WHAT'S THE USE OF THE PATENT STRICT UTILITY REQUIREMENT?

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The current interpretation of patent utility prohibits patents on inventions that do not have a known use to members of the public such as consumers or patients. This interpretation is not required by the Constitution or the Patent Act nor was it the interpretation for most of U.S. history. The current interpretation came about in the 1960s, most famously in Brenner v. Manson *(1966). Even then, it was not until* In re Fisher *(2005) that the Federal Circuit definitively closed the door to patentability for inventions lacking known utility to end users. This Article makes two contributions. First, the Article shows that the current interpretation of utility arose from an unproven, and probably incorrect, assumption of unduly high transaction costs of licensing patents on inventions of unknown end-user utility (research intermediaries). The Article examines the history of patent utility in the U.S. and shows that the current interpretation of utility arose not from empirical study or the recognition of significant problems arising under the historic standard. Rather, the Patent Office, and then the Supreme Court, seem to have simply assumed that transaction costs would be high, that thickets and hold-ups would result, and that downstream research would be significantly impeded. This assumption may have been reasonable at the time (although several dissenting judges disagreed), but it seems increasingly unsupported given history and experience showing how adept markets are at clearing IP rights in crowded fields using mechanisms such as patent pools, contractual requirements of fair reasonable and nondiscriminatory licensing (FRAND licensing), and copyright clearance mechanisms such as the American Society of Composers, Authors, and Publishers (ASCAP) and the Copyright Clearance Center (CCC). The second contribution of the Article shows that the thicket/hold-up problem is likely to be less severe for research intermediaries than for other types of inventions, such as high-tech inventions. Thickets and hold-ups are most likely to occur in vertical supply chains with many patent owners, or in cases in which many inventions must be combined to produce a single product. This is the well-known "double marginalization," or "successive monopoly," problem. The Article shows that given the economic realities of research and development (R&D) involving inventions with unknown end-user utility, the double marginalization problem is less likely to occur because the economic incentives around patented research intermediaries will result in joint-venture approaches rather than successive monopolization.*

INTRODUCTION

In 1966, the Supreme Court modified the utility requirement in patent law to disallow patents on "research intermediaries"[1]—inventions of unknown end-user utility—and other products or processes for which the applicant did not know the ultimate use at the time of filing.[2] Before this point, if one invented, say, a novel and nonobvious chemical compound that one thought

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1. This Article uses the term "research intermediaries" to describe these inventions of new molecules and processes of unknown real-world use. This Article uses this term because these inventions may be of interest and value to researchers in academia and industry even if the strict utility standard declares them not to be of use.

2. Brenner v. Manson, 383 U.S. 519, 531–35 (1966).

might be useful for treating a disease, the compound was patentable.[3] In the past, the uncertainty as to whether the compound would be useful for therapeutic or commercial purposes did not matter for purposes of the utility requirement.[4] It was enough that the compound was of interest to researchers.[5] It was left to the market to determine how useful and how valuable these research intermediaries were.[6]

In the 1966 decision *Brenner v. Manson*, the Supreme Court rejected usefulness to researchers as a way to meet the patent utility requirement and held that only inventions that have uses valuable to end users—consumers and patients—meet the utility requirement.[7] The Court in *Manson* evinced concern that allowing patents on research intermediaries would negatively affect downstream innovation.[8] The Court worried that allowing patents on inventions without a known end use would block the crucial next step of determining that end use.[9] The Court presumed that holders of patents on inventions of unknown utility would fail to license use of the invention by others so that end uses could be discovered and delivered to the market.[10] This presumption is problematic in two ways. First, it is contrary to the pecuniary interest of a patent holder to block the development of the invention into a usable, and thus profitable, good or service for consumers.[11] Second, because under the Court's opinion that only a single use for an invention need be known at the time of filing, the Court's decision allows patent rights in cases in which many ultimate uses have yet to be discovered.[12] In other words, the Court has not prevented patent owners from blocking downstream experimentation and discovery of new uses of inventions.[13] Instead, the Court has only prevented such control in situations in which there is no known end use for the invention.[14] So long as a patentee knows at least one end use for her invention

3. *See, e.g.*, *In re* Nelson, 280 F.2d 172, 180–81 (C.C.P.A. 1960) (reversing the rejection of a patent on a process yielding chemical intermediates "useful to chemists doing research on steroids" despite the lack of evidence that any of the produced steroids were themselves "useful").

4. *See, e.g.*, Tech. Tape Corp. v. Minn. Mining & Mfg. Co., 143 F. Supp. 429, 437 (S.D.N.Y. 1956) ("Lack of commercial success per se does not establish lack of utility."), *aff'd*, 247 F.2d 343 (2d Cir. 1957).

5. *See, e.g.*, *In re* Nelson, 280 F.2d at 180–81 (reversing the rejection of a patent on a process yielding chemical intermediates "useful to chemists doing research on steroids" despite the lack of evidence that any of the produced steroids were themselves "useful").

6. *Id.*

7. *Manson*, 383 U.S. at 531–35.

8. *Id.* at 534.

9. *Id.* The Court was concerned about scientific development—"[u]ntil the process claim has been reduced to production of a product shown to be useful . . . [i]t may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public." *Id.* (footnote omitted).

10. *See id.* at 534–35.

11. *See infra* Section IV.C.

12. *See infra* notes 266–67 and accompanying text.

13. *See infra* Section IV.B.

14. *See infra* Section IV.B.

at the time of filing, that person is granted a patent and can control all further research and downstream use of the patented invention.[15] If the ability to block others from discovering new uses of an invention was something to avoid, the Court's decision in *Manson* left a gaping opening for doing so.

The arguments that the Court made to support this concern are not limited to research intermediaries, however. The concerns the Court expressed apply equally well to many fields in which multiple inputs are needed to create final products.[16] In fact, circumstances are much more severe in terms of patent thickets in other fields.[17] But the Court also made a mistake. It didn't realize that one problem that affects other vertical-supply-chain scenarios does not affect patents on research intermediaries because blocking patents solve the problem.[18] It is well known that successive monopolies in a vertical supply chain decrease social welfare more than a single monopolist.[19] Fear of upstream monopolists charging supracompetitive prices for their inputs seems to also have motivated the Court in its decision to make research intermediaries unpatentable.[20] After all, adding a monopoly upstream to a compound or method of making a compound in addition to the patent on a particular drug regime seems to create the "successive monopoly" problem, also known as the "double marginalization" problem.[21] What those worried about double marginalization regarding patents on research intermediaries miss, however, is that once an end use for a research intermediary is discovered, the research intermediary will not be produced and sold merely as an input into the drug-making process.[22] Rather, once a researcher has discovered a use for the research intermediary and patented that use, we have a classic "blocking patents" scenario.[23] Assuming that the research intermediary patent is still in effect, the only way to produce and sell the drug is for licensing to occur between the owner of the research intermediary patent and the patent on the method of use.[24] At this point, the two patent owners are not participants in a vertical supply chain.[25] Rather, they are embarking on a joint venture that requires both of their assets (permission under each patent).[26] The resulting product of the joint venture will be the use of the research intermediary

15. *See Manson*, 383 U.S. at 519.
16. *See infra* Section II.A.
17. *See infra* Parts II & III.
18. *See infra* notes 261–79 and accompanying text.
19. *See generally* Patrick Rey & Jean Tirole, *The Logic of Vertical Restraints*, 76 AM. ECON. REV. 921, 934–37 (1986) (comparing the welfare outcomes of different types of vertical restraints).
20. *See infra* note 67 and accompanying text.
21. *See infra* note 315 and accompanying text.
22. *See infra* notes 261–79 and accompanying text.
23. *See infra* notes 261–79 and accompanying text.
24. *See infra* notes 261–79 and accompanying text.
25. *See infra* Section IV.D.
26. *See infra* Section IV.D.

according to the patented method of use.[27] Thus, only one product will be sold, and the question will be how to divide up the profits from this venture.[28] The owner of the research intermediary patent will not treat its patent as a separate input for which profits should be maximized nor will the owner of the method-of-use patent treat its patent as a separate asset on which profits should be maximized.[29] Instead, they will view the value as the method of use of the research intermediary—and will price accordingly.[30] Assuming that there are no close substitutes for the research intermediary used in the patented way, there will be market power over the product so used.[31] Thus, the patent owners will charge a single monopoly price, as is common for patent owners with market power.[32] Importantly, however, they will not charge two successive monopoly prices, so society will be better off because no double marginalization will occur.[33] This means that research intermediary patents are actually less likely to cause double marginalization problems than are other types of products that are regularly patented and used in vertical supply chains.

Patent law contains several requirements that limit the scope of the patent right. These limits serve the overarching goal of patent law—to provide the optimal level of incentive to invent and distribute useful products and processes.[34] The optimal level of incentive is the amount that encourages invention and distribution that would not otherwise be made but does not grant exclusive rights beyond those needed to incentivize the invention and distribution activity.[35] Put more simply, it is socially optimal to provide incentives in the form of exclusive patent rights only in cases in which non-patent incentives are inadequate, and such patent rights should be no greater than what is needed to promote the desired amount of invention and distribution.[36] In determining optimal patent rights, a policymaker must balance the value to society of the additional invention being promoted against the cost to society of the exclusive right, which may allow monopoly pricing and

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27. *See infra* Section IV.D.
28. *See infra* Section IV.D.
29. *See infra* Section IV.D.
30. *See infra* Section IV.D.
31. *See infra* Section IV.D.
32. *See infra* Section IV.D.
33. *See infra* Section IV.D.
34. *See* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 9 (1966); *see generally* WILLIAM M. LANDES & RICHARD POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW (2003).
35. *See* Mark Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 131 (2004) ("[T]he incentive theory of intellectual property dictates that intellectual property rights should be granted only where necessary.").
36. *See* David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMPLE L. REV. 181, 182–84 (2009) (describing and collecting literature about the incentive function of patent law and restrictions on patent scope); Paul Klemperer, *How Broad Should the Scope of Patent Protection Be?*, 21 RAND J. ECON. 113, 114–15 (1990) (discussing optimal scope of patents to provide profit to inventors while minimizing societal loss).

deterrence of competition during the term of the patent. Thus, many of the requirements in patent law can be thought of as "policy levers" that can be adjusted to optimize patent scope in service of the goal of social welfare.[37]

Policymakers in patent law include members of the legislative, executive, and judicial branches. Congress writes and amends the patent statute.[38] The Patent and Trademark Office (PTO) administers it and makes certain, limited interpretations of it.[39] The PTO also sets certain priorities as to administration of the patent system.[40] The judiciary interprets the patent statute, as well as any constitutional issues that arise regarding patent law.[41] In the case of patent law, while Congress does make significant amendments to the statute from time to time, Congress has been content to leave development and adjustment of the law to the courts. Even when Congress made significant changes to patent law, as in the 1952 Patent Act and the 2011 America Invents Act, Congress either explicitly or implicitly endorsed the judicially developed law in areas not subject to the amendments.[42] Consequently, some areas of patent law provide scant direction in the statutory text but have a rich history of judicial development. Section 101 of the Patent Act is one such example.[43] Section 101 has been interpreted as containing both the novelty requirement and the utility requirement for patentability.[44] This section of the statute has remained effectively unchanged since the first Patent Act of 1790.[45]

This Article focuses on the utility requirement in patent law. This Article asks whether the judicial evolution of the utility requirement from a nugatory requirement to the current strict standard that disallows patenting of numerous inventions of admitted value is good policy. Part I of the Article traces the history of the utility requirement—which was mostly toothless until around 1967—and arguably only became the current strict version in 2005. Part II examines the differential application of the utility requirement in less predictable fields, like chemistry and life science as compared to mechanical and high-tech fields. Part III examines the arguments for a strict utility requirement, noting that the arguments in favor of the requirement are based largely on assumptions about transaction costs and the functionality of markets regarding rights in "upstream" inputs. Part IV examines arguments against the strict utility requirement, including utility's overlap with other restrictions in patent law such

37. *See generally* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

38. *See* 35 U.S.C. §§ 1–390.

39. *See id.* § 1.

40. *See* U.S. PAT. & TRADEMARK OFF., 2022–2026 STRATEGIC PLAN (2023).

41. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 527 (1966).

42. *See, e.g.*, Tanner Mort, *Abstract Ideas*, 56 IDAHO L. REV. 384, 386–89 (2021).

43. *See* 38 U.S.C. § 101.

44. *See* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 12 (1966).

45. The 1952 Patent Act changed the word "art" in Section 101 to "process" but both legislative history and subsequent judicial decisions treated this as a mere updating to modern language usage rather than a substantive change.

as novelty, nonobviousness, enablement, and written description. This Part seeks to isolate the benefits of the strict utility requirement that are not already provided for by these other patent law requirements, as well as its costs. Part V considers alternatives to the strict utility requirement to better serve the incentive, sharing, and commercialization goals of the patent system.

I. HISTORY OF THE UTILITY REQUIREMENT

The power to grant patents and copyrights is one of the few explicit powers granted to Congress in the Constitution. Article I, Section 8, Clause 8 (the Intellectual Property or IP Clause) states: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[46] As befitting a constitutional grant of power, the language is relatively broad, leaving Congress the flexibility to decide how best to shape patent and copyright law. The IP Clause does have certain limitations on Congress's power, however. The Supreme Court has held that the promotion of "Science" and "useful Arts"[47] via the IP Clause is limited to granting exclusive rights to "Authors" and "Inventors"[48] for limited times[49] and that such exclusive rights can apply only to "Writings" (copyrightable material) and "Discoveries" (patentable matter).[50] The Court has rejected attempts to grant rights under the IP Clause for other types of subject matter, such as trademarks.[51] The "useful Arts" provision of the IP Clause has been interpreted as a limitation on subject matter,[52] but the Supreme Court has not grounded a specific utility requirement in the Constitution.

Nor is a strict utility requirement clearly required by the Patent Act. Section 101 of the Act states, in full: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the

46. U.S. CONST. art. I, § 8, cl. 8.

47. The Constitution's use of "Science" in the IP Clause encompasses the liberal sciences generally, including writings and all the categories that fall under modern copyright law. *See* Golan v. Holder, 565 U.S. 302, 318 (2012). The Constitution's use of "useful Arts" likewise encompasses all the types of invention covered by modern patent law. Kara W. Swanson, *Beyond the Progress of the Useful Arts: The Inventor as Useful Citizen*, 60 HOUS. L. REV. 363, 365 (2022).

48. This restriction bars Congress from granting monopolies to favored constituents, which was the practice in England before the Statute of Anne. For a history of the use of letters patents for patronage and other purposes, see Craig W. Dallon, *The Problem with Congress and Copyright Law: Forgetting the Past and Ignoring the Public Interest*, 44 SANTA CLARA L. REV. 365, 389–404 (2004).

49. Thus, no perpetual monopolies are allowed for copyrights or patents. *See Golan*, 565 U.S. at 319.

50. Sean O'Connor, *The Overlooked French Influence on the Intellectual Property Clause*, 82 U. CHI. L. REV. 733, 735 (2015).

51. *See, e.g.*, *In re* Trade-Mark Cases, 100 U.S. 82 (1879).

52. *See generally* Swanson, *supra* note 47, at 368.

conditions and requirements of this title."[53] Courts have focused on the single word "useful" as the basis for the utility requirement.[54] For a long time, this term was interpreted as almost nugatory.[55]

A prominent example of this early interpretation of the utility requirement occurred in the 1817 case *Lowell v. Lewis*, in which Justice Story, riding circuit, held that meeting the patent-law requirement of utility demanded only that an invention "not be frivolous or injurious to the well-being, good policy, or sound morals of society."[56] The issue in the case was whether the pump for which plaintiff held a patent needed to be more useful than pumps in existence before its invention.[57] Justice Story demurred, stating that "[t]he word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral."[58] Beyond these limited exceptions, Justice Story reasoned that decisions about the utility of a patented invention should be left to the marketplace: "[I]f the invention steers wide of these [other patent restrictions], whether it be more or less useful is a circumstance very material to the interests of the patentee, but of no importance to the public. If it be not extensively useful, it will silently sink into contempt and disregard."[59]

In the years after *Lowell v. Lewis*, courts generally treated as meeting the utility requirement any patent application that taught how to make and use an invention.[60] This included products and processes useful to end users as well as research tools, research intermediaries, and chemical molecules whose "real world" uses were not yet known.[61] Thus, whether a new product was a mechanical device, a new chemical compound, or a process affecting some

53. 35 U.S.C. § 101.

