PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS: EXAMINING MORALITY AND ORDRE PUBLIC IN THE UNITED STATES

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Abstract

This paper critically examines the patentability of biotechnological inventions, arguing that considerations of morality and 'ordre public' should be integral to the process. Through an analysis of pertinent statutory provisions and case law within the United States patent system, this study challenges the existing framework and highlights the necessity of incorporating ethical considerations into the evaluation of biotechnological patents. The objective is to provide a nuanced understanding of the intricate interplay between morality, public interest, and intellectual property law in the context of biotechnological advancements in the United States. Additionally, it seeks to address the ethical implications of such inventions and their potential societal impact.

Keywords: Patents, Biotechnology, Morality, *Ordre public*, Uniter States, TRIPS Agreement, United States Patent and Trademark Office (USPTO)

1. Introduction

Biotechnology, characterised by its rapid and significant progress, holds immense transformative potential across various fields. Each paradigm-shifting breakthrough within this domain not only captures our attention but also showcases the relentless pursuit of scientific excellence. Undoubtedly, the dynamic landscape of biotechnology carries immense potential to revolutionise multiple domains, encompassing medicine, diagnostics, therapeutics, agriculture, vaccine research, environmental sustainability, energy production, industrial processes, and information technology. From personalised medicine and gene therapies that revolutionise healthcare to genetically modified crops that enhance agricultural productivity and reduce environmental impact, biotechnology undeniably permeates various facets of our lives.

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Patents have long been integral to the field of biotechnology, incentivising innovation and protecting Intellectual Property (IP). They provide exclusivity and financial incentives for inventors, enabling them to recoup investments and attract funding. They are not just legal protections; they are catalysts of transformative innovation. By safeguarding IP and fostering collaborations, patents can drive economic growth, attract investment, and propel the commercialisation of life-changing discoveries. Further, patents have gained significant recognition for their crucial role in fostering the disclosure of biotechnology inventions, enabling inventors to obtain exclusive rights in exchange for making their innovations accessible to the public and allowing them to benefit commercially from their creations. It is worth mentioning that a substantial portion of the top-selling medications including hormones, growth factors, enzymes, antibiotics, and vaccines, originate from biotech breakthroughs and have been secured by corresponding patents in the field of biotechnology. Whether it is the Pfizer-BioNTech and Moderna COVID-19 mRNA vaccines,[1] or Pliva's patented antibiotic Azithromycin,[2] these innovations have revolutionised modern medicine and continue to shape the future of healthcare. Similarly, the global market for therapeutic monoclonal antibodies has experienced substantial growth since the first monoclonal antibody was approved by the United States Food and Drug Administration (U.S. FDA) in 1986. In 2018, the market was estimated to be worth approximately $115.2 billion, with projections indicating an increase to $150 billion by the close of 2019 and reaching $300 billion by 2025.[3]

However, the ethical implications of patents in biotechnology have always been a subject of significant controversy, often sparking political debates and ardent discussions. A formidable challenge lies in achieving a delicate equilibrium between protecting Intellectual Property Rights (IPRs) and serving the interests of the public. It is particularly pertinent when dealing with innovations that are morally contentious and have attracted considerable attention. In his review of controversial biotech inventions, Bagley (2007) pointed out that they encompass a wide range of developments. These

1 Alshrari S. Ahmed, Shuaibu A Hudu, *et.al*., "Innovations and Development of COVID-19 Vaccines: A Patent Review", 15(1) *Journal of Infection and Public Health* 124 (2022).

2 World Intellectual Property Organization (WIPO), "Azithromycin: A World Best-Selling Antibiotic", *available at*: https://www.wipo.int/en/web/ip-advantage/w/stories/azithromycin-a-world-best-selling-antibiotic (last visited on February 04, 2025).

3 Ruei-Min Lu, Yu-Chyi Hwang, *et.al*., "Development of Therapeutic Antibodies for the Treatment of Diseases", 27(1) *Journal of Biomedical Science* 1 (2020).

encompass isolated medical procedures, genetic material such as isolated genes and sequenced DNA, embryonic stem cells, techniques for animal cloning, and the cloning of human genes involving the transfer of human chromosomes into animal cells to create chimeric human-animal entities. Additionally, they include practices that exploit women for reproductive resources and raise ethical concerns regarding human ownership.[4] This broad scope of biotechnological patents reflects the author's concern that patent protections risk legitimising ethically questionable research by prioritising commercial and scientific progress over moral considerations.

Despite opposition from those who disagree that genetic engineering can enhance the quality of human life by modifying living organisms, patents have become increasingly accepted by academics and researchers in the public sector, leading to a surge in applications that may surpass those from the industry.[5] Therefore, it becomes imperative to engage in discussions and make adaptations in patent law to ensure responsible action and protect public safety. Amidst the fervent debates surrounding patentability in this field, a profound question arises: should the pursuit of innovations in biotechnology be shielded from considerations of morality and the *ordre* public?

Proponents of this viewpoint maintain that surpassing these limits is crucial because they believe ethical concerns can act as restrictions, holding back the limitless possibilities of human creativity. They argue that this research and development (R&D)-intensive field necessitates patent protection as a protective shield to monopolise profits and drive incentives for further innovations.[6] Since the technology demands significant investment to support the expenses related to experimentation, the issues go beyond the patents themselves to encompass the fundamental research that underpins them.[7]

Respectfully, the author seeks to maintain a contrasting perspective on the matter. While the author acknowledges the vast potential of the fusion between

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4 Margo A. Bagley, "A Global Controversy: The Role of Morality in Biotechnology Patent Law", 57 *University of Virginia Law School Public Law and Legal Theory Working Paper Series* 319 (2007).

