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Bioethics of Patents and Licensing

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"Science knows no country, because knowledge belongs to humanity, and is the torch which illuminates the world."
— Louis Pasteur[1]

Modern biomedical, biotechnology, and pharmaceutical sciences and technology have produced astounding advances and continue to do so. However, these fields are only beginning to grapple with bioethics and patent law intersections, which began with discussions about the morality exception to patentability (a legal standard) and have shifted to ethical licenses (forms

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1. Rebecca F. Grais, Amadou A. Sall & Stewart T. Cole, *Science Knows No*

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of private governance). This Article provides a socially responsible framework for incorporating bioethics into patents and their licensing—termed bioethical licensing—that considers bioethics principles as paramount to private restrictions on ethical licenses. In applying this framework to countries with religious bodies of law, bioethical licensing has significant ability to align private governance with those societies' public interests. Contrary to prevailing characterizations of ethical licensing as a gatekeeper for patent holders, bioethical licensing in alignment with a religion-driven legal system promotes socially responsible innovation that balances private discretion and public interests.

As commonly understood, patent license mechanisms concern the governance and use of patents. Unlike a government's role in, and policies for, patent licensing, such as through compulsory licensing, ethical licensing addresses private governance that directs use for good as a form of private ordering. This Article, however, challenges this conception (when applied to biomedical, biotechnology, and pharmaceutical innovations) as being unconcerned with socially responsible considerations, both on a normative and a religious level. At a normative level, bioethical licensing should embody socially responsible values centered around restriction against societal dangers. At a religious level, the virtues of bioethical licensing are magnified by socially responsible innovation consonant with underlying value systems, as illuminated by this Article's emphasis on alignment with religious bodies of law. Building on these insights, this Article sketches the contours of balanced bioethical licensing approaches in countries with religious bodies of law.

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I. INTRODUCTION

On several occasions, neurologist and geneticist Alan Roses—who first identified genetic risk factors for Alzheimer's disease in 1993[2]—

Country: Fulfilling Louis Pasteur's Legacy, 400 LANCET 2163 *passim* (2022); Irving A. Lerch, *Truth, Justice, and the American Way*, ADVANCING PHYSICS, https://www.aps.org/apsnews/1999/06/truth-justice-and-the-american-way [https://perma.cc/87E7-PH9N (staff-uploaded)] (last visited Apr. 3, 2025) (discussing a discovery by a scientist and inventor on a patent on yeast, a living organism, filed in 1873); *see* P.J. Federico, *Louis Pasteur's Patents*, 86 SCI. 327, 327 (1937); Maurice Cassier, *Louis Pasteur's Patents: Agri-Food Biotechnologies, Industry and Public Good*, *in* LIVING PROPERTIES: MAKING KNOWLEDGE AND CONTROLLING OWNERSHIP IN THE HISTORY OF BIOLOGY 39 *passim* (Jean-Paul Gaudillière, Daniel Kevles & Hans-Jörg Rheinberger eds., 2009).

2. Seol-Heui Han, Christine Hulette, Ann M. Saunders, Gillian Einstein, Margaret Pericak-Vance, Warren J. Strittmatter, Allen D. Roses & Donald E. Schmechel, *Apolipoprotein E Is Present in Hippocampal Neurons Without Neurofibrillary Tangles in Alzheimer's Disease and in Age-Matched Controls*, 128 EXPERIMENTAL NEUROLOGY 13, 15 (1994), Warren J. Strittmatter, Ann M. Saunders, Donald Schmechel, Margaret Pericak-Vance, Jan Enghild, Guy S. Salvesen & Allen D. Roses, *Apolipoprotein E: High-Avidity Binding to Beta-Amyloid and Increased Frequency of Type 4 Allele in Late-Onset Familial Alzheimer Disease*, 90 PROCS. NAT'L ACAD. SCIS. U.S. AM. 1977, 1978 (1993); Allen D. Roses, *Apolipoprotein E Affects the Rate of Alzheimer Disease Expression: β-Amyloid*

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founded biotechnology companies to commercialize his research findings.[3] Each time, Professor Roses was assertive in restricting the use of his patents for conduct he viewed as morally objectionable.[4] In one example, when sublicensee Smart Genetics sought permission to begin offering direct-to-consumer genetic risk testing for Alzheimer's disease, Roses permitted testing only for those with a physician's certification.[5] Roses wished to restrict ethically problematic uses of his patents and viewed patents as a means of exerting influence over the market for his diagnostics, drug discovery, and genetic testing innovations.[6] After Roses and his employer, Duke University, made it clear to Smart Genetics that it fell afoul of their ethical license restrictions in patent license agreements, Smart Genetics ultimately ceased its operations.[7] Such an example is a part of a broader trend of how ethical restrictions in patent licensing can be used to limit controversial applications of biomedical, biotechnology, and pharmaceutical ("biomed, biotech, and pharma") innovations.

Given the great concern that current patent attainment limits (such as the patent eligibility doctrine) inhibit patenting of ethically

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Burden Is a Secondary Consequence Dependent on APOE Genotype and Duration of Disease, 53 J. NEUROPATHY & EXPERIMENTAL NEUROLOGY 429, 429 (1994); Warren J. Strittmatter & Allen D. Roses, *Apolipoprotein E and Alzheimer Disease*, 92 PROC. NAT'L. ACAD. SCI. 4725, 4726 (1995); Marilynn Larkin & Allen Roses, *"Enfant Terrible" of Alzheimer's Research*, 349 LANCET 1302, 1302 (1997). In 1993, Roses reported in the Proceedings of the National Academy of Sciences that the APOE4 variant of apolipoprotein is associated with an increased risk of Alzheimer's disease. Allen D. Roses et al., *Gene Dose of Apolipoprotein E Type 4 Allele and the Risk of Alzheimer's Disease in Late-Onset Families*, 261 SCI. 921, 921–23 (1993).

3. ADAM HEDGECOE, THE POLITICS OF PERSONALISED MEDICINE: PHARMACOGENETICS IN THE CLINIC 31–55 (2004); Bonginkosi Shozi, *Using Patents as a Gavel: Governing Biotechnology with Ethical Licensing Restrictions*, STAN. L. SCH. (Oct. 14, 2024), https://law.stanford.edu/2024/10/14/using-patents-as-a-gavel-governing-biotechnology-using-ethical-licensing-restrictions/ [https://perma.cc/UHL9-DKH2].
4. Shozi, *supra* note 3.
5. HEDGECOE, *supra* note 3; Katie Skeehan, Christopher Heaney & Robert Cook-Deegan, *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer's Disease*, 12 GENETICS MED. S71, S73 (2010).
6. Skeehan, *supra* note 5, at 11.
7. Shozi, *supra* note 3.

controversial biomed, biotech, and pharma inventions,[8] *licensing* of patented advancements reflects a significant new development in the commercialization and distribution of these inventions. The Broad Institute, a biomedical and genomics research center, is another organization that has placed ethical restrictions in patent licenses that limit controversial uses of its patented scientific and technological advancements.[9] For instance, a 2016 patent license between the Broad Institute and Monsanto allowed the Broad Institute (the patent holder) to demand that Monsanto (the patent licensee) ethically promote access to broad segments of society.[10] This is part of a larger trend in biomed, biotech, and pharma innovation: Patents are being used to *ethically* restrict or promote access to controversial scientific and technological advancements.[11] However, ethical licensing's apparent neglect of bioethics considerations and its scholarly focus on private restrictions and private governance is striking. Rather than being ignored, bioethical principles should figure prominently in the patent licensing of biomed, biotech, and pharma inventions. Yet while issues of bioethics have been front and center within medicine and biomedical research, they nevertheless remain peripheral to mainstream accounts of U.S. patent law—particularly regarding patent eligibility and ethics restrictions in patent licensing.

This Article offers a normative challenge to the notion that ethics restrictions in patent licenses should focus on private governance, arguing they should instead focus on bioethics and societal views of them. Normatively, this Article argues bioethics principles are a wholly appropriate focus that advances the objectives of those who

8. Talha Syed, *Reconstructing Patent Eligibility*, 70 AM. U. L. REV. 1937, 1994 (2021); Erika Ellyne, *Patent Eligibility: The 'Sick-Man' of Patent Law*, *in* ACCESS TO INFORMATION AND KNOWLEDGE 155–60 (Dana Beldiman ed., 2013).

9. Christi J. Guerrini Margaret A. Curnutte, Jacob S. Sherkow & Christopher T. Scott, *The Rise of the Ethical License*, 35 NATURE BIOTECH. 22, 23 (2017); Aisling McMahon, *Accounting for Ethical Considerations in the Licensing of Patented Biotechnologies and Health-Related Technologies: A Justification* 163, 163, *in* PATENTING BIOTECHNOLOGICAL INNOVATION: ELIGIBILITY, ETHICS AND PUBLIC INTEREST (Naomi Hawkins ed., 2022).

10. Jacob S. Sherkow, *Patent Protection of CRISPR: An ELSI Review*, 4 J. LAW & BIOSCIS. 565, 572 (2017); *Licensing for Profit and for Good*, 40 NATURE BIOTECH. 439, 439 (2022).

11. McMahon, *supra* note 9, at 12; Sherkow, *supra* note 10, at 572.

patent biomed, biotech, and pharma inventions. Accordingly, this Article decries how bioethics has been neglected in the scholarly debate and practical application of ethical licensing restrictions. To fully realize the potential of bioethics in commercializing and distributing such innovations, scholars and innovators in biomed, biotech, and pharma innovation should embrace what this Article terms "bioethical licensing." Furthermore, it argues that legal systems with religious bodies of law already include numerous bioethical principles aligning with those of their societies; such religious principles should encourage the development and distribution of socially responsible biomed, biotech, and pharma innovations.

This Article proceeds in three Parts. Part II argues that despite notable and newsworthy emerging biomed, biotech, and pharma inventions (on which the bioethics-patent debate has placed its focus largely on the patent eligibility doctrine), contemporary patent law has often failed to address important patent licensing and use considerations in controversial ethical debates. Part III begins by exploring traditional approaches to the government's role in addressing potential patent licensing harms through government-driven licensing and use and norms setting and is followed by limitations of these approaches.

Part III then demonstrates the powerful ways in which market-driven private ordering can shape applications of biomed, biotech, and pharma research and open new lines of products and services. Part IV introduces ethical implications of private governance via patent licensing, describes how they promote a form of private governance, and offers several ways they differ from other private ordering mechanisms. In doing so, it provides a framework for thinking about the normative implications faced by innovators who incorporate ethical restrictions into their patent license agreements.

Part IV then turns to normative analysis, arguing that bioethics as a normative principle should be adopted by innovators considering ethical restrictions on patent licenses; it also introduces the term "bioethical licensing." Part IV then argues that bioethical principles are fully consonant with the objectives of legal systems with religious bodies of law, balancing societal interests and enabling commercial transactions. In doing so, Part IV sketches a bioethical licensing

agenda for countries with religious bodies of law and suggests future areas of law and policy research regarding biomed, biotech, and pharma innovations in those countries.

II. Improving the Disconnect Between Patent Law and Bioethics

As conventionally understood, the U.S. patent system does not consider an invention's bioethical impacts—neither when evaluating patentability (the legal requirements for attaining a patent) at the United States Patent and Trademark Office ("USPTO") nor when engaging in patent licensing (the contractual agreements that use patents as assets in a transaction).[12] Therefore, even though cloning, COVID-19 vaccines, clustered regularly interspaced short palindromic repeats ("CRISPR") gene editing, organoids, pharmaceutical drug development, and stem cells are immensely controversial and newsworthy, their bioethical impact is *not* a legal consideration for patentability nor patent licensing.[13]

The legal requirements for attaining a patent—which include patent eligibility, enablement and written description, novelty,

12. Aisling McMahon, *Gene Patents and the Marginalisation of Ethical Issues*, 41 EUR. INTELL. PROP. REV. 608, 609 (2019); Andrea Panagopoulos & Katerina Sideri, *Prospect Patents and CRISPR; Rivalry and Ethical Licensing in a Semi-Commons Environment*, J.L. & BIOSCIS., 8:2 (July–Dec. 2021), at 13.

