THE SINKING SHIP OF THE HATCH-WAXMAN ACT "SAFE HARBOR" PATENT INFRINGEMENT DEFENSE: AN ARGUMENT FOR INCLUDING RESEARCH TOOLS

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ABSTRACT

Patents incentivize the disclosure of novel technology by granting the inventor the right to exclude others from the production, use, import, or sale of their invention for a limited time. When considered in the context of medical devices and pharmaceutical drug therapies, patent exclusivity implicates patient and societal health and wellness. Amidst the rise in drug prices, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, addressed the seemingly competing interests of incentivizing medical innovation through patent protection and lowering consumer drug prices by increasing access to generic drug products. Congress bridged this divide, in part, by establishing a new statutory scheme aimed at resolving two unintended distortions in an invention's patent term.

The Hatch-Waxman Act altered the patent law landscape by providing the first legislative exemption to patent infringement, known as the "Safe Harbor." Generally, for the Safe Harbor infringement exemption to shield an otherwise infringing activity, the "patented invention" must be used for specific purposes of creating information required under a federal law regulating the manufacture, use, or sale of drugs. But what are the types of "patented inventions" that Congress envisioned? Did Congress intend the scope of Safe Harbor's "patented invention" clause to exclusively encompass inventions subject to regulatory approvals, like drugs, or did the clause encompass a broader, more general collection of patented research technology, like a fluorescent tagged antibody?

This note argues that the term "patent invention" should be interpreted broadly, to include research tools that are not themselves subject to federal regulatory approval. First, principles of statutory interpretation support the plain reading of the Safe Harbor provision to include research tools and weigh against reading unfounded restrictions into the provision's terms. Second, endorsement of this broad interpretation is checked by the Safe Harbor's additional requirement that the unauthorized use of the "patented invention" be solely for uses reasonably related to the creation of information required under federal law regulating drugs. And, ultimately, public policy favors lowering drug prices by increasing the number of competitive drugs in the marketplace, which would be facilitated by opening research tools to the statutory protections afforded by the Safe Harbor.

INTRODUCTION

Patent rights play a central role in growing the bounty of knowledge in society. They provide an incentive for an inventor's disclosure of novel technology in exchange for the exclusive ability to reap economic value from the invention.[1] However, the coin of exclusivity has two sides: one that incentivizes innovation and one that quenches it.[2] When placed in the context of the biotechnology and pharmaceutical industries, the ability to make or use an invention patented by another implicates the well-being of the group that patent rights were designed to benefit—society.[3]

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, provided the first and only statutory exemption to patent infringement.[4] A provision of the Act, commonly known as the Safe Harbor, exempts an otherwise infringing activity from liability, provided that the patented invention was infringed solely for reasons related to the submission of information required under federal law regulating the manufacture, use, or sale of drugs.[5] From the beginning, the Hatch-Waxman Act unsurprisingly implicated elements of patent law but, whether intentional or not, produced an exhibition on statutory interpretation.[6] Suits litigating the language of the Safe Harbor provision have twice garnered the attention of the Supreme Court and continue to maroon the

1. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1576–77 (2003).

2. Christopher A. Cotropia & James Gibson, *The Upside of Intellectual Property's Downside*, 57 UCLA L. REV. 921, 922–23 (2010).

3. Burk & Lemley, *supra* note 1, at 1580.

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 & 35 U.S.C. § 271(e)(1)).

5. *Id.*; *see also* Erik Neumann, *Sen. Orrin Hatch's Influence of US Health Care*, ABC NEWS (Jan. 2, 2019, 4:36 PM), https://abcnews.go.com/Health/sen-orrin-hatchs-influence-us-health-care/story?id=60120082 (explaining that the Drug Price Competition and Patent Term Restoration Act is commonly referred to as the Hatch-Waxman Act because of the Act's two primary sponsors, Senator Orrin Hatch (R-UT) and Congressman Henry Waxman (D-CA)).

6. *See* Jonathan A. Hareid, Comment, *Testing Drugs and Testing Limits:* Merck KGaA v. Integra Lifesciences I, Ltd. *and the Scope of the Hatch-Waxman Safe Harbor Provision*, 7 MINN. J.L. SCI. & TECH. 713, 740–53 (2006); *see also* Kate Y. Jung, Comment, *Hatch-Waxman's Safe-Harbor Provision for Pharmaceutical Development: A Free Ride for Patent Infringers?*, 13 J. MARSHALL REV. INTELL. PROP. L. 445, 447–48 (2014).