5 *Supra* note 3.

6 Darryl R. J. Macer and Makina Kato, "Biotechnology, Patents, and Bioethics", Institute of Biological Sciences, University of Tsukuba, Japan, *available at*: https://www.iatp.org/sites/default/files/Biotechnology_Patents_and_Bioethics.htm (last visited on June 25, 2024).

7 Congressional Research Service, "An Examination of the Issues Surrounding Biotechnology Patenting and Its Effect Upon Entrepreneurial Companies", *available at*: https://www.everycrsreport.com/reports/RL30648.html (last visited on August 31, 2024).

biotechnology and the patent system, and that patents should be recognised as facilitators rather than hindrances in the progress and dissemination of technology, however, it is imperative that we conduct a thoughtful assessment of the societal implications of the resulting creations. The ethical dimension provokes profound introspection, as it raises fundamental questions that inquiries into the moral implications of human intervention in the coding of life, compelling us to contemplate the boundaries of *"playing God"* and the ethical responsibilities that come with it.

In his book review of *"Patent Politics"* by Parthasarathy,[8] Professor Dutfield underscores that the complex interplay within IP systems, illustrating how their influence reaches beyond mere laws and government agencies. He highlights the involvement of diverse participants such as legal experts, courts, businesses, consumer groups, scientists, and lobbyists, stressing their crucial roles in shaping the dynamic functioning and significant impact of these systems.[9] In this context, the author is concerned that patents granted to controversial subject matter may be susceptible to unforeseen and potentially disruptive events. These events could include unintended environmental and public health consequences arising from DNA manipulation, reminiscent of what Nassim Nicholas Taleb describes as *"Black Swans"*. In his best-selling book *"The Black Swan,"* Taleb aptly describes how our cognitive framework is burdened with limitations that shape our inclination to prioritise reactive measures over proactive ones. This cognitive bias obstructs our ability to fully comprehend the importance of anticipating and mitigating risks, impeding our collective progress towards a more resilient and proactive approach.[10]

The author shares a strong alignment with Taleb's insights, firmly believing that our tendency to overlook the moral and ethical questions enclosing the patenting of contentious subjects in biotechnology, as evident in the United States' case, stems from the limitations inherent in our cognitive framework. These limitations incline us towards prioritising reactive measures rather than proactive ones, impeding our comprehensive understanding of the importance of anticipating and addressing risks. While it may appear intricate, in my perspective the ethical and social dimensions of patent law should

[8] Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe*, (University of Chicago Press, 2017).

[9] Graham M. Dutfield, "Review of Parthasarathy, Shobita, *Patent Politics: Life Forms, Markets, and the Public Interest in the United States and Europe*", *H-Sci-Med-Tech, H-Net Reviews* 2-3 (2017).

[10] Nassim Nicholas Taleb, *The Black Swan: The Impact of the Highly Improbable* (Random House Publishing Group, New York, 2007).

transcend mere exploitation and encompass a comprehensive framework. Consequential factors like infringement, defenses, licensing, and the impact on research, innovation, and public access must be given due consideration when analysing the broader landscape of patent law. This assessment becomes particularly crucial in striking the intricate balance between fostering innovation and safeguarding the public interest. In essence, it is essential to cultivate a resilient approach that allows us to navigate controversial patents while embracing those that bring positive advancements to society. Thus, by embracing the significance of preventive actions, we can foster a proactive and sustainable approach, effectively mitigating the risks of triggering negative *"Black Swan"* events and safeguarding against their disruptive consequences.

Patent law, being territorially bound, exhibits jurisdictional variations worldwide, reflecting diverse legal frameworks influenced by customs and rules of conduct. The controversies surrounding biotech patenting have sparked global interest, leading to extensive international studies and reports that address ethical concerns. In this context, key international governing frameworks such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), the International Covenant on Civil and Political Rights (ICCPR), the International Bill of Rights including the Universal Declaration of Human Rights (UDHR), and the International Covenant on the Human Genome and Human Rights (UDHGHR) hold significant importance in dealing with issues related to *ordre public*, morality, as well as the right to health for all.[11]

The TRIPS Agreement, in its Article 27.2, allows member states to exclude certain inventions from patentability if their commercialisation is deemed necessary to protect *ordre public* or morality. These exclusions may cover measures to ensure the safety of human, animal or plant life and health, as well as to prevent significant environmental harm.[12] In essence, Article 27.2 establishes specific limitations regarding *ordre public* and morality that can be employed to evaluate the patentability of biotechnological inventions. However, acknowledging the diverse interpretations and

[11] Dorkina Carmell Myrick, "The Impact of Ordre Public and Morality on the Regulation of Gene Editing Patents in the United States and the European Union", 10 *WIPO - ITCILO - University of Turin Joint Master of Laws in Intellectual Property; University of Oxford - Policy Advisor* (2023).

[12] Kevin W. McCabe, "The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology", 6(1) *Journal of Intellectual Property Law* 50 (1998).

implementations of these two concepts across legal systems, it is crucial to recognise the influence of cultural nuances in shaping these perceptions within different countries.