54. *See, e.g.*, Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817).

55. *See, e.g.*, *id.*

56. *Id.* at 1019.

57. *Id.*

58. *Id.* Justice Story went on to say, "For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention." *Id.* Interestingly, this was the one part of the decision that did have the effect of making the utility requirement stricter. Based on what was arguably dicta in the opinion, courts for most of the nineteenth and twentieth centuries rejected patent applications for devices that could have "immoral" uses, such as coin returns, Schultz v. Holtz, 82 F. 448 (N.D. Cal. 1897) or toy-horse racetracks that could be used for gambling. Nat'l Automatic Device Co. v. Lloyd, 40 F. 89, 90 (C.C.N.D. Ill. 1889). It was not until 1999 that the Federal Circuit definitively rejected any requirement of "moral utility." *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999) (rejecting the notion that the possibility of an invention being used for immoral purposes fails the utility requirement).

59. *Lowell*, 15 F. Cas. at 1019.

60. *See, e.g.*, *In re* Nelson, 280 F.2d 172, 181 (C.C.P.A. 1960). The Court of Customs and Patent Appeals held that the chemical molecules at issue met the utility requirement even without knowledge of their usefulness to their practical application in the commercial or medical fields, stating, "[t]he new [chemical molecules] being *useful to research chemists* for the purposes disclosed by appellants, are clearly useful to society and their invention contributes to the progress of an art which is of great potential usefulness to mankind. They are new steroids which in known ways can be made into other steroids, thus furthering the development of this useful art." *Id.*

61. *Id.*

physical change, courts allowed patentability merely because the invention could be useful to researchers interested in what the effects of the invention might be.[62] It was not a bar to patentability that the ultimate use of a product or process was unknown or that the only current use of the compound would be in research laboratories.[63]

In the 1950s, however, the U.S. Patent Office broke with its long-held position on the patenting of research intermediaries and adopted a requirement that ultimate uses of a compound must be known to meet the utility requirement.[64] The Patent Office's position conflicted with long-standing law, including from the United States Court of Customs and Patent Appeals (CCPA), the predecessor to the Federal Circuit. In 1960, in the case of *In re Nelson*, the CCPA addressed and rejected the Patent Office's position on strict utility.[65] The CCPA, considering whether steroid research intermediaries were patentable under the utility requirement, held that intermediaries are practically useful to scientists involved in steroid research and therefore patentable; to find otherwise would be against the policy of encouraging dissemination of information.[66]

Chief Judge Worley's dissent in *In re Nelson* included the assertion that granting patents for research intermediaries would give the applicant "an unearned monopoly on a substantial area in the field . . . and prevent others, unless they are willing to risk infringement, from also experimenting in a field which should remain open to all."[67] The dissent made reference to the "quid pro quo" of patent law—granting a limited monopoly in exchange for adequate disclosure of an invention—and claimed that an overly broad utility requirement produces patents that fall short of adequate disclosure.[68]

That same year, in January 1960, Andrew Manson applied for a patent on a chemical process that produced a steroid of unknown utility.[69] The process had previously been patented to produce a homologue adjacent to the steroid claimed in the Manson application to have "tumor-inhibiting effects" when

62. *See, e.g.*, *id.*

63. *See* Brenner v. Manson, 383 U.S. 519, 540 (1966) (Harlan, J., concurring in part) ("[U]sefulness was typically regarded as inherent during a long and prolific period of chemical research and development in this country.").

64. *See, e.g.*, *In re* Kirk, 376 F.2d 936, 952–53 (C.C.P.A. 1967) (Rich, J., dissenting) ("[I]n the past very little attention was paid to the requirement for a disclosure of utility in chemical cases. Some chemical patents were issued with specifications reciting the barest suggestions of uses for the new compounds claimed, or even without uses being stated at all. It was generally the position of the Patent Office that a chemical compound could be regarded as an intermediate substance useful in the preparation of other compounds, since it was regarded as obvious that any organic compound could be so used." (quoting Robert C. Watson, Comm'r of Pats., U.S. Pat. Off., Remarks to the Division of Medicinal Chemistry of the American Chemical Society (Sept. 19, 1956))).

65. *In re* Nelson, 280 F.2d at 172, *overruled by In re* Kirk, 376 F.2d 936.

66. *See id.* at 180–81.

67. *Id.* at 190 (Worley, J., dissenting).

68. *See id.* (emphasis omitted).

69. Brenner v. Manson, 383 U.S. 519, 521 (1966).

administered to mice.[70] The Manson application was denied by an examiner at the Patent Office, and the rejection was affirmed by the Board of Patent Appeals for "failure 'to disclose any utility for' the chemical compound produced by the process."[71] The utility requirement, according to the examiner, was not met by demonstrating that a homologue adjacent to the chemical produced by the claimed process provided the requisite utility.[72] The CCPA reversed the decision of the Board of Patent Appeals, holding that "a process which operates as disclosed to produce a known product is [itself] 'useful' within the meaning of § 101."[73]

The Supreme Court accepted certiorari in *Brenner v. Manson*[74] and used the case as the vehicle to overturn the long-standing laxity of the utility requirement and to deny patentability to compounds or other research intermediaries whose ultimate use was not known at the time of filing the patent application.[75] The applicant in *Manson* described five potential demonstrations of utility.[76] The first tier, and the most broad, was essentially Justice Story's *Lowell* approach, which the *Manson* Court acknowledged: utility is met where the invention is not "frivolous and insignificant."[77] The Court denied this approach, holding that it either (1) adds nothing to the exercise of defining utility or (2) broadly encompasses all inventions "not positively harmful to society."[78] Neither interpretation of Justice Story's utility, according to the Court, was substantiated by evidence of congressional intent.[79] The second tier, slightly narrower than the first, encompassed processes that "yield[ed] [an] intended product."[80] The third tier included processes that "produce[d] a compound whose potential usefulness is under investigation by serious scientific researchers."[81] The fourth tier was one in which utility could be met by disclosing the utility of an adjacent homologue.[82] None of the above tiers satisfied the Court as to the proper scope of the utility requirement.[83]

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70. *Id.* at 520–22.

71. *Id.* at 521 (quotations omitted).

72. *Id.* at 521–22.

73. *In re* Manson, 333 F.2d 234, 236 (C.C.P.A. 1964), *rev'd sub nom. Manson*, 383 U.S. 519 (1966).

74. *Manson*, 383 U.S. at 519.

75. *Id.* at 528–36.

76. *See id.* at 530–35.

77. *Id.* at 532–33.

78. *Id.* at 533.

79. *See id.* ("Justice Story's language sheds little light on our subject. Narrowly read, it does no more than compel us to decide whether the invention in question is 'frivolous and insignificant' . . . . Read more broadly, so as to allow the patenting of any invention not positively harmful to society, it places such a special meaning on the word 'useful' that we cannot accept it in the absence of evidence that Congress so intended.").

80. *Id.* at 530–31.

81. *Id.* at 531.

82. *Id.*

83. *See id.* at 531–33.

The fifth and most narrow tier discussed by the Court was a requirement of "substantial utility" and "specific benefit exist[ing] in currently available form."[84] The *Manson* Court adopted this interpretation of the utility requirement by considering the purpose of the patent system and implications of the decision.[85] The Court, considering the implication of a loose interpretation of utility, expressed concern for granting a monopoly for a "vast, unknown, and perhaps unknowable area" of scientific development.[86] The Court reasoned that the patent system should encourage disclosure, and the Court partially relied on this pillar of patent law when adopting a stricter utility requirement.[87]

Justice Fortas, for the majority, recognized the potential costs of such a strict utility standard, stating that the "inability to patent a process to some extent discourages disclosure and leads to greater secrecy than would otherwise be the case."[88] Justice Fortas maintained, however, that an inventor who cannot discover a use for the product of his discovered process would nevertheless disclose the invention to those who could help ascertain a "use."[89] Justice Fortas asserted that patenting a product (or process yielding a product) with unknown utility may disincentivize the search for a use for the patented product or process if other researchers faced the patentee's ability to enforce their patent rights over the product or process.[90] The Court held that inventors need to show proof of a (1) specific and (2) substantial benefit (3) in currently available form to satisfy the utility requirement.[91]

In subsequent years, the Federal Circuit followed the Court's decision in *Manson*, notwithstanding minority views on the Federal Circuit urging that only a narrow construction of *Manson*'s holding was appropriate. In *In re Kirk*, the court overruled *In re Nelson* based on the holding in *Manson*, and Judge Rich dissented.[92] Judge Rich provided a sharp counter-viewpoint to the Court in *Manson*.[93] Judge Rich attempted to minimize the scope of the *Manson* decision by pointing out that the applicant included no disclosure of utility.[94] He categorized the *Manson* requirement of "specific, substantial utility which

84. *Id.* at 534–35.

85. *See id.* at 533–36.

86. *Id.* at 534.

87. *See id.* at 533–34.

88. *Id.* at 533.

89. *See id.* at 533–34.

90. *See id.* at 534. ("However, in light of the highly developed art of drafting patent claims so that they disclose as little useful information as possible—while broadening the scope of the claim as widely as possible—the argument based upon the virtue of disclosure must be warily evaluated. . . . [H]ow likely is disclosure of a patented process to spur research by others into the uses to which the product may be put? To the extent that the patentee has power to enforce his patent, there is little incentive for others to undertake a search for uses.").

91. *See id.* at 534–35.

92. *In re* Kirk, 376 F.2d 936, 947–48 (C.C.P.A. 1967) (Rich, J., dissenting).

93. *See id.*

94. *Id.* at 948.

provides specific benefit in currently available form" as dicta because of this distinction.[95] Further, Judge Rich argued that the Court in *Manson* intentionally refrained from commenting on the requirement for non-zero disclosures, specifically where research intermediaries "useful to research workers in their research" are claimed.[96] The dissenting opinion took issue with the circular analysis of § 101 regarding utility, where § 101 is the basis for the matter described to § 112 standards, and then the § 112 description is used as reference for invalidating an application on § 101 grounds.[97]

The *Kirk* dissent essentially suggested that the utility requirement be restored to pre-*Manson*: (1) finding new and non-obvious chemical compounds per se useful under § 101 and (2) conclusively presuming that persons having ordinary skill in the art (PHOSITAs) know how to use claimed compounds within the meaning of § 112.[98] The opinion then listed a number of resulting benefits to the Patent Office, courts, researchers, and public from this approach.[99] The dissent insisted that useless inventions will meet their demise in the marketplace—echoing the opinion of Justice Story in *Lowell v. Lewis*.[100] A lowered standard for utility would meet the quid pro quo expected by patent applications, the dissent posited, because "[t]he only quid pro quo demanded by statute is full disclosure of a new and unobvious invention which is of some use to someone."[101]

In the case of *Nelson v. Bowler*, the CCPA somewhat relaxed its approach to practical utility by focusing on claims of possible utility as a matter of probability or certainty.[102] In its analysis, the *Bowler* court recognized that there is value in

95. *See id.*

96. *Id.* at 956 (emphasis omitted).

97. *See id.* at 954.

98. *See id.* at 957.

99. *Id.* at 957–58 ("(1) rendering the law definite, (2) removing a burden from the examining corps it is not equipped to deal with effectively, (3) reducing appeals, (4) speeding up disclosure with consequent facilitation of research, (5) increasing the incentives to produce and disclose new compounds . . . for experimental purposes which will develop new uses for them, thus advancing the art and advantaging the public, (7) putting an end to the wasting of time and money in concocting uses merely for compliance with Patent Office requirements[,] . . . and (8) stopping the present illegal practice of requiring two inventions to be made before one can be patented—inventions often made by different people working for different employers, one inventing the compound and another discovering the use.").

100. *See id.* at 963–64 ("An invention which meets the first four requirements is a patentable invention. . . . Though patentable, it may or may not be an invention of commercial value; patentability, in legal theory, has nothing to do with commercial value. . . . Not every horse places in a race but those which do make the race very attractive. . . . It is quite possible that what is disclosed either totally lacks or has very little practical or commercial value. But this is how the system operates to promote progress. It produces the dross with the gold. You cannot get cream without producing milk. There is no way to tell ahead of time with any practical degree of accuracy which is going to be which. . . . [I]t is one of the legal beauties of the system that what is given by the people through their government—the patent right—is valued automatically by what is given by the patentee. His patent has value directly related to the value of his invention, as determined in the marketplace." (emphasis omitted)).

101. *Id.* at 955 (emphasis omitted).

102. Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980).

equipping the medical field with "an arsenal of chemicals having known pharmacological activities," and the court stated that practical utility could be shown by adequate proof of such pharmacological activity.[103] This approach opened the door again to patenting research intermediaries in at least some cases to incentivize continued research, depending on the likely certainty of the results of pharmaceutical research.[104] The *Bowler* court did not change the meaning of practical utility ("provid[ing] some immediate benefit to the public") but rather altered the scope of the term "benefit" to include the value of knowledge in every step of research.[105] This approach shifted the focus for utility towards adequate reduction to practice instead of commercial usefulness.[106]

The broadening trajectory of utility in the Federal Circuit was reined in when the court heard *In re Fisher* in 2005. There, the Federal Circuit definitively rejected relaxing the utility requirement as seen in cases like *Bowler*, and the court reaffirmed the Federal Circuit's adherence to the *Manson* approach.[107] The court found that *Fisher*'s utility assertions for an "expressed sequence tag[]," or EST, were "so general as to be meaningless."[108] To satisfy the substantial-utility requirement, the court held that the use asserted by an applicant must provide a "significant and *presently available* benefit to the public."[109] In addition, the court held that the use must be "well-defined and particular."[110]

In *Fisher*, the Federal Circuit endorsed the approach taken by the Patent Office in the Manual of Patent Examining Procedure (MPEP) in declaring that "research tools"—defined as "inventions whose asserted utility requires further research to identify or reasonably confirm"—are unpatentable.[111] The MPEP gives instruction and guidance to patent examiners who determine whether to grant a patent to an applicant.[112] MPEP § 2107 governs the § 101 utility analysis. Section 2107 requires that an examiner first read and determine what exactly an applicant is claiming in their specification.[113] The examiner must then verify

103. *Id.* at 856.

104. *See id.* at 857.

105. *Id.* at 856 ("It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities.").

106. *Id.* at 856–57; *see also* Fujikawa v. Wattanasin, 93 F.3d 1559, 1563 (Fed. Cir. 1996) ("[A]ctual reduction to practice . . . cannot be established absent a showing of practical utility."); Campbell v. Wettstein, 476 F.2d 642, 646–47 (C.C.P.A. 1973) ("[U]nder well-established precedent, evidence establishing substantial utility for *any purpose* is sufficient to show reduction to practice." (emphasis added)).

107. *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

108. *Id.* at 1367, 1370 (emphasis omitted).

109. *Id.* at 1371 (emphasis added).

110. *Id.*

111. *Id.* at 1372 (citation omitted).

112. U.S. DEP'T OF COM., PAT. & TRADEMARK OFF., MANUAL OF PATENT EXAMINING PROCEDURE § 2107(II) (9th ed., rev. July 31, 2022) [hereinafter MPEP].