13. Duncan Matthews, Timo Minssen & Ana Nordberg, *Balancing Innovation, 'Ordre Public" and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*, 29 EUR. J. HEALTH L. 562, 564 (2022); Panagopoulos & Sideri, *supra* note 12, at 15–17; Karin R. Jongsma & Annelien L. Bredenoord, *Ethics Parallel Research: An Approach for (Early) Ethical Guidance of Biomedical Innovation*, BMC MEDICAL ETHICS, 21:81 (2020), at 7; Viola Prifti, The "Ordre Public" and "Morality" Clause in EU and Japanese Patent Law: The Case of Human Embryonic Stem Cell Inventions iv–v, vii (unpublished manuscript) (2018), https://www.iip.or.jp/e/summary/pdf/detail2017/e29_09_Prifti.pdf (https://perma.cc/542X-RW3N)]; Dorinka Myrick, The Impact of *Ordre Public* and Morality on the Regulation of Gene Editing Patents in the United States and the European Union 66 (Feb. 7, 2023), https://ssrn.com/abstract=4347343 [https://perma.cc/S75Z-BM6P (staff-uploaded)]; Frank R. Lichtenberg & Tomas J. Philipson, *The Dual Effects of Intellectual Property Regulations: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry* 5–6 (Nat'l Bureau of Econ. Rsch., Working Paper No. 9303, 2002), https://www.nber.org/papers/w9303 [https://perma.cc/6BSE-9PKK].

nonobviousness, and utility—largely evaluate the innovativeness of an invention and sufficiency in its disclosure.[14] Unlike the field of bioethics, U.S. patent law lacks an analog for examining the ethical decisions and actions in the field of biological sciences, medicine, and healthcare.[15] Put differently, rather than weighing bioethical impacts, patentability determinations are dominated by scientific and technical considerations.[16] Furthermore, no U.S. framework exists for making ethically sound decisions related to biomed, biotech, and pharma inventions after the issuance of a U.S. patent.[17] Of course, a significant caveat applies: The U.S., along with other countries that adhere to international agreements, can enact laws stating that violations of *ordre public* may warrant exclusion for patent eligibility.[18] However, the U.S. patent system currently does not require such an assessment.[19]

Nestled in the Trade-Related Aspects of Intellectual Property Rights agreement ("TRIPS") is the seed for an ethical principle in the context of patent law—the term *ordre public*.[20] Countries that are signatories to TRIPS may (but are not required to) have morality provisions when considering the exclusion of inventions from their patent system.[21] The *ordre public* exception to patent law bolsters the balancing of research, clinical, ethical, and societal goals with market and economic forces in biomed, biotech, and pharma innovation.[22] Beyond this ethical principle, however, the U.S. patent system generally does not inquire into the specific ethical impacts of

14. 35 U.S.C. § 101-3, 112.

15. Panagopoulos & Sideri, *supra* note 12, at 16.

16. Sivaramjani Thambisetty, *The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making*, *in* ETHICS AND LAW OF INTELLECTUAL PROPERTY: CURRENT PROBLEMS IN POLITICS, SCIENCE AND TECHNOLOGY 247, 253 (Christian Lenk, Nils Hoppe & Roberto Andorno eds., 1st ed. 2007).

17. *Id.*

18. Myrick, *supra* note 13, at 12–13.

19. *Id.*

20. Kathleen Liddell, *Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality*, *in* NEW FRONTIERS IN THE PHILOSOPHY OF INTELLECTUAL PROPERTY 140, 140 (Annabelle Lever ed., 2012).

21. Myrick, *supra* note 13, at 3.

22. *Id.* at 4.

particular inventions.[23] The *ordre public* exception is rarely invoked to deny patents in countries with ethically objectionable inventions, and in many countries, few records exist to verify its enforcement by their patent offices.[24] Generally speaking, patent offices have scientific and technological neutrality due to resistance in weighing ethical considerations and focusing on inventiveness when making a determination on patentability.[25]

A. *The Challenge of Integrating Bioethics into Patent Law*

Restrictions on attaining patents could, in theory, be based on international agreements that enable denial on moral grounds.[26] Patent doctrine's hesitancy to weigh ethical impact when determining patentability is reflected in two ways: (1) an uneasiness about considering inventions' bioethical impacts, and (2) a disconnect between understanding scientific and technological advancements themselves and their associated bioethical tensions. Additionally, many countries are reluctant to develop bioethical governance, choosing instead to emphasize scientific and technical inventive steps in their patent laws.[27] Rather than promoting ethics, objective well-being, and social value when it comes to biomed, biotech, and pharma innovations, patent law's normative grounds follow Professor Margo

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23. Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 475 (2003).

24. Ana Nordberg, *Patentability of Human Enhancement: From Ethical Dilemmas to Legal (Un)Certainty*, *in* INTELLECTUAL PROPERTY PERSPECTIVES ON THE REGULATION OF NEW TECHNOLOGIES (Tana Pistorius ed., 2016) (forthcoming) (manuscript at 1–2), https://ssrn.com/abstract=2768071 [https://perma.cc/SW2A-W896 (staff-uploaded)].

25. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002)

26. Margo A. Bagley, *The Morality of Compulsory Licensing as an Access to Medicines Tool*, 102 MINN. L. REV., 2463, 2465 (2018); Bagley, *supra* note 23, at 475.

27. WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTELLECTUAL PROPERTY AND BIOETHICS – AN OVERVIEW 14 (Consultation Draft, 2007), https://www.wipo.int/edocs/pubdocs/en/intproperty/932/wipo_pub_b932ipb.pdf [https://perma.cc/B29C-BKT7]; NED SNOW, INTELLECTUAL PROPERTY AND IMMORALITY: AGAINST PROTECTING HARMFUL CREATIONS OF THE MIND 3 (2022); David O. Taylor, *On Snow's Intellectual Property and Immorality*, 11 TEX. A&M J. PROP. L. 191, 202 (2025).

Bagley's observation of "patent first, ask questions later."[28] There are challenges to integrating bioethics into patent doctrine.

First, integrating bioethics into patentability assessment would challenge a patent office's institutional design. Patent examiners lack bioethics training, and hiring qualifications do not include an ability to make bioethical evaluations.[29] Perceived limitations of USPTO patent examiners' capacity to assess ethical dimensions of scientific and technological advancements—which played a role in the moral utility doctrine's demise[30]—are procedural barriers to the USPTO's operations.[31] Furthermore, bioethical assessment disincentivizes inventors from disclosing ethically questionable inventions in patent applications, which are publicly viewable.[32] Furthermore, inventive

28. Bagley, *supra* note 26, at 475.

29. Tabrez Y. Ebrahim, *Computational Experimentation*, 21 VAND. J. ENT. & TECH. L. 591, 642–43 (2019) (describing that patent examiner hiring norms are based on specific educational backgrounds and degrees, along with expertise in specific technological areas); JOSHUA D. SARNOFF, RELIGIOUS AND MORAL GROUNDS FOR PATENT-ELIGIBLE SUBJECT MATTER EXCLUSIONS 38, 56–58 (2019) (discussing religious exclusions for discoveries of science, nature, and ideas that involve moral considerations); *Sensitive Application Warning System*, U.S. PAT. & TRADEMARK OFF. (Mar. 2, 2015), https://www.uspto.gov/patents/initiatives/patent-application-initiatives/sensitive-application-warning-system [https://perma.cc/GQ54-E7ED].

30. Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 690–92 (2004) The "demise of the moral utility requirement" refers to the gradual decline and eventual rejection of the legal doctrine that a patent can be denied if its intended use is considered morally harmful or detrimental to society, meaning that the USPTO should not grant protection to inventions deemed ethically problematic, even if they are technically functional. *Id.* at 691. This trend is most notably seen in recent patent law where courts are increasingly hesitant to make subjective moral judgments when evaluating patent applications. *Id.* at 692.

31. Juicy Whip, Inc. v. Orange Bang, 185 F.3d 1364, 1368 (Fed. Cir. 1999) ("The requirement of 'utility' in patent law is not directive to the Patent and Trademark Office or the courts to serve as arbiters of deceptive trade practices. Other agencies, such as the Federal Trade Commission and the Food and Drug Administration, are assigned the task of protecting consumers from fraud and deception in the sale of food products.").

32. Allan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 404 (2010); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L.

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effort itself may even be thwarted if inventors know a bioethical assessment could present yet another hurdle to the patentability of their biomed, biotech, and pharma inventions.

In addition to these concerns at the patent office level, there are also concerns about bioethical evaluation within the broader patent system, which does not have a history of ethical considerations. Unlike other areas of the law where ethical evaluation is present—such as conflicts of interest, financial disclosures, post-employment negotiation restrictions, procurement and contracting, taxes, and political activities—U.S. patent law has largely ignored the consideration of ethics, specifically bioethics, throughout its history.[33]

Second, consideration of bioethics could impact the timing of patent prosecution (the negotiation process between a patent applicant and the patent office to attain a patent). The process of attaining a patent is lengthy and costly, and adding bioethical considerations could further delay examination of a patent application.[34] By imposing an additional step for patentability, bioethical evaluation and implementation could provide a significant disincentive for inventors to seek patents. As a corollary, if patent prosecution were to require careful consideration of bioethics concerns, it could delay the development of certain scientific and technological advancements. Further, scientists and engineers may lack the expertise to describe bioethics in their inventions, which could possibly lead them to abandon their inventions.

Third, bioethical integration would be a departure from the perceived scientific and technological neutrality of patent law, both in

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REV. 539, 546 (2009); Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information*, 25 HARV. J.L. & TECH. 531, 537 (2012); Joseph Scott Miller, *Enhancing Patent Disclosure for Faithful Claim Construction*, 9 LEWIS & CLARK L. REV. 178, 179 (2005).

33. U.S. OFF. OF GOV'T ETHICS, COMPILATION OF FEDERAL ETHICS LAWS *passim* (2023).

34. Naira Rezende Simmons, *Putting Yourself in the Shoes of a Patent Examiner: Overview of the United States Patent and Trademark Office (USPTO) Patent Examiner Production (Count) System*, 17 J. MARSHALL REV. INTELL. PROP. L. 33, 41 (2017); *Budget and Financial Information*, U.S. PAT. TRADEMARK OFF., https://www.uspto.gov/about-us/performance-and-planning/budget-and-financial-information [https://perma.cc/J6W7-RFSZ].

patent offices and the patent system. The USPTO and the U.S. patent system are expected to treat all inventions neutrally, refraining from tailoring patentability assessments based on distinctions in sciences and technology[35] that would accelerate review of certain patent applications at the expense of others.[36] However, the USPTO and the U.S. patent system are not nearly as neutral as commonly perceived. Instead, certain kinds of inventions are *already* treated differently. For example, the USPTO accelerates the examination of certain patent applications and has had programs encouraging patent applications in certain scientific and technological fields to be filed by offering prioritized examination.[37] Additionally, the U.S. patent system provides independent legal classification or unique (otherwise known as *sui generis*) patent rights for several invention categories—including asexually reproduced plants,[38] sexually reproduced plant varieties,[39] semiconductor masks,[40] and vessel hulls.[41] By encouraging innovation in particular areas, the USPTO and U.S. patent system have already departed from their theoretical underpinnings of neutrality. Building on this foundation, this Article argues there are virtues to considering bioethics for patent law more generally.[42]

B. The Virtues of Bioethics for Patent Law

While integrating bioethics into patent law is not without obstacles and practical limitations, it offers several benefits to innovation, law and policy, and society. The normative insights and

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35. Burk, *supra* note 25, at 1156.

36. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1578–79, 1630 (2003).

37. Taras Hrendash, *Prioritized Examination and Its Impact on Commercialization of Patents* 3 (CERGE-EI, Working Paper No. 638, 2019), https://ssrn.com/abstract=3396364 [https://perma.cc/VLD3-3ZRS (staff-uploaded)]; Press Release, U.S. Dep't of Com., U.S. Commerce Department's Patent and Trademark Office to Accelerate Review of Green Technology Patents to Speed Deployment to Marketplace (Dec. 7, 2009), https://2010-2014.commerce.gov/node/11670.html [https://perma.cc/5F6T-PV39].

38. Plant Patent Act, 35 U.S.C. §§ 161–164 (1930).

39. Plant Variety Protection Act, 7 U.S.C. §§ 2321–2582 (1970).

40. Semiconductor Chip Protection Act, 17 U.S.C. §§ 901–914 (1984).

41. Vessel Hull Design Protection Act, 17 U.S.C. §§ 1301–1332 (1998).

42. *See infra* Part III.

proposals this Article present are not a panacea for patent law's treatment of biomed, biotech, and pharma inventions. Rather, this Article suggests that beyond relying on economic justifications, patents and patent licensing should also account for *bioethical* considerations, such as ethical restrictions in patent licensing generally. More specifically, for countries with religious bodies of law, this would include licensing restrictions that ethically align with those bodies of law. Indeed, many of the deficiencies of patent law define the strengths of bioethical principles.