Court of Appeals for the Federal Circuit and the district courts on an island of ambiguity.[7]

This Note will focus on the current state of the Hatch-Waxman Act's Safe Harbor patent infringement exemption and how the lack of clarity in the federal courts leaves pharmaceutical and biotechnology litigants unsure if the shield of Safe Harbor will apply. In Part I, the common law historical background which preceded the Hatch-Waxman Act's patent infringement exemption is discussed in addition to how this history informed Congress's decision to enact the Safe Harbor provision. Next, in Part II, this Note will contextualize the Supreme Court's decisions in *Eli Lily* and *Merck KGaA* and how the cases shaped the early landscape of Safe Harbor litigation by defining the exemption's scope. Part III will discuss how divergent interpretations of what inventions qualify for the Safe Harbor exemption continue to reverberate throughout the Court of Appeals for the Federal Circuit and district courts. Lastly, Part IV contends that a broad construction of the scope of the Safe Harbor provision's patent infringement exemption is supported by the legislative history, judicial interpretation, protections from the provision itself, and public policy.

To that end, this Note argues that competing constructions of what is considered a "patented invention" under the Safe Harbor provision should be resolved broadly to include research tools, under the Federal Circuit's decisions in *Proveris* and *Momenta I*. This contention gathers support through the legislative aims of the Hatch-Waxman Act's to lower consumer drug prices. Furthermore, this broad construction is not without limitation. The Safe Harbor provision provides an identifiable and necessary limit to its own application and requires that any use of a patented invention be reasonably related to the submission of information as required under Federal law.

I. BACKGROUND PRINCIPLES OF PATENT LAW EXEMPTIONS

Congress was authorized to create the United States patent system to "promote the Progress of [the] useful Arts."[8] From its inception, the patent system operated by offering a bargain to inventors: disclose your invention to the public in exchange for the right to exclude others from making, using, importing, selling, or offering to sell the invention

7. *See* Jonathan McPherson, Note, *The Impact of the Hatch-Waxman Act's Safe Harbor Provision on Biomedical Research Tools after* Merck KGaA v. Integra Lifesciences I, Ltd., 10 MICH. ST. U. J. MED. & L. 369, 374–77 (2006).

8. U.S. CONST. art. I, § 8, cl. 8.

for a limited time.[9] The premise of the patent system is that society benefits from new technology.[10] The patent system meets this utilitarian function by offering legal protection and provides an opportunity to the inventor to realize the economic value in their invention, thereby creating further incentive for the discovery of new technology.[11]

The penalties for violating the exclusive patent rights of the patentee may subject the infringer to monetary damages or an injunction.[12] In addition, the statutory language is clear: a patentee has an unqualified right to exclude others from "making, using, offering to sell, or selling" the patented invention.[13] Despite the absence of statutory authority or congressional intent to provide an exemption to patent infringement, the body of patent law developed a narrow and seldomly applied patent infringement exemption for experimental use.[14] Common law sculpted the experimental use exemption through the lens of legal and economic patent law theory.[15] From the early seventeenth century through the mid-1980s, and beyond, the experimental use exemption provided researchers with a narrow defense from infringement liability.[16]

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9. *See* CRAIG ALLEN NARD & R. POLK WAGNER, PATENT LAW 1 (2008); *see also* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) ("The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" (quoting U.S. CONST. ART. 1, § 8, cl. 8)).

10. NARD & WAGNER, *supra* note 9, at 7.

11. *See* David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 182–83 (2009) (explaining that "absent the right to exclude that patents provide, copycats will quickly enter the market and drive down prices below the price at which the inventor can recoup her research and development costs. In other words, without patent grants, too little innovation will occur because the rational inventor will not bother to invent knowing that she will not be able to recoup the cost of invention.").

12. Matthew D. Powers & Steven C. Carlson, *The Evolution and Impact of the Doctrine of Willful Patent Infringement*, 51 SYRACUSE L. REV. 53, 56 (2001); *see also* 35 U.S.C. § 271(e)(4).

13. 35 U.S.C. § 271(e)(3) (2022).

14. Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad*
Exemption, 100 YALE L.J. 2169, 2169 (1991); *see* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

15. *See* Karp, *supra* note 14, at 2172–74.

16. Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 494–504 (2006); *See* Madey v. Duke Univ., 307 F.3d 1351, 1361–62 (Fed. Cir. 2002) (discussing why the district court's broad conception of the experimental use exemption was incorrect—"[b]oth formulations are too broad and stand in sharp contrast to our admonitions in

Over a century after the first court expounded the doctrine of the experimental use exemption to patent infringement, Congress addressed patent infringement exemptions on similar grounds.[17] In 1984, Congress enacted the first, and only, statutory exemption to patent infringement in the Drug Price Competition and Patent Term Restoration Act.[18]

A. The First Exemption to Infringement: Experimental Use

The utilitarian philosophy of patent law looks to inventors as stimuli for future innovation that benefits society.[19] However, since the Constitution's primary charge to Congress is to "promote the Progress of [the] useful Arts,"[20] a balance was struck between ensuring proper economic incentive for inventors while avoiding stagnant rigidity. This balance was first addressed in 1813 by Justice Story's opinion in *Whittemore v. Cutter*.[21]

In *Whittemore*, Justice Story reasoned that it could never have been the purpose of the legislature to punish someone "who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[22] Again, nearly five months after deciding *Whittemore*, Justice Story further elaborated on the experimental use exemption to patent infringement in *Sawin v. Guild*.[23] In *Sawin*, Justice Story explained that to qualify as infringement, "the making of a patented machine . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."[24] Therefore, the genesis of the experimental use exemption was drawn along the lines of comparing commercial and non-commercial use, or in Justice Story's words, to qualify as infringement, "the making [of the patented

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Embrex and *Roche* that the experimental use defense is very narrow and strictly limited.").

17. JOHN R. THOMAS, THE HATCH-WAXMAN ACT: A PRIMER 1 (2016), https://crsreports.congress.gov/product/ pdf/R/R44643/3 ("[T]he Hatch-Waxman Act established several practices intended to facilitate the marketing of generic pharmaceuticals while providing brand-name firms with incentives to innovate.").

18. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 & 35 U.S.C. § 271(e)(1)).

19. Olson, *supra* note 11, at 182–83.

20. U.S. CONST. art. I, § 8, cl. 8.

21. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

22. *Id.*

23. Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813).

24. *Id.*

invention] must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery."[25]

The sister cases of *Whittemore* and *Sawin* illustrate Justice Story's two-part examination of whether the experimental use exemption applies: (1) the activity must be for philosophical purposes or to ascertain the adequacy of the disclosed invention, and (2) there must be no intention to profit from such activities.[26] However, under this inquiry, questions remained: would a nonprofit organization be entitled to a de facto patent infringement research exemption if the use of the patented invention was for scientific research, or, would sufficient proof of the lack of profit motive shield an otherwise infringing party from liability?[27]

Subsequent decisions attempted to broach these questions and advanced Justice Story's exposition of the experimental use exemption and the biotechnology and pharmaceutical industries provided an ideal test-case.[28] Companies in these industries have a substantial interest in economizing the research and development of new drugs given the significant investment required in personnel, materials, and clinical trials.[29] In research driven pharmaceutical and biotechnology companies, the availability of the experimental use infringement exemption would be financially beneficial to all but the patentee, since a

25. *Id.*; *see* WILLIAM C. ROBINSON, LAW OF PATENTS FOR USEFUL INVENTIONS 56 (1890) ("The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. . . . Hence acts of infringement must attack the right of the patentee to these emoluments . . . . Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized.").

26. David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615, 627 (1994) (explaining that the two-pronged approach of Justice Story may be viewed instead as a one-part test, asking "was the use of the patented invention intended to be a 'use for profit'?").

27. *See* Hagelin, *supra* note 16, at 492.

28. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) ("It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee."); *see generally* Palmer v. United States, 20 Ct. Cl. 432 (1885) (determining that the defendant's use of a patented knapsack design was experimental).

29. *See* Predeep Suresh & Prabir K. Basu, *Improving Pharmaceutical Development and Manufacturing: Impact on Cost of Drug Development and Cost of Goods Sold of Pharmaceuticals*, 3 J. PHARM. INNOVATION 175, 177 (2008) (describing costs associated with development of pharmaceutical products and potential routes of improving efficiency).

competitor would not need to obtain a license to conduct research using a pharmaceutical compound or technology.