Many countries, including emerging economies and developing nations, often look to established patent systems like those in the U.S. and the European Union as benchmarks and sources of inspiration when shaping their own legal frameworks. These systems serve as influential models, offering valuable insights into the development of robust IP protection. However, in instances where the patent system lacks established guidelines for evaluating controversial patents, it creates a notable void in terms of accountability and oversight. In this study, the author strives to take a comprehensive look at the U.S. distinctive approach to morally controversial biotech subject matter, which sets it apart from most other countries. Through a detailed examination of this unique perspective, the objective of the paper is to uncover the inherent limitations of the approach adopted by the U.S. and to shed light on its broader societal implications.

2. THE U.S. OUTLOOK

The patent law of the U.S. does not include a specific provision that enables the U.S. Patent and Trademark Office (USPTO) or a court to deny patent protection for morally controversial biotechnological subject matter. In practice, the U.S. patent system follows a *de facto "Patenting First, Asking Questions Later"* approach. This causes ethical oversight and regulatory gaps, allowing morally controversial biotech inventions to receive patent protection before thorough societal, legal, and ethical evaluations are conducted. As a result, patents may legitimise practices such as cloning involving human genes, genetic modification, and chimeric research, which hold significant implications not only for specific biotech patents but also for broader societal values, public trust in science, and the balance between innovation and moral responsibility in American society.[13] Parthasarathy, in her book *"Patent Politics,"* provides a compelling analysis of the U.S. patent system, depicting it as a *"techno-legal"* domain that is narrowly specialised and distinct from other spheres that govern innovation.[14] In addition to this viewpoint, it is firmly believed that this historical retrospective approach undertaken by

[13] Margo A. Bagley, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law", 45(2) *William & Mary Law Review* 469-470 (2003).
[14] *Supra* note 8.

Congress carries substantial ramifications for the global community at large. This underscores the wide-reaching impact of such practices on a global scale.

The U.S. has historically recognised patents as constitutionally protected private property. Clause 8 of Section 8, Article I of the U.S. Constitution grants Congress the authority *"to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."*[15] The Patent Act of 1952 outlines the conditions under which an individual is eligible to secure a patent for their invention, setting forth the statutory requirements that must be met.[16] Section 101 of the U.S. Code provides that *"whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ... may obtain a patent therefore,"*[17] and additionally, Section 102 emphasises the conditions for patentability, including novelty and non-obviousness.[18] In this context, a process of making or using a composition of matter can be considered patentable if they involve a new discovery that meets the criteria for patentability. While the patent law explicitly forbids the patenting of products of nature, laws of nature, and mathematical algorithms, it does not preclude the possibility of issuing a patent for a specific extraction from nature that has undergone a significant transformation into a practical and valuable composition of matter. Further, the patentability of morally controversial biotech subject matter is not explicitly addressed within the statutory framework.

The establishment of Genentech, Inc. in 1976 marked a pivotal moment in the inception of the U.S. biotechnology industry,[19] coinciding with a period of landmark court decisions that provided an optimistic outlook for the biotech patenting landscape and set the stage for transformative advancements in the field. In a landmark ruling in 1979, the Court of Customs and Patent Appeals, in the case of *In re Bergy*, unequivocally affirmed

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15 United States Congress, "Constitution Annotated: Article I, Section 8, Enumerated Powers, Clause 8. Intellectual Property", *available at*: https://constitution.congress.gov/browse/article-1/section-8/clause-8/ (last visited on February 04, 2025).

16 United States Code, *Title 35 - Patents, Appendix L Consolidated Patent Laws-January 2023 Update*, *available at*: https://www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf (last visited on February 04, 2025).

17 35 U.S.C. 101, "Inventions Patentable", *available at*: https://www.govinfo.gov/app/details/USCODE-2011-title35/USCODE-2011-title35-partII-chap10-sec101 (last visited on February 04, 2025).

18 *Ibid*.

19 Malcolm Gladwell, "Top Biotech Firm Sold to Swiss Company", *available at*: https://www.washingtonpost.com/archive/politics/1990/02/03/top-biotech-firm-sold-to-swiss-company/8d9287e1-1f3e-4d8d-9884-a2c18f98127c/ (last visited on February 04, 2025).

that a pure bacterial culture could be granted patent protection under Section 101 as one of a manufacture or composition of matter, firmly distinguishing it from a mere "product of nature". This pivotal decision highlighted the critical role played by meticulously controlled laboratory conditions in the production of the culture in its pure form, reinforcing its non-natural origin and reinforcing its eligibility for patent protection.[20]

Subsequently, in another ground-breaking decision the Supreme Court in 1980, in *Diamond v. Chakrabarty*, established that bacteria, genetically engineered for the purpose of cleaning up oil spills were eligible for patent protection. The Court recognized that these organisms, being "a non-naturally occurring manufacture" and a testament to human ingenuity, represented a significant advancement in biotechnology.[21] In yet another significant development, the Supreme Court further solidified the legal framework for patenting innovations in plant biotechnology in the case of *E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* (2001). Building on the precedent established by the *Chakrabarty* decision, the Court reaffirmed that both sexually and asexually reproducible plants could qualify for utility patents.[22] Despite the existence of more specific statutory protection schemes for these plant types enacted by Congress,[23] the Court upheld the granting of utility patents, emphasizing the broader scope of patentable subject matter in biotechnology. Therefore, it becomes evident that through a progressive judicial expansion, the scope of patent eligible subject matter has come to encompass a wide range of innovations, encapsulating *"anything under the sun that is made by man."*[24]