First, bioethics—unlike patent law—maintains a high level of emphasis on public interest and societal implications. As such, relative to patent law, bioethics focuses on "soft impacts" to emerging scientific and technological breakthroughs—with its emphasis on values such as autonomy, human flourishing, harm, and safety.[43] Under the lens of bioethics, normative analysis of patent law can shift from *potential intended use* to *actual use* in an ethical manner.[44] U.S. patent law—as well as many countries' patent law—allows biomed, biotech, and pharma researchers and inventors to pursue inventions on science and technology without considering broader societal or ethical concerns.[45] While researchers often attain government agency research grants with ethical guidelines, and while researchers' employers—universities and research centers—have ethical and legal compliance standards, these guidelines are entirely separate from the U.S. patent system.[46]

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43. Jongsma & Brednoord, *supra* note 13, at 6.

44. Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 34, 399 (2010); Maayan Perel, *From Non-Practicing Entities (NPEs) to Non-Practiced Patents (NPPs): A Proposal for a Patent Working Requirement*, 83 U. CIN. L. REV. 747, 751 (2015).

45. CLAUDE BARFIELD & JOHN E. CALFEE, AM. ENTER INST., BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 29 (2007); Hannah M. Mosby, Note, *Biotechnology's Great Divide: Strengthening the Relationship Between Patent Law and Bioethics in the Age of CRISP-Cas9*, 19 MINN. J. L. SCI. & TECH. 565, 566 (2018).

46. Shrikant Panigrahi, Mohd Darun, Muhammad Waris & Senthil Kumar, Promoting Research Governance Through Integrity and Ethical Practices: A Qualitative Study 462 (Apr. 12, 2017), https://ssrn.com/abstract=2949333 [https://perma.cc/ADR2-QNLW (staff-uploaded)]; Seth C. Oranburg, University Disentanglement: Toward a Theory of University Governance 18–

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Ethical guidelines and research compliance standards do *not* restrict the scope of patent protection; rather, the U.S. patent system allows for issuance of patents on "anything under the sun made by man," even inventions other countries may consider to be morally controversial.[47] In short, inventors who seek exclusive legal rights for their biomed, biotech, and pharma research in the U.S. need not consider broader ethical and societal impacts.[48] However, the day has long passed in which U.S. patent law can ignore the potential societal impacts on biomed, biotech, and pharma inventions.

Second, and relatedly, bioethical approaches—unlike patent law—are sensitive to interdisciplinary perspectives and interinstitutional input from multiple stakeholders. As noted, bioethics is a field that prioritizes ethical dialogue, frameworks, and public policy discourse.[49] Recent biomedical controversies illustrate struggles with various issues that will undoubtedly reshape health systems, pharmaceutical industries, and health economies globally. Examples of such controversies include genomics (genes or DNA sequences and pharmacogenomics),[50] synthetic biology,[51] cell lines,[52] stem cells

19 (2024), https://ssrn.com/abstract=4997569 [https://perma.cc/JLH6-KDYB (staff-uploaded)].

47. Bagley, *supra* note 23, at 475 (providing examples of morally questionable inventions such as "isolated genes, sequenced DNA, medical procedures, embryonic stem cells, genetically modified transgenic animals, and methods of cloning mammals"); James E. Daily & F. Scott Kieff, *Anything Under the Sun Made by Humans: Patent Law Doctrines as Endogenous Institutions for Commercializing Innovation*, 62 EMORY L. J. 967, 978–80 (2013).

48. Jacob S. Sherkow, Eli Y. Adashi & I. Glenn Cohen, *Governing Human Germline Editing Through Patent Law*, 326 JAMA 1149, 1149–50 (2021).

49. Valerie A. Tornini, Santiago Peregalli Politi, Lori Bruce & Stephen R. Latham, *Maximizing Biomedical Research Impacts Through Bioethical Considerations*, DISEASE MODELS & MECHANISMS, 16:4 (Apr. 24, 2023), at 2.

50. Mosby, *supra* note 45 *passim*; Sherkow et al., *supra* note 48, at 1149–50.

51. Matthew Rimmer, *Patent Law and the Emerging Science of Synthetic Biology*, 36 L. IN CONTEXT 1 (2017); Christopher M. Holman, *Developments in Synthetic Biology Are Altering the IP Imperatives of Biotechnology*, 17 VAND. J. ENT. & TECH. L. 385 *passim* (2020).

52. Christopher Scott Pennisi, *More on Moore: A Novel Strategy for Compensating the Human Sources of Patentable Cell-Line Inventions Based on Existing Law*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 747 *passim* (2001).

(human or embryonic),[53] genetically modified organisms,[54] gene editing,[55] and diagnostics.[56] Scholars and critics may contend that considering various viewpoints to bioethical considerations with U.S. patent law invites interference from ethicists, religious views, and personal political biases when evaluating inventions or issued patents, thereby lessening the incentive to invent.[57] Put differently, integrating bioethics into the patent system may simply allow too many voices, changing the system's foundational principles and presenting challenges for operationalizing patent law.

The consideration of bioethical impact in patentability assessment distributes significant authority into social and value choices, rather than solely legal or technical assessments.[58] Additionally, because implementing bioethical guidance would lead to a denial of patentability only in certain cases, it would seem prudent to instead utilize a tailored patent system in narrow circumstances—but scholars have cautioned that such tailored systems are ineffective.[59] Nonetheless, bioethics presents a fresh lens to patent issuance and

53. Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 309–10 (2003); Joshua Whitehill, *Patenting Human Embryonic Stem Cells: What Is So Immoral?*, 34 BROOK. J. INT'L L. 1045, 1058 (2009).

54. Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Comparative Analysis*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 103, 151 (2002); Robert L. King, *The Modern Industrial Revolution: Transgenic Animals and the Patent Law*, 67 WASH. U. L. REV. 653 *passim* (1989).

55. Jessica Wachowicz, *The Patentability of Gene Editing Technologies Such as CRISPR & the Harmonization of Laws Relating to Germline Editing*, 10 INTELL. PROP. BRIEF 34, 40 (2019).

56. Shahrokh Falati, *Patent Eligibility of Disease Diagnosis*, 21 N.C. J.L. & TECH. 63, 104–05 (2020).

57. Joshua D. Sarnoff, *Religious and Moral Grounds for Patent-Eligible Subject Matter Exclusion*, *in* PATENTS ON LIFE: RELIGIOUS, MORAL AND SOCIAL JUSTICE ASPECTS OF BIOTECHNOLOGY AND INTELLECTUAL PROPERTY 38, 56–57 (Thomas C. Berg, Roman Cholij & Simon Ravenscroft eds., 2019).

58. Sivaramjani Thambisetty, *The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making*, *in* ETHICS AND LAW OF INTELLECTUAL PROPERTY: CURRENT PROBLEMS IN POLITICS, SCIENCE, AND TECHNOLOGY 247, 247–49 (Christian Lenk, Nils Hoppe & Roberto Andorno eds., 2002).

59. Burk & Lemley, *supra* note 36, at 1634.

licensing that could drive conversations about ethics within innovation and enable real-time, parallel input to biomed, biotech, and pharma research.

Third, bioethics—unlike patent law—marshals significant amounts of input from individual biomedical researchers and institutions. Though the USPTO has previously attempted to consider bioethics under the Sensitive Application Warning System (developed in 1994 to allow patent examiners to alert the USPTO leadership when a patent might be issued on a sensitive matter), this system involved only a small number of patent applications.[60] Though novel, the USPTO's warning system did not motivate policymakers to develop other interventions.

Additionally, the information upon which the USPTO bases its decisions can be limited to a very narrow perspective, thus illuminating a major advantage to utilizing bioethics. Policymakers can lean on biomedical researchers at the forefront of innovation to provide guidance on broad policy objectives: considering public interests and societal benefits and serving the concerns of effectiveness, fairness, and safety. Eliciting bioethical considerations can address the long lags between the emergence of potentially controversial and disruptive biomed, biotech, and pharma innovations and adequate policy responses to them.[61]

Ultimately, socially responsible invention can be promoted by mobilizing the input of those closest to inventive activity. This does

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60. *Sensitive Application Warning System (SAWS)*, U.S. PAT. & TRADEMARK OFF. (Mar. 2, 2015), https://www.uspto.gov/patents/initiatives/patent-application-initiatives/sensitive-application-warning-system [https://perma.cc/XN79-PCJP]; John R. Lee, *The Patent Office's SAWS Program*, FISH & RICHARDSON BLOG (Feb. 10, 2015), https://www.fr.com/insights/thought-leadership/blogs/the-patent-offices-saws-program [https://perma.cc/DCM2-L5LX]; Devon Rolf, *Secret Examination Procedures at the USPTO: My Experience with SAWS*, IPWATCHDOG (Dec. 14, 2014), https://ipwatchdog.com/2014/12/14/secret-examination-procedures-at-the-uspto-my-experience-with-saws/id=52638/ [https://perma.cc/4R2W-7DS3]; Lawerence Ashery, *Patent Office Disbands Warning System: Defenses Still in Place*, LEGAL INTELLIGENCER 2–3 (Mar. 25, 2015), http://www.caesar.law/files/2014/11/Patent-Office-Disbands-Warning-System.pdf [https://perma.cc/EP9B-7NEQ].

61. *See* Arti K. Rai, *Evolving Scientific Norms and Intellectual Property Rights: A Reply to Kieff*, 95 NW. L. REV. 707, 709–13 (2001).

not impose external, heavy-handed government regulation. Rather, it uses a softer approach that links scientific and technological expertise to ethically controversial inventions. Similarly, peer evaluation plays a significant role in governing scientific and technological research and innovative communities.[62] Over time, such input may strengthen a norm in which biomed, biotech, and pharma researchers utilize their expertise to give input on the potential societal impact of their inventions.

Consideration of bioethics in the patent system has many virtues, including reducing downstream or end-of-pipeline ethical questions, leveraging multi-stakeholder input, providing peer reviews, and reducing policing costs. By orienting various mechanisms for bioethical considerations into the patent system, the broader societal impacts of biomedical innovation can cultivate a norm of ethical considerations in the biomed, biotech, and pharma research community, the USPTO, and innovation law and policy.

III. DOWNSTREAM USE OF PATENTED BIOMED, BIOTECH AND PHARMA INVENTIONS

Having explored the virtues of remedying the disconnect between patent law and bioethics in the process of *attaining* patents from a patent office, such as the USPTO, this Article now turns to downstream considerations of a patent's potential *use* after issuance.[63] Rather than focusing on *patentability* of biomed, biotech, and pharma inventions, this Part focuses on their *commercialization* and use mechanisms with a focus on equitable sharing, namely a comparison of government-driven approaches and private ordering.

Scientific and technological advancements present distinct challenges for the biomed, biotech, and pharma industries, especially due to the potential for negative externalities in health and

62. Kelly J. Cobey, Tara Sadeghieh & Khosrow Adeli, *Peer Review in Scientific Publications: Benefits, Critiques, & A Survival Guide*, 4 ELEC. J. INT'L FED'N CLINICAL CHEMISTRY & LAB'Y MED. 227, 228 (2014); Martin Reinhart & Cornelia Schendzielorz, *Peer-Review Procedures as Practice, Decision, and Governance—The Case of Research Funding*, 51 SCI. & PUB. POL'Y 543, 543 (2024).

63. Patent holders act as gatekeepers to give permission of their patented scientific or technological advancement while deriving income streams.

pharmaceutical innovation.[64] Society faces a dilemma that presents itself because of biomed, biotech, and pharma innovation advancements and their impact on access to healthcare, essential medicines, and quality of life. This dilemma creates unique policy choices concerning the use of patented inventions and associated issues that lie at the intersection of bioethics, patents, and innovation, along with the trade-off between government-driven regulation and market-driven approaches.[65]

A central consideration within biomed, biotech, and pharma innovation is the extent to which government, instead of private ordering, should have a role.[66] The difficulty in analyzing this issue arises from the healthcare benefits provided by biomed, biotech, and pharma innovation.[67] This leads to a dilemma: choosing between promoting beneficial healthcare technology or restricting its commercial use after a patent grant.[68]

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64. Jongsma & Brednoord, *supra* note 13, at 7–8; Kevin Callison, Michael E. Darden & Keith F. Teltser, *Externalities from Medical Innovation: Evidence from Organ Transplants* 1–3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 31673, 2023), https://www.nber.org/papers/w31673 [https://perma.cc/7BKQ-VDSC].

65. Margaret Eaton, *Ethical Issues Associated with Pharmaceutical Innovation*, *in* ETHICS OF SCIENCE AND TECHNOLOGY ASSESSMENT: BUSINESS ETHICS OF INNOVATION 39, 39 (Gerd Hanekamp ed., 2007); Sirpa Soini, Ségolène Aymé & Gert Matthijs, EUR. SOC'Y HUM. GENETICS, *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 EUR. J. HUM. GENETICS S10, S10–12 (2008) (Austria).