In *Pfizer, Inc. v. International Rectifier Corp.*, a federal district court addressed whether a competitor's activity was protected by the experimental use exemption.[30] The court held that Pfizer's competitor, International Rectifier Corp. ("IR"), infringed upon Pfizer's patent for the pharmaceutical compound doxycycline and granted an injunction against IR from "directly or indirectly making, using or selling doxycycline."[31] Despite the injunction, IR continued its infringing activity by shipping doxycycline abroad with the disclaimer "Laboratory Samples. For experimental purposes only."[32] Predictably, the primary defense used by IR was that the post-injunction activities were experimental.[33] The court found that IR produced over one-hundred thousand tablets of doxycycline in twenty-one months following the injunction and that IR labeled the shipments "[f]or experimental use only. No commercial value."[34] Even with IR's attempts to justify their sale of doxycycline, the court determined IR's activities to be infringing and held IR in contempt of court.[35] In its reasoning, the court evaluated the history of the experimental use exemption and stated that there is nothing in the Patent Act that mentions any experimental use, and the common law doctrine cannot be invoked for the protection of one who uses a patented invention commercially.[36] Ultimately, the court believed that IR's argument was "utterly without merit."[37] The *International Rectifier* decision illustrates the blurred line between "experimental" and "commercial" activities—even labelling activities as such is insufficient. Experimentally driven pharmaceutical and biotechnology industries were therefore put on notice of the narrow common law exemption's pitfalls.

B. The Straw that Broke the Camel's Back: The Bolar Decision

After many cases involving the experimental use exemption were resolved at federal district courts, the Court of Appeals for the Federal Circuit provided an authoritative pronouncement and application of

30. Pfizer, Inc. v. Int'l Rectifier Corp., 217 U.S.P.Q. 157, 159–61 (C.D. Cal. 1982).
31. *Id.* at 158.
32. *Id.* at 158–59.
33. *See id.* at 159–60.
34. *Id.*
35. *Int'l Rectifier Corp.*, 217 U.S.P.Q. at 162.
36. *See id.* at 160–62.
37. *Id.* at 160.

the doctrine in *Roche Products Inc. v. Bolar Pharmaceutical Co*.[38] The case involved Bolar Pharmaceutical's ability to complete development activities required to market a generic drug equivalent to Roche's patented sleeping pill, Dalmane (flurazepam), upon the expiration of Roche's patent which was set to expire on January 17, 1984.[39] However, in mid-1983, Bolar began their effort to obtain federal approval for the generic form of Dalmane by importing five kilograms of the drug from a foreign manufacturer to conduct Food and Drug Administration ("FDA") required bioequivalency and blood serum studies.[40] Roche brought a patent infringement suit alleging Bolar's imported use of flurazepam infringed on Roche's patent for the drug.[41]

Likely considered in Bolar's decision to begin FDA required studies while Roche's patent was in force, was the fact that the success of generic drugs is closely tied to how quickly the generic drug is brought to the market after the name-brand patent expires. However, the Federal Circuit was not sympathetic to Bolar's commercial considerations and was likewise not persuaded by the argument that the tests were for "true scientific inquir[y]."[42] The court held that the experimental use exemption is "truly narrow," and that the court could not broaden the exemption to allow the violation of patent rights under the "guise of scientific inquiry," especially when the infringing activities had "definite, cognizable" commercial purposes.[43]

It is apparent from the facts in *Bolar*, that Bolar's activities failed to fall within the lines of Justice Story's original experimental use

38. *See generally* Roche Prods. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984) (applying the experimental use exemption doctrine narrowly); *see also* Ronald D. Hantman, *Experimental Use as an Exemption to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 620–22 (1985) (explaining that the *Bolar* decision produced a large amount of commentary and is viewed to have "narrowed the experimental use exemption, or at the very least, confirmed the narrowness of the exemption.").

39. *Roche Prods.*, 733 F.2d at 860–61; *see Generic Drug Facts*, FOOD & DRUG ADMIN. (Nov. 1, 2021), https://www.fda.gov/drugs/generic-drugs/generic-drug-facts ("A generic medicine is required to be the same as a brand-name medicine in dosage, safety, effectiveness, strength, stability, and quality . . . . Generic medicines also have the same risks and benefits as their brand-name counterparts.").