113. *See id.* § 2107(II)(A).

that the claimed invention is within patentable subject matter.[114] Next, the MPEP states the standard for "well-established utility," which, if readily apparent, prohibits the examiner from rejecting an application for lack of utility.[115] Well-established utility is present where "(i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention . . . and (ii) the utility is specific, substantial, and credible."[116] Citing *Fisher*, the MPEP defines specific and substantial utility as a well-defined and present benefit to the public.[117] The MPEP also gives a number of examples of claimed subject matter that should raise red flags for the examiner:

> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
> (B) A method of treating an *unspecified* disease or condition;
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.[118]

The MPEP contains a section specifically directing examiners to carefully review utilities for therapeutic or pharmacological applications.[119] Section 2107.03 provides that the utility requirement for therapeutic uses may be met where there is a "reasonable correlation between the [pharmacological or other biological] activity and the asserted use."[120] The MPEP then states that statistical certainty is not required, and a reasonable correlation can be shown with as little as "arguments or reasoning."[121]

II. RESEARCH INTERMEDIARIES

Having explored the history of the utility requirement in U.S. law, the question arises: What types of inventions are currently prohibited by the strict utility standard that would not be prohibited under the older utility standard? This Part of the Article explains that the only substantial areas this change in the utility standard affects are chemistry and biology, specifically the creation of

114. *Id.* § 2107(II)(B).
115. *Id.* § 2107(II)(A)(3).
116. *Id.*
117. *Id.* § 2107.01(I).
118. *Id.* § 2107.01(I)(B).
119. *Id.* § 2107.03.
120. *Id.* § 2107.03(I).
121. *Id.*

new molecules and processes for pharmaceutical and industrial use—research intermediaries.

A. Patentability of Most Inventions Is Identical Under Strict or Relaxed Utility

Perhaps surprisingly, the patentability of most types of inventions does not change under either a strict or relaxed utility standard. Mechanical inventions that accomplish any desired function meet the utility standard.[122] This is because utility is not judged in relation to whether the machine works better than prior models, whether it accomplishes some socially desirable function, or whether anyone will want to buy it.[123] So long as a machine does something and meets the other requirements for patentability in the statute, the PTO will grant a patent for the machine.[124] Thus, for example, a machine that has some physiological effect, which is of unknown (or no) therapeutic value, will meet the strict utility requirement because the machine is accomplishing something.[125] Likewise, machines that cause some physical, chemical, energy, or other effect on the physical world, even if the effect is of unknown value, meet the strict utility requirement because they cause some effect in the world.[126]

Likewise, processes for causing physical transformations in the real world generally are held to meet the strict utility requirement, unless the transformation is related to human health, in which case the strict utility requirement is generally held not to have been met.[127] Thus, processes for causing chemical or energy effects that may (or may not) be useful for industrial purposes are generally granted patents, but processes causing chemical effects in the human body generally are not, unless the chemical effect can be shown to have beneficial effects on health.[128]

Novel molecules or chemical or biological processes that are useful in creating other useful molecules can be patented if the real-world utility of the final molecule is known, but they do not meet the strict utility requirement if the real-world use of the final molecule is unknown.[129] On the other hand, if a molecule or process is useful for creating a molecule or result that has known

122. *See id.* § 2107(II)(B)(1).

123. *See id.*

124. *See id.* (stating that if "the claimed invention is [asserted as] useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art," a patent should not be "reject[ed] based on lack of utility").

125. *See id.* § 2107.02(I) (stating that "regardless of the category of invention that is claimed (e.g., product or process), an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112; additional statements of utility, even if not 'credible,' do not render the claimed invention lacking in utility" (citations omitted)).

126. *See id.*

127. *See id.* § 2107.02(II)(A) (citing Brenner v. Manson, 383 U.S. 519 (1966)).

128. *See In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967).

129. *See Manson*, 383 U.S. at 534–35.

real-world utility, then it is patentable, and that patent can be used to stop others from using the molecule or process to create new real-world effects that were unknown at the time of the original patent on the molecule or process.[130] This means that even under the strict utility requirement, patents can be used to block the creation of new molecules or new uses of processes that depend on the use of the underlying patented molecule or process.[131] Thus, the potential for blocking downstream research and development is not negated by the strict utility requirement.[132] So long as at least one known use for a molecule or process is known at the time of filing the patent, the granted patent can be used to block all subsequently discovered uses of the invention.[133]

When it comes to methods of treating a disease, either utility standard comes to the same result: the method will only be patentable if it can be proven to treat the disease at the time of filing.[134]

This is the case because even under the older, relaxed utility requirement, the claimed use must be known at the time of filing the patent.[135] If a patent claims to treat disease *X*, then under either utility standard, a patent will only be valid as to utility if the inventor can prove at the time of filing that there was adequate evidence that the method achieved what it claimed to do.[136]

Given the above, a careful consideration of the effects of the strict utility standard shows that its only significant effect is to block patenting of new molecules and processes of unknown real-world use.[137] This is substantiated by the fact that almost all cases in which the Patent Office or courts hold that a claimed invention fails the strict utility standard are in the chemical and biological fields.[138] Section II.B examines what research intermediaries are and how they are developed.

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130. Timothy R. Holbrook, *Method Patent Exceptionalism*, 102 IOWA L. REV. 1001, 1011 (2017) ("Even though the first inventor had no idea that the [patented] chemical could be used to treat [a different condition], her patent on the chemical itself means any subsequent use of the chemical to treat [a different condition] would infringe her patent."); Sean B. Seymore, *The Research Patent*, 74 VAND. L. REV. 143, 163 (2021).

131. *See id.*

132. *See id.*

133. *See id.*

134. This is easy to understand under the strict utility requirement set out in Brenner v. Manson, 383 U.S. 519 (1966), because under this requirement the real-world use must be known. But even under the prior relaxed utility requirement, credible utility was required, which means that a method of treating a disease that does not state the disease to be treated fails to be credible as an invention of anything. *See* 1 WILLIAM ROBINSON, TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS 463–64 (1890).

135. *See id.*

136. *See id.*

137. Patents on impossible inventions that violate the laws of science, such as perpetual motion machines, have always been held to fail the utility requirement and continue to be a basis for rejecting patents on some claimed inventions. *See e.g.*, Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1359 (Fed. Cir. 1999); Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989).

138. *See generally* Timothy J. Baits, *Substantial Utility, Technology Transfer, and Research Utility: It's Time for a Change*, 52 SYRACUSE L. REV. 105 (2002) (discussing the higher utility standard for life sciences).

B. Research Intermediaries: The Research and Development of New Molecules

The processes for researching and developing new molecules are largely the same whether the molecules are for industrial application or for use in pharmaceuticals, although molecules used for pharmaceuticals must also be safe and non-toxic.[139] The processes for the research and development of small-molecule drugs and large-molecule biologics also have a number of similarities, but the complexity of the protein structures in large-molecule biologics makes the development of the molecules more complex.[140]

The discovery and development of a new pharmaceutical drug involves a series of stages encompassing research, development, and testing.[141] It commences with the initial phase of discovery and target identification, typically carried out in academic institutions.[142] During this phase, scientists engage in fundamental research aimed at comprehending the mechanisms underlying a particular disease, often focusing on cellular or molecular aspects.[143] Their investigations involve studying the fundamental processes of the disease and pinpointing potential targets, such as specific molecules or proteins involved in

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139. *See* Grazyna Biala et al., *Research in the Field of Drug Design and Development*, 16 PHARMS. 1283, 1283 (2023).

140. The development of traditional, small-molecule drugs is well known and describes the type of chemical compounds that have been used to treat disease via chemical interactions in the body once the chemical compound is metabolized in the liver. *See* Malin Lemurell, *A Big Future for Small Molecules: Targeting the Undruggable*, ASTRAZENECA, https://www.astrazeneca.com/r-d/next-generation-therapeutics/small-molecule.html [https://perma.cc/9CHK-AE2T]; *see also Small Molecule Drug Metabolism*, IONSOURCE, https://www.ionsource.com/tutorial/metabolism/met_slide3.htm [https://perma.cc/H58D-HQ4T]. Large-molecule drugs, or "biologics," are living organisms and may be administered via injection. *Biologics (Biologic Medicine)*, CLEV. CLINIC, https://my.clevelandclinic.org/health/treatments/biologics-biologic-medicine [https://perma.cc/8PYJ-5CNG]. Some biologics can more directly target genetic or other activity in the body. *See id.* Insulin is one of the earliest examples of a biologic. Kelley George & Gillian Woollett, *Insulins as Drugs or Biologics in the USA: What Difference Does It Make and Why Does It Matter?*, 33 BIODRUGS 447, 447 (2019). To develop large-molecule drugs, or "biologics," researchers first must determine the genetic mutation(s) causing a health condition. *See* Richard C. Mohs & Nigel H. Greig, *Drug Discovery and Development: Role of Basic Biological Research*, 3 ALZHEIMER'S & DEMENTIA: TRANSLATIONAL RSCH. & CLINICAL INTERVENTIONS 651, 651 (2017). This involves extensive research to locate and determine the gene mutations that correlate to a health condition. *See generally id.* at 651–52. Once the target gene mutation is determined, researchers have several potential treatment options. They can seek to inhibit the function of the gene or proteins created by the gene, they can seek to counteract the function of the gene mutation, or they can seek to replace the mutated gene with a well-functioning gene ("gene therapy"). In order to accomplish this, researchers need access to libraries of genetic information. They also need access to chemical libraries of chemical compounds that can be useful in helping create and test biologics. Researchers tend to keep secret their novel biologics, biospecimens, and genetic-screening information until they have a known, real-world use for them so as not to lose control and competitive advantage. *See generally* Robin Feldman, *Trade Secrets in Biologic Medicine: The Boundary with Patents*, 24 COLUM. SCI. & TECH. L. REV. 1 (2022); W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 IOWA L. REV. 1023, 1046–49 (2016).

141. *See* JP Hughes et al., *Principles of Early Drug Discovery*, 162 BRIT. J. PHARMACOLOGY 1239, 1239 (2011).

142. *See id.*

143. Ingrid Torjesen, *Drug Development: The Journey of a Medicine from Lab to Shelf,* PHARM. J. (May 12, 2015), https://pharmaceutical-journal.com/article/feature/drug-development-the-journey-of-a-medicine-from-lab-to-shelf [https://perma.cc/245V-VA88].

the disease pathway.[144] By formulating hypotheses, scientists propose that inhibiting or activating a particular protein or pathway could yield a therapeutic effect in treating the disease, such as blocking a vital receptor.[145]

After identifying a potential target, researchers embark on a search for a suitable molecule or compound that can interact with this target.[146] Traditionally, scientists have explored natural compounds derived from plants, fungi, or marine organisms as the foundation for these candidate drugs.[147] However, with advancements in genetic and protein research, computer-aided techniques are now increasingly employed to design new molecules.[148] This process involves analyzing genetic and protein data to create novel compounds with desired properties.[149] In this pursuit, researchers evaluate as many as 10,000 compounds and gradually narrow down the selection to approximately ten to twenty molecules that have the potential to disrupt the disease process.[150] These chosen drug candidates then undergo preclinical testing, which involves conducting experiments in laboratory and animal models.[151] The efficacy, safety, and pharmacokinetics of the candidates are assessed during this stage.[152] Animal models, such as mice or nonhuman primates, are employed to examine the drug's effects and determine appropriate dosage levels.[153] Researchers investigate whether the drug can prevent or combat the disease in these models, and researchers also study the drug's absorption, distribution, metabolism, and elimination within the body.[154]

Following preclinical testing, approximately half of the candidates successfully progress to the next stage.[155] If the results of preclinical testing are promising, researchers submit an Investigational New Drug (IND) application to regulatory authorities.[156] This application includes data from preclinical studies and outlines the proposed plan for clinical trials in humans.[157] The clinical-trial phase consists of three stages: Phase 1 involves testing the drug's safety and dosage range in a small number of healthy volunteers, while Phase 2 expands the trial to a larger group of patients to evaluate effectiveness and

144. Hughes et al., *supra* note 141.

145. Torjesen, *supra* note 143.

146. *Id.*

147. *Id.*

148. *Id.*

149. *Id.*

150. *Id.*

151. *Id.*

152. *See* Hughes et al., *supra* note 141, at 1246–48.

153. *See id.*

154. *See id.* at 1248–49.

155. Torjesen, *supra* note 143.

156. *See Step 3: Clinical Research,* U.S. FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/4CHP-M55C].

157. *See id.*

safety.[158] Phase 3 involves testing the drug in a larger population to confirm efficacy, monitor side effects, and compare it to existing treatments or a placebo.[159] Positive results from the clinical trials are compiled into a New Drug Application (NDA), which is submitted to regulatory authorities for review.[160] The NDA includes comprehensive information about the drug's safety, effectiveness, manufacturing, labeling, and proposed usage.[161] Regulatory authorities conduct a thorough review process, assessing the drug's benefits, risks, and quality.[162] This process can take several months or years, and additional information or clarification may be requested.[163] If the drug is deemed safe and effective, it may receive regulatory approval for marketing and use.[164] Once approved and released to the market, post-marketing surveillance is conducted to monitor the drug's safety and effectiveness in larger populations.[165]

In the twenty-first century, and particularly recently with the acceleration in artificial intelligence (AI) computing, many researchers and drug developers have incorporated computer-aided drug design (CADD) into their research processes.[166] Theoretical and discovery chemists—aided by computers and AI—come up with new molecular structures that may (or may not) be useful in the real world.[167] While many molecules can be designed theoretically, this does not mean that they can be produced in the real world—at least not in any cost-effective way.[168] To synthesize a molecule that has been conceived, a chemist must have access to the necessary starting materials, and as a practical matter, the materials and process necessary to make the molecule need to be cost effective.[169] A billion-dollar molecule may be conceivable to theorists, but no chemist will make it. Accordingly, theoretical and design chemists can develop models of thousands of potential molecules that may be of use in the real world but will then test them using computer models before deciding which few

158. *See id.*; Torjesen, *supra* note 143.

159. *See Step 3: Clinical Research*, *supra* note 156; Torjesen, *supra* note 143.

160. *See Step 4: FDA Drug Review*, U.S. FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review [https://perma.cc/WXL2-BFLU].

161. *See id.*

162. *See id.*

163. *See id.*; Torjesen, s*upra* note 143.

164. *See Step 4: FDA Drug Review*, *supra* note 160; Torjesen, s*upra* note 143.

165. *See Step 5: FDA Post-Market Drug Safety Monitoring*, U.S. FDA (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-5-fda-post-market-drug-safety-monitoring [https://perma.cc/J3QX-N683].

166. *See* Alison E. Cantor, Note, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 HARV. J.L. & TECH. 267, 280 & n.76 (2000).

167. *See* Philippe Ducor, *New Drug Discovery Technologies and Patents*, 22 RUTGERS COMPUT. & TECH. L.J. 369, 418–20 (1996).

168. *See* B. Thomas Watson, Note, *Carbons into Bytes: Patented Chemical Compound Protection in the Virtual World*, DUKE L. & TECH. REV., Jan. 2014, at 25, 26.

169. *See id.*

molecules are worthy of the attempt to synthesize them.[170] In addition, even when a chemist can translate a new molecule from a computer to a real-world molecule, the results may not conform to expectations because of unforeseen interactions in a real-world environment.

III. ARGUMENTS FOR A STRICT UTILITY REQUIREMENT

This Part of the Article examines arguments for a strict utility requirement. This Part shows that there are legitimate reasons to fear patent thickets and decreased downstream innovation if the utility requirement is relaxed and many products and processes are allowed to be patented without known commercial or therapeutic uses. There are five main arguments for the strict utility standard. These arguments are closely related, but it aids analytical clarity to separate each argument. First, patent thickets may inhibit innovation by crowding the field with many patents that must be navigated in order to do further research.[171] Second, owners of patents may demand unreasonable prices for licensing their patents, or otherwise make use of their patents difficult.[172] Third, transaction costs for licensing patents may be high enough that some valuable uses are blocked because the transaction costs will be higher than the value of the use of the patented invention, or the uncertainty as to the value of using the patented invention may make the cost of the patent licenses and concomitant transaction costs too high to overcome the uncertain value of the use.[173] Fourth, if multiple patented inventions need to be combined to create a final complex product (e.g. multiple precursors need be combined for a final drug), royalty hold-up problems can block the production of valuable complex products

170. *See id.*

171. *See, e.g.*, Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735, 778–83 (2000) (arguing that patent availability for research intermediaries would result in large pharmaceutical and genomics firms filing patents "to extract as high a price as possible from licensees"); John F. Duffy, *Embryonic Inventions and Embryonic Patents: Prospects, Prophecies, and Pedis Possessio*, *in* PERSPECTIVES ON COMMERCIALIZING INNOVATION 234, 245–48 (F. Scott Kieff & Troy A. Paredes eds., 2012); Gavin Clarkson & Joshua Newberg, *Blunt Machetes in the Patent Thicket: Modern Lessons from the History of Patent Pool Litigation in the United States Between 1900 and 1970*, J. TECH. L. & POL'Y, Fall 2017, at 1, 8–11.