66. *See generally* Steven L. Schwarcz, *Private Ordering*, 97 NW. U. L. REV. 319 (2002); Avery Katz, *Taking Private Ordering Seriously*, 144 U. PA. L. REV. 1745, 1745 (1995); Gillian K. Hadfield, *Privatizing Commercial Law*, REGUL., Spring 2001, at 40, 41 ("From the Middle Ages to the infant digital age, there are examples of law developed and administered by private entities with varying degrees of state involvement."). The term "privatizing law" is sometimes used as a synonym for private ordering. Tehila Sagy, *What's So Private About Private Ordering?*, 45 LAW & SOC'Y REV. 923, 923 (2011).

67. Joe Albanese, *Roadblock to Progress: How Medicare Impedes Health Care Innovation*, PARAGON HEALTH INST. 2–4 (Sept. 2023), https://paragoninstitute.org/wp-content/uploads/2023/09/medicare-roadblock-to-progress.pdf [https://perma.cc/7TTU-TMZH]; Rai, *supra* note 61, at 709–12.

68. Michael J. Kasdan, *Patent Licenses: Licensing Fundamentals*, LEXISNEXIS *1 (2019), https://www.wiggin.com/wp-content/uploads/2019/10/MKasdan-Patent-Licenses_Licensing-Fundamentals.pdf [https://perma.cc/2LTU-WRB2]; *Field-*

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Scholarship addressing the issue of government regulation versus private ordering—in the context of patenting biomed, biotech, and pharma innovations—can be broadly categorized into two approaches. One approach focuses on centralized *governance* intended to maximize innovations' societal benefits and impacts on public health, such as access to essential medicines, pharmaceutical pricing, and quality of human life.[69] The other approach contemplates patent *transactions* (especially patent licenses), examining the trade-off between promoting freedom to contract concerning patents versus restricting controversial applications based on society-wide fairness considerations.[70]

The trade-off between these approaches seeks to answer the normative question—regulation versus market-driven balancing—and stems from the ramification of the rise of the "ethical license" (that is, terms in a patent license that prohibit a use the patent holder deems unethical).[71] The answer to this trade-off and the scrutiny of the ethical license in biomed, biotech, and pharma innovation has significant ramifications for the life sciences and pharmaceutical industries, healthcare, and society.

A. *Government's Role in Equitable Sharing*

Government can regulate biomed, biotech, and pharma innovation in several ways. These healthcare- and medicine-focused innovations present a complex governance challenge for policymakers.

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of-Use Limitation, WESTLAW: PRAC. L. (2024), https://us.practicallaw.thomsonreuters.com/1-502-2751 [https://perma.cc/GW9E-Y4GA]; Joshua D. Sarnoff, *Strengthening the Relationship Between Patent Law and Bioethics: A Schema for Utilizing the Patent Prosecution Process as a Forum for Ethical Debate*, 12 MINN. J.L. SCI. & TECH. 465, 465 (2011); *Bioethics and Patent Law: The Relaxin Case*, WIPO MAG. (Apr. 14, 2006), https://www.wipo.int/web/wipo-magazine/articles/bioethics-and-patent-law-the-relaxin-case-35201 [https://perma.cc/TA7T-XMMB].

69. Jacky Swan, Anna Goussevskaia, Sue Newell, Maxine Robertson, Mike Bresnen & Ademola Obembe, *Modes of Organizing Biomedical Innovation in the UK and US and the Role of Integrative and Relational Capabilities*, 36 RSCH. POL. 529, 529 (2007).

70. Robert P. Merges, *Updating the Private Law of Patent Contracting*, 64 IDEA 295, 298, 302, 398 (2024).

71. Guerrini et al., *supra* note 9, at 23.

Most government interventions are centralized and entail policymakers setting agendas that either promote or constrain innovative activity.[72] One type of government intervention is ex post: It is reactive after biomed, biotech, and pharma scientific and technological innovations have manifested, thereby giving policymakers limited time to make regulation decisions before the innovations become adopted by society or controlled by a limited set of companies.[73] Another type of government intervention is centralized public funding, which refers to maximizing an investment's social benefit through grants, prizes, and mission-oriented or moonshot innovation programs.[74]

This Part describes one example of ex post intervention—compulsory licensing—and introduces the role of government institutions in facilitating norms, such as cultivating ethically responsible biomed, biotech, and pharma innovation. This Part also raises objections and potential responses.

1. Government-Driven Licensing & Use Through Statutes

Government policies concerning patent licensing and use have the potential to affect distribution and use of scientific and technological advancements, including biomed, biotech, and pharma patented inventions. These policies implicate choices about who in society has the right to use biomed, biotech, and pharma innovations and under what conditions.

In the U.S., the government funds a substantial amount of biomed, biotech, and pharma research through grants and other programs. In some scenarios, the U.S. government seeks to have access to scientific and technological advancements so that the public can benefit from the innovation. In doing so, such government initiatives seek to

72. Sean O'Connor, *Creators, Innovators, and Appropriation Mechanisms*, 22 GEO. MASON L. REV. 973, 973–75 (2015).

73. *See generally* Jongsma & Bredenoord, *supra* note 13.

74. Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 544 (2019); W. Nicholson Price II, *Grants*, 34 BERKELY TECH. L.J. 1, 1 (2019); Michael J. Burstein & Fionna E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401 *passim* (2016); NAT'L SCI. FOUND., INNOVATION INDUCEMENT PRIZES AT THE NATIONAL SCIENCE FOUNDATION 9–14 (2007).

balance private rights gained through patents and public benefits from the scientific and technological advancements through three different mechanisms: (1) compulsory licensing, (2) march-in rights, and (3) government patent use. The U.S. government can utilize statutes that allow federal agencies to produce scientific and technological advancements with the patent owner's permission—the U.S. Bayh-Dole Act,[75] including § 203(a), and 28 U.S.C. § 1498[76]—as the statutory basis for such government initiatives.

Through compulsory licensing, a government allows a third party to practice a patented invention without the patent owner's permission and requires that third party to pay a government-specified royalty to the patent owner.[77] In exchange, the government pays adequate renumeration to the patent owner.[78] A compulsory license enables the patent owner to gain compensation for use of the invention through royalties from the third party's use.[79] A compulsory

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75. 35 U.S.C. §§ 200–12.

76. 28 U.S.C. § 1498; Sapna Kumar, *Compulsory Licensing of Patents During Pandemics*, 54 U. CONN. L. REV. 57, 64 (2022).

77. Bagley, *supra* note 26, at 2464–65; David O. Taylor, *Using Reasonable Royalties to Value Patented Technology*, 49 GA. L. REV. 79, 81–91 (2014); Kumar, *supra* note 76, at 57, 59–63; CONG. RSCH. SERV., R43266, COMPULSORY LICENSING OF PATENTED INVENTIONS 3–5 (Jan. 14, 2014), https://www.congress.gov/crs_external_products/R/PDF/R43266/R43266.8.pdf, [https://perma.cc/CG2N-TH3P].

78. CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 127 (2011).

79. Bagley, *supra* note 26, at 2463.

Compulsory licensing is considered a useful tool for countries seeking pharmaceutical drugs for their citizens during public health emergencies. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 31(h), Marrakesh Agreement Establishing the Word Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [https://perma.cc/TRU5-UHDL] [hereinafter TRIPS].

Many developing countries, which have patent entities in place, have sought to reduce high drug prices by making use of compulsory licensing to allow the production or importation of generic medicines without the consent of the patent holder. *See* Anna Niesporek, Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries 14–16 (2005) (M.A. thesis, Linköping University) (Sweden), https://

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licensing scheme is employed in the Bayh-Dole Act, which allows the recipients (such as research institutions, universities, and companies) of grants and certain types of government funding to patent their inventions only if they grant the United States "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States [the] invention throughout the world."[80]

Similar to compulsory licensing through the U.S. Bayh-Dole Act, march-in rights allow a government agency to grant others a patent license for a funded scientific or technological advancement if the funding recipient has not sufficiently developed, commercialized, or achieved practical application of the invention.[81] The goal of march-in rights is to serve as a governance mechanism of government-funded

liu.diva-portal.org/smash/get/diva2:21332/FULLTEXT01.pdf [https://perma.cc/4228-TSG7]; Yousuf Vawda, *Compulsory Licensing and Government Use: Challenges and Opportunities*, *in* ACCESS TO MEDICINES AND VACCINES: IMPLEMENTING FLEXIBILITIES UNDER INTELLECTUAL PROPERTY LAW 73, 73 (2022).

Compulsory licensing is an opportunity for recourse, but it has been known to have no meaningful impact on low- and middle-income countries. *See* Bagley, *supra* note 26, at 2465, 2467, 2489–92. Pharmaceutical companies do not lower their prices enough in low- and middle-income countries or the Global South, where there is high-income inequality. *Id.* Such companies tend to focus on maximizing profits by setting a price unaffordable for most people in need, even with the presence of compulsory licensing. *Id.* Because wealthy persons in low- and middle-income countries or the Global South are expected to purchase the originator pharmaceutical company's products, compulsory licensing does not have meaningful impact. *Id.*

Problems are highly likely in the future unless measures are in place to mitigate or entirely prevent harms caused by overextending patent grants beyond their social bargain. *See* Jessica C. Lai, *Open Source Licensing for Biotechnology: Safeguarding the Social Contract of Patent Law?*, *in* RECHT UND GESELLSCHAFT 217–25 (Mariela Maidana-Eletti & Carly Toepke eds., 2014).

80. 35 U.S.C. § 202(c)(4).

81. *Id.* § 203(a).

research.[82] It aims to distribute the fruits of the research to the public so as to alleviate health or safety needs.[83]

Moreover, the government has patent use rights, through 28 U.S.C. § 1498, that allow for use or manufacture of a patented invention without a license. But unlike march-in rights, patent use rights are at a cost instead of being free, meaning the government must pay the patent owner reasonable compensation for such use and manufacture.[84] In effect, 28 U.S.C. § 1498 operates as a public restriction on private ownership of scientific and technological advancements and moves the patented invention into the public sphere.

In each of these situations, the paradigmatic feature of a patent—the patent owner's right to exclude—is transformed by the government's interest in public health and welfare. Government policies concerning the use of patented inventions are a form of power over the application and trajectory of scientific and technological advancements. There are, however, other forms of government involvement beyond such statutorily driven mechanisms.

2. Government's Norms Setting

In addition to the government practice of regulating scientific and technological advancements through statutory mechanisms, other government practices can *indirectly* influence private parties and institutions through norms-based governance. Norms, which are effectively unwritten rules that guide behavior, can shape the research environment of institutions, universities, and companies active in biomed, biotech, and pharma research, development, and innovation.

While norms have generally been considered as operating outside of government actions and government-driven regulation,

82. John H. Raubitschek & Norman J. Latker, *Reasonable Pricing - A New Twist for March-in Rights Under the Bayh-Dole Act*, 22 SANTA CLARA HIGH TECH. L.J. 149, 149 (2005); Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 631 (2001).

83. 35 U.S.C. § 203(a).

84. 28 U.S.C. § 1498.

governments can define or dismantle norms among a community.[85] As such, government can shape, initiate, and promulgate a norm that, in turn, can be integrated into the practices of biomed, biotech, and pharma research institutions, universities, and companies.[86]

Government-led norm-setting can occur in many ways. As one example, government can shape norms by cultivating ethically responsible biomedical- and healthcare-related *advancements*. Government can set biomed, biotech, and pharma research guidelines,[87] organize interdisciplinary gatherings to discuss bioethical issues and regulation of emerging technologies,[88] and provide recommendations.[89] In doing so, government can initiate consensus around biomed, biotech, and pharma research norms and further help to promulgate them. As a second example, government can initiate a norm around the *release* of new biomed, biotech, and pharma research and development, such as sharing of publicly funded genomics databases or biomedical data, thereby altering the behaviors of

85. Albert C. Lin, *Herding Cats: Governing Distributed Innovation*, 96 N.C. L. REV. 945, 981 (2018).

86. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. L. REV. 77, 146 (1999).

87. NAT'L INSTS. HEALTH, OFF. OF INTRAMURAL RSCH., GUIDELINES AND POLICIES FOR THE CONDUCT OF RESEARCH IN THE INTRAMURAL RESEARCH PROGRAM AT NIH 40 (8th ed. 2023), https://oir.nih.gov/system/files/media/file/2025-01/guidelines-conduct_research.pdf [https://perma.cc/T9BD-EDJR].