In the same year, the enactment of the Bayh-Dole Act by the U.S. Congress empowered universities, small businesses and non-profit research institutions to patent, and commercialise inventions resulting from federally funded research. This legislation standardised patent policies and technology transfer processes, driving innovation, economic development, and sparked a global trend of embracing commercialisation in

[20] *Application of Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *available at*: https://case-law.vlex.com/vid/application-of-bergy-appeal-886523115 (last visited on February 05, 2025).
[21] *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980).
[22] *JEM Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 122 S. Ct. 593, 151 L. Ed. 2d 508 (2001).
[23] Plant Protection Act (as amended, December 23, 2004), *available at*: https://www.aphis.usda.gov/plant_health/downloads/plant-protect-act.pdf.
[24] Senate Report No. 1979, 82d Cong., 2d Sess. (1952).

scientific innovations.[25] In the years that followed, biotechnology's transformative power became evident as it revolutionised multiple domains through significant advancements, particularly in cloning,[26] gene therapy,[27] and genetically modified organisms (GMOs).[28]

However, despite the initial excitement surrounding these advancements, they have been recognised as challenging, expensive, and risky procedures with low success rates and high rates of associated risks. For instance, the observed deformities in cloned animals, including the premature death of Dolly,[29] and the unfortunate death of a patient undergoing experimental gene therapy treatments in the U.S. in 1999,[30] have raised significant questions regarding unacceptable scientific conduct, safety concerns, ethical considerations and grant of patents. Moral objections to patents may arise from the granting of exclusive rights to carry out practices related to the patent's subject matter, such as human cloning[31] or creating human-animal hybrids[32] or genetically modified organisms (GMO)[33] in general. Additionally, objections can stem from exclusive control over the practices, particularly in areas like medical processes and surgical procedures where limited access to treatments may be a concern.[34]

Notwithstanding the ongoing challenges and uncertainties surrounding these technologies, the USPTO persisted in granting morally controversial biotech patents without clear guidelines, a trend that has seen a significant increase since the *Diamond v. Chakrabarty* ruling. This persistence remained despite widespread public outrage and

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25 David C. Mowery, Richard R. Nelson, *et.al*., "The Growth of Patenting and Licensing by US Universities: An Assessment of the Effects of the Bayh–Dole Act of 1980", 30 *Research Policy* 100-101 (2001).

26 Michael R. Green and Joseph Sambrook, *Molecular Cloning: A Laboratory Manual* (Cold Spring Harbor Laboratory Press, New York, 4th ed., 2012).

27 Inder M. Verma and Nikunj Somia, "Gene Therapy: Promises, Problems and Prospects", *389 Nature* 239-242 (1997).

28 Leslie Pray, "Recombinant DNA Technology and Transgenic Animals", *available at*: https://www.nature.com/scitable/topicpage/recombinant-dna-technology-and-transgenic-animals-34513/ (last visited on September 01, 2024).

29 Nigel Williams, "Death of Dolly Marks Cloning Milestone", 13(6) *Current Biology* R209 (2003).

30 Doris Teichler Zallen, "US Gene Therapy in Crisis", 16(6) *Trends in Genetics* 274 (2000).

31 Leon R. Kass and James Q. Wilson, *The Ethics of Human Cloning* vii (American Enterprise Institute Press, Washington D.C., 1998).

32 Koko Kwisda, Lucie White, *et.al*., "Ethical Arguments Concerning Human-Animal Chimera Research: A Systematic Review", 21 *BMC Medical Ethics* 1-14 (2020).

33 Yann Devos, Pieter Maeseele, *et.al.*, "Ethics in the Societal Debate on Genetically Modified Organisms: A (Re)quest for Sense and Sensibility", 21 *Journal of Agricultural and Environmental Ethics* 29-61 (2008).

34 Gregory F Burch, "Ethical Considerations in the Patenting of Medical Processes", 65(6) Texas Law Review 1139 (1987).

fervent calls to prohibit such research and issue of patents related to cloning,[35] human genes,[36] and genetic modification of animals.[37] Notable examples of patents issued include the patents for multicellular polyploidy oysters[38] (April 7, 1987), the Onco-mouse[39] (April 12, 1988), and U.S. Patent No. 6,211,429, which involves the production of cloned mammals and methods for transplanting nuclei.[40] Additionally, there are several filed and pending patents related to these areas. Furthermore, numerous patents on human cDNAs and transgenic animals containing human genetic material have already been granted.[41, 42]

This practice of the USPTO, granting patents for morally controversial subject matter raises a significant inquiry into the underlying factors that shape their decision-making process. Upon careful analysis of the court's statement in the *Diamond v. Chakrabarty* ruling, it is realised that the court's statement emphasised that the USPTO does not have the power to reject patents on the eligible subject matter, regardless of any references made in their notices. The determination of patent eligibility limits is ultimately set by Congress, with the Supreme Court as the final interpreter. In essence, it is Congress and the judiciary, not the USPTO, that have the ultimate power to define the scope of patent eligibility. Further, the courts deliberated morality in light of the "utility" requirement under Section 101.[43]

"Utility" typically imposes a minimal requirement for an invention to demonstrate practical capability in achieving a desired outcome as opposed to being associated with mischief or immorality.[44] In the decades leading up until the 1990s, the courts in the U.S. have employed the *"utility"* requirement as a means to invalidate patents associated with inventions deemed immoral or fraudulent. In numerous initial