40. *Roche Prods.*, 733 F.2d at 860.

41. *See id.*

42. *Id.* at 863.

43. *Id.* ("[Performing] unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention."); *see also* Hantman, *supra* note 38, at 621 (explaining that Bolar's use of Roche's flurazepam while Roche's patent was active clearly operated outside Justice Story's margins of the experimental use exemption).

exemption.[44] To start, Bolar conceded that under the traditional notions of the experimental use exemption, its activities were out of bounds.[45] Bolar explicitly began using Roche's patented product for the purposes of gaining a head start on the FDA's mandatory requirements for generic drug approval, making Bolar's quest everything but philosophical.[46] Furthermore, the fundamental mechanism of Roche's drug, Dalmane (flurazepam), was already established, given the FDA's approval of the drug and the United States Patent and Trademark Office's grant of the patent and disclosures therein.[47] Lastly, Bolar's acts were completed for purposes of securing future FDA approval—a largely commercial motive.[48]

The implications of the *Roche v. Bolar* decision were two-fold. First, the Federal Circuit made clear that the experimental use exemption was intentionally narrow and efforts by litigants to expand such an exemption would be met with judicial skepticism.[49] Second, the holding precluded a generic company from beginning FDA mandated research and development until the patent for the protected name-brand drug expired. This outcome produced a lag period between the expiration of a name-brand drug patent and the time that a generic alternative was available.

The lag period was viewed as costly to consumers who sought the lower drug prices brought by the generic drug market, because presumably the name-brand drug was more expensive. The lag also meant that brand manufacturers enjoyed a de facto extension in the period of exclusivity because generic drug manufacturers were required to satisfy mandatory FDA premarket approval requirements only after the brand-name patent expired.[50] These premarket approvals were instated under the Food, Drug, and Cosmetic Act's ("FDCA") New Drug Application ("NDA") requirement.[51] And although generic manufacturers faced FDA premarket approval requirements, it was equally true

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44. *See* Parker, *supra* note 26, at 627 (stating the two-pronged approach to Justice Story's experimental use patent infringement exemption).

45. *See Roche Prods.*, 733 F.2d at 863.

46. *See Id.* at 860.

47. *See id.*

48. *See id.*

49. *See* Hantman, *supra* note 38, at 620.

50. *See generally* SUSAN THAUL, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS 1–8 (2018) (describing the FDA drug approval and regulation process).

51. 21 U.S.C. § 355(b) (2023); *see also* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

that brand manufacturers faced the same scrutiny years earlier, before gaining FDA market approval for the brand drug product.[52]

Therefore, a bookend distortion in pharmaceutical drug patent term was created.[53] In essence, a pharmaceutical drug patentee's ability to utilize the patent's market exclusivity was limited to the period after FDA premarket approval of the drug, and similarly, once the patent term expired, the market monopoly was extended until a generic drug alternative satisfied the FDCA's NDA premarket approval requirements.[54]

II. ENACTMENT OF THE DRUG PRICE COMPETITION & PATENT TERM RESTORATION ACT & THE SAFE HARBOR PROVISION

In response to the favorable public policy of reducing drug prices, which were at least in part due to the FDCA's rigid NDA requirement, and the Federal Circuit's *Bolar* decision that failed to curb unintended distortions in patent term, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act").[55] For 113 years prior to the enactment of the Hatch-Waxman Act, patent terms were set at seventeen years but did not account for the reality of patent term distortions.[56]

However, in the late 1970s, patent owners became restless as patent applications were tied up in the federal regulatory review and approval processes.[57] The legislative history of the Hatch-Waxman Act is replete with proposed amendments and testimony that examined the economic and health policy impact that may result from a patent infringement exemption like the Safe Harbor.[58]

After months of long deliberations in the House of Representatives and Senate Judiciary Committee, on September 24, 1984, the Hatch-Waxman Act became law.[59] The Act contained numerous

52. *See* THAUL, *supra* note 50, at 1–3; *see also Roche Prods.*, 733 F.2d at 864 (citing a 1983 study that indicated the average time for a pharmaceutical company to satisfy regulatory requirements may span seven to ten years).

53. *See* Jung, *supra* note 6, at 450.

54. *See id.*

55. Mossinghoff, *supra* note 51, at 188–91; *see* Burk & Lemley, *supra* note 1, at 1616–17.

56. *See* H.R. REP. NO. 98-857, pt. 2, at 3 (1984).