88. *Bioethics Programs: May - July 2025*, YALE INTERDISCIPLINARY CTR. FOR BIOETHICS 25, https://bioethics.yale.edu/sites/default/files/files/2025%20Summer%20Program%20Brochure.pdf [https://perma.cc/G8XT-QNA9] (discussing an interdisciplinary "foundations in bioethics" course); Lori Bruce, *Fostering Ethical Deliberation Through Interdisciplinary Policy Forums*, YALE INTERDISCIPLINARY CTR. FOR BIOETHICS (2021), https://bioethics.yale.edu/programs/international-policy-forum [https://perma.cc/FT2U-G2WL] ("The Forum intends to foster collaboration, community, and education to promote increased ethical deliberation related to health policy. These policies may be institutional or governmental, as both forms of policy have a substantial impact on patients and the community.").

89. Jonathan Montgomery, *Bioethics as a Governance Practice*, 24 HEALTH CARE ANALYSIS 3, 4–6 (2016); David B. Resnik, *Bioethics*, NAT'L INST. HEALTH: NAT'L INST. ENV'T HEALTH SCIS., https://www.niehs.nih.gov/research/resources/bioethics [https://perma.cc/3N2Q-E66Y] (last visited Apr. 5, 2025).

researchers.[90] A third and final example is that government can promulgate a norm of ethically responsible biomed, biotech, and pharma *research* among scientists, technologists, and institutions—as evidenced by the National Science Foundation's funding and broader impact statement, which considers the ethical, legal, and societal impact of its supported research.[91]

In sum, norms initiated by government and its policies can lead research institutions, universities, and companies to participate in ethically responsible innovation. There are a variety of circumstances where norms arise, and while they may not be as transparent as government-driven licensing through statutes, they present a circumstance under which government can impact the scientific and technological advancements and have an indirect impact on the research environment for their patenting and eventual licensing.

3. Anticipating Objections and Providing Responses

Having described the avenues by which government can shape biomed, biotech, and pharma innovation, this Article addresses a potential objection: that government having a more active role—such as through compulsory licensing or norms setting—may chill incentives for valuable biomed, biotech, and pharma research, impacting the innovation trajectory of patented inventions. Detractors may argue government's role in biomed, biotech, and pharma innovation can impair commercialization and reduce upfront

90. *See* Jorge L. Contreras, *Genomic Data Sharing and Intellectual Property*, *in* GENOMIC DATA SHARING: CASE STUDIES, CHALLENGES, AND OPPORTUNITIES FOR PRECISION MEDICINE 189, 189–201 (Jennifer McCormick & Jyotishman Pathak eds., 2023); *Framework for Responsible Sharing of Genomic and Health-Related Data*, GLOB. ALLIANCE FOR GENOMICS & HEALTH, https://www.ga4gh.org/framework/ [https://perma.cc/M47U-TFXS] (last visited Apr. 23, 2025); *cf.* F. Marijn Stok, Emely de Vet, Denise T.D. de Ridder & John B.F. de Wit, *The Potential of Peer Social Norms to Shape Food Intake in Adolescents and Young Adults: A Systematic Review of Effects and Moderators*, 10 HEALTH PSYCH. REV. 326, 326 (2016) (noting "significant associations" between "peer social norms" and young people's "food intake").

91. NAT. SCI. BD., NATIONAL SCIENCE FOUNDATION'S MERIT REVIEW CRITERIA: REVIEW AND REVISIONS 11–42 (2011) https://www.nsf.gov/nsb/publications/2011/meritreviewcriteria.pdf [https://perma.cc/AAB5-PW47].

incentives and investments into their research and development.[92] By contrast, allowing biomed, biotech, and pharma research institutions, universities, and companies flexibility to respond to scientific and technological advancements would promote exploration and unleash the potential for optimal innovation trajectories.

Such objectors may express a preference for private ordering, an alternative to government involvement that deals with interactions and agreements between private parties. This is the subject of Part IV. Limits on government involvement create an opportunity for private ordering—such as through patent licensing—that can supplement government-driven initiatives by promoting more equitable sharing than with compulsory licenses and ethically-responsible innovation with norms setting.[93]

It bears emphasizing, however, that government-driven roles in equitable sharing of biomed, biotech, and pharma innovation comprise an approach that contradicts private ordering, which focuses on extralegal forums and where parties agree on how to regulate themselves.[94] Private ordering emphasizes agreements among private parties driven by their commercial interests in hopes of operating more efficiently than government by using market mechanisms.[95]

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92. STEVE OLSON & STEPHEN MERRILL, COMM. ON MEASURING ECON. & OTHER RETURNS ON FED. RSCH. INV., NAT'L RSCH. COUNCIL, MEASURING THE IMPACTS OF FEDERAL INVESTMENTS IN RESEARCH: A WORKSHOP SUMMARY 31–33 (2011); John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, 29 PAT. & INNOVATION REV. 285, 321 (2016).

93. Merges, *supra* note 70, at 295; Robert P. Merges, *Patents, Validity Challenges, and Private Ordering: A New Dispensation for the Easy-Challenge Era*, 23 NEV. L.J. 263, 263 (2023); Séverine Dusollier, *Sharing Access to Intellectual Property through Private Ordering*, 82 CHI.-KENT L. REV. 1391, 1392–94 (2007); Reto M. Hilty, *IP and Private Ordering*, *in* THE OXFORD HANDBOOK OF INTELLECTUAL PROPERTY LAW 898, 898–90 (Rochelle Dreyfuss & Justine Pila eds., 2017).

94. Schwarcz, *supra* note 66, at 391–93; Katz, *supra* note 66, at 1745.

95. Jorge L. Contreras, *From Private Ordering to Public Law: The Role of Standards Development Organizations*, 30 HARV. J.L. & TECH. 211, 215 (2017); Merges, *supra* note 70, at 295; Merges, *supra* note 93, at 263; Hilty, *supra* note 93, at 898–91.

B. *Private Ordering*

Private markets play several important roles within the modern innovation landscape of biomed, biotech, and pharma patents. These market-driven transactions concerning such patents hold significant benefits. Specifically, by harnessing the powerful incentives of market participants, these transactions can help to lower information, coordination, and other transaction costs.[96] The advancement of science and technology presents opportunities and limitations for patent licensing in the innovation marketplace.

1. *Opportunities for Licensing*

Foremost, private licensing transactions are more efficient than formal governmental policymaking because they do not require consensus among multiple stakeholders or time for policymaking to occur.[97] Instead, patent licensing requires the commitment of only a single entity—the patent owner, which, as the developer of the biomed, biotech, or pharma scientific or technological advancement, is in the best position to anticipate licensing opportunities or receive of a licensing inbound interest.[98]

Private ordering-based contracts in the form of patent licensing can, for example, apply a patent owner's technology to a new field or product line or integrate a patented feature into something beneficial to the licensee.[99] For example, in one view, patent licensing might seem more stable and predictable than reliance on a compulsory licensing

96. Robert P. Merges, *Patents, Validity Challenges, and Private Ordering: A New Dispensation for the Easy-Challenge Era*, 23 NEV. L.J. 263, 302–03 nn. 112–13 (2023).

97. *See* Yong F. S. Wang, Arijit Mukherjee & Chenhang Zeng, *Does Technology Licensing Matter for Privatization?*, 22 J. PUB. ECON. THEORY 1462, 1471–72 (2020) (describing a simulation that finds greater efficiency in private transactions); Theodore A. Khoury, Erin G. Pleggenkuhle-Miles & Jorge Walter, *Experiential Learning, Bargaining Power, and Exclusivity in Bioscience Licensing Transactions*, 45 J. MGMT. 1193, 1193 (2019).

98. Mark A. Lemley & Robin Feldman, *Patent Licensing, Technology Transfer, and Innovation*, 106 AM. ECON. R. 188, 188–90 (2016); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663–65 (1996).

99. Merges, *supra* note 70, at 306.

scheme.[100] In another view, patent licenses can increase competitiveness in an industry whereas government-driven norm setting would promote communal processes that inhibit competitive responses such as developing improvements to others' innovations.[101]

2. Limitations with Licensing

Patent licensing can also serve as a tool to limit potentially controversial uses of biomed, biotech, and pharma scientific and technological advancements as they enter the marketplace. The controversial ethical and social concerns about such advancements raise bioethics issues and accompanying novel licensing issues and questions: Must an organization employing a controversial biomed, biotech, and pharma innovation consider bioethics quandaries before it attempts commercialization? If so, then from whom, or in what ways, should it seek bioethical guidance on its licensing terms? What shape would the licensing agreements and deals take? How would the terms of the license limit revenues that it generates for the patent owner?

These are emerging problems and questions with licensing of bioethically questionable patented inventions. For example, CRISPR technology has been found to alter the health, behavior, and appearance of life forms.[102] As another example, germline applications can alter patterns of biological inheritance such that engineered genes

100. Bagley, *supra* note 26, at 2465; Jorge L. Contreras, *Global Rate Setting: A Solution for Standard-Essential Patents?*, 94 WASH. L. REV. 701, 701 (2019).

101. Yafit Lev-Aretz & Katherine J. Strandburg, *Privacy Regulation and Innovation Policy*, 22 YALE J.L. & TECH. 256, 256–57 (2020); Yafit Lev-Aretz & Katherine J. Strandburg, *Regulation and Innovation: Approaching Market Failure from Both Sides*, 38 YALE J. REGUL. 1, 2 (2020).

102. Daria Kim, Reto Hilty, Elisabeth Hofmeister, Peter R. Slowinski & Miriam Steinhart, *CRISPR/Cas Technology and Innovation: Mapping Patent Law Issues* 2 (Max Planck Inst. for Innovation & Competition Research Paper No. 22-06, 2022) (Germany), https://ssrn.com/abstract=4106075 [https://perma.cc/9GWQ-PHPK (staff-uploaded)]; Yoona Lee, *Balancing Innovation and Ethics: A CRISPR Approach to Patent Law*, COLUM. UNDERGRADUATE L. REV. (Oct. 7, 2024) https://www.culawreview.org/journal/balancing-innovation-and-ethics-a-crispr-approach-to-patent-law?rq=Yoona%20Lee [https://perma.cc/Z5G9-TCEM]; Jacob S. Sherkow, *Patent Protection for CRISPR: An ELSI Review*, 4 J.L. & BIOSCIENCES 565, 565–66 (2017); Jacob S. Sherkow, *CRISPR, Patents, and the Public Health*, 90 YALE J. BIOLOGY & MED. 667, 667 (2017).

can always be passed along to future generations.[103] Yet another example is the ability to knock out a human gene while introducing another gene and cause resistance to certain diseases—which, absent limitations on the license, presents uses and potential abuses by downstream licensees.[104]

Understanding these questions and the link between bioethics and patent licensing would entail a detailed analysis of the implications of emerging biomed, biotech, and pharma scientific and technological advancements. There may need to be limitations to their licensing while determining if their uses and applications are for what society deems to be desirable. Biomed, biotech, and pharma industries are particularly sensitive to how bioethics can address the marketplace of transactions entailing the patented invention.[105] Patented inventions

103. Tetsuya Ishil & Iñigo de Miguel Beriain, *Safety of Germline Genome Editing for Genetically Related "Future" Children as Perceived by Parents*, 2 CRISPER J. 370, 370 (2019); Guido De Wert et al., *Responsible Innovation in Human Germline Gene Editing*, 26 EUR. J. HUM. GENETICS 450, 450 (2018) (Austria); Tim Lewens, *Blurring the Germline: Genome Editing and Transgenerational Epigenetic Inheritance*, 34 BIOETHICS 7, 7–9 (2019); Rebecca A. Lea & Kathy K. Niakan, *Human Germline Genome Editing*, 8 NAT. CELL BIOLOGY 1479, 1479 (2019).

104. Gan Sha et al., *Genome Editing of a Rice CDP-DAG Synthase Confers Multipathogen Resistance*, 618 NATURE 1017, 1018–20 (2023) (describing the findings on an experiment to use genome editing on rice plants); Nikhil Deep Kolanu, *CRISPR–Cas9 Gene Editing: Curing Genetic Diseases by Inherited Modifications*, 11 GLOB. MED. GENETICS 113, 113 (2024); Virginia M. G. Borrelli, Vittoria Brambilla, Peter Rogowsky, Adriano Marocco & Allesandra Lanubile, *The Enhancement of Plant Disease Resistance Using CRISPR/Cas9 Technology*, FRONTIERS PLANT SCI., Aug. 2018, at 1; Tianxian Li et al., *Cas9 Therapeutics: Progress and Prospects*, SIGNAL TRANSDUCTION TARGETED THERAPY, Jan. 2023, at 1–3; *CRISPR in Agriculture: Improving Disease Resistance*, INNOVATIVE GENOMICS INST., https://innovativegenomics.org/crisprpedia/crispr-in-agriculture/ [https://perma.cc/KV3Z-FCYB] (last visited Apr. 5, 2025).