172. *See, e.g.*, Alan Devlin, *Patent Law's Parsimony Principle*, 25 BERKELEY TECH. L.J. 1693, 1717 (2010) (arguing against patents on upstream inventions of multiple potential uses, stating: "[t]hese fields of discovery bear unique potential for overcompensation, given their upstream nature and the concomitant proclivity for ubiquitous downstream application"); Thomas F. Cotter, *Patent Holdup, Patent Remedies, and Antitrust Responses*, 34 J. CORP. L. 1151, 1160, 1170–71 (2009); *see generally* Michael Risch, *Reinventing Usefulness*, 2010 BYU L. REV. 1195 (arguing for an even stronger utility standard that would require both practical utility and commercial utility).

173. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1073–74 (1989) ("[U]ncertainty or disagreement as to the value of the patented invention, the likely outcome of the research project, and the validity and scope of the patent claims might make it difficult for the parties to agree on a price for a license."); *see* Mirela V. Hristova, *Are Intellectual Property Rights Human Rights? Patent Protection and the Right to Health*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 339, 358 (2011).

(including drugs).[174] Fifth, and related to the hold-up problem, yet distinct, if multiple patented inventions are inputs in a vertical supply chain to a final product, the successive monopoly problem may cause prices to be much higher than they would be for a product with a single patent, resulting in either excessively high prices for consumers or the product not being produced at all because it is too costly (for instance multiple research intermediaries may be needed for the process of creating precursors, chemicals, and molecules in a vertical supply chain to get to a final drug or product).[175]

If one takes the five arguments for strict utility as a whole, the argument for a strict utility requirement that disallows patents on research intermediaries is logical and intuitive. It is possible for researchers to create hundreds or even thousands of chemical and biological compounds that may be useful in the treatment of health conditions.[176] If downstream researchers are forced to license each individual compound that they find of interest for research purposes, research could grind to a halt due to the transaction costs of licensing as well as the cost of paying for each compound used in research.[177] This nightmare scenario seems to motivate the change in judicial decisions on utility discussed above in Part I, which discusses numerous opinions touting the strict utility requirement to avoid problems patents could cause in the development of therapeutic or commercial products.[178]

One can see these concerns animating the Court in *Brenner v. Manson* and the Patent Office in the earlier shift from a lax utility requirement to a strict utility requirement.[179] Both the Patent Office and the Supreme Court expressed concern that if patents are allowed on novel products or processes for which the ultimate use in medicine or commerce is unknown, it will block the further development of such ultimate use.[180] This is intuitive to a certain extent. If one must license upstream inputs for research and development (R&D), this increases the cost of R&D, and thus, at the margins, should decrease total

174. *See* Daniel L. Rubinfeld, *IP Privateering in the Markets for Desktop and Mobile Operating Systems*, 33 BERKELEY TECH. L.J. 85, 117–18 (2018); Dirk Auer & Julian Morris, *Governing the Patent Commons*, 38 CARDOZO ARTS & ENT. L.J. 291, 308–09 (2020).

175. *See* Anne Layne-Farrar, *An Economic Defense of Flexibility in IPR Licensing: Contracting Around "First Sale" in Multilevel Production Settings*, 51 SANTA CLARA L. REV. 1149, 1179–81 (2011); Guy Sagi, *A Comprehensive Economic and Legal Analysis of Tying Arrangements*, 38 SEATTLE U. L. REV. 1, 16 (2014); Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 530–31 (2015).

176. *See* Arti K. Rai et al., *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 7 (2008) ("Many pharmaceutical firms own collections, or 'libraries,' of hundreds of thousands of small molecules that they have either synthesized internally or have purchased from outside vendors.").

177. *See* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 831–33 (2001); Simone A. Rose, *On Purple Pills, Stem Cells, and Other Market Failures: A Case for a Limited Compulsory Licensing Scheme for Patent Property*, 48 HOW. L.J. 579, 596–97 (2005).

178. *See supra* Part I.

179. *See supra* notes 64–91 and accompanying text.

180. *See supra* notes 64–91 and accompanying text.

R&D.[181] The amount by which upstream patents will decrease downstream R&D depends on the following factors: (1) the number of upstream patents that must be licensed, (2) the prices charged for the upstream patents, (3) the transaction costs to license the necessary patents, and (4) the ability to correctly predict the value of the commercializable products that result from licensing the upstream patented inputs.[182] The greater the number of upstream patents, the higher the prices charged for those patents, and the higher the transaction costs of licensing, the more this will depress R&D, downstream innovation, and commercialization.[183] Likewise, the more difficult it is to determine the likelihood that any compound or research intermediary will result in a usable downstream product, and the more uncertainty there is about the value of that ultimate product, the less incentive there is to license the research intermediary.[184] It is this calculus that seems to have driven the evolution of the strict utility requirement to disallow patents on research intermediaries and anything that does not have a known ultimate use at the time of patent filing. The above calculus indicates that even if the magnitude of the effect on downstream innovation is hard to determine, there must be some negative effect at the margins. Eliminating this negative effect seems to be the goal of the strict utility requirement.

IV. ARGUMENTS AGAINST A STRICT UTILITY REQUIREMENT

This Part examines arguments for the patenting of research intermediaries—products and processes with no known commercial or therapeutic use. This Part shows that patentability increases the incentives to make and share inventions of products and processes with no currently known commercial or therapeutic use. More importantly, this Part shows that fears about the effect on downstream innovation from upstream patents are based on flawed intuitions about incentives and transaction costs. This Part argues that, in fact, the incentive of owners of research intermediary patents is to facilitate use by downstream researchers, often at low or no cost.

181. *See* Robert P. Merges & Michael Mattioli, *Measuring the Costs and Benefits of Patent Pools*, 78 OHIO ST. L.J. 281, 291–95 (2017).

182. *See* Eisenberg, *supra* note 173, at 1073; Emily Michiko Morris, *The Irrelevance of Nanotechnology Patents*, 49 CONN. L. REV. 499, 515–18 (2016).

183. *See* Morris, *supra* note 182, at 517–18 (discussing ways "to reduce transaction costs by removing the need to license upstream patents").

184. *See* Eisenberg, *supra* note 173, at 1073–74 ("[U]ncertainty or disagreement as to the value of the patented invention, the likely outcome of the research project, and the validity and scope of the patent claims might make it difficult for the parties to agree on a price for a license.").

A. The Problem of Secrecy

Secrecy and lack of sharing compounds, genetic information, and biospecimens significantly hinders R&D of therapeutics and commercial products.[185] The National Academy of Medicine has identified as a significant hurdle to R&D the unshared proprietary libraries of chemical compounds and biomolecules.[186] In addition, while numerous molecules are synthesized as part of academic work, these molecules are often not available to researchers seeking to create therapeutic and commercial products.[187] The irony of the status quo under the strict utility standard is that research intermediaries are often not shared, hindering follow-on research that could result in medical and commercial breakthroughs.[188] To be sure, patentability of research intermediaries would not eliminate all uses of trade secrecy by drug manufacturers, but increasing disclosure would prevent much wasted duplication of efforts.[189]

Researchers can synthesize thousands of molecules virtually, and progress is continually being made in reducing these computer-designed molecules to real-world molecules.[190] Nevertheless, creation of real-world versions of synthesized molecules is often still slow and laborious work.[191] Even when that work is done, the resulting molecules are often not available to other researchers.[192] Obtaining access to libraries of molecules is key to drug development and testing.[193] For academic researchers, their incentive is often

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185. *See* COMM. ON ACCELERATING RARE DISEASES RSCH. & ORPHAN PROD. DEV., INST. OF MED., RARE DISEASES AND ORPHAN PRODUCTS: ACCELERATING RESEARCH AND DEVELOPMENT 141–43 (Marilyn J. Field & Thomas F. Boat eds., 2010) [hereinafter RARE DISEASES AND ORPHAN PRODUCTS], https://doi.org/10.17226/12953 (noting that proprietary databases and biospecimen libraries inhibit research and development and recommending that methods to share both be pursued).

186. *See id.*

187. *See id.* at 143–44 (discussing the need for a shared research and resource system between private commercial entities and government and academic entities to further develop research for rare diseases).

188. *See* Price II & Rai, *supra* note 140, at 1048–49 (discussing the impact trade secrecy has on follow-on R&D, including follow-on researchers having to spend more time and resources reverse-engineering chemical products).

189. *See id.* at 1046–49.

190. *See* Francesco Gentile et al., *Artificial Intelligence-Enabled Virtual Screening of Ultra-Large Chemical Libraries with Deep Docking*, 73 NATURE PROTOCOLS 672, 672 (2022) (discussing the significant increase in the number of "synthesizable molecules" available in virtual "make-on-demand libraries").

191. *See* Megan Stanley & Marwin Segler, *Fake It Until You Make It? Generative De Novo Design and Virtual Screening of Synthesizable Molecules*, CURRENT OP. IN STRUCTURAL BIOLOGY, Oct. 2023, at 1, 1–4, https://www.sciencedirect.com/science/article/pii/S0959440X2300132X [https://perma.cc/R87T-RXC9] (recognizing barriers to synthesizing molecules from virtual sources, including evaluating whether "computationally proposed molecules [are] synthetically feasible for laboratory testing" and identifying and gathering needed materials).

192. Paul J. Hergenrother, *Obtaining and Screening Compound Collections: A User's Guide and a Call to Chemists*, 10 CURRENT OP. IN CHEM. BIOLOGY 213, 215 (2006) ("[M]ore often than not the products, intermediates and side products produced by synthetic chemists are not used in any further experiments — the goal of these studies is the synthetic *tour de force*, not the generation of material for biological testing.").

193. *See* RARE DISEASES AND ORPHAN PRODUCTS, *supra* note 185.

simply to synthesize new molecules for the sake of showing it can be done.[194] These molecules then sit in freezers in academic libraries without further diffusion.[195] When it comes to commercial companies, their incentive is to reserve the molecules they create for themselves, and thus they rely on tight control and secrecy over their molecules.[196] While development partnerships are common, they are the result of significant efforts and time to craft deals that protect the proprietary molecules that the partners have created, and they are filled with many restrictions on the use and sharing of the molecules.[197] Due to the strict utility requirement, these companies cannot rely on patent rights to control their molecules, and thus opt for trade secrecy instead.[198] The result is that each major drug developer has libraries of thousands of molecules that are not shared—or even known about—outside of the company.[199] National Academy of Medicine researchers have identified this lack of sharing as a significant hurdle to more rapid development of drugs,[200] and the same holds true for the development of commercial applications of new molecules.[201] If these molecules were patentable, they could be shared more widely without fear of losing the value of the molecules.[202] The patents alone would publicize the molecules.[203] In addition, patent-licensing and pooling arrangements could make the molecules available for further R&D by a much wider array of entities than the ones with which a particular company has development deals.[204] These patent-licensing and pooling arrangements could take many forms.[205] Some might allow the widespread use of the molecules for research for a low cost or free, while reserving rights to commercialization. Others might set standard

194. *See* Hergenrother, *supra* note 192.

195. *See* Rai et al., *supra* note 176, at 13–15 (discussing the National Institutes of Health's recognition of the problem of the failure of academics to share assays and potential drug-target proteins and the need to encourage further collaboration between academic and commercial entities to develop and distribute new drugs).

196. *See id.* at 21 (discussing molecular libraries maintained as trade secrets by commercial entities and the resultant problem of slower drug development).

197. *See* RARE DISEASES AND ORPHAN PRODUCTS, *supra* note 185.

198. *See* Rai et al., *supra* note 176 ("Many pharmaceutical firms own collections, or 'libraries,' of hundreds of thousands of small molecules that they have either synthesized internally or have purchased from outside vendors. Because the functional attributes of these molecules have not generally been studied in any depth, they typically do not meet even the relatively lax [utility] standards for patentability currently applied by the courts. To protect their investment, firms impose a strict regime of trade secrecy." (footnote omitted)).

199. *Id.*

200. *See* RARE DISEASES AND ORPHAN PRODUCTS, *supra* note 185.

201. *See id.*

202. *See* Rai et al., *supra* note 176.

203. Section 112 of the Patent Act requires disclosure of the patented invention in sufficient detail to enable a person having ordinary skill in the art to make and use the invention without having to engage in undue experimentation. 35 U.S.C. § 112.

204. *See, e.g.*, Rai et al., *supra* note 176, at 30.

205. *See* Scott Sher et al., *The Role of Antitrust in Evaluating the Competitive Impact of Patent Pooling Arrangements*, 13 SEDONA CONF. J. 111, 112–13 (2012).

rates for sharing the value of subsequent commercialization of the molecules or derivatives therefrom. Still others might allow use of the molecules in certain cases but not others. Experience with successful patent-pooling arrangements in the high-tech sector provides numerous examples of how patent licensing and pooling of research intermediaries might be accomplished.[206] An important additional benefit is that patentability of research intermediaries would increase incentives to create new compounds and then share them.[207]

B. The Strict Utility Requirement Causes Inventors to Substitute Other IP and Legal Protections that Can Inhibit Dissemination of Knowledge More than Patents

Ironically, the patent strict utility requirement can cause inventors to substitute other methods of protecting their research that is more restrictive than patent law. A significant benefit of patents is that to be granted a patent, an inventor must fully disclose her invention sufficiently to enable those with skill in the art to make and use the invention.[208] Patent applications are published eighteen months after they are filed.[209] Thus, even though patents give inventors exclusive rights to their inventions for twenty years from the date of patent filing,[210] the information about the invention is shared with the public soon after filing, and generally before the patent has been granted.[211]

When patents are not available, inventors utilize other methods of protection including trade-secret law, non-disclosure agreements, and corporate structuring.

1. Trade-Secret Protection

Trade secrets are protected by both state and federal law.[212] Prior to 2016, trade-secret protection was solely the purview of state law.[213] While trade-secret law grew out of common law doctrines in tort and contract law, the Uniform Law Commission published a proposed Uniform Trade Secrets Act (UTSA) in

206. *See* Rai et al., *supra* note 176, at 30.

207. Eisenberg, *supra* note 173, at 1074 n.224 (arguing that "the value of a newly invented chemical may derive as much from its usefulness in facilitating the discovery of other chemicals in future research as from its usefulness in its present form to non-research consumers" and "[i]f a patent on the chemical allowed the inventor to capture the value of the chemical to non-research consumers but not its value as an input to subsequent research, patent incentives to derive new chemicals would be reduced").

208. *See* 35 U.S.C. § 112.

209. There is a limited exception for inventors who opt out of publication by affirming that they are not filing in any jurisdiction outside the U.S. that requires patent publication, but this is rarely utilized, especially for those filing patents in multiple countries. *Id.* § 122.

210. *Id.* § 154.

211. *See id.* § 122.

212. *See* Jonathan R. Chally, *The Law of Trade Secrets: Toward a More Efficient Approach*, 57 VAND. L. REV. 1269, 1270–71 (2004).

213. *See* Camilla A. Hrdy & Sharon K. Sandeen, *The Trade Secrecy Standard for Patent Prior Art*, 70 AM. U. L. REV. 1269, 1286 (2021).

1979, which it amended in 1985.[214] This model statute has since been adopted by every state except New York and North Carolina.[215] Thus, treatment of trade secrets under state law is quite uniform.[216] In 2016, Congress passed the federal Defend Trade Secrets Act (DTSA), which was codified as 18 U.S.C. §§ 1831–39.[217] The DTSA closely resembles the UTSA, with differences that are not important for purposes of this Article.[218] Thus, in discussing trade secrets, this Article will refer to the DTSA and UTSA interchangeably, unless a difference of treatment applies.

