criticize biotechnology related patents are ungrateful and hesitant to give those people their due reward who have worked to make great advancements

²⁷ DONALD S. CHISUM ET AL., CASES & MATERIALS: PRINCIPLES OF PATENT LAW, 35-36 (N.Y. Found. Press, 1998).

²⁸ Hetal Patel & Sandesh Lodha, *Case Study on Rejected Patents in India*, in CASE STUDY ON REJECTED PATENTS IN INDIA, INTECHOPEN (2020), <https://www.intechopen.com/chapters/72054>

²⁹ A.H. Chrost, *Introduction to Aquinas*, 19 AM. J. JURIS. 1 (1974).

³⁰ *Bioethics & Patent Law: The Relaxin Case*, WIPO MAGAZINE, Apr. 14, 2006, https://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html.

³¹ Annabelle Lever, *Is It Ethical to Patent Human Genes?*, in INTELLECTUAL PROPERTY & THEORIES OF JUSTICE (Axel Gosseries et al. eds. 2008).

³² Gabriel Ben-Dor, *Ethics of Gene Patenting: Moral, Legal, and Practical Perspectives*, STANFORD-BROWN IGEM (2012), https://static.igem.org/mediawiki/2012/d/dc/Gene_Ethics.pdf

in the field of medicine and science because such inventions usually demand skills and human endeavors.³³

While it is often claimed in patent applications that such protection fosters a positive environment for more research and development, there is no way to ensure that the real latent motive behind such applications is not creating a monopoly and promoting a materialistic perception of life for commercial valuation.³⁴ The idea of enjoying royalties by patenting human genes sounds immoral on its face. However, a comprehensive outlook reveals that there is a high chance of productive knowledge becoming trade secrets if not patented and such an invention will never enter the public domain of knowledge restricting further advancement in this field.³⁵ When considering this argument another question arises which is more general in nature: do patents actually increase the innovation we often associate it with? Though this may result in an increase in patenting,³⁶ which can be studied by referring to the incremental advancement in science, there is a lack of any empirical evidence to show that a rise in patents leads to higher innovative activity³⁷ which is far more fostered by lead-time and branding.³⁸

IV. FROM GENOME TO RESURRECTING SPECIES: A REVOLUTIONARY LEAP?

Another buzzworthy topic in biotechnology is the patenting of de-extinct animals which is hitherto not explored by India or any other country. Bringing back an organism which either resembles or is extinct was something which humans could not even think about but the last few years witnessed technology achieving the unattainable. This can be achieved using a range of techniques like “selective breeding”, “genome editing” and “cloning”.³⁹ Selective breeding refers to choosing parents with certain traits to subsequently make them breed together to produce offsprings of the desirable characteristics. Genome editing refers to changing the DNA of organisms by adding, removing or modifying the DNA. Lastly, cloning refers to the process of making individuals with identical genes. This can be achieved either naturally or using artificial methods. Beth Shapiro, an

³³ P. Ossorio, *Legal and Ethical Issues in Patenting Human DNA*, in A COMPANION TO GENETHICS: PHILOSOPHY AND THE GENETIC REVOLUTION 418 (J. Burley & J. Harris eds. 2002).

³⁴ Darryl R. J. Macer & Makina Kato, *Biotechnology, Patents, and Bioethics*, INST. OF BIOLOGICAL SCIENCES, UNIV. OF TSUKUBA, https://www.iatp.org/sites/default/files/Biotechnology_Patents_and_Bioethics.htm

³⁵ *Discussion Paper on the Interplay between patents and trade secrets in medical technologies*, WIPO (October 2023), https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=621851.

³⁶ Bronwyn Hall, *Patents and Patent Policy*, 23 OXFORD REV. ECON. POL'Y 568, 574 (2007).

³⁷ Jeremy De Beer, *Evidence-Based Intellectual Property Policymaking: An Integrated Review of Methods and Conclusions*, 19 J. WORLD INTEL. PROP. 150, 169 (2016).

³⁸ JAMES BESSEN & MICHAEL JAMES MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS AND LAWYERS PUT INNOVATORS TO RISK* 98, (Princeton Univ. Press 2009).