105. Andrew Slutsky, *The Ethics of Patents in the Medical Field: An Analysis of Drug and Pharmaceutical Patents and Their Enforcement in the U.S. and France*, 23 CHI.-KENT J. INTELL. PROP. 71, 75 (2024); KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING 22 (2021), https://crsreports.congress.gov/product/pdf/R/R46679 [https://perma.cc/XD2C-ARR6 (staff-uploaded)]; Anja von der Ropp & Tony Taubman, *Bioethics and Patent Law: The Case of*

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in this domain may need to be subjected to bioethical analysis, which may dampen patent law's impact on private licensing.[106] Such licensing limitations may become part of a larger discussion on patent licensing of patented biomed, biotech, and pharma inventions—a concern that licensing transactions are occurring in an efficient and ethically sound way. This is discussed in Part IV of this Article.

3. Anticipating Objections and Providing Responses

Given the potential for worrisome applications of emerging biomed, biotech, and pharma scientific and technological advancements, restrictions on licensing usage can provide an opportunity to evaluate these applications' safety, efficacy, and risks (alongside ethical limitations in a particular country's laws). Such considerations are important issues for both bioethics and innovation.

What does it matter for the laws and policies of patents and innovation? It may seem odd to suggest that the U.S. Congress has any role in private licensing agreements and transactions. However, Congress can establish the legal framework that governs how patent owners (as licensors) and private firms (as licensees) can negotiate licenses and set restrictions.[107] Should Congress reevaluate the background rules of patent law or develop limits to patent licensing, thereby adjusting the shadow that patent licensing casts on biomed, biotech, and pharma innovation? Should licensing terms have restrictions and limits to shift the balance between patent owners and

Myriad, WORLD INTELL. PROP. MAG. (Aug. 1, 2006), https://www.wipo.int/web/wipo-magazine/articles/bioethics-and-patent-law-the-case-of-myriad-35334 [https://perma.cc/YJB9-6V5L]; Sara Parker-Lue, Michael Santoro & Greg Koski, *The Ethics and Economics of Pharmaceutical Pricing*, 55 ANN. R. PHARMACOLOGY & TOXICOLOGY 191, 192 (2015).

106. Phil Ciciora, *Use Patent Law to Curb Unethical Human Genome Editing*, CARL R. WOESE INST. FOR GENOMIC BIOLOGY (Aug. 29, 2021), https://www.igb.illinois.edu/article/use-patent-law-curb-unethical-human-genome-editing [https://perma.cc/DJA6-E98M]; *see* von der Ropp & Taubman, *supra* note 105; Anja von der Ropp & Tony Taubman, *Bioethics and Patent Law: The Relaxin Case*, WIPO MAG. (Apr. 14, 2006), https://www.wipo.int/en/web/wipo-magazine/articles/bioethics-and-patent-law-the-relaxin-case-3520 [https://perma.cc/TA7T-XMMB].

107. Rai & Eisenberg, *supra* note 53, at 305; Jorge L. Contreras, *A Market Reliance Theory for FRAND Commitments and Other Patent Pledges*, UTAH L. REV. 479, 497 (2015).

wide dissemination of patented inventions? These unaddressed questions suggest there is an incomplete and imperfect understanding of how patent licensing in the marketplace interacts with bioethics. Furthermore, without significant historical evidence of patent licensing transaction terms, a concern arises that bioethics-driven policy might be directed by less-than-clear evidence.[108]

The lack of answers to these questions and the general lack of evidence concerning licensing terms in this domain highlights the need for further research on how bioethics shapes (or should shape) private agreements over patent licenses with biomed, biotech, and pharma innovation. As for objections centered on lack of clarity, this Article argues for the development of policy recommendations for how the law might evolve to better address the changes wrought by ongoing biomed, biotech, and pharma innovation and its intersection with bioethics.

IV. TOWARD BIOETHICAL LICENSING

A widely accepted objective of the U.S. patent system is to form an economics-driven regime that utilizes exclusive legal rights and market mechanisms to promote the development and distribution of scientific and technological advancements.[109] As such, the patent

108. Shozi, *supra* note 3; Timothy Caulfield, Robert M. Cook-Deegan, F. Scott Kieff & John P. Walsh, *Evidence and Anecdotes: An Analysis of Human Gene Patenting*, 24 NATURAL BIOTECH. 1091, 1091 (2006); Thambisetty, *supra* note 16, at 263; *Demand Letters and Consumer Protection: Examining Deceptive Practices by Patent Assertion Entities: Hearing Before the S. Comm. on Com., Sci., & Transp., Subcomm. on Consumer Prot., Prod. Safety & Ins.*, 113th Cong. 11 (2013) (statement of Adam Mossoff, Professor of Law, George Mason Univ. Sch. of L.); Adam Mossoff, *The History of Patent Licensing and Secondary Markets in Patents: An Antidote to False Rhetoric*, GEORGE MASON UNIV.: CTR. FOR INTELL. PROP. X INNOVATION POL'Y (Dec. 9, 2013), https://cip2.gmu.edu/2013/12/09/the-history-of-patent-licensing-and-secondary-markets-in-patents-an-antidote-to-false-rhetoric [https://perma.cc/W4FE-VLEU].

109. While a comprehensive evaluation of potential responses to attaining patents on ethically questionable biomed, biotech, and pharma inventions could extend the earlier Part of this Article and lies beyond the scope of this Part, a high-level description and normative assessment of ethical guidelines for the potential sharing of the use of the patented biomedical inventions through patent licensing reveals several general insights.

system is less centrally concerned with ethical principles such as access, distribution, equity, pricing, and safety.[110] Although patent licensing introduces the potential for controversial uses of biomed, biotech, and pharma scientific and technological advancements as they enter the marketplace, the focus traditionally, and still overwhelmingly, concerns maximizing economic output for the licensor. While patent licensing is a powerful mechanism for controlling the uses and distribution of patented scientific and technological advancements, it exhibits significant bioethics deficiencies. Patent licensing's apparent neglect of bioethics is even more striking given the debates accompanying emerging biomed, biotech, and pharma innovations.

While the promotion of market-driven motivations and overall innovation outputs dominate conversations about patent licensing of biomed, biotech, and pharma inventions, the emergence of ethical licensing terms exhibits curious new normative considerations. In this context, "ethical licensing terms" refers to conditions placed by licensors (the patent holders) onto licenses based on ethical views about how the patented invention should be used; the terms aim to discourage ethically contentious uses while promoting socially responsible applications.[111] Patent holders can impose their ethical stance when they publicly announce their intention to impose restrictions and include specific clauses in licensing agreements.[112] While ethical terms in patent license agreements are contractual provisions, their impact can extend beyond the immediate parties, especially for platform technologies that form the basis for subsequent research and development.[113] What results is a balancing act: Ethical terms in patent license agreements attempt to balance patent monetization with incorporation of social responsibility and ethical considerations into the invention's use.

Building on the prior analysis of the challenges to integrating bioethics into patent law, including patent licensing, this Part

110. Lydia O'Sullivan, Edelweiss Aldasoro, Áine O'Brien, Maeve Nolan, Cliona McGovern & Áine Carroll, *Ethical Values and Principles to Guide the Fair Allocation of Resources in Response to a Pandemic: A Rapid Systematic Review*, BMC MED. ETHICS 23:70 (July 7, 2022), at 11.

111. *See generally* McMahon, *supra* note 9.

112. Shozi, *supra* note 3.

113. *Id.*

describes how bioethics can be internalized as integral components of patent licensing agreements for patented biomed, biotech, and pharma inventions. This Part argues that innovators' use of ethical restrictions in patent license agreements should more generally integrate bioethical considerations. In doing so, this Part builds upon prior proposals to recommend a more robust consideration of bioethical interactions with patents, such as with issues, normative implications, and proposals related to their licensing.[114] Consistent with this Article's recommendation to integrate bioethics with patent law, this Part argues for the virtues of integrating ethical terms into patent license agreements, before turning to the potential of its practical implementation in countries with religious bodies of law.[115]

A. Ethical Considerations in Patent Licensing

Ethical considerations are a new dimension of the legal literature on the licensing of biomed, biotech, and pharma innovations with ethical licenses. Ethical terms in patent licensing can serve as an important tool to ensure biomed, biotech, and pharma inventions are not utilized in ways that are contrary to the patent owner's interests,[116] problematic or unaligned with broader public interests,[117] or against the ethical principles of legal systems with religious bodies of law.[118] The rise of ethical licensing terms in patent licensing provides a basis for investigating the balance between bioethics and patent law—specifically, the use of an invention after an inventor has attained patent protection.

By prohibiting uses the patent holder deems unethical, ethical considerations in patent licensing serve to function as a tool of private

114. *See supra* Part IV.B.

115. *See supra* Part II.B., *infra* Part IV.B.

116. Shozi, *supra* note 3; McMahon, *supra* note 9, at 20; Guerrini et al., *supra* note 9, at 23.

117. McMahon, *supra* note 9, at 19; *see* Guerrini et al., *supra* note 9, at 23.

118. Kathy Liddell & Simon Ravenscroft, *Morality, Religion, and Patents*, *in* PATENTS ON LIFE: RELIGIOUS, MORAL, AND SOCIAL JUSTICE ASPECTS OF BIOTECHNOLOGY AND INTELLECTUAL PROPERTY 25, 25–37 (Thomas C. Berg, Roman Cholij & Simon Ravenscroft eds., 2019); McMahon, *supra* note 9, at 17; Guerrini et al., *supra* note 9, at 22.

governance.[119] In effect, when formal policymaking and government-driven efforts fail to halt controversial or worrisome effects of emerging biomed, biotech, and pharma advancements, ethical terms in patent licensing can create the desired stoppage.

There are many considerations a licensor must keep in mind when contemplating usage of ethical considerations. One is that ethical terms in patent licensing allow the patent owner to play the role of ethicist, which may weaken the value of the license. Additionally, patent owners face a trade-off: considering the beneficial healthcare limitations of their patents and making difficult assessments of their impact on entire societies.[120] Each of these trade-offs is imprecise and involves the patent owner evaluating patent licensing in less-than-profit-maximizing ways. Other considerations include the potential to generate goodwill among licensing parties and collaboration towards ethical causes with societal impact, as well as the potential for inconsistent or even mutually defeating license terms.[121]

B. Normative Implications of Bioethics in Patent Licensing

Having explored patents earlier in this Part and their licensing for biomed, biotech, and pharma innovations and explored ethical considerations in patent licensing, this Article now turns to normative implications of ethical terms in patent licensing. There is particular concern with ethical terms in patent licenses due to the controversial

119. Ole Hansen, Clement Salung Petersen & Vibe Garf Ulfbeck, *Private Governance and the Potential of Private Law*, 28 EUR. REV. PRIV. L. 333, 374 (2020).

120. *Research Ethics and Patents*, NAT'L RSCH. ETHICS COMM. (Jan. 2, 2016), https://www.forskningsetikk.no/en/resources/the-research-ethics-library/the-researchsocietal-relationship/research-ethics-and-patents/ [https://perma.cc/82WH-XKTZ]; Thambisetty, *supra* note 16, at 265; Aisling McMahon, *Covid-19, Patents & Healthcare: The Need for a (Bio)ethics Space Within Patent Law*, BMJ MED. ETHICS BLOG (Apr. 16, 2020), https://blogs.bmj.com/medical-ethics/2020/04/16/covid-19-patents-healthcare-the-need-for-a-bioethics-space-within-patent-law/ [https://perma.cc/JZ47-KR74].

121. Jeremy Sugarman et al., *Ethical Considerations in the Manufacture, Sale, and Distribution of Genome Editing Reagents*, 18 AM. J. BIOETHICS 3, 4 (2018); McMahon, *supra* note 9, at 3; Guerrini et al., *supra* note 9, at 23.

and worrisome effects from the licensing of biomed, biotech, and pharma patented inventions.[122]

One of the most striking and undertheorized aspects of patent law is the interplay between patents, their licensing, and the complex ethical issues in biomed, biotech, and pharma innovation.[123] While patent law and innovation scholarship has fruitfully explored the normative considerations of the patent eligibility doctrine for *patentability* of biomed, biotech, and pharma inventions, this Part explores the undertheorized contribution of bioethics to patent *licensing*. It argues that bioethics *can* and *should* inform the debate of patent licensing. This normative viewpoint serves two purposes: (1) to build upon and diverge from the influential economic justifications of patents, and (2) to provide a more nuanced account of ethical contributions to exclusive legal rights.