35 Adèle Langlois, "The Global Governance of Human Cloning: The Case of UNESCO", 3 *Palgrave Communications* 1-8 (2017).
36 *Supra* note 32
37 Christopher M. Holman, "The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation", 76(2) *UMKC Law Review* 295 (2007).
38 D.J. Quigg, "Animals - Patentability", 1077 *Official Gazette* 24 (1987).
39 Eileen Morin, "Of Mice and Men: The Ethics of Patenting Animals", 5 *Health Law Journal* 147 (1997).
40 Richard Guerra, "Therapeutic Cloning as Proper Subject Matter for Patent Eligibility", 43 *IDEA* 695 (2003).
41 R.A. Berg, *U.S. Patent No. 5,667,839* (1997) (issued by U.S. Patent and Trademark Office).
42 D.M. Tanamachi, P. Brams, *et.al., U.S. Patent No. 7,910,798* (2011) (issued by U.S. Patent and Trademark Office).
43 Anna Lumelsky, "Diamond v. Chakrabarty: Gauging Congress's Response to Dynamic Statutory Interpretation by the Supreme Court", 39 *University of San Francisco Law Review* 645 (2005).
44 *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396 (1873).

rulings, patents on inventions proposed for activities such as gambling or other disfavoured pursuits were dismissed on these grounds. Notably, patents for items such as a lottery device, a slot machine, and a toy automatic race course were invalidated due to the perception that their purposes were seen as morally objectionable. Additionally, inventions intended to deceive consumers were also deemed to lack utility and were thus invalidated by the courts.[45] So, the "*test of utility*" for biotechnological inventions was also deemed fulfilled when an invention was claimed to be "useful" which in turn meant that it demonstrated non-frivolous and non-injurious characteristics. This strategy effectively served as a mechanism for the USPTO to proactively exclude morally objectionable or harmful inventions from consideration during the patent evaluation process.

In the following years, by the mid-1990s, the moral utility doctrine had significantly diminished in importance within patent law, and the scope of patentable inventions had expanded greatly. During this period, the criteria for patent eligibility became more inclusive, allowing for a wide range of inventions to be protected by patents. It seemed evident that the *"utility"* requirement evolved to accommodate changing societal views on morality and the difficulties in establishing clear criteria for determining morally acceptable inventions.[46] However, the utility doctrine was revived in 1997 when Jeremy Rifkin and Professor Stuart Newman submitted a bold patent application with the USPTO, aiming to assert ownership over human-animal chimeras. The aim of filing this application was to raise public awareness about the potential developments in developmental biology and provoke discussions on ethical and societal implications.[47] In response, the USPTO referenced the *Thirteenth Amendment*,[48] which prohibits slavery, and also cited a quote from Justice Story's *Lowell v. Lewis* case.[49] The USPTO released a media statement and contended that inventions involving human/non-human chimeras could not satisfy the public policy and ethical standards of the "utility" criterion and

[45] *Ex parte Murphy*, 670 So. 2d 51 (Ala. 1995).
[46] Laura A. Keay, "Morality's Move Within US Patent Law: From Moral Utility to Subject Matter", 40 AIPLA Quarterly Journal 409 (2012).
[47] Stuart A. Newman, "My Attempt to Patent a Human-Animal Chimera", 27 *L'Observatoire de la Génétique* 1 (2006).
[48] Risa L. Goluboff, "The Thirteenth Amendment and the Lost Origins of Civil Rights", 50 *Duke Law Journal* 1609 (2000).
[49] *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817).

therefore could not be considered patentable.[50] By invoking these legal and moral considerations, the USPTO expressed its position on the patentability of such inventions and emphasised the importance of upholding societal values in the evaluation of patent applications. Although the patent application was ultimately rejected, it marked a significant turning point, leading to extensive public discourse and media attention surrounding the ethical, legal, and biotechnological implications of these entities. While the rejection did not set a legal precedent, it constrained the novelty aspect of future patent applications related to human-animal chimeras. However, the question of whether such chimeras are suitable for patent protection remains unsettled, as the U.S. Congress has not provided any further explicit guidance on this matter.[51]

Nonetheless, eventually, in the Federal Circuit decision of *Juicy Whip v. Orange Bang* in 1999,[52] the concept of *"moral utility"* was unequivocally discarded. The case involved a post-mix dispenser with a deceptive transparent bowl. The court firmly rejected the argument that a patent could be invalidated based solely on the deceptive nature of the invention. This marked a significant shift in the perspective on "*utility*" in patent law, which now emphasises that an invention satisfies the utility requirement as long as it can lawfully serve at least one purpose. So, rather than automatically excluding inventions with potential unlawful uses, the test shifted to allow an invention to meet the moral utility requirement if it had *"at least one moral, legal purpose"* making the *"utility"* requirement appeared to be a relatively easy obstacle to overcome. In other words, an invention could be deemed useful under patent law if it could achieve positive outcomes, even if it could also be utilised for negative purposes.