³⁹ Aisling McMahon & David M Doyle, *Patentability and de-extinct animals in Europe: the patented woolly mammoth?*, 7(1) J. L. & BIOSCIENCES (2020).

evolutionary biologist who is also the chief scientific officer of Colossal Biosciences, had affirmed her intentions to bring back the genome of extinct animals mainly dodo birds and woolly mammoths.⁴⁰ She expressed that the reason why her team has decided to take such a big step by tweaking the DNA of live animals to bring back the dead is “because while traditional approaches to conservation are great and have had some successes, we still have this exceptionally high rate of extinction. We should be thinking about how to grow our conservation toolkit as we move forward.”⁴¹ India does not have any specific legal framework to confront this new area as there is lack of any explicit provision or interpretation of Section 3(j) of the Patents Act for the same. So, to assess the potential implications of patent laws on the de-extinction of animals, one needs to understand the need behind it. Firstly, the scope and pace of de-extinction are conditional on the resources that its supporters will attract.⁴² Secondly, the significant investment⁴³ that de-extinction requires in terms of capital, time and research can only be compensated by some sort of protection in the form of patents⁴⁴ because they are considered to be “the most important way in which researchers can protect the income that might come from ideas or technologies they have developed.”⁴⁵ But at the same time, this protection can also be used to generate lump sum of money for instance displaying the “revived” animals in a zoo.⁴⁶ Well, who would not pay to see, let’s say, a woolly mammoth once in their lifetime?⁴⁷ Thirdly, due to the polarizing nature of such patents, the scientists conscious of ethical principles would want to have control over the revived animals⁴⁸ to prevent others from using the technology inadvertently.⁴⁹ The ethical questions discussed earlier are also applicable to de-extinction of animals attacking the possibility of their patenting on the grounds of ecological impact, health concerns,⁵⁰ and the plausibility of this paving the path for revival of extinct human species.⁵¹ From a human rights perspective, it can be claimed that the right to life and health will be severely affected by the treatment of animals as “moral

⁴⁰ Nicholas Fleur, *Q&A: What de-extinction of woolly mammoths can teach us with evolutionary biologist Beth Shapiro*, STAT (Apr. 4, 2024), <https://www.statnews.com/2024/04/04/de-extinction-woolly-mammoths-biologist-beth-shapiro/>.

⁴¹ *Ibid.*

⁴² J. Donlan, *De-extinction in a Crisis Discipline*, 6(1) FRONTIERS OF BIOGEOGRAPHY 25–8 (2014).

⁴³ BETH SHAPIRO, *HOW TO CLONE A MAMMOTH: THE SCIENCE OF DE-EXTINCTION*, (Princeton Sci. Libr., (2015).

⁴⁴ *Supra* note 29.

⁴⁵ Angad Singh, Sharanabasava Hallihosur & Lastha Rangen, *Changing Landscape in Biotechnology Patenting*, 31 WORLD PAT. INF. 219–225 (2009).

⁴⁶ D. M. Doyle, S. Mccorristine & A. McMahon, *De-Extinction, Regulation and Nature Conservation*, 32(2) J. ENVTL. L. (2020).

⁴⁷ Tori Herridge, *Mammoths are a huge part of my life. But cloning them is wrong*, THE GUARDIAN, (Nov. 18, 2014) <https://www.theguardian.com/commentisfree/2014/nov/18/mammoth-cloning-wrong-save-endangered-elephants>

⁴⁸ J. Sherkow, *Patent Protection for Crispr: An Elsi Review*, 4(3) J. L. BIOSCI. 565–576 (2017).

⁴⁹ Aisling McMahon, *Biotechnology, Patents and Licensing for ‘Ethical Use’: A Regulatory Opportunity?* J. INTELL. PROP. STUDIES (2020).

⁵⁰ R. Sandler, *The Ethics of Reviving Long Extinct Species*, 28(2) CONSERV. BIOL. 354–360 (2014).

⁵¹ *Id.* note 48.

patients”⁵² raising doubts about the well-being of donors and surrogates in the process of regenerating species.⁵³ Even if the de-extinction of animals surpasses the moral test, what is novel here? The whole purpose of de-extinction lies in bringing back something which already existed in nature,⁵⁴ thus, the animals were already “available to the public” earlier.⁵⁵ Hence, it ultimately depends on which is more fundamental in determining the test of novelty: “surface similarity or the underlying genetic distinctiveness.”⁵⁶ “Raising the dead” has turned out to be “raising a raft of legal and regulatory uncertainties.”⁵⁷ As advancements in biotechnology continue to push the boundaries of innovation, nations worldwide are grappling with the challenge of balancing scientific progress with ethical and legal considerations. India will also have to face the conundrum of deciding the scope of patents in biotechnology sooner or later while creating a plausible path for patents law such that it embodies the ethical standards and responsibilities in the post-grant stage.