The consideration of bioethical principles in patent licensing extends beyond the traditional economic focuses of patent law and licensing: scientific and technological innovation. The current patent system, including patent licensing based on private ordering, is configured to allocate resources for inventions based only on market value; a focus on bioethics would correct for access and distribution disparities in the market.[124] Because a system constructed to maximize economic value will not always consider bioethics, correctives and considerations in patent licensing are necessary to promote balance in society.

Though the adoption of bioethics as a normative lens for ethical terms in patent licensing should be immensely important to biomed, biotech, and pharma innovations, it has nevertheless been

122. Jordan Paradise & Lori Andrews, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 404 (2005); Aisling McMahon, *Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance Tools in Healthcare*, 47 J. MED. ETHICS 142, 146 (2020); Thambisetty, *supra* note 16, at 248.

123. Arti K. Rai, *Bioethics and Patent Law: The Relaxin Case*, WIPO MAG., Apr. 2006, at 8.

124. David S. Abrams, Ufuk Akcigit & Jillian Grennan, *Patent Value and Citations: Creative Destruction or Strategic Disruption?*, 36 RAND J. ECON. 16, 16 (2018); Nir Eyal et al., *How Bioethicists Can Help Reduce Global Health Inequities*, HASTINGS CTR. REP., Mar. 25, 2014, at 9, 9.

understudied. By exploring the significance of bioethics—as well as its divergence from the classical normative aims of patents and their licensing championed by countries with patent systems—a society can more appropriately match ethical values with the use and distribution of biomed, biotech, and pharma innovations.[125] Additionally, by considering the implications for patents in countries with religious bodies of law, a bioethics-motivated, normative lens contributes to a more theologically sound and aligned framework for innovation law and policy in those countries.[126] This Article provides both such analyses.

The question of how bioethics should fit with patent licensing is important, for bioethics possesses new normative potential for innovation and society. Although new to some in the patent and licensing law communities, bioethics has raised theoretical and practical issues with bioethicists, biomedical researchers, philosophers, physicians, scholars, and theologians for centuries.[127] Indeed, patent law and licensing law fit uncomfortably in bioethics—a discipline that seeks to establish standards of conduct, analyze the basis of judgment about what is right and wrong, and address moral choices with unique missions, norms, and principles.[128] Such considerations give rise to significant new normative and policy questions regarding behaviors and values of patent licensing—a field, similar to patent law in general, that is predominantly driven by

125. Renée C. Fox & Judith P. Swazey, *Examining American Bioethics: Its Problems and Prospects*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 361, 364 (2005).

126. *See infra* Part IV.D.

127. Duncan Wilson, *What Can History Do for Bioethics?*, 27 BIOETHICS 215, 215 (2013); Jennifer Flynn, *Theory and Bioethics,* STANFORD ENCYC. OF PHIL. (Nov. 25, 2020), https://plato.stanford.edu/entries/theory-bioethics/ [https://perma.cc/HB7C-UP2F]; Daniel Adler & Randi Zlotnik Shaul, *Disciplining Bioethics: Towards a Standard of Methodological Rigor in Bioethics Research*, 19 ACCOUNTABILITY RSCH. 187, 190 (2012); Alicia Ouellette, *Shaping Parental Authority Over Children's Bodies*, 85 IND. L.J. 955, 957 (2010).

128. Wendy Lipworth & Renata Axler, *Towards a Bioethics of Innovation*, 42 J. MED. ETHICS 445, 445 (2016); Mosby, *supra* note 45, at 566–68; Paradise & Andrews, *supra* note 122, at 127.

economics and, with the exception of the patent eligibility doctrine,[129] has rarely considered such ethical choices.[130] To address the normative implications with bioethics for patent licensing, this Article examines the potential bioethics basis of patent policy and its implications for licensing.

First, integrating broad bioethical principles with patent licensing's traditional emphasis on economic utility and welfare, this Part advances a novel normative theory for internalizing bioethical foundations within patent licensing: "bioethical licensing." Patent law's treatment of patent eligibility has attracted significant attention to *ordre public* exclusions,[131] through which TRIPS-member countries bar the patenting of inventions that offend their society's morality.[132] More recently, additional scholarship has explored some underappreciated, broader bioethics principles, including access and transparency, prior informed consent, equitable-benefit sharing, and pluralism with value systems in the field of patent licensing.[133]

Historically, relations between patent law and bioethics were characterized by a focus on the *ordre public* exception of patent

129. Charles Duan, *Examining Patent Eligibility*, 97 ST. JOHN'S L. REV. 47, 50–53 (2023); Charles Duan, *Gene Patents, Drug Prices, and Scientific Research: Unexpected Effects of Recently Proposed Patent Eligibility Legislation*, 24 MARQ. INTELL. PROP. L. REV. 139, 143 (2020); Paul Gugliuzza, *The Procedure of Patent Eligibility*, 97 TEX. L. REV. 571, 581 (2019); J. Jonas Anderson, *Applying Patent-Eligible Subject Matter Restrictions*, 17 VAND. J. ENT. & TECH. L. 267, 270 (2015).

130. Robert P. Merges, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 253 (1994).

131. GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, EUR. PAT. OFF. 769–70 (2024), https://www.epo.org/en/legal/guidelines-epc/2024/g_ii_4_1.html [https://perma.cc/F9UK-MSNX]; Duncan Matthews, Timo Minssen & Ana Nordberg, *Balancing Innovation, 'Ordre Public' and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*, 29 EUR. J. HEALTH L. 562, 576 (2022).

132. Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 27(2), Marrakesh Agreement Establishing the Word Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [https://perma.cc/TRU5-UHDL]; *Patents: Ordre Public and Morality*, in RESOURCE BOOK ON TRIPS AND DEVELOPMENT 375, 375 (Jan. 18, 2010).

133. INTELLECTUAL PROPERTY AND BIOETHICS – AN OVERVIEW, *supra* note 27, at 3; Paradise & Andrews, *supra* note 122, at 404.

eligibility and generally mutual exclusion, based in the perceived normative conflicts between ethics and exclusive legal rights on patents.[134] This historical viewpoint has been reflected in patent licensing as well. However, the contents, norms, and practices of *bioethics*—a largely peripheral concern for patent licensing—should be further integrated into the commercial narrative of patent licensing's treatment of biomed, biotech, and pharma with bioethical licensing.

Second and relatedly, bioethical licensing as a normative theory of internalization shows bioethics *should* be applied to a patent holder and licensor entity. Bioethics suggests that patent licensing should exclude and control the fruits of a granted patent or treat certain biomedical-related patents differently from other scientific and technological innovations.[135] Throughout history, patent systems have allowed patent licensing to keep innovations in the control of patent owners and afford patent owners the right to exclude others from practicing the invention.[136] However, when the Doha Declaration on the Agreement on TRIPS and Public Health[137] ("Doha Declaration") was adopted in 2001, it enhanced the flexibility of governments to make exceptions to patent holders' rights and emphasized the need for a broader effort to address public health issues via bioethical considerations.[138] The Doha Declaration helped countries that could not make their own medicines import pharmaceuticals made under compulsory licensing and addressed access to lifesaving medicines in

134. Haochen Sun, *Patent Responsibility*, 17 STAN. J. C.R. & C.L. 321, 338 (2021); *The Ethics of Patenting DNA: A Discussion Paper*, NUFFIELD COUNCIL ON BIOETHICS 34 (2002), https://cdn.nuffieldbioethics.org/wp-content/uploads/The-ethics-of-patenting-DNA-a-discussion-paper.pdf [https://perma.cc/G282-4NTS].

135. Paradise & Andrews, *supra* note 122, at 407.

136. ROBERT MERGES, AMERICAN PATENT LAW: A BUSINESS AND ECONOMIC HISTORY 1 (2023); Petra Moser, *Patent Laws and Innovation: Evidence from Economic History*, 27 J. ECON. PERSPECTIVES 23, 40 (2013).

137. World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002) [hereinafter Doha Declaration].

138. Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health*, QUAKER U.N. OFF. (Switz.) (Feb. 9, 2022), https://quno.org/sites/default/files/resources/Compulsory-Licensing.pdf [https://perma.cc/M7M9-U72P].

poor countries.[139] More recently, "march-in-rights" on biomed, biotech, and pharma patents on inventions—created using taxpayer funds—have increasingly required U.S. patent holders to license federally funded patented inventions.[140]

Third, incorporating bioethical licensing provides a normative lens into the discussion about ethical terms in patent license agreements. It enhances the contemporary biomed, biotech, and pharma innovation landscapes in societies with patent systems where societal views of bioethics are more paramount than free market economies.[141] This inquiry is complicated: Countries with varying levels of bioethical considerations can interact with their patent systems in different ways, and a patent system is far from monolithic. Patent systems encompass a range of national patent laws, *ordre public* exceptions, and statutes and regulations; varying degrees of primacy of bioethics in a society can manifest in different ways.[142] The tensions that arise between economic justifications and bioethical considerations of patents—twin trends over biomed, biotech, and pharma innovations—vary among such countries. These tensions are ripe for assessment, which can help bring new trade-offs and vantage points to the forefront rather than leaving them unaddressed.

In sum, bioethical licensing promotes a socially responsible framework for considering bioethics principles as paramount to ethical license terms in patent licensing. Here, patent licensing can learn from bioethics to promote a more robust vision of using patent licensing to align the use and distribution of biomed, biotech, and

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139. Sarah M. Dickhut, *Ethical and Procedural Barriers to Accessing Critical Medicines in Least Developed Countries: A Look at TRIPS and the Doha Documents*, 20 J. GENDER, RACE & JUST. 207, 223 (2016).

140. Lisa Larrimore Ouellette, *The Feasibility of Using Bayh-Dole March-In Rights to Lower Drug Prices: An Update* 3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 32217, 2024), https://www.nber.org/papers/w32217 [https://perma.cc/3Z35-7XCG]; JOHN R. THOMAS, CONG. RSCH. SERV., R44597, MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 1 (2016), https://sgp.fas.org/crs/misc/R44597.pdf [https://perma.cc/NV9D-MZYM].

141. Mosby, *supra* note 45, at 568.

142. Margo A. Bagley, *A Global Controversy: The Role of Morality in Biotechnology Patent Law* (Univ. of Va., Legal Working Paper No. 57, 2007), https://law.bepress.com/cgi/viewcontent.cgi?article=1097&context=uvalwps [https://perma.cc/HF5F-JAG5].

pharma innovation with social values. Ethical terms in patent licensing represent a promising approach to aligning innovation with societal values and promoting responsible scientific and technological development in biomed, biotech, and pharma innovation.

However, to ensure they effectively contribute to socially responsible innovation without unduly restricting access or progress, the implementation of ethical license terms also requires careful consideration of various ethical, legal, and practical factors and trade-offs. Challenges and considerations include defining ethical standards, [143] addressing enforcement issues, [144] remedying the potential for misuse, [145] and balancing innovation and access. [146] A comprehensive evaluation of such challenges and considerations is the ambit of future research that lies beyond the scope of this Part. However, a review of the normative assessment of the bioethics of patent licensing is particularly necessary because of the centrality of practical implementation and the significance of legal systems with religious bodies of law.

C. Normative Assessments with Bioethics of Patent Licensing

A socially responsible framework for incorporating bioethics into patent licensing should assess potential legal costs. This is particularly evident for legal systems with religious bodies of law, where such a framework is closer to application. While a comprehensive evaluation of all costs lies beyond the scope of this Part, a high-level assessment reveals general trade-offs. In doing so, the integration of bioethical principles into the consideration of ethical terms for patent licensing can enhance alignment with societal values, though trade-offs may ultimately lessen or undermine bioethics benefits if left unaddressed.

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143. Determining what constitutes an "ethical" use of a technology can be subjective and may vary across different cultures and contexts.

144. Ensuring compliance with ethical licensing terms can be challenging, especially on a global scale.

145. There are concerns that ethical licensing could be used as a tool for market control or to stifle competition under the guise of ethical consideration.

146. While ethical licensing can promote responsible innovation, overly restrictive terms might inadvertently hinder broader technological progress.

1. Constraints

This Part aims to normatively evaluate the internalization of bioethical principles. To make usage clearer here, "ethics" (in the context of ethical terms in patent licensing) refers to the ethical goals and guidance of new and emerging biomed, biotech, and pharma scientific and technological advancements. Legal agreements formed between parties using patented science or technology can utilize ethical constraints—ones that embody the ethical practices under which such licensing agreements are framed.