In the midst of this, genetic testing experienced significant advancements with the discovery of genes associated with sickle-cell anaemia, cystic fibrosis, and Huntington's disease. Initially offered mainly in hospitals, testing later expanded to commercial services and private clinics.[53] A 1975 report by the National Research Council examined the emerging trends in genetic testing, while a 1983 report on Ethical

[50] USPTO, "2105 Patent Eligible Subject Matter - Living Subject Matter [R-10.2019]", *available* at: https://www.uspto.gov/web/offices/pac/mpep/s2105.html (last visited on February 05, 2025).
[51] Stuart A. Newman, "Averting the Clone Age: Prospects and Perils of Human Developmental Manipulation", 19(2) *Journal of Contemporary Health Law & Policy* 431 (2002).
[52] *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 51 U.S.P.Q.2D (BNA) 1700 (Fed. Cir. 1999).
[53] Shobita Parthasarathy, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* 31 (MIT Press, 2007).

Problems in Medicine and Biomedical and Behavioural Research by the President's Commission discussed these challenges from a scientific, legal, and medical perspective. Both reports supported genetic testing, emphasising the importance of autonomy, patient confidentiality, well-being, equity, and the provision of useful knowledge to patients.[54]

Concurrently, genetic testing in the U.S. increased significantly, prompting discussions on regulation. In the ensuing years, the debate over gene patents reached a boiling point with the landmark case of *Association for Molecular Pathology v Myriad Genetics, Inc*. case.[55] Myriad Genetics had obtained patents for multiple mutations in the BRCA1 and BRCA2 genes, securing their position as a leading genetic testing provider. With support from healthcare providers, laboratories, insurers, and physicians. Despite controversy over gene patents and proposed reforms, Myriad's commercialisation strategy persisted with limited government involvement. In subsequent years, bills challenging gene patents and advocating for genetic testing accessibility faced opposition and did not pass. The Secretary's Advisory Committee on Genetics, Health, and Society further addressed concerns such as insurance discrimination and reimbursement. Eventually, the American Civil Liberties Union (ACLU) and the Public Patent Foundation challenged gene patents associated with breast and ovarian cancer, leading to a ground-breaking Supreme Court case. In a landmark decision on June 13, 2013, the Supreme Court invalidated Myriad's patents on the BRCA1 and BRCA2 genes, ruling that naturally occurring DNA sequences cannot be patented reaffirmation of the *Product of Nature* Doctrine.[56, 57] This ruling reflected moral concerns about equity, social justice, and the potential exploitation of genetic knowledge for profit, highlighting the ethical implications of granting patent rights to parts of the human genome, which, if allowed, could be viewed as commodifying human life itself. Thus, the decision reinforced the principle that nature should not be privatised through patents, emphasising the public

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54 Kathi E. Hanna, "The Ethical, Legal, and Social Implications Program of the National Center for Human Genome Research: A Missed Opportunity?", in Ruth Ellen Bulger, Elizabeth Meyer Bobby, *et.al*. (eds), *Social and Ethical Decision Making in Biomedicine* (National Academics Press, Washington D.C., 1995), available at: https://www.ncbi.nlm.nih.gov/books/NBK231976/ (last visited on February 05, 2025).

55 Jacob S. Sherkow and Henry T. Greely, "The History of Patenting Genetic Material", 49 *Annual Review of Genetics* 161 (2015).

56 E. Richard Gold and Julia Carbone, "Myriad Genetics: In the Eye of the Policy Storm", 12(4) Genetics in Medicine S39 (2010).

57 *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 133 S. Ct. 2107, 186 L. Ed. 2d 124 (2013).

policy interest in prioritising access to essential healthcare over the control of critical medical knowledge by a few companies. This enabled broader clinical testing and sparked debates on the role of patents in genetic research, marking a transformative moment in the intersection of science, commerce, and intellectual property.

However, in the years that followed, the evolving landscape of gene patenting kept underscoring the ongoing ethical, and legal considerations in the field of biotechnology. With the completion of the Human Genome Project (HGP) in 2003, concerns surrounding patenting in the field of biotechnology gained further attention. Following the ability to isolate individual gene sequences from the genome, the Patent Office began granting composition of matter patents. In April 2009, the USPTO issued its 50,000th DNA-related patent,[58] as recorded in Georgetown University's DNA Patent Database, and by 2010, thousands of isolated human genes being patented. The HGP's successful sequencing and mapping of the human genome brought to the forefront the question of who should hold the rights to genetic discoveries.[59] This issue continued to be a subject of debate as advancements like CRISPR gene-editing technology emerged, raising new challenges in determining patent rights and their impact on scientific progress.[60] CRISPR-Cas9, as one of the most transformative of these advancements, has spurred innovation across various sectors, including agriculture, industry, and medicine. In healthcare, it has played a pivotal role in diagnosing and treating diseases like sickle cell anaemia, HIV, and muscular dystrophy, as well as in COVID-19 diagnostics and vaccine development. Additionally, CRISPR is being utilised in CAR-T immunotherapy for cancer, making patenting these technologies an essential step to support their continued development and address the complex issues surrounding IPRs.

The U.S. CRISPR-Cas9 patent landscape is led by the Broad Institute, which holds 31 patents, including 26 for eukaryotic cell applications, while UC Berkeley holds earlier patents on foundational discoveries. However, ownership disputes remain complex, with both institutions claiming key contributions. The USPTO ultimately ruled in favour of Broad for CRISPR-Cas9 use in eukaryotic cells, but legal battles continue,

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58 Robert Cook-Deegan and Christopher Heaney, "Patents in Genomics and Human Genetics", 11 *Annual Review of Genomics and Human Genetics* 1 (2010).