57. *See id.*

58. *See id.* at 8, 26–28. For example, one witness argued that enacting a patent infringement exemption that permits a patent's manufacture or use during the life of the patent's term effectuates a Fifth Amendment taking. *See id.* at 27.

59. THOMAS, *supra* note 17, at 5.

provisions, each tailored to ameliorate a particular shortcoming in drug price policy.[60] The Safe Harbor provision provides, in its entirety:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[61]

Expert witness testimony in the House Judiciary Committee estimated that enactment of the Safe Harbor provision would bring low-cost, generic drugs to market between eighteen to twenty-four months earlier than without the provision.[62] Members of Congress celebrated the Safe Harbor provision's enactment by comparing the momentous occasion to the congressional recognition of the copyright doctrine of fair use.[63] Moreover, Congress enacted another provision in tandem with the Safe Harbor, which permitted brand-name drug developers to extend, under certain circumstances, the seventeen-year patent term for "products" because of lengthy regulatory delays and premarket approval processes.[64] Ideally, the Safe Harbor and patent term extension provisions would act in parallel to address the book-end distortion of patent term. Despite these ideations and Congress's belief that the Act seemingly "balance[ed] the need to stimulate innovation against the goal of furthering the public interest," the Hatch-Waxman Act's failure to define what type of "patented invention" qualified for Safe Harbor's infringement exemption set the stage for subsequent litigation.[65]

60. *See id.* at 188–91.

61. 35 U.S.C. § 271(e)(1) (2023).

62. *See* H.R. REP. NO. 98-857, *supra* note 56, at 29.

63. *See id.* at 30.

64. *See* 35 U.S.C. § 156(a), (f)(1) (2022) (allowing an extension and including in the term "products" drugs, medical devices, food coloring and additives, and other items addressed in the Food, Drug, and Cosmetic Act).

65. H.R. REP. NO. 98-857, *supra* note 56, at 30.

A. Building the Breakwall: Defining the Boundaries of the Safe Harbor

The Hatch-Waxman Act's Safe Harbor provision carved an exemption from patent infringement but left significant interpretation of the statute to the courts. Of note, the Hatch-Waxman Act failed to define key phrases and terms within the Safe Harbor provision, leaving questions open to the courts: What is a "patented invention"? What limits exist on how a "patented invention" may be used? Or in other words, what qualifies as "reasonably related" to the submission of information under a federal law?

At the outset, the legislative history of the Hatch-Waxman Act's Safe Harbor provision established that the genesis of the exemption was in the context of the pharmaceutical research and development of drugs.[66] However, in 1990, the Supreme Court had its first opportunity to assess the scope of Safe Harbor in *Eli Lilly & Co. v. Medtronic*, where the infringed invention was not a drug, but a medical device.[67] In *Lilly*, the pivotal question was whether the Safe Harbor provision shields from liability activities that would otherwise constitute patent infringement, provided the activities are conducted for the purpose of developing and submitting information to the FDA.[68]

Eli Lilly & Co. was the patentee of a class III cardiac defibrillator with patents that were set to expire in 1990 and 1993.[69] Eli Lilly alleged that Medtronic, Inc. blatantly infringed on Lilly's defibrillator

66. *See* Jung, *supra* note 6, at 452–53.

67. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 664 (1990).

68. *See id*. at 664. The FDCA provision at issue in *Eli Lilly v. Medtronic* was 21 U.S.C. § 360e, which provides premarket approval activities for medical devices. *Eli Lilly*, 496 U.S. at 663–64; *see* 21 U.S.C. § 360e (2023).

69. *Eli Lilly*, 496 U.S. at 664; *see* U.S. Patent No. Re 27,757; *see also* U.S. Patent No. 3,942,536. Under U.S. federal law, medical device classes are defined into three categories by their respective risk to patients: Class I devices are subject to minimal regulation under "general controls" because the device is "not purported or represented to be for a use in supporting or sustaining human life" and was found to pose "no unreasonable risk of illness or injury" to patients (e.g., elastic bandage). Class II devices are regulated by more stringent "special controls" where it is found that general controls are "insufficient to provide reasonable assurance of the safety and effectiveness of the device" (e.g., contact lens). Class III devices present a "potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," (e.g., cardiac defibrillator). *See* 21 U.S.C. § 360c(a)(1)(A)–(C) (2023); *see also Product Classification*, FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (last updated 12/25/2023).