Trade-secret protection extends substantially more broadly than does patent protection.[219] The Department of Justice has provided guidance as to civil and criminal enforcement of trade-secret protections under the DTSA. It states that "trade secrets must be only 'minimally novel'" or "contain[ing] some element that is not known and sets it apart from what is generally known."[220] The DOJ further states that a "trade secret can include a combination of elements that are in the public domain if the trade secret constituted a unique, 'effective, successful and valuable integration of the public domain elements.'"[221]

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214. *See* UNIF. TRADE SECRETS ACT (UNIF. L. COMM'N 1985).

215. *See Trade Secrets Act: Enactment Map*, UNIF. L. COMM'N, https://www.uniformlaws.org/committees/community-home?communitykey=3a2538fb-e030-4e2d-a9e2-90373dc05792 [https://perma.cc/D54N-FZ76].

216. *See id.*

217. *See* 18 U.S.C. §§ 1831–39.

218. For example, here is the definition of a "trade secret" under the UTSA:

> [I]nformation, including a formula, pattern, compilation, program, device, method, technique, or process, that . . . derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and . . . is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

UNIF. TRADE SECRETS ACT § 1.4. Similarly, here is the definition of a "trade secret" under the DTSA:

> [T]he term "trade secret" means all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if— (A) the owner thereof has taken reasonable measures to keep such information secret; and (B) the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information.

18 U.S.C. § 1839(3).

219. *See* Michael R. McGurk & Jia W. Lu, *The Intersection of Patents and Trade Secrets*, 7 HASTINGS SCI. & TECH. L.J. 189, 191 (2015).

220. *Criminal Resource Manual 1127. 18 U.S.C. § 1831 Element Three—The Information Was a Trade Secret*, U.S. DEP'T OF JUST., https://www.justice.gov/archives/jm/criminal-resource-manual-1127-18-usc-1831-element-three-information-was-trade-secret [https://perma.cc/CSH2-QBVE].

221. *Id.* (quoting Rivendell Forest Prods. Ltd. v. Georgia-Pacific Corp., 28 F.3d 1042, 1046 (10th Cir. 1994)).

Trade-secret protection can also last much longer than patent protection. Patents last only twenty years from the date of filing,[222] with the result that pharmaceuticals on average only have about thirteen years of patent protection left by the time they complete FDA trials and are cleared for the market.[223] Trade secrets, on the other hand, last until the information has become "generally known."[224] Thus, even if multiple participants in an industry know the information, each can maintain it as a trade secret—and sue anyone who misappropriates the information—until such time that the information becomes generally known.[225] While it is true that a company will seek to patent a molecule once it has proven its real-world use, and thus trade secrecy will end eighteen months after the patent is filed, some areas of research that may go on for decades will be protected by trade-secret law until the inventor files a patent or someone independently discovers and publishes the information.[226]

Moreover, in contrast to patent law, "[t]rade secret law is the most expansive in applying the fruit of the poisonous tree doctrine" because "[w]hen the defendant acquires a plaintiff's secret through improper means, or uses or discloses it in violation of a duty to keep it confidential, trade secret law will find misappropriation even if the defendant's final product differs in whole or in part from the plaintiff's."[227] In addition,

> [w]hile other IP regimes celebrate designing around, trade secrecy punishes it just the same as outright duplication. Courts scold defendants who study an existing invention and use it "as a springboard to launch [one's] own approach," as if that were a bug rather than a feature of the innovation process. When prior exposure to a trade secret gives an individual knowledge, the case law's but-for standard of causation essentially tells that individual not to put that knowledge to commercial use.[228]

In *Kewanee Oil Co. v. Bicron Corp.*, Justice Marshall also observed the relationship between trade secrets and patent law, writing that he had "no doubt that the existence of trade[-]secret protection provides in some instances a substantial disincentive to entrance into the patent system, and thus deprives

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222. 35 U.S.C. § 154.

223. *See* Austin Frakt, *How Patent Law Can Block Even Lifesaving Drugs*, N.Y. TIMES (Sept. 28, 2015), https://www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html [https://perma.cc/S8SL-CLFT] (discussing the limited patent life remaining after FDA clearance).

224. *See Trade Secrets / Regulatory Data Protection*, U.S. PAT. AND TRADEMARK OFF., https://www.uspto.gov/ip-policy/trade-secret-policy [https://perma.cc/DN92-9P5Z] (stating that as long as a trade secret is "not . . . generally known," "has value to others," and "reasonable efforts to maintain its secrecy" are taken, "there is no limit on the amount of time a trade secret is protected").

225. *See* Deepa Varadarajan, *Forfeiting IP*, 59 AM. BUS. L.J. 175, 184–85 (2022).

226. *See id.* (stating that "a trade secret has no fixed term").

227. Mark A. Lemley, *The Fruit of the Poisonous Tree in IP Law*, 103 IOWA L. REV. 245, 250 (2017).

228. Joseph P. Fishman & Deepa Varadarajan, *Similar Secrets*, 167 U. PA. L. REV. 1051, 1078–79 (2019) (footnotes omitted).

society of the benefits of public disclosure of the invention which it is the policy of the patent laws to encourage."[229]

Trade-secret law can be particularly useful in protecting research intermediaries because information qualifies for trade-secret protection merely by "not being generally known" and from being of value for not being known.[230] Thus, while a molecule that shows promise for treating a disease cannot be patented until the link to disease treatment is proven, the molecule and all information surrounding it, including research tools, qualify for trade-secret protection.[231] Trade-secret law goes so far as to cover information about research dead ends, including molecules and processes one company has discovered are not effective in treating disease.[232] Thus, trade secrets can give companies a competitive advantage by allowing them to hide what does not work so that their competitors will have to spend the time and money discovering those dead ends on their own.[233] This makes sense from a competitive standpoint, but it is detrimental to the discovery of new molecules and processes that could save and improve lives.[234] Instead, society is left with duplicative research that arrives at the same dead ends.

2. Non-Disclosure Agreements and Corporate Structure

Companies also use non-disclosure agreements (NDAs) and corporate structure to protect their research and avoid sharing it widely.[235] While collaboration is very important in chemical, biological, and pharmaceutical research, fear of losing control of discoveries inhibits sharing.[236] In addition to utilizing the protections of trade-secret law, when companies collaborate with others, they are careful in the information they share and make widespread use of NDAs to limit the further sharing of the information and the uses that can

229. 416 U.S. 470, 494 (2019) (Marshall, J., concurring).

230. *See Trade Secrets / Regulatory Data Protection*, *supra* note 224.

231. *See* Wolrad Prinz zu Waldeck und Pyrmont, *Research Tool Patents After* Integra v. Merck – *Have They Reached a Safe Harbor?*, 14 MICH. TELECOMM. TECH. L. REV. 367, 417 (2008) (discussing the ease of achieving trade-secret protection for potentially unpatentable research tools).

232. *See* Dustin Ferzacca, *Transforming the Pile of Junk: A Model for Cross-Competitive Negative Knowledge Sharing,* 60 IDEA: L. REV. FRANKLIN PIERCE CTR. FOR INTELL. PROP. 460, 463–65 (2020) (discussing the availability of trade-secret protection for "negative knowledge" trade secrets consisting of knowledge and information on failed endeavors).

233. *Cf.* Prinz zu Waldeck und Pyrmont, *supra* note 231, at 417–18 (focusing on research tools to make the widely applicable point that when patent protection is not available, but trade-secret protection is, "[t]he kind of technology transfer between firms, which is facilitated through the publication of the patent specification, will be severely curtailed and result in a wasteful duplication of research and development efforts").

234. *See id.* at 417; *see also* Jeffrey Steven Gordon, *Silence for Sale*, 71 ALA. L. REV. 1109, 1112–13, 1136 (2020); Ferzacca, *supra* note 232, at 467–68.

235. *See* Gordon, *supra* note 234, at 1112, 1135–36.

236. *See supra* notes 186–205 and accompanying text.

be made with the information shared.[237] These NDAs significantly restrict the free flow of research advances and may limit researchers who move companies from using what they have learned.[238] Threats of enforcement action and lawsuits are common tools to deter the spread of information and to deter departing employees from utilizing what they have learned.[239] While use of NDAs and trade-secret law is common surrounding know-how and internal research even with regard to patented inventions, once an invention is patented, the information on the invention cannot be restricted nor can anyone be stopped from learning from patents or applying what they have learned to further research.[240]

The unavailability of patent protections and consequent reliance on trade secrecy and NDAs also encourages companies to integrate their R&D vertically and horizontally or to acquire companies with substantial research pipelines.[241] This integration, for the most part, allows the companies full access to the proprietary information of their acquired companies,[242] but it also locks down that information from sharing outside of the company.[243] Again, if the information were patented, the information on how to make and use the inventions could not be restricted.[244]

C. Financial Incentives Encourage Patentees to Facilitate Follow-On Research

While the case for a strict utility requirement to ensure adequate downstream R&D is intuitive, it is important to note that both the Patent Office and Supreme Court's decisions to implement a strict utility requirement were based on assumptions about the way patents on research intermediaries would be used rather than empirical evidence showing a problem.[245]

Judges' fears about the blocking of downstream research evolved in response to changing attitudes and assumptions by judges, rather than because of changing information or evidence. The Supreme Court in *Brenner v. Manson*

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237. *See* Young Park, *Non-Disclosure Agreements and Equitable Access to Covid-19 Vaccines*, N.Y.U. J. INT'L L. & POL. 117, 118–20 (2022) (discussing "bilateral deals [between governments and] large pharmaceutical companies" and observing that "NDAs are common practice in pharmaceutical contracts").

238. *See* W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, 55 B.C. L. REV. 491, 553 (2014) (pointing out that non-disclosure agreements may limit the ability of employees to freely move between companies).

239. *See* Gordon, *supra* note 234, at 1124–25.

240. *See* Hon. Paul R. Michel & Matthew J. Dowd, *From a Strong Property Right to a Fickle Government Franchise: The Transformation of the U.S. Patent System in 15 Years*, 69 DRAKE L. REV. 1, 24 (2021) ("No patent 'forecloses' future invention, as research within a patented area is plainly permitted, and a patent owner rarely seeks to exclude such follow-on research.").

241. *See* Rai, *supra* note 177, at 834–36.

242. Although, trade-secret agreements and NDAs can in some cases restrict what an acquiring party can do with information shared as part of a joint research project, depending on the restrictive covenants.

243. *See* Brenda M. Simon, *Patents, Information, and Innovation*, 85 BROOK. L. REV. 727, 745–46 (2020).

244. *See* Michel & Dowd, *supra* note 240.

245. *See* Janet Freilich, *Paths to Downstream Innovation*, 55 U.C. DAVIS L. REV. 2209, 2220–24 (2022).

was not responding to comprehensive evidence of problems with downstream innovation being blocked by upstream patents, including patents on research intermediaries.[246] Instead, certain Justices became worried about the effect of upstream patents and acted based on that.[247] This raises the question of whether these assumptions are valid. There is no definitive way to answer this question without being able to examine a parallel universe in which the Court did not make the utility requirement stricter in comparison to our universe in which the Court did. Instead, the best we can do is (1) examine theoretically the incentives that should govern behavior in each circumstance, (2) look at evidence of the effects on downstream innovation when there are many patented upstream inputs, and (3) look at industries in which there are many patents that must be licensed to facilitate downstream production, including areas in which there are so-called "patent thickets."[248]

Stopping at the above calculation ignores three things, however: (1) the increased incentive to develop new compounds and research intermediaries that result from patentability thereof,[249] (2) the increased incentive to share new compounds and intermediaries if they are protected by patents,[250] and (3) the incentive of patent owners to facilitate R&D of their patented compounds and intermediaries.[251] The increased incentive to invent new research intermediaries is obvious. If a researcher believes she can recoup some money from inventing and licensing research intermediaries, she is more likely to do so. Likewise, once a researcher has a patent on a research intermediary, she has an incentive to spread knowledge of the patented product or process and encourage others to license it. The incentives go further than this, however. If a researcher develops a new product or process of unknown usefulness to end users, she has an incentive to facilitate the creation of value around that product or process. This may be in the form of charging the highest price the market for research will bear. But it may also be to allow free use of the process or product to determine ultimate usefulness in the market because follow-on innovation generally increases the value of the underlying patent.

This is easiest to understand in the case of a patented molecule. If a researcher creates a new molecule similar to other molecules useful in treating a certain condition, that molecule will be of interest to researchers seeking

246. *See id.*

247. *See id.*

248. *See generally id.* at 2220–23.

249. *See* Robert P. Merges & Richard Nelson, *On the Complex Economics of Patent Scope,* 90 COLUM. L. REV. 839, 902–03, 912–14 (1990).

250. *See* F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 351–53 (2006).

251. *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267–71 (1977).

treatments for that condition.[252] They may wish to experiment with that molecule, among many others, to determine improved treatments for the condition.[253] At the point of experimentation, however, the likelihood of any one molecule resulting in an improved treatment may be very uncertain.[254] Thus, a researcher is not likely to pay a significant fee to license the use of any one molecule, or even a number of molecules.[255] In such a case, significant license fees may drive researchers away from experimenting with patented molecules.[256] This is contrary to the interest of the owner of a patent in the molecule because it means there will be little return to licensing the molecule for experimental use. If, however, a researcher is able to determine that the molecule is indeed useful to treat a condition and comes up with a method of treatment using the molecule, the market value of the molecule will skyrocket.[257] Thus, in many cases, it may be in the interest of the owner of the patent in the molecule to offer the use of the molecule for research purposes for free. In effect, the patent owner will get free labor in the form of others doing the research to determine the value of the molecule in the therapeutic market.[258] Once the therapeutic use of the molecule has been determined, the owner of the patent on the molecule can make much more money by licensing the molecule to pharmaceutical companies who will use it to manufacture a drug.[259] Evidence that this occurs includes the fact that many academic researchers assume they have a right to experiment with patented molecules because their research is not challenged by patent owners.[260]

If the owner of the patent on the molecule can control its use, one might think that there is no incentive for others to experiment with the molecule and determine its therapeutic use. This is not the case, however, because discoveries

252. *See* Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 151–53 (2004).

253. *See id.*

254. *See id.* at 165 (discussing difficulties in reaching licensing agreements for research tools, including ascertaining the tool's value because when the agreement is being negotiated, the ultimate use and value of the research tool in the form of a final product, service, or commercial application is unknown).

255. *See id.*

256. *See id.* at 165–66 (identifying facing multiple licensing or royalty fees as a deterrent for companies seeking to use multiple patented research tools).

257. *See* Tami Luhby, *Ozempic, Mounjaro and Hundreds of Other Drugs Become Even More Expensive in 2024*, CNN (Feb. 15, 2024, 11:35 AM), https://www.cnn.com/2024/02/15/economy/ozempic-mounjaro-drug-prices-increase/index.html [https://perma.cc/HBG3-LLY5] (discussing the price increases of medications used to treat diabetes after another use—helping with weight loss—was found).

258. *Cf.* Kitch, *supra* note 251, at 267–71.

259. *See* Mireles, *supra* note 252, at 163–64.