V. THE NEW WIPO TREATY: ALL RHYME BUT NO RHYTHM?

On May 24, 2024, the World Intellectual Property Organization finally adopted a treaty on IP, Genetic Resources and Associated Traditional Knowledge after years of negotiation.⁵⁸ The main provision of the treaty is the mandatory disclosure requirements of the source of those inventions which use generic resources and traditional knowledge. In case the invention is related to genetic resources [“GR”], the applicant is required to disclose the origin country and if it’s based on traditional knowledge [“TK”], the indigenous community associated with it has to be disclosed. Articles 3.1 (b) and 3.2 (b) read with Article 2 specify that in case neither of the aforesaid information is available with the applicant, he has to reveal any source from which the relevant resource was obtained.⁵⁹ Such patent disclosure requirements prevent misappropriation⁶⁰ of that knowledge which is used without any authorization weakening the free-riding incentive to take

⁵² W. M. Adams, *Geographies of Conservation 1: De-Extinction and Precision Conservation*, 41(4) PROG. HUM. GEOG. 534–545 (2017).

⁵³ C. Friese & C. Marris, *Making De-Extinction Mundane?*, 12(3) PLOS BIOLOGY 1–3 (2014).

⁵⁴ *Supra* note 29.

⁵⁵ *Supra* note 42.

⁵⁶ N.F. Carlin, Ilan Wurman & Tamara Zakim, *How to Permit Your Mammoth: Some Legal Implications Of “De-Extinction”*, 33(1) STANF. ENVTL. LAW J. 3–57, 51 (2013).

⁵⁷ *Supra* note 44.

⁵⁸ Wipo Treaty On Intellectual Property, Genetic Resources And Associated Traditional Knowledge, GRATK/DC/7, May 24, 2024, Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources.

⁵⁹ *Ibid.*

⁶⁰ Sarnoff & Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, United Nations Conference on Trade and Development, (2006).

advantage of someone else's GR or TK without prior consent or deserved compensation.⁶¹ This practice increases the transparency and efficiency of patenting reducing the scope of erroneous patents while making it consonant with the Nagoya Protocol under the Convention of Biological Diversity, the objective of which is "the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies."⁶² According to Article 15 read with Article 5 of the Nagoya Protocol On Access to Genetic Resources and The Fair and Equitable Sharing On of Benefits Arising from Their Utilization,⁶³ the protocol demands compliance of the domestic legislation in sharing the benefits, monetary or non-monetary, due to use of genetic resources and traditional knowledge in a fair and equitable manner. Coming back to the WIPO treaty, in case the applicant is not aware of the source, a declaration has to be submitted affirming that the content is true to the best of his knowledge but this creates a sideway for applicants to claim naivety and submitting the declaration without any rigorous research.⁶⁴ Another point to note is the urge of developing countries for greater protection of traditional knowledge at an international level which can be attributed to the intellectual property regime favoring the developed,⁶⁵ and large emerging countries.⁶⁶ As suggested by Peter K. Yu, "strategic inconsistencies" may act as the last resort for developing countries to recover the foregone policy room in the IPR regime so they continue to demand more exceptions and differential treatment at the international level.⁶⁷ Such instability has a great probability of hampering the creation of international treaties and agreements. This WIPO treaty was no exception to loopholes however there is no evidence as to whether the reason for the same was the inconsistency pointed out above or whether there exist other latent irregularities. Talking about this ambiguity in the treaty, Article 5.3 specifies that a patent can't be revoked, invalidated or rendered unenforceable solely on the grounds of non-disclosure of the relevant information which is quite ironical as it is clearly against the reason why this treaty came into force.⁶⁸ The only exception to this is a case where the non-disclosure is based on fraudulent intent according to Article 5.3 read with Article 5.4.⁶⁹ So the next step is to verify the authenticity of

⁶¹ Claudio Chiarolla & Burcu Kılıç, *Developing Patent Disclosure Requirements Related To Genetic Resources And Traditional Knowledge – Key Questions*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, (2017).