patents.[70] Medtronic defended its activities by claiming that its use of Lilly's defibrillator patents was permitted under section 271(e)(1) Safe Harbor because the provision broadly applied to "patented inventions" and not simply drugs, and Medtronic's uses were "reasonably related to the development and submission of information" under the FDCA.[71]

Prior to arriving at the Supreme Court, the United States District Court for the Eastern District of Pennsylvania rejected Medtronic's argument and concluded that section 271(e)(1) does not apply to the development and submission of information relating to medical devices.[72] The Court of Appeals for the Federal Circuit reversed, holding that section 271(e)(1) did apply, because the phrase "patented invention" includes medical devices.[73] Once at the Supreme Court, Justice Scalia began the majority decision by broadly summarizing the *real* issue, stating, "the issue in this case concerns the proper interpretation of a portion of [section 271(e)(1)]" and that "the core" of the issue was how to contextualize "patented invention" under the Safe Harbor's infringement exemption.[74] The Court explained that the phrase "patented invention" in § 271(e)(1) is defined to include "all inventions," not drug-related inventions alone.[75] In part, this construction of the phrase is supported by the parallel enactment of 35 U.S.C § 156, which grants context specific patent term extension for more than just drug products.[76] Furthermore, in the latter portion of the Safe Harbor provision, the Court construed the phrase "under a Federal law" to mean *any* federal law, including the FDCA, which regulates the marketing and use of both drugs and medical devices.

The exercise in statutory construction that Justice Scalia demonstrated in writing the opinion in *Lilly* is indicative of the vague nature of the Safe Harbor provision. In fact, Justice Scalia remarked,

> [a]s far as the text is concerned . . . we conclude that we have before us a provision that somewhat more naturally reads as the Court of Appeals determined, but that is not plainly

70. *See* Brief for Petitioner at 6–7, Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1989) (No. 89-243).

71. *Eli Lilly*, 496 U.S. at 664 (internal quotations omitted).

72. *See* Eli Lilly & Co. v. Medtronic, Inc., 696 F. Supp. 1033, 1033–34 (E.D. Pa. 1988), *rev'd*, 872 F.2d 402 (Fed. Cir. 1989).

73. Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 406 (Fed. Cir. 1989).

74. *Eli Lilly*, 496 U.S. at 665–66.

75. *Id.* at 665; *see* 35 U.S.C. § 100(a) (2023) ("When used in [title 35] unless the context otherwise . . . [t]he term 'invention' means invention or discovery.").

76. *See Eli Lilly*, 496 U.S. at 670–71; *see* 35 U.S.C. § 156(a) (2023).

> comprehensible on anyone's view. Both parties seek to enlist legislative history in support of their interpretation, but that sheds no clear light. . . . No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.[77]

B. Statutory Symmetry: Preferred or Required?

The *Lilly* court's initial determination that Safe Harbor's use of the phrase "patented invention" includes "all inventions" was supported by the Congress's enactment of two key provisions within the Hatch-Waxman Act, codified at 35 U.S.C §§ 156 and 271(e)(1) which both work in tandem to address distortions of patent term and rising drug prices.[78] As noted previously, prior to the Hatch-Waxman Act, two distortions in the patent term frustrated patentees and potential market competitors: the first distortion resulted from regulatory and premarket approval delays, which decreased the effective life of the patent; and the second resulted from generic drug manufacturer's satisfaction of regulatory premarket approval requirements upon the expiration of the brand-drug patent, thereby granted brand-drug patentee a de facto extension of patent term.[79]

The Supreme Court viewed the Hatch-Waxman Act's Safe Harbor, 35 U.S.C § 271(e)(1), and patent term extension provision, 35 U.S.C § 156, to be harmonious and address the two patent term distortions in tandem.[80] First, the § 156 patent term extension would resolve the loss in the effective patent term for products which are subject to lengthy premarket approval and regulatory delays.[81] Second, the § 271(e)(1) Safe Harbor provision would allow non-brand competitors to conduct required research and development activities during the life of the controlling patent, so that once the patent expires, non-brand competitors may complete the pre-market approval process quickly and enter the market to lower prices for consumers.[82]

Because the Supreme Court construed "under a Federal law which regulates the manufacture, use, or sale of drugs" to mean *any* federal law, the "products" (e.g., drugs, medical devices, food coloring

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77. *Eli Lilly*, 496 U.S. at 669, 679.