260. *See* Marcia Barinaga, *Scientists Named in PCR Suit*, 268 SCI. 1273, 1274 (1995) (discussing and quoting researchers who did not have "concerns about license violations" because they were not "'violating the patent for profit'"); *see also* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 458 (2004) (discussing how researchers may seek to "help[] to foster basic science" while working in the pharmaceutical industry).

of new uses of a known product are also patentable.[261] Thus, if a researcher determines that a particular molecule is useful in a particular dosage administered in certain circumstances, this discovery—so long as it is new and nonobvious—qualifies for a separate patent.[262] At this point there are two patents that cover the administration of the molecule as a pharmaceutical treatment.[263] First is the patent on the molecule itself. Second is the patent on the method of use of the molecule. To bring the molecule to market as a pharmaceutical according to the discovered method of use, the FDA process will require proof of its safety and effectiveness and then will label the drug for its proven beneficial use.[264] Because there are two patents that cover the pharmaceutical, the molecule (product) patent and the method-of-use (process) patent, the drug cannot be sold for its pharmaceutical use until both patent owners give permission.[265] This is a classic "blocking patents" scenario.[266] Note that blocking patents do not block the manufacture and distribution of the molecule itself.[267] Instead, they are called blocking patents because each patent owner is blocked from selling the drug for the particular use in the method-of-use patent.[268] The owner of the molecule patent cannot sell the molecule to treat disease in the way discovered by the second inventor without the permission of the second inventor because the second inventor owns a patent on the method of treatment.[269] Likewise, the owner of the method-of-treatment patent cannot sell the molecule to treat disease without permission of the owner of the molecule patent.[270] Thus, each is blocked from independently selling the drug to treat the condition.[271] This generally is not a problem, however, because

261. *See* MPEP, *supra* note 112, § 2131 (stating that an invention lacks novelty when a prior art reference "teach[es] every element required by the claim").

262. *See id.*

263. *See* Ulrich Storz, *Extending the Market Exclusivity of Therapeutic Antibodies Through Dosage Patents,* 8 MABS, 841, 841 (2016) (discussing "extend[ing] the market exclusivity of an approved drug beyond the lifetime of the patent" by seeking "dosage patents," in which a patent is filed for "a new dosage regimen for a given drug").

264. *See Development & Approval Process*, U.S. FDA (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs [https://perma.cc/CB3B-GYM5] (outlining the FDA's process for approving pharmaceutical products, which may include requiring and evaluating data from clinical trials).

265. *See* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 127 (1999).

266. *See* Auer & Morris, *supra* note 174, at 308–09.

267. *See* Robert D. Cooter & Uri Y. Hacohen, *Progress in the Useful Arts: Foundations of Patent Law in Growth Economics*, 22 YALE J.L. & TECH. 191, 237–38 (2020) (recognizing that blocking patents impede the parties' abilities "to practice the improvement," but not necessarily the first, non-improved product); *see also* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1010 (1997) (discussing incentives blocking-patent owners have to negotiate with each other, including "the benefit of the improvement" being accessible to both parties).

268. Rai, *supra* note 265 (stating that "[i]n [a] blocking patent situation, neither the initial patent holder nor the follow-on improver can sell the improvement without cross-licensing").

269. *Id.*

270. *Id.*

271. *Id.*

each patent owner has an incentive to come to an agreement that divides the profit from the sale of the drug for its pharmaceutical use and no incentive to enforce its patent to block the sale of the drug.[272] For a molecule with a previously unknown use, without the molecule being sold as an FDA-approved drug for treating a condition, each patent is effectively worthless.[273] Thus, whether one party licenses the other, or they cross-license, or both patent owners license to the same third party to manufacture and sell the drug, their incentives are firmly aligned to make a deal in which both patent owners will profit, and the public will benefit.

It is true that occasionally, blocking patents may result in preventing the discovered use of the patented compound in the market,[274] but generally beneficial use will occur because the incentives are strong for a deal to be made allowing one or the other patent owner—or a third party—to make and sell the drug for the newly discovered use.[275] The value of the two patented inventions together is far greater than the value of either invention on its own (the method-of-use patent has no value without a license to use the compound and the compound has little or no value without a commercial use).[276] Thus, notwithstanding the term "blocking patents," one sees that such patents generally allow everyone to profit and, therefore, facilitate coordination around making and selling innovation.[277] What this means is that facilitating the patenting of research intermediaries and methods of using them can facilitate R&D, invention, commercialization, and better public health. Of course, the incentive is affected by the transaction costs of licensing patents. If transaction costs are higher, fewer beneficial deals will be done.[278] If transaction costs are lower, more deals will get done and the public will benefit more.[279]

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272. *Id.*

273. *Id.*

274. *See* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341, 353 (2010) (recognizing that there may be situations where transaction costs are too substantial for blocking-patent owners to reach an agreement).

275. *See* Lemley, *supra* note 267 ("The original patent owner can prevent the improver from using his patented technology, but the improver can also prevent the original patent owner from using the improvement. Unless the parties bargain, no one gets the benefit of the improvement."); *see also* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, J. ECON. PERSPS., Winter 1991, at 29, 30 (1991) (discussing the relationship between follow-on inventions and a patent-protected invention, stating that "proper incentives to find fundamental technologies may require that the first patent holder earn profit from the second[-]generation products that follow" because "[t]here will be no such profit if no second-generation products follow").

276. *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 79 (1994).

277. *See* F. Scott Kieff, *Coordination, Property, and Intellectual Property: An Unconventional Approach to Anticompetitive Effects and Downstream Access*, 56 EMORY L.J. 327, 351–53 (2006); *see also* F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 76–77, 102–04 (2003).

278. *See* Rai, *supra* note 177, at 832.

279. *See id.*; *see also* Merges, *supra* note 276.

Note that this condition applies even to new uses of a drug that is already being sold to treat a condition. If the drug is found to be effective in treating an additional condition, then the market value of the drug increases, and it is again in the interest of the drug's patent owner and the method-of-treatment patent owner to make a deal so that the drug can be sold for the new use.[280] New uses and off-label uses of drugs are common, as researchers experiment with current drugs to determine whether they may have additional beneficial uses.[281]

This is an important point. Proponents of strict utility worry that allowing product patents on inventions without known real-world use will lock up the patented product and prevent discoveries of its uses.[282] But in reality, many products are patented once they have one known use.[283] Thereafter, researchers continue to experiment with the patented product and discover new uses for it, which they then patent.[284] This overlapping activity and these overlapping patent rights seem to drive a lot of innovation rather than stunting it.[285] The number of commercialized inventions subject to blocking patents illustrates this fact.[286]

This occurs for a reason. Even after a use for a patented molecule has been discovered and the molecule is being sold in the market, it is often in the interest of the owner of the patent on the molecule to continue to allow free research use of the molecule.[287] If researchers can come up with other beneficial uses of

280. *See* Storz, *supra* note 263, at 841 (observing that pharmaceutical companies often continue to experiment with their products after patenting and that such experimentation may lead to additional profitable and patentable aspects, such as dosage methods).

281. *See* Cassie Tomlin, *New Uses for Existing Treatments: The Practice of Drug Repurposing*, CEDARS-SINAI (Sept. 19, 2023), https://www.cedars-sinai.org/discoveries/practice-of-drug-repurposing.html [https://perma.cc/RY2W-5AHF] (identifying that finding new uses for existing drugs has become increasingly common due to rising pharmaceutical development costs and technological improvements).

282. *See* Julian David Forman, *A Timing Perspective on the Utility Requirement in Biotechnology Patent Applications,* 12 ALB. L.J. SCI. & TECH. 647, 651–52 (2002).

283. Seymore, *supra* note 130, at 163–65 (noting that products with even trivial discovered uses can be patented and these patents can serve as blocking patents for downstream innovation, and arguing that there is not a compelling reason to allow these patents but not patents on the invention of the product itself without a known use).

284. *See, e.g.*, Holbrook, *supra* note 130, at 1005.

285. *See* Freilich, *supra* note 245, at 2223 ("First, focusing on how patents block research does not fit with facts on the ground: it is quite clear that downstream research occurs even when patentees have not permitted it, and some studies have found that downstream research occurs equally frequently in the presence or absence of a blocking patent.").

286. *See* F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 720 (2001) (pointing out the many commercial products made notwithstanding plentiful upstream patents).

287. *See* Burk & Lemley, *supra* note 37, at 1581–82 (discussing the financial and time costs of pharmaceutical development, including "[p]harmaceutical companies [having to] try hundreds of compounds before identifying a possible drug").

the molecule, it will become even more valuable.[288] As an example of what has been discussed above, a patent on a molecule that is used to treat a skin condition will become more valuable if another researcher discovers it can also be used to treat an autoimmune disorder.

The profit-sharing function of blocking patents explains why researchers will provide the "free" labor of figuring out the use of a compound or research intermediary.[289] By discovering the use, the second researcher may apply for a patent, and thus have a claim to the subsequent profits from the sale of the drug.[290] The person who created and patented the original compound will also be compensated because a license from the compound patent owner will be necessary to manufacture the compound for the newly discovered and patented method of treatment. Because both patent owners will have a monetary incentive to license their patents so that the drug can be sold, we can expect that the necessary licensing will occur.[291]

It is true that without patentability, academic and non-profit researchers may do basic research to discover new compounds because they have non-monetary incentives such as the desire to publish their work.[292] But as discussed in Section IV.A of this Article, there is a lack of incentive to share the many compounds that academics create that do not make their way into publications.[293]

The case of *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* provides an example.[294] Myriad discovered and owned the genes for BRCA 1 and 2, mutations of which corresponded to greatly increased chances of breast and ovarian cancer.[295] Myriad was famous for strict—if not ruthless—enforcement of its patents in the marketplace.[296] Myriad charged as much as $4,000 to perform the diagnostic tests to determine whether a person had mutations of the BRCA 1 and 2 genes correlated with higher likelihoods of cancer.[297] And Myriad did not have the types of programs often seen that facilitated provision

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288. *See* Storz, *supra* note 263, at 841 (observing that pharmaceutical companies often continue to experiment with their products after patenting and that such experimentation may lead to additional profitable and patentable aspects, such as dosage methods).

289. Merges, *supra* note 276, at 81.

290. *Id.*

291. *Id.*

292. *See* Constance E. Bagley & Christina D. Tvarnó, *Promoting "Academic Entrepreneurship" in Europe and the United States: Creating an Intellectual Property Regime to Facilitate the Efficient Transfer of Knowledge from the Lab to the Patient*, 26 DUKE J. COMPAR. & INT'L L. 1, 58–60 (2015).

293. *See id.* at 4–5 (discussing the incentives to publish and the relatively small profit made by universities in relation to the amount of research performed).

294. *See* 569 U.S. 576 (2013).

295. *Id.* at 582–83.

296. *See id.* at 585–86; Matthew Rimmer, *The Race to Patent the SARS Virus: The TRIPS Agreement and Access to Essential Medicines*, 5 MELBOURNE J. INT'L L. 335, 341 (2004).

297. Andrew Pollack, *Myriad Genetics Ending Patent Dispute on Breast Cancer Risk Testing*, N.Y. TIMES (Jan. 27, 2015), https://www.nytimes.com/2015/01/28/business/myriad-genetics-ending-patent-dispute-on-breast-cancer-risk-testing.html [https://perma.cc/93UN-NJG9].

of its services to those who could not pay.[298] In addition, Myriad forbade researchers working with genetic samples of the BRCA 1 and 2 genes from informing the people from whom the samples came if they were at an increased risk of cancer based on their genes, unless those persons paid the price of a BRCA screening to Myriad.[299] This restriction made a number of researchers unwilling to continue working with genetic samples of the BRCA 1 and 2 genes because they believed it was unethical not to share increased risk of cancer with the people providing the genetic samples.[300]

Notwithstanding this singular focus on profit maximization, Myriad allowed university and non-profit researchers to freely conduct research on the BRCA 1 and 2 genes without any payments.[301] Myriad did this because the profit motive aligned with allowing others to freely research the genes.[302] The more researchers discovered about gene variants and the links to cancer, the more valuable Myriad's diagnostic screenings became.[303] Moreover, if a researcher discovered a genetic therapy to repair BRCA 1 and 2 mutations, this would have greatly increased the value of Myriad's monopoly on screening for BRCA 1 and 2 mutations.[304] Not only would more people have the incentive to get screened (currently some people choose not to know because the main treatments are only increased monitoring, mastectomies, and hysterectomies)[305] but the maker of the gene therapy would have licensed use of the gene from

298. *See* Brief for Petitioner at 45, *Ass'n for Molecular Pathology*, 569 U.S. 576 (No. 12–398); Rochelle Cooper Dreyfuss, *Reconsidering Experimental Use*, 50 AKRON L. REV. 699, 709–10 (2016) ("[O]nly Myriad could test patients: second-opinion testing became unavailable, patients whose insurance companies did not deal with Myriad could not obtain reimbursement for the tests . . . .").

299. *See* Brief for Petitioner, *supra* note 298, at 43.

300. *See id.* at 43; Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System, a Single Company Has Gained Control over Genetic Research and Testing for Breast Cancer, and Scientists, Doctors, and Patients Have to Play by Its Rules*, BOS. GLOBE MAG., Feb. 24, 2002, at 10.

301. *See* W. Lesser, *Myriad & Prometheus, Laws & Products of Nature: Are the Courts Considering an Economic Non-Statutory Subject Matter Exclusion?*, 53 IDEA: L. REV. FRANKLIN PIERCE CTR. FOR INTELL. PROP. 173, 213–14 (2013) ("Generally, if [the] work [of non-profit entities, such as universities] does not involve fees . . . such organizations are largely ignored; some may receive a cease-and-desist notification, but notifications are rare and frequently ignored. Myriad, for example, allowed tests so long as fees were not charged."); Eisenberg, *supra* note 173, at 1071–72 ("Even if the patent holder knows about . . . use [by researchers], it might not be worth the trouble and expense of pursuing a lawsuit against a researcher who does not represent a significant threat to the patent holder's commercial interests." (footnote omitted)).

302. *See* Eisenberg, *supra* note 173, at 1072; Bagley & Tvarnó, *supra* note 292; Dreyfuss, *supra* note 260, at 709.

303. *See* Dreyfuss, *supra* note 260, at 709 (discussing broader applications of Myriad's patented genes and tests that were inhibited by Myriad's patent enforcement, including "researchers looking for other causes of early onset breast cancer").

304. *See id.* (identifying the market power Myriad held because Myriad was "the holder of patents on BRCA 1 and BRCA 2 gene sequences" and had "developed a diagnostic test that it refused to license to other laboratories").

305. *See BRCA Gene Changes: Cancer Risk and Genetic Testing*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet (click on "How can a person who has inherited a harmful change in BRCA1 or BRCA2 manage their risk of cancer?") [https://perma.cc/FJV6-CW4E].

Myriad.[306] Thus, even for actors motivated purely by profits, there is often an incentive to allow research on patented compounds, genes, or research intermediaries at low or no cost.[307]

The case of patents on processes that produce research intermediaries can be somewhat different. In this case, the patent owner only owns the right to control the specific process that results in a product.[308] Others are free to design around the process patent by coming up with other processes that achieve the same product.[309] Thus, a process patent gives less coverage than a patent on the resulting compound and is generally less valuable.[310] If a valuable use for the product that results from the process is found, the incentive to design around the original process patent greatly increases.[311] Accordingly, owners of process patents cannot be sure that they will continue to benefit if a beneficial use is discovered for the product that results from the patented process. This may give such patent owners more incentive to extract profits at the research stage. On the other hand, if the process-patent owner believes that it has discovered a particularly good or efficient way to make the product, it may be comfortable allowing free use of the process for research with the thought that it will make much more profit if a beneficial use is found, and a manufacturer then needs to

306. *See* Eisenberg, *supra* note 173, at 1071–72.

307. *See id.* at 1072 ("Moreover, some patent holders might not object to the unlicensed use of their inventions in their own fields if they think the research might open up new markets for their inventions or improve upon them in ways that increase the value of their patent rights."); Freilich, *supra* note 245, at 2240 ("There is often little value in enjoining a research project because a patentee may not find out about the research project until it is finished and published and further, patentees may decline to sue academic infringers because of the reputational costs of such a suit."); *The Myriad Pledge*, MYRIAD GENETICS, https://perma.cc/4YUV-B8VE (explaining Myriad's pledge to "not impede noncommercial, academic research that uses patented technology licensed or owned by [Myriad]" and to "continue to offer [a] financial assistance program"); Damian Garde, *Myriad Targets Gene by Gene in Second BRCA Patent Suit*, FIERCE BIOTECH (July 10, 2013, 3:21 PM), https://www.fiercebiotech.com/medical-devices/myriad-targets-gene-by-gene-second-brca-patent-suit [https://perma.cc/U2D5-KCEA] (discussing Myriad's 2013 pledge to allow certain academic uses of their technology and to provide patients with financial help). Note that genomic DNA is no longer patentable subject matter after *Ass'n. for Molecular Pathology v. Myriad Genetics, Inc.*, and because, with the completion of the sequencing of the human genome, even isolated DNA sequences (genes) can no longer be considered novel because they have all been discovered. *See* 569 U.S. 576, 595–96 (2013). Some exceptions may exist for mutations of genes not sequenced. New genetic sequences are patentable, of course. Chemical compounds and biologics that are new do not suffer from the patentable subject-matter problem that caused the Supreme Court to hold that naturally occurring genes are not patentable. *See id.* at 591–95.