Admittedly, if innovators lack an appreciation for the importance of ethics in the first place, then ethical constraints may not have a clear, direct effect upon patent licensing. Ethical constraints can, however, shape the circumstances of *industries*, thereby serving as a parameter that changes the scope of ethical terms in patent licensing negotiation and agreements. This makes ethical constraints especially important for the biomed, biotech, and pharma industries—sectors on the cusp of precipitating great societal change.

If understood properly, ethical constraints can also become innovative policy levers that affect commercialization costs of biomed, biotech, and pharma innovations. In doing so, ethical constraints can also impact the business models of these industries and the characteristics of the biotechnology, drugs, genes, and molecules they create.

Like other mechanisms that shape innovator behaviors—such as laws, norms, markets, and technology itself—ethical constraints (when included as ethical terms in patent license agreements) can shape and modify behaviors in an industry. As such, ethical constraints reflect underlying mechanisms that impact bioethical licensing.

2. Costs

By virtue of the exclusive legal rights they create, patents force some parties in an industry to acquire a license. The biomed, biotech, and pharma industries fall in this category by virtue of being known to have "patent thickets" (that is, dense webs of overlapping rights). These are often navigated through licensing agreements. Any time an innovative research and development entity, manufacturer, or distributor needs a license to produce or scale up a kernel or key

feature of a biomed, biotech, and pharma innovation, a licensing negotiation (or a cross-licensing scenario) can usually be contemplated. The time and money associated with the licensing process, as well as fees and attorneys' costs, generate transaction costs for adding ethical terms to patent license agreements. Furthermore, problems associated with patent thickets and royalty-stacking can exacerbate licensing costs for bioethical licensing, similar to other industries.

Though it is possible to characterize a bioethical license's *nature*, a full accounting of its *costs* is nearly impossible to develop.[147] Already, scholars have attempted to quantify licensing measures through surveys; advancing such work further would require data specific to the biomed, biotech, and pharma industries. A potential survey could inquire about associated costs: the discovery of the licensing opportunity, the magnitude and number of negotiations, and the characteristics of licensing proposals. A study of the transaction costs would allow for learning about the impact of ethical terms in patent license agreements in biomed, biotech, and pharma industries, and also quantify the cost of entry into the business of bioethical licensing.

The potential and propensity of bioethical licensing create friction to the commercialization of biomed, biotech, and pharma innovations and affects the amount of transaction costs. While such transaction costs present trade-offs in most legal systems, their consideration is part of legal systems with religious bodies of law, which give primacy to ethical considerations.

D. Bioethical Alignment in Legal Systems with Religious Bodies of Law

Having laid a normative foundation for fitting bioethics principles within patent license ethical terms, this Article explores another extension of bioethics: Legal systems with religious bodies of law should wield a similar alignment with their *societal* values to ethically advance biomed, biotech, and pharma innovations.[148] The potential for

147. Mark A. Lemley, Erik Oliver & Kent Richardson, *The Patent Enforcement Iceberg*, 97 TEX. L. REV. 801, 801–03 (2019).

148. A bioethics perspective can invite new considerations, such as from a religious viewpoint, to the policy debates about patent law. By introducing

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bioethical licensing—or the consideration of bioethics during negotiations of patent license ethical terms—in legal systems with religious bodies of law can wield significant alignment, compliance, and diffusion of biomed, biotech, and pharma innovations.

To this point, this Part has discussed the complicated legal environment for emerging biomed, biotech, and pharma patents as ethical constraints and transaction costs. Though patent owners and innovators in these scientific and technological spaces find themselves facing licensing considerations that constrain their businesses, these licensing terms can also present opportunities—particularly in countries with legal systems comprised of religious law.[149] As such, bioethical licensing is a new step forward in how innovations are

religion as a viable normative framework for justifying and evaluating patents, one aim can be to align the interests of the individual and the public. A bioethics perspective that draws upon a religious lens offers several benefits, including preserving human dignity and autonomy, guarding against negative externalities, and utilizing stewardship and responsibility for the good individually and collectively.

A religious or faith-based perspective (which is not a monolith, but can be defined as the sacred, spiritual, or unseen-mystical) can aim to shift normative views of patents with protections, objectives, ethical dilemmas, and new issues. Much of the contemporary patent law scholarly debate has been about assessing a theoretical lens for an end goal—incentives to induce innovation, access and equity, and empower previously disempowered groups in society. Religion integrates these multiple aims with a human-centered approach directed toward human flourishing. The goal of integrating bioethics perspectives into patent law is to not to reject other central insights; it is to urge scholars to integrate them and recognize their relationships from a different and undertheorized perspective.

Doing so does not ignore that religion includes some underlying moral values that may not align with others and that the U.S. legal system is considered secular. Rather, it addresses potential criticism by explaining that the U.S. legal system (including its patent law) (1) has some historical basis in religion and alignment with many religions; (2) is already a form of moral regulation that expresses something about the nation's morals—even if superficially disconnected from religion; and (3) is open to considering new scholarly lenses as an aim of a pluralistic society. The integration of bioethics perspectives into patent law brings to the attention of patent scholars the important ways that religion frames a balanced approach to exclusive legal rights in society.

149. Liddell & Ravenscroft, *supra* note 118, at 25–37.

licensed—a better way to work within the marketplace for emerging biomed, biotech, and pharma patents—that becomes even more valuable when aligned with a country's ethical expectations. In fact, some of these innovations that push ethical boundaries in licensing might create more value in countries with religious bodies of law when deemed to be compatible or compliant with religious principles.[150]

In societies with religious bodies of law, bioethical licensing *increases* ethical consideration of religious principles. Paradoxically, bioethical licensing can improve perception, reliance, and self-regulation of industry and the spillover effects of their biomed, biotech, and pharma innovations. In countries with religious bodies of law where ethical considerations are paramount (such as Islamic legal systems or those where canon law is influential), biomed, biotech, and pharma organizations could increase revenue by adapting their patent licensing practices to these countries' environments.[151] Furthermore, in such countries, religious law should treat biomedical-related innovations differently than other innovations to advance broader innovation policy objectives—including promotion of research, technology transfer, and economic development—and align with theological interpretations.[152]

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150. Thomas C. Berg, *Life Patents, Religion, and Justice: A Summary of Themes*, *in* PATENTS ON LIFE: RELIGIOUS, MORAL, AND SOCIAL JUSTICE ASPECTS OF BIOTECHNOLOGY AND INTELLECTUAL PROPERTY 209, 301 (2019); Tabrez Y. Ebrahim, *Intellectual Property Through a Non-Western Lens: Patents in Islamic Law*, 37 GA. ST. U. L. REV. 789, 797 (2021).

151. Such a proposal for private industry in countries with legal systems based on religious law (such as Islamic law) may gain prominence to the degree their bioethical views and values differ from Western legal systems. For example, on the one hand, Muslim countries' internalized constraints have vanished to the extent that economic interests typical of Western legal systems now inform general rules of patentability and patent licensing. On the other hand, internalized constraints could see a resurgence in Muslim countries in special carveouts that specifically follow Islamic rulings.

152. Traditionally, policymakers relied on government-driven licensing (such as through compulsory licensing) and government norm-setting due to the influence of government's central role in such societies. Unlike Western countries—where tensions are more pronounced between government's desire to improve access and pricing of biomed, biotech, and pharma innovations and industry's desire to have mostly unfettered licensing through

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Countries with religious bodies of law can create powerful incentives for industry to consider bioethical licensing. As a result, innovation in patent licensing practices will flourish in such countries. In the context of biomed, biotech, and pharma scientific and technological advancements in these countries, licensing innovations could include new types of terms within patent licensing agreements—or even entirely new kinds of bioethical licensing agreements. An innovation in licensing might arise on the licensor or licensee side of the licensing negotiation, or it may come from a combination of the two sides.[153]

These innovations in bioethical licensing would be rooted in the religious body of law's goals in several ways. Foremost, bioethical licensing in countries with religious bodies of law can seek more flexibility in ethical characteristics, opening up new features that previous patent licenses did not allow for or follow. For example, bioethical licenses may have societal ethical functions that previous licensing agreements did not need to consider.[154] A patent license may have typical terms—such as certain fields of use, upfront fees, royalty rates, and specific geographies—but perhaps a bigger hurdle could be the ethical innovation to secure compliance within a religious body of law.[155] Sometimes, the bioethical license may simply need to increase

private ordering—in countries with religious body of law, the government's rule-setting (based on bioethical religious principles) will supersede industry's goals.

153. Robin Feldman & Mark A. Lemley, *Do Patent Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 138–39 (2015); Mark A. Lemley & Robin Feldman, *Patent Licensing, Technology Transfer, & Innovation*, 106 AM. ECON. REV. 188, 190 (2016).

154. James F. Pierce, *Ethical Considerations in Intellectual Property Licensing*, FRANKLIN PIERCE L. CTR. 5 (1999), https://ipmall.law.unh.edu/sites/default/files/hosted_resources/ALI_Presentations/ALI_1999/Pierce_law_1999_Ethical%20Considerations%20vin%20Intellectual%20Property%20Licensing.pdf [https://perma.cc/3RVB-C8CW]; McMahon, *supra* note 9, at 12.

155. Kirsten Leute, AUTM TECHNOLOGY TRANSFER PRACTICE MANUAL: ANATOMY OF A LICENSE AGREEMENT, AUTM (2010), https://inqbationlab.northwestern.edu/resources/autm_ttp_v4_anatomy-of-a-license.pdf [https://perma.cc/6BGA-R7UR]; Kasdan, *supra* note 68, at 6; *Essential Guide to Patent License Agreements*, RUNSENSIBLE BLOG (June 17, 2024), https://www.runsensible.com/blog/patent-license-agreement/ [https://perma.cc/

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ethical alignment with certain parameters. Other times, the bioethical license might change the payment structure—such as shifting from the licensee to the licensor—to payment from the licensee to the government with the aim of distributing the benefits of the innovation throughout society. Understanding innovative bioethical licensing and its implications in countries with religious bodies of law will allow policymakers to improve consideration of socially responsible innovation, coordination of public and private efforts, and recognition of public welfare.

V. Conclusion

Though the patent system was designed to benefit society by encouraging the invention of new products and services, modern biomed, biotech, and pharma innovations often fail to address bioethical considerations when obtaining or licensing patents. This needs to change.

Bioethics principles should be integrated with innovation. This integration of bioethics should not be limited to the patent eligibility doctrinal debate, which merely asks what may enter the patent system. Rather, bioethics integration must tackle the way markets *react* to patents: By utilizing licensing clauses, patent holders can discourage ethically contentious uses of patented biomedical-related technologies.

The machinations of private ethical licensing clauses are largely outside the clear view of policymakers, thereby making it difficult to base policy on evidence. However, the internalization of bioethics principles in ethical terms of patent licensing agreements—which this Article refers to as "bioethical licensing"—would add a new dimension to legal scholarship and policymaking on the regulation and licensing of patented biomed, biotech, and pharma inventions.

Understanding the link between bioethics and the emergence of ethical terms in patent licensing suggests policymakers should pay attention to what transpires in private licensing negotiations and transactions. This attention to the private market is important for

WSG6-TVSV]; Michael Kasdan, *Intellectual Property Licensing*, *in* THE OXFORD HANDBOOK OF INTELLECTUAL PROPERTY LAW 652, 654–59.

answering numerous questions. Are biomed, biotech, and pharma patents being utilized in a bioethical manner? Are access, pricing, or quality-of-human-life concerns emerging that need to be addressed? Is legislative reform necessary to address market failures by adjusting the negotiating balance between patent owners and downstream innovators? The tensions that play out between bioethics and patent licensing in biomed, biotech, and pharma innovation is far too important to be ignored.

Reforms of the patent system, including patent licensing, should remain aware of the complex dynamics between bioethics principles and ethics terms in patent license agreements, the latter of which is often formed in negotiations between licensors and licensees. Effective patent and biomedical innovation policies will not be possible without a holistic consideration of this link and interplay. This Article argues that the patent system should bolster its consideration of broader bioethical principles during patent licensing of biomed, biotech, and pharma innovations.

Furthermore, for countries with legal systems comprising religious bodies of law, this Article advises policymakers to consider the bioethical impact of ethical terms in patent license agreements. By doing so, this Article seeks to cultivate discussion that the significant alignment, compliance, and diffusion of biomed, biotech, and pharma innovations can (beyond creating a competitive advantage for innovators) orient innovation with a country's ethical expectations to drive policy reforms.