78. *See* Samuel M. Kais, *A Survey of 35 U.S.C. 271(e)(1) As Interpreted by the Courts: The Infringement Exemption Created by the 1984 Patent Term Restoration Act*, 13 SANTA CLARA COMPUTER & HIGH TECH L. J. 575, 577–78 (1997).

79. *See* Jung, *supra* note 6, at 450.

80. *Eli Lilly*, 496 U.S. at 672–74.

81. Kais, *supra* note 78, at 577–78.

82. *Id.* at 578.

and additives) eligible for patent term extension under § 156 were also products eligible for Safe Harbor infringement exemption under § 271(e)(1).[83] Or in other words, both § 156 and § 271(e)(1) formed a "perfect 'product' fit"— a type of statutory symmetry.[84]

The Supreme Court also acknowledged that at times, the statutory symmetry and product fits between § 156 and § 271(e)(1) could break down for patentees.[85] This acknowledgement served as the tinder for the metaphorical fire that ensued for the following decades at the Court of Appeals for the Federal Circuit, which is discussed below. The Supreme Court did not view statutory symmetry as a necessity — "there may be some relatively rare situations in which a patentee will obtain the advantage of the [§ 156 patent term] extension but not suffer the disadvantage of the [§ 271(e)(1) Safe Harbor] noninfringement provision, and others in which [the patentee] will suffer the disadvantage without the benefit."[86]

The Court in *Lilly*, therefore, set forth the initial scope of the Safe Harbor—the term "patented inventions" includes all inventions and statutory symmetry may be preferrable but not required. Further, there exists "rare" situations exist where a patentee suffers the disadvantage of the Safe Harbor noninfringement exemption without receiving the benefit of patent term extension. In sum, there may come a time where an invention is not subject to pre-market approval but nonetheless falls beneath the Safe Harbor noninfringement exemption.

III. WHAT DOES "PATENTED INVENTION" MEAN TO THE FEDERAL CIRCUIT?

Following the Supreme Court's decision in *Lilly*, the task fell to the Federal Circuit to apply what many viewed as a broadened scope of the Safe Harbor and to determine what qualifies as a "patented

83. *Id.* at 578–79.

84. *Eli Lilly*, 496 U.S. at 673–74.

85. *Id.* at 671.

86. *Id.* at 671–72. Statutory symmetry refers to the complementary nature between 35 U.S.C §§ 156 and 271(e)(1). Where products eligible for patent term extension under § 156 (e.g., drugs, medical devices, food additives) appear to "fit" with the § 271(e)(1) Safe Harbor patent noninfringement exemption—if a product is eligible for patent term extension under § 156, then the product may be shielded from patent infringement liability under § 271(e)(1) and used in activities that would otherwise be considered infringing under 35 U.S.C § 271(a). *See Ely Lilly*, 496 U.S. at 671–72; *see also* Angela M. Davison, *Shrinking Waters in the Safe Harbor: Has* Integra Lifesciences v. Merck *Turned the Tide by Narrowing Available Exempted Infringing Uses?*, 59 FOOD & DRUG L.J. 79, 89 (2004).

invention" in case-by-case litigation.[87] Seven years after the *Lilly* decision, in 1997, the Court of Appeals for the Federal Circuit addressed in *AbTox, Inc. v. Exitron Corp.* whether a class II medical device not eligible for § 156 patent term extension was subject to the § 271(e)(1) Safe Harbor noninfringement provision.[88] This marked the first of the "rare situations" acknowledged by the Supreme Court in *Lilly* where a patented invention may fall outside the statutory symmetry of §§ 156 and 271(e)(1), but nonetheless suffer the disadvantage of the Safe Harbor patent noninfringement exemption.[89]

The technology at issue in *AbTox* was a medical device patent which sterilizes medical instruments using partially ionized gas.[90] The device was characterized as a class II medical device, and therefore not eligible for § 156 patent term extension.[91] AbTox attempted to distinguish their case before the Federal Circuit from *Lilly* on the grounds that the medical device at issue in *Lilly* was characterized as class III.[92] As discussed above, in *Lilly* the