308. Matthew Erramouspe, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races*, 43 UCLA L. REV. 961, 966 (1996) ("A process patent prevents others from using the particular process without compensating the patent holder, but does not prevent other inventors from using or even patenting different processes yielding the same product.").

309. *See id.*; Julie Dohm, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole*, 156 U. PA. L. REV. 151, 170 (2007) (discussing the design-arounds that may occur when molecules are protected by process patents).

310. *See* Erramouspe, *supra* note 308, at 966.

311. *See* William B. Lafferty, *Statutory and Ethical Barriers in the Patenting of Medical and Surgical Procedures*, 29 J. MARSHALL L. REV. 891, 915 (1996) ("[W]hen the [US]PTO issues [a medical or therapeutic-process] patent, there exists an incentive for others in the field to design around the patent and break new scientific ground . . . .").

license the process to produce the product. In other cases, however, there may already be other ways to make the product that are only slightly less efficient, or the owner of a process patent may believe that such alternatives will likely be discovered if a valuable use is found for the product that results from the process.[312] In such a case, the incentive may be to license researchers to use the process to create the product, with a sharing of the profits in the ultimate use discovered. Note, however, that in such a case, the amount the patent owner can charge researchers is limited both by the fact of the uncertainty of the value of the resulting product as well as by the likely availability of alternate processes to make the product.[313] In such a case, the process is of some, but limited, value, and any license fee will have to reflect that the patent owner wants to find researchers willing to license the process.

D. Research Intermediary Patents Create Joint Ventures, Not Successive Monopolies

Part III of this Article discusses the arguments for the strict utility standard and against allowing patents on research intermediaries. One of those arguments rests on the successive marginalization problem. Successive marginalization, which is also known as double, or successive, monopoly, is well known in economics.[314] Successive marginalization occurs when multiple parties in a vertical supply chain have monopolies on supply chain elements.[315] Each monopoly owner will charge a monopoly price on its input to the supply chain, thus downstream users accept that monopoly price as part of the cost of providing their input.[316] Because monopolists base their pricing on their costs, as well as the demand curve, they charge higher prices when their costs are higher.[317] The result is that the end good in the vertical supply chain has a

312. *See id.*

313. *See id.* at 915–16.

314. *See, e.g.*, James Langenfeld, *Non-Horizontal Merger Guidelines in the United States and the European Commission: Time for the United States to Catch Up?*, 16 GEO. MASON L. REV. 851, 857 (2009); Cotter, *supra* note 172; Erik Hovenkamp & Herbert Hovenkamp, *Tying Arrangements and Antitrust Harm*, 52 ARIZ. L. REV. 925, 958–60 (2010); Hristova, *supra* note 173; Layne-Farrar, *supra* note 175; Herbert Hovenkamp, *Antitrust and the Movement of Technology*, 19 GEO. MASON L. REV. 1119, 1128–29 (2012); Herbert Hovenkamp, *A Symposium on Tying: Antitrust and Nonexcluding Ties*, 8 COMPETITION POL'Y INT'L 41, 45–46 (2012); Mark A. Lemley & Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2157–59 (2013); Sagi, *supra* note 175; Hovenkamp, *supra* note 175; Norman V. Siebrasse & Thomas F. Cotter, *A New Framework for Determining Reasonable Royalties in Patent Litigation*, 68 FLA. L. REV. 929, 984–85 (2016); Clarkson & Joshua, *supra* note 171; Rubinfeld, *supra* note 174; Auer & Morris, *supra* note 174.

315. *See* Hovenkamp & Hovenkamp, *Tying Arrangements and Antitrust Harm*, *supra* note 314, at 958 ("Double marginalization occurs when complementary goods or services are both sold in less-than-perfectly competitive markets and the two sellers are not able to coordinate their output to the joint maximizing level.").

316. *Id.* ("The classic case involves vertical integration, in which both an upstream and a downstream firm have some measure of market power.").

317. *Id.*

> The first firm, perhaps a manufacturer, computes its monopoly output and price by equating marginal cost and marginal revenue. The second firm, perhaps a retailer which also has some

substantially higher price when double, or successive, monopolists are part of a vertical supply chain.[318] This is why the DOJ and FTC have traditionally recognized that allowing monopolists in a vertical supply chain to merge results benefits the public.[319] When only a single monopolist exists in a vertical supply chain, it will charge a lower monopoly price because it will base its pricing on the market costs of the vertical inputs rather than the elevated prices that successive monopolists would charge.[320] This results in an end product that is lower priced, and thus that more users of the input can afford to buy.[321] The resultant increase in allocative efficiency means that more products are available at cheaper prices for use by businesses and the public, resulting in higher gross domestic product and consumer utility.[322] In the area of pharmaceuticals, eliminating the successive monopoly problem means that more drugs will be produced for lower prices to hospitals and patients.

At first glance, allowing patents on research intermediaries seems likely to substantially increase the successive marginalization problem. After all, if research intermediaries are patented, then those researching, say, whether they can be useful for a drug to treat a condition, will have to pay the price charged by the owner of the patent to the research intermediary.[323] If the owner of the patent on a research intermediary such as a new molecule of unknown usefulness charges a monopoly price, and the drug company that discovers a use for the molecule also charges a monopoly price for its patented method of treatment, two monopolies result, with the classic successive monopoly problem driving prices to patients higher than if there were only a single monopolist.[324]

But in general, patents on research intermediaries will not be priced at a monopoly price as an input into a patented treatment. Instead, owners of research intermediary patents will have an incentive to enter what are effectively

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> market power, purchases from the manufacturer at this monopoly price and then equates its own marginal cost and marginal revenue, in the process adding on yet another monopoly markup.

Id.

318. *Id.* ("The result [of successive marginalization] is even lower output and higher prices.").

319. The FTC/DOJ Draft Merger Guidelines released December 18, 2023, take a more skeptical view of vertical mergers, but this is not in accordance with the mainstream of economic analysis. *See* MERGER GUIDELINES, U.S. DEP'T OF JUST. AND THE F.T.C. (Dec. 18, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p859910draftmergerguidelines2023.pdf [https://perma.cc/KT4N-882E].

320. Lemley & Melamed, *supra* note 314, at 2157–59.

321. Hovenkamp & Hovenkamp, *Tying Arrangements and Antitrust Harm*, *supra* note 314, at 961.

322. *Id.*

323. Toshiko Takenaka, *Unravelling Inventorship*, 21 CHI.-KENT J. INTELL. PROP. 71, 81 (2022) ("Ultimately, the collaboration of different stakeholders in the linear innovation process resulted in products covered by upstream and downstream patents owned by different patent owners, which presented coordination challenges for conducting further research.").

324. *See* Hovenkamp & Hovenkamp, *Tying Arrangements and Antitrust Harm*, *supra* note 314, at 958-61. Double marginalization, or royalty stacking, occurs when the producers of two complementary products with some monopoly power are unable to coordinate their output. *Id.* at 958. The result will be that price will be higher and output lower than under-coordinated pricing.

joint ventures with the researchers who discover real-world applications of the patented research intermediary molecules. The reason for this is that the molecules will not be sold to the drug makers as an input. Rather, the owner of the research intermediary patent and the drug company will each hold blocking patents as to the manufacture and sale of the drug. They will need to enter a licensing agreement so that the drug can be sold. This will effectively put them in the position of participants in a joint venture.[325] The drug will be sold at a single monopoly price, with the patent owners dividing up the monopoly profits. Moreover, as discussed in Section IV.C, because patents on new research intermediary molecules will be of low value until a real-world use is discovered for the molecule,[326] patent owners will have significant incentive to charge low, or no, license fees for those wishing to conduct research on potential uses of the new molecules, in hope that a significant use is discovered that can lead to a profitable splitting of profits on the subsequent drug or industrial use of the molecule.

While the successive monopoly problem generally should not occur with research intermediaries, there are some cases in which the problem could occur. If a new molecule is used as a precursor to create the chemical inputs into more than one drug, that precursor may be priced and sold as an input to the vertical supply chain. At that point, each patent on a precursor will create a successive monopoly problem. It should be noted, however, that precursor molecules can be patented as long as a single use of them can be shown in the creation of a drug or product with real world use.[327] Thus, many precursor molecules can be patented under the current strict utility standard, and this successive monopoly problem already exists in many cases with regard to precursors. It is uncertain the extent to which the ability to patent new molecules that can be used as precursors will exacerbate the successive monopoly problem of precursors. But allowing patents on research intermediaries will not be creating this problem; it may simply add to it somewhat in cases of new molecules for which use as a precursor in a successful drug or product has not already been discovered.

One should also note that under the strict utility standard, as Sections IV.A–B discuss, there is currently a significant incentive to keep secret the creation of new molecules, including potential precursor molecules.[328] This incentive of secrecy would be removed if new molecules were patentable under the relaxed patentability standard. This increase in sharing and dissemination of new molecules must be weighed against the potential for some increase of successive marginalization regarding new precursor molecules without any current known use.

325. *See* Lemley, *supra* note 267, at 1010.

326. Mireles, *supra* note 252, at 165.

327. *See supra* notes 275–76 and accompanying text.

328. *See* Price & Rai, *supra* note 188, at 1048–49.

Even if relaxing the utility standard to allow patents on research intermediaries does result in some issues of successive marginalization, this is the norm in supply chains. Many industries are characterized by numerous patents on products in the supply chain, but nevertheless, new and better products are made and sold every year.[329] Because research intermediary patents will, for the most part, result in joint-venture incentive structures instead of successive monopolies, the risk from such patents is low and the benefits are high.

V. BETTER ALTERNATIVES TO THE STRICT UTILITY REQUIREMENT

This Part of the Article considers alternatives to the current strict utility requirement. Section V.A argues that the best approach to the utility requirement is for the Supreme Court to return to the utility requirement as it existed before *Brenner v. Manson*. Notwithstanding this preferred approach, this Section explores two other alternatives to mitigate the problems of the strict utility requirement. Section V.B considers the benefits and drawbacks to granting limited "research patents" as Professor Sean Seymore has urged. Finally, Section V.C considers the approach adopted in a Boards of Appeal decision from the European Patent Office, which held that utility could be satisfied by showing that a research intermediary is of interest to researchers in industry.

A. Returning to a Minimalist Utility Requirement

This Article has shown that the benefits of allowing patents on research intermediaries outweigh the costs. Accordingly, this Article urges a return to the approach that preceded *Brenner v. Manson*,[330] when courts held that the utility requirement was satisfied by creating a new product.[331] Creation of a new compound or molecule is useful to researchers interested in experimenting with new compounds to determine beneficial uses.[332] If new compounds were truly useless, then the concerns present in the arguments for strict utility would have no foundation.[333] A completely useless composition of matter cannot hinder

329. *See* Kieff, *supra* note 286, at 720:

> It cannot be, however, that patents on inputs generally prevent the production of outputs. Entire industries have come and gone using scores of patented inputs. . . . Every car is made using countless patented parts, fasteners, processes, and subsystems. Even the biological scientist manages to use a variety of patented machines, reagents, and equipment in the ordinary course of research. It does not appear that [critics] would argue that producers of biological innovations should not have to pay the licensing fee for ordinary inputs, including, for example, the intermittent windshield wiper subsystems on the car they drive to the laboratory in the morning.

330. Brenner v. Manson, 383 U.S. 519, 531–35 (1966).

331. *See supra* notes 98–104 and accompanying text.

332. Eisenberg, *supra* note 173, at 1974 n.224.

333. *See supra* Part IV.

downstream research because no one need use a useless compound.[334] As this Article has shown, the concerns that led the Patent Office and courts to embrace the strict utility standard all depend on the potential usefulness of the newly created compound and worries that compound patent owners will use their exclusive rights to block downstream research.[335] This Article shows that newly created compounds and molecules—research intermediaries—are useful to researchers.

B. Research Patents

While returning to a minimalist utility requirement is the preferred approach, another alternative is to grant limited patent rights for research intermediaries. Sean Seymore has argued for such a limited patent right, which he calls the "research patent."[336] Seymore's proposed research patent would grant the inventor of a research intermediary a limited patent on the compound invented.[337] The inventor would have an exclusive right to control the research use of the compound but not a right to control the making, using, selling, or importing of the compound for other purposes.[338] Seymore's proposed research patent would allow the inventor to profit from licensing research uses of the compound, but the inventor would have no right to control use of the compound as a drug, industrial application, or other method of "real-world" use.[339]

While Seymore's proposal is initially appealing, for several reasons it is ultimately inferior to simply allowing a full patent for new research intermediaries. First, this Article has contributed to the literature by showing that patents on research intermediaries solve the successive marginalization problem.[340] As discussed earlier, patents on research intermediaries effectively create joint-venture scenarios rather than successive monopoly scenarios.[341] This means that when a downstream researcher discovers an applied use for a research intermediary and obtains a patent on that method of use, the economics are such that the owner of the research intermediary patent and the method-of-use patent are incentivized to come to an agreement on the sale of the compound for its discovered method of use.[342] This agreement will put them in the position of pricing the use of, say a drug, as a single item of

334. *See supra* Part II.
335. *See supra* Parts III and IV.
336. Seymore, *supra* note 130.
337. *Id.* at 167–69.
338. *Id.* at 169.
339. *Id.* at 167.
340. *See generally id.*
341. *See supra* Section IV.D.
342. *See supra* Section IV.D.

commerce.[343] Thus, allowing full patents for research intermediaries will not result in patents on upstream products in a manufacturing supply chain, but instead in joint-venture negotiations.[344] This provides maximum incentive for the owner of the research intermediary patent to publicize her new compound and to encourage widespread research as to the use of the compound, often free use, in fact.[345]

The problem with Seymore's research patent proposal is that it would destroy this joint-venture incentive structure. If the inventor of a research intermediary can only extract value from the research use of the compound, that inventor has an incentive to charge as high a price as possible, eliminating research by those who cannot pay and by those seeking lower value uses of the compound that would still be socially beneficial. In addition, if the developer of a method of use for the compound desires to do further research to improve the effectiveness of the compound, the owner of the research patent has an incentive to now charge a higher price for that further research to capture some of the value of the use of the compound in the marketplace. This could lead to hold-up problems of the sort that concern both Seymore and those in favor of the strict utility standard. The problem is the one identified in this Article, giving control of a compound only for research purposes creates the successive monopoly problem that a full patent on the compound solves by creating a joint-venture incentive structure.[346]

Seymore recognizes that owners of his proposed research patents would desire to extract value from the applied use of the compounds covered by their research patents.[347] He suggests that courts could assign reach-through damages in infringement cases such that the owner of the research patent could obtain some share of the later-discovered use of the compound.[348] However, there are problems with this suggestion. One problem is that reach-through damages would only apply to infringement cases, not licensed research use.[349] Another problem is that, as Seymore himself recognizes, reach-through damages are far from certain in infringement cases involving research tools.[350] Thus, the adoption of Seymore's proposed research patent would introduce a great deal of uncertainty into what compensation rights a research patent owner would have. It would give those patent owners the incentive not to license their patents

343. *See supra* Section IV.D.

344. *See supra* Section IV.D.

345. *See supra* Section IV.D.

346. *See supra* Section V.D.

347. Seymore, *supra* note 130, at 170.

348. *Id.*

349. *See* Alfred C. Server et al., *Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools*, 1 HASTINGS SCI. & TECH. L.J. 21, 112–20 (2009).