⁶² Nagoya Protocol on Access to Genetic Resources and The Fair and Equitable Sharing On of Benefits Arising from Their Utilization, Art. 1, Oct. 29, 2010, Convention on Biological Diversity United Nations.

⁶³ *Id* at art. 5.

⁶⁴ Dr. Anson C. J., *WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge: Concerns of India and Developing Nations- Part I*, SPICYIP (June 3, 2024), <https://spicyip.com/2024/06/wipo-treaty-on-intellectual-property-genetic-resources-and-associated-traditional-knowledge-concerns-of-india-and-developing-nations.html>.

⁶⁵ Daniel Gervais & Peter K. Yu, *TRIPS and the Stratification of Intellectual Property*, in ROUTLEDGE HANDBOOK ON INTERNATIONAL ECONOMIC LAW (David Collins & Valentina Vadi eds. 2024).

⁶⁶ Peter K. Yu, *TRIPS and Its Contents*, 60 IDEA 149 (2020).

⁶⁷ Kal Raustiala, *Density & Conflict in International Intellectual Property Law*, 40 U.C. DAVIS L. REV. 1021 (2007).

⁶⁸ *Supra* note 18.

⁶⁹ *Id*.

patent applications but to the surprise of many,⁷⁰ Article 3.5 states that the contracting Parties shall not place any obligation on the offices to corroborate the genuineness of patents making this provision a weak adversary.⁷¹ So, the treaty outfoxed in the end and delivered the final blow of allowing the contracting parties to provide post-grant sanctions or remedies in case of fraudulent intent with no mechanism to determine it. If India decides to sign this, it will have to let go of the permissible opposition for the patent application to the Controller if “the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention” as per Section 25 (1) (j) of the Patents Act⁷² and a patent can also be revoked on the same grounds according to Section 64 (1) (p) resulting in the loss of safeguards against spurious applications.⁷³ Hence, this treaty has the potential to transform the field of biotechnology by increasing a fair benefit-sharing practice but India despite calling it “a win for the global south”⁷⁴ faces a challenge of incongruity between its domestic legislation and international law.⁷⁵

VI. CONCLUSION

As biotechnology continues to push boundaries, it is important to balance innovation with ethical responsibility, ensuring that patent laws evolve in a manner that aligns with both international standards and national interests. India’s approach to biotechnology protection, specifically under the TRIPS agreement, illustrates a complex legal landscape. Ethical considerations such as the sanctity of life and the potential for modern slavery contrast with theories supporting property rights and utilitarian benefits. Further, the WIPO treaty despite its aim for transparency and benefit-sharing has loopholes that may hinder its effectiveness, particularly concerning non-disclosure penalties. India needs to develop its legal framework strategically, taking into consideration its quickly expanding biotechnology industry, while maintaining its dedication to advancing innovation and public well-being. With better legal clarity, India has the opportunity to become a global leader in the field of biotechnology. Thus, the future of biotechnology patents will undoubtedly be dynamic requiring constant evaluation and adaptation to uphold the principles of fairness, morality and scientific progress.

⁷⁰ Praharsh Gour, *Finally, WIPO Adopts a Treaty on IP, Genetic Resources and Associated TK! But at What Cost?*, SPICYIP, (May 25, 2024), <https://spicyip.com/2024/05/wipo-adopts-a-treaty-on-ip-genetic-resources-and-associated-tk-finally-but-at-what-cost.html>.

⁷¹ *Supra* note 27.

⁷² The Patents Act, 1970, §25 (1) (j).

⁷³ The Patents Act, 1970, §64 (1) (p).

⁷⁴ Rajeev Jayaswal, *India says WIPO Treaty a significant win for Global South*, THE HINDUSTAN TIMES (May 26, 2024), <https://www.hindustantimes.com/india-news/india-says-wipo-treaty-a-significant-win-for-global-south-101716734414688.html>.

⁷⁵ Viviane Kunisawa, *The Biotechnology Revolution: The Impact of the New WIPO Treaty on Genetic Resources*, IP WATCHDOG (June 07, 2024), <https://ipwatchdog.com/2024/06/07/biotechnology-revolution-impact-new-wipo-treaty/id=177647/>.