59 *Ibid*.

60 John J Mulvihill, Benjamin Capps, *et al*., "Ethical Issues of CRISPR Technology and Gene Editing Through the Lens of Solidarity", 122(1) *British Medical Bulletin* 2 (2017).

reflecting the broader challenges of patenting biotechnological innovations.[61] Beyond legal disputes, CRISPR also presents profound ethical dilemmas, requiring careful legal and societal regulation to balance its potential to cure diseases against risks of misuse, inequality, and unforeseen consequences. Gene editing in plants, animals, and ecosystems is feared to threaten biodiversity, food security, and ecological balance. Concerns also exist about CRISPR's potential biosecurity risks and whether non-medical genetic modifications could diminish natural diversity and widen social inequality. Similarly, germline editing raises worries about consent, as future generations would have no say in genetic changes made before birth, prompting broader debates on parental authority, autonomy, and the sanctity of human life.[62] [63] This issue highlights the complexities of patenting CRISPR gene-editing technology, requiring a balance between ethical considerations, patent rights, and scientific progress.

Furthermore, the USPTO's issuance of patents to the Wisconsin Alumni Research Foundation (WARF) introduced a new layer of complexity to the ongoing debate over patenting stem cell innovations. These patents, covering both human embryonic stem cells and their creation processes, have further intensified discussions on the ethical and legal implications of owning fundamental biological discoveries.[64] WARF's broad patents have sparked concerns about stifling innovation, while moral objections, centered on the destruction of embryos, raise questions about human dignity. The differences between implanted and un-implanted embryos, along with their associated rights to life and dignity, coupled with the distinction between totipotent, pluripotent, and multipotent stem cells in terms of moral value and rights, raise profound and complex ethical questions. Additionally, varying viewpoints on patenting embryos versus related processes and concerns regarding consent for the donation of materials for human stem cell research further intensify the ethical landscape.[65] Furthermore, the

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[61] "For Journalists: Statements and Background on the CRISPR Patent Process", *available at*: https://www.broadinstitute.org/crispr/journalists-statement-and-background-crispr-patent-process (last visited on February 05, 2025).

[62] Amal Ferahtia, Halilat Mohammed Tahar, *et.al.*, "Surface Water Quality Assessment in Semi-Arid Region (El Hodna Watershed, Algeria) Based on Water Quality Index (WQI)", 66(1) *Studia Universitatis Babeș-Bolyai. Chemia* (2021).

[63] *Supra* note 60.

[64] David B. Resnik, *The Commercialization of Human Stem Cells: Ethical and Policy Issues*, 10 *Health Care Analysis* 127-131 (2002).

[65] Jeanne F. Loring and Cathryn Campbell, "Intellectual Property and Human Embryonic Stem Cell Research", 311 *Science* 1716 (2006).

ethical concerns surrounding early clinical trials of Human Stem Cell (HSC) therapies, particularly regarding their safety, effectiveness, and the potential risks to participants, along with the need for stringent oversight to ensure that research progresses responsibly and equitably, still demand careful and nuanced discussion.[66] [67]

Shifting to animal cloning and xenotransplantation, although these practices raise significant ethical concerns regarding the use of genetically modified animals for human benefit, legal considerations also come into play. This was highlighted in the 2014 ruling by the United States Court of Appeals for the Federal Circuit in the case *In re Roslin Institute (Edinburgh)*. The court ruled that Dolly the sheep, being a genetic replica of her donor, was ineligible for patent protection, noting that any variations between Dolly and her donor were due to environmental factors, not genetic differences. However, the court granted the Roslin Institute a patent for the cloning method used to create Dolly, known as Somatic Cell Nuclear Transfer (SCNT).[68] This same technique is now used to clone genetically modified pigs for xenotransplantation and biomedical research.[69] The use of genetically modified pigs for organ harvesting raises significant ethical concerns, as it exploits animals bred for donation, challenging moral principles related to animal rights, autonomy, and dignity. Additionally, the informed consent of patients in desperate conditions may be compromised, as many may not fully grasp the experimental nature of the procedure, while the risk of zoonotic diseases spreading from genetically modified pigs poses significant public health concerns.[70]

Reading this post by Mandy (2014), which highlighted the high failure rate of pig organ transplants, with none of the patients surviving beyond two months, underscoring the significant scientific and medical challenges of xenotransplantation, leaves me to question its reliability and viability as a long-term solution for organ

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66 David B. Resnik, "Embryonic Stem Cell Patents and Human Dignity", 15(3) *Health Care Analysis* 211 (2007).

67 Bernard Lo and Lindsay Parham, "Ethical Issues in Stem Cell Research", 30(3) *Endocrine Reviews* 204 -213 (2009), *available at*: https://pmc.ncbi.nlm.nih.gov/articles/PMC2726839/ (last visited on February 05, 2025).

68 Robin Feldman and Vern Norviel, "Dolly the Sheep: A Cautionary Tale", Yale Journal of Law & Technology, *available at*: https://yjolt.org/blog/dolly-sheep-cautionary-tale (last visited on February 05, 2025).

69 Hongsheng Ouyang, Jianyong Han and Yongye Huang, "Pig Cloning Using Somatic Cell Nuclear Transfer", in Kejin Hu (ed), *Nuclear Reprogramming: Methods and Protocols* 1 (2021).

70 Mandy Nguyen, *Should We Put Pig Organs in Humans? We Asked an Ethicist*, Vox (Nov. 30, 2024), *available at*: https://www.vox.com/future-perfect/388544/pig-organ-transplants-xenotransplantation-ethics-consent (last visited on February 05, 2025).

transplantation. It also prompts concerns about the ethical and environmental implications of large-scale breeding of genetically modified pigs. While the benefits of these technologies are undeniable, our intellectual superiority does not grant us the right to exploit other life forms as mere tools for our own gain. So, the benefits of patenting SCNT should indeed be carefully weighed against the ethical concerns surrounding genetic modification and the potential risks involved in such high-stakes experimentation.

Nevertheless, a growing number of patent law experts in the U.S. are voicing their frustration with the current framework, calling on Congress to redefine what constitutes patentable subject matter in order to restore clarity and consistency in patent eligibility.[71] One notable proposal, the Patent Eligibility Restoration Act of 2023 (PERA), also seeks to overturn decisions like *Myriad* that prohibit patents on isolated, naturally occurring DNA sequences. Proponents argue that such changes would reinvigorate innovation and technological progress, while opponents caution that it could hinder scientific research and restrict patient access to essential genetic testing.[72] These contentions require deeper inquiry into the fundamental principles and considerations that shape perspectives on the moral status, *ordre public*, and patentability of biotechnological innovations. It is therefore essential to establish well-defined guidelines or directives that address patent eligibility and exclusions based on moral and *ordre public* considerations, in order to provide a solid foundation of legal certainty and ensure ethical integrity in biotechnological innovations.[73] The guidelines should be formulated with careful consideration of their social implications and offer clear and explicit rules to differentiate between patentable and non-patentable subject matter, accompanied by possible illustrative examples that help clarify the limits of the *ordre public* and morality exception.[74] Given the absence of specific guidelines in the U.S. the need for clear

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71 Robert Cook-Deegan, Janis Geary, *et al*., "Sorry You Asked? Mayo, Myriad, and the Battles Over Patent-Eligibility", 11(1) *Journal of Law and the Biosciences* 1 (2024).

72 Gail H. Javitt and Jeffrey N. Gibbs, "A Reversal on Sequencing? Proposed Legislation Would Allow Patenting of Naturally Occurring Genes", *available at*: https://www.thefdalawblog.com/2024/10/a-reversal-on-sequencing-proposed-legislation-would-allow-patenting-of-naturally-occurring-genes/ (last visited on February 05, 2025).

73 Carrie F. Walter, "Beyond the Harvard Mouse: Current Patent Practice and the Necessity of Clear Guidelines in Biotechnology Patent Law", 73(3) *Indiana Law.Journal* 1025 (1998).

74 Aisling McMahon, "Accounting for Ethical Considerations in the Licensing of Patented Biotechnologies and Health-Related Technologies: A Justification", in Naomi Hawkins (ed), *Patenting Biotechnical Innovatio*n 163 (Edward Elgar, 2022).

directives becomes even more pressing in light of the PERA, as it seeks to redefine patentable subject matter.

3. CLOSING REFLECTIONS

We must not underestimate the profound power and knowledge we have acquired in our ability to manipulate the very essence of life. The scope of our advancements demands a responsible approach that encompasses factors like human dignity, animal dignity, environmental consequences, and the overall well-being of society. Looking back at historical cases, it becomes evident that the U.S. court has recognised Congress's authority to designate certain types of inventions as non-patentable for various reasons, including deception, as seen in the *Juicy Whip v. Orange Bang* case. Without specific action from Congress, the court finds no legal grounds in Section 101 of patent law to declare inventions unpatentable even if it is based solely on the potential to deceive some members of the public.

However, it is believed that the approach taken by the USPTO in rejecting claims related to controversial biotech inventions is subjective and lacks consistent criteria. As Bagley (2007) aptly points out, the term *"human"* is also open to individual interpretation by examiners, resulting in a lenient utility requirement and potentially leading to inconsistency in decision-making processes. Also, the U.S. Court's broad interpretation of Section 101, which defers the determination of moral boundaries to Congress, introduces uncertainty and raises valid concerns regarding fairness and transparency within the patent system. It is crucial to prioritise considerations of public interest, ethics, and long-term societal well-being rather than merely reacting to patent applications as they arise, as this reactive approach can lead to public backlash and ethical controversies. A lucid and objective definition of what qualifies as a *"human"* invention would provide much-needed clarity and ensure consistent evaluation of patent claims. Neglecting to address these concerns jeopardises public trust in the patent system and calls into question the alignment of patent law with societal values.

By embracing a patent system that prioritises ethics and the well-being of the public, we can strike a delicate balance between scientific progress, economic considerations, and fundamental ethical principles. This approach ensures that the advancements in biotechnology align with the values of long-term well-being and

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collective progress. By redirecting research towards non-controversial innovations that offer sustainable benefits and promote societal harmony, for instance, growing human organs from a patient's own cells, resources can be more effectively allocated to solutions that do not rely on animal exploitation. This approach would address ethical concerns while fostering positive impacts across various sectors, including healthcare, agriculture, and environmental sustainability. Through our dedicated efforts towards ethical and sustainable solutions, we can shape a future where biotechnology acts as a catalyst for positive change, benefiting both current and future generations. As this paper draws to a close, a final reflection emerges: "*A patent system bound by moral principles and ordre public can foster a symphony of progress and societal harmony*."