350. Seymore, *supra* note 130, at 170 (citing Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 871 (Fed. Cir. 2003), *rev'd on other grounds*, 545 U.S. 193 (2005), for the proposition that the Federal Circuit has "suggested" that reach-through damages for infringement of patent tools "may" be appropriate).

so that they could instead sue for patent infringement and reach-through damages if a use is later discovered. And instead of the parties bargaining a priori and directly, it would leave to courts the difficult task of trying to determine the share of the downstream value of the compound that should be attributed to the research patent owner. Simply allowing full patents on research intermediaries avoids all of these problems. It leaves to those directly concerned the decision of how to divide the value of the compound's method of use. Those directly concerned are also the ones with the most incentive to come to an agreement that benefits both parties.

Finally, Seymore's proposed research patent might ironically deter the dissemination of knowledge about newly invented compounds. If the way to extract maximum value from the research patent is to sue for infringement once a use has been discovered, then research patent owners have the incentive to patent new compounds but not widely share the information about the compounds with others, hoping instead to hold up drug developers and others once an applied use is discovered. It may even give inventors filing research patents the incentive to keep secret the best methods of making the compound, notwithstanding that disclosure of "best mode" technically remains a requirement of patent law.[351] Thus, while Seymore's article is a persuasive contribution to the literature as to the problems with the strict utility requirement, his proposed solution ultimately falls short.[352] This Article shows that relaxing the utility requirement to allow patenting of any new compound is a superior approach, solving the successive monopoly problem and creating the social-welfare-maximizing joint-venture incentive structure.

C. Satisfying the Utility Requirement by Showing a Research Intermediary Is of Interest to Industrial Researchers

There is another alternative to fully relaxing the strict utility requirement that merits discussion. Either the Supreme Court or Congress could adopt the position laid out by the Boards of Appeal of the European Patent Office in its 2004 decision that granted a patent on a compound with no known use but that was of interest to industrial researchers.[353] This approach would be a middle ground, allowing patents on promising research intermediaries when the inventor could provide evidence to the PTO that the research intermediaries are of interest to applied researchers. Compounds in which there was no

351. While 35 U.S.C. § 112(a) retains the requirement that a patentee "set forth the best mode contemplated by the inventor . . . of carrying out the invention," 2011 revisions to the patent statute eliminated failure to set forth best mode as grounds for invalidating a patent, leaving best mode a technical requirement that has no effect on patentability if it is omitted. *See* 35 U.S.C. § 282(b)(3)(A).

352. Interestingly, Seymore in an earlier article argued against any utility requirement at all, which seems a more beneficial approach than his research patent suggestion. *See* Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046 (2014).

353. For discussion of the Boards of Appeal opinion, see Part II, *supra*.

demonstrable interest at the time of filing would fail this middle-ground utility standard.

The utility requirement in the European Union is similar to the requirement under U.S. law.[354] Article 52 (Patentable Inventions), Paragraph 1 of the Convention on the Grant of European Patents (European Patent Convention or EPC) states: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."[355] Article 57 defines "industrial application," stating: "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."[356] The European Patent Office (EPO) Guidelines state: "'Industry' is understood in its broad sense as including any physical activity of 'technical character' . . . i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts; it does not necessarily imply the use of a machine or the manufacture of an article."[357] The EPO Guidelines state: "Art. 57 excludes from patentability very few 'inventions' which are not already excluded by the list in Art. 52(2)."[358] Rule 42(1)(f) of the EPC Implementing Regulations requires a patent application to specify the utility of a claimed invention when it is not obvious from the description of the invention.[359] In

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354. *See generally* Toshiko Takenaka, *The Best Patent Practice Or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a "First-to-Invent" Exception for Domestic Applicants*, 11 TEX. INTELL. PROP. L.J. 259, 340–41 (2003) (discussing differences between the utility standard in the United States and the EPO's industrial-applicability standard).

355. Convention on the Grant of European Patents art. 52, ¶¶ 1–3, Oct. 5, 1973, 13 I.L.M. 268 (last updated Apr. 2024) [hereinafter EPC]. This Article goes on to say:

> (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
>
> (a) discoveries, scientific theories and mathematical methods;
>
> (b) aesthetic creations;
>
> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
>
> (d) presentations of information.
>
> (3) The provisions of paragraph 2 shall exclude the patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent relates to such subject-matter or activities as such.

Id.

356. *Id.* at art. 57. Note that the EPC is not strictly co-extensive with EU member states. The EPC is an international treaty independent of the EU. Its members are comprised of those who have acceded to the EPC. Thus, the United Kingdom, for example, is still a member of the EPC even though it has left the EU. For a current list of EPC member states, see *Member States of the European Patent Organisation*, EUR. PAT. ORG., https://www.epo.org/en/about-us/foundation/member-states [http://perma.cc/DKE4-DAC4].

357. Eur. Pat. Off. [EPO], *Guidelines for Examination in the European Patent Office*, pt. G, ch. III, § 1 (Mar. 2024), https://new.epo.org/en/legal/guidelines-epc/2023/g_iii_1.html [https://perma.cc/6ZX8-P6XK].

358. *Id.* For the list of exceptions to patentability in Article 52(2), see *supra* note 355.

359. Eur. Pat. Off. [EPO], *Implementing Regulations to the Convention on the Grant of European Patents*, pt. III, ch. II, r. 42(1)(f) (last amended Dec. 14, 2023), https://www.epo.org/en/legal/epc/2020/r42.html [https://perma.cc/CX2U-ZZAQ] (stating that the patent should "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.").

summary, there is no express requirement of strict utility—in the form of known use to treat a real-world condition—anywhere in the language of the EPC, the EPC Implementing Regulations, or the EPO Examination Guidelines. The EU patent statutes and regulations thus are similar to the vague term "useful" in the U.S. Patent Act, in that the statutory language does not require a strict utility approach.

Decisions from the Boards of Appeal of the EPO (Boards of Appeal) are not entirely clear as to the EPO utility standard. Some Boards of Appeal decisions state that the industrial-applicability requirement should be construed broadly to include any "immediate concrete benefit."[360] Other decisions have interpreted the EU statutory language in a way very similar to the U.S. requirement of strict utility.[361] Boards of Appeal decisions have held that simply showing that a new substance could be produced did not fulfill the utility requirement;[362] instead "some profitable use for which the substance [could] be employed" is required.[363] Nor is inventing a new compound and describing its structure enough to meet utility.[364] The Boards of Appeal have argued that "[i]t

360. Hematopoietic receptor/ZYMNOGENETICS, T 0898/05, Decision, ¶ 6 (EPO Bds. App. July 7, 2006), https://www.epo.org/boards-of-appeal/decisions/pdf/t050898eu1.pdf [https://perma.cc/3FN4-5PHP].

361. BDP1 Phosphatase/MAX-PLANCK, T 0870/04, Decision, ¶ 4 (EPO Bds. App. May 11, 2005), https://www.epo.org/boards-of-appeal/decisions/pdf/t040870eu1.pdf [https://perma.cc/JHJ4-ZZNP] ("[A] 'practical' application of the invention [must] be disclosed.") (a "disease or condition . . . attributable to an excess or deficiency of the substance" must be known, or some other practical use suggested, before the industrial-application requirement could be met).

362. *Id.*

363. *Id.*

364. *Id.* ¶ 6 (stating that when a genetic substance (DNA sequence) is "identified, . . . structurally [characterized,] and made available through some method" but "its function is not known, . . . then industrial applicability cannot be acknowledged."); Hematopoietic receptor/ZYMNOGENETICS, T 0898/05, Decision, ¶ 7 (EPO Bds. App. July 7, 2006), https://www.epo.org/boards-of-appeal/decisions/pdf/t050898eu1.pdf [https://perma.cc/3FN4-5PHP] (applying EPC Articles 56, 57, and 83, as interpreted in EPC Rules 23e(3) and 27(1)(f), to hold that "a product whose structure is given (e.g. a nucleic acid sequence) but whose function is undetermined or obscure or only vaguely indicated might not fulfil[l] the above criteria, in spite of the fact that the structure of the product per se can be reproduced (made)" (citations omitted)); Serine protease/BAYER, T 1452/06, Decision, ¶ 23 (EPO Bds. App. May 10, 2007), https://www.epo.org/boards-of-appeal/decisions/pdf/t061452eu1.pdf [https://perma.cc/E45F-JVWF] (stating that the indication of industrial application in a patent "must have 'a sound and concrete technical basis,' as a 'speculative indication of possible objectives that might or might not be achievable by carrying out further research with the tool as described is not sufficient'" to fulfil[l] the industrial applicability requirement (emphasis omitted) (citations omitted)); Multimeric Receptors/SALK Inst., T 0338/00, Decision, ¶¶ 2, 3 (EPO Bds. App. Nov. 6, 2002), https://www.epo.org/boards-of-appeal/decisions/pdf/t000338eu1.pdf [https://perma.cc/LN99-BBSZ] (examining whether the invention was "merely an interesting research result" and finding that "[t]he activities and products disclosed . . . are . . . aimed . . . at a direct technical result that may clearly be applied in an industrial activity (modulation of the expression of a gene/product of interest in a particular expression system, screening of products with specific pharmacological activity, etc. . . .)"); PF4A receptors/GENETECH, T 0604/04, Decision, ¶¶ 13, 18 (EPO Bds. App. Mar. 16, 2006), https://www.epo.org/boards-of-appeal/decisions/pdf/t040604eu1.pdf [https://perma.cc/G87W-BG8N] (stating that only "identif[ying] applications for the claimed polypeptides which may ultimately lead to some profitable use" leaves the understanding of their function(s) "at best incompletely understood," but that at the time, the functions of the family of the claimed polypeptides "were considered not only to be interesting in

should not be left to the skilled reader to find out how to exploit the invention by carrying out a research program[]."[365] The Boards of Appeal have justified their strict utility requirement in language that could be found in U.S. judicial opinions on utility: "If a patent is granted therefor, it might prevent further research in that area, and/or give the patentee unjustified control over others who are actively investigating in that area and who might eventually find actual ways to exploit it."[366]

Interestingly, however, there is a Boards of Appeal decision that looked at the issue of patents on research intermediaries differently. In 2004, a patent applicant directly raised to the Boards of Appeal the question of whether a product that is useful only to researchers can be patented.[367] The applicant argued that EPC Article 57 has broad language and cannot be overruled or narrowed by implementing legislation or EPO patent guidance and rules.[368] The applicant argued that "industrial application" in Article 57 includes all commercial or productive uses of a patented substance, including merely for research.[369] The Boards of Appeal avoided directly answering the question of whether any new product can be patented simply because it may be of interest to researchers; instead, the Boards of Appeal decided for the applicant on a narrower ground.[370] The Boards of Appeal found that while the application provided a structural characterization of the polypeptide receptors that bind members of the PF4A family of chemokines, there was no characterization of the ligands, and therefore the function was not completely understood.[371] In a number of previous decisions, the Boards of Appeal had hinted that this might be enough to fail the industrial-application requirement of Article 57.[372] But this Boards of Appeal decision did not find a lack of utility. Instead, the Boards of Appeal relied on "the common general knowledge at the priority date" to find that chemokines were interesting not just to academic researchers but also to the pharmaceutical industry "irrespective of whether or not their role had been clearly defined."[373] The Boards of Appeal found that the receptors that were the subject of the patent application were likewise of interest to the pharmaceutical industry because the chemokines mode of action is through the

fundamental research but also as important for the pharmaceutical industry irrespective of whether or not their role had been clearly defined" (emphasis omitted)).

365. *Hematopoietic receptor/ZYMNOGENETICS*, T 0898/05, ¶ 6.
366. *Id.* ¶ 7.
367. *See PF4A receptors/GENETECH*, T 0604/04, ¶ 13.
368. *Cf. id.*
369. *See id.* ¶ 18.
370. *See id.* ¶ 13.
371. *Id.*
372. *See id.* ¶ 14–15.
373. *Id.* ¶¶ 15, 18 (emphasis omitted).

receptors.[374] Given this, the Boards of Appeal held that the patent should be granted.[375]

This decision did two noteworthy things. First, it dodged taking up directly whether EPC Rules 23 and 27 conflict with, and are thus voided by, Article 57. Second, the decision granted a patent on a substance whose function was not fully understood but was of interest to researchers in the pharmaceutical industry. The decision seems to indicate that substances that are of interest only to academic researchers do not meet the industrial-application requirement but that substances of interest to researchers in the pharmaceutical industry do. This decision suggests a departure from the path U.S. courts have taken on the question of utility. The Boards of Appeal decision offers a middle path along which substances of interest to researchers in an industry may be patented.[376]

While this patentable-if-interesting-to-industry-researchers alternative may be appealing, it is not without its own difficulties. For one thing, the methods for determining and proving that a compound is of interest to industrial researchers are far from obvious. In the 2004 EPO decision, the Boards of Appeal stated that there was "common general knowledge at the priority date" that the compound was of interest to the pharmaceutical industry and not just the academic community.[377] The Boards of Appeal did not discuss what methods and indicia of proof are sufficient to prove interest to industry, instead stating that the interest was common knowledge in that case.[378] In many cases, however, whether a compound is of interest to industry will not be common knowledge. This raises the question of how much interest would be needed, how strong an interest, and whether the interest needs to be widespread or if interest from a single industrial researcher would be sufficient. Moreover, given sponsored research agreements and start-up activity from academia, drawing the line between academic interest and industry interest could be another significant difficulty. Depending on the answers to these questions, holding that utility is met for compounds of unknown use if they are of interest to industrial researchers may effectively result in patentability for research intermediaries widely, only in select cases, or not at all. Given the joint-venture incentives that simply allowing patentability for all research intermediaries would create, it seems both unwise and unnecessary to attempt this middle way.

374. *Id.* ¶ 18.

375. *Id.* ¶ 19.

376. *See id.* ¶ 18.

377. For discussion of this EPO Boards of Appeal decision, see *supra* notes, 367–76 and accompanying text.

378. PF4A receptors / GENENTECH, T 604/04, Decision, 21–22 (EPO Bds. App. Mar. 16, 2006), https://www.epo.org/boards-of-appeal/decisions/pdf/t040604eu1.pdf [https://perma.cc/4EGZ-F8BC].

CONCLUSION

This Article has shown that the shift from the relaxed to the strict utility standard in patent law resulted from assumptions about the effects of patents on inventions with unknown real-world uses rather than from empirical evidence or plain evidence of a significant problem with the relaxed utility standard. The Article discussed arguments against a relaxed utility standard, as well as counterarguments undercutting the strength of some of those arguments, including that patent owners on research intermediaries will have incentive to facilitate research on their patented products and processes, and that fears of royalty stacking and successive marginalization are largely misplaced. Instead, the blocking patents that would result from patents on research intermediaries and on discoveries of their methods of use would drive the patent holders into a joint-venture incentive structure that would incentivize sharing the revenues from the use of the compound at no higher price to the public than if a single patent were at issue. The Article explored the recognition of the serious harm to research and development that the secrecy incentivized by the strict utility standard has caused and the reasons why a relaxed utility standard would greatly alleviate this secrecy problem. The Article showed that inventors of research intermediaries are currently substituting IP and other protections that can be significantly more restrictive than patent law of the flow of information and sharing of research advances. Given the exploration and analysis of this Article, it concludes that the strict utility standard is not well supported by evidence, history, or theory, and that there is reason to believe that a relaxed utility standard could be more socially beneficial. The Article also shows that the Federal Circuit could return to a relaxed utility standard without the need of federal legislation or the Supreme Court. The Federal Circuit could again adopt the more relaxed approach to utility that it took in cases such as *Nelson v. Bowler*, which it followed for years after the Supreme Court decided *Brenner v. Manson* in 1966. Eventually, the Federal Circuit changed its approach and adopted the strict utility requirement by a 2–1 vote in the 2005 case, *In re Fisher*.[379] The Federal Circuit panel that decided this case made the decision to adopt the strict utility standard of its own accord.[380] There was no change to the patent statute nor had the Supreme Court overruled or narrowed the Federal Circuit's relaxed utility line of cases.[381] The Federal Circuit is now free to undo this approach with a single en banc decision.

379. *In re* Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

380. *See id.*

381. *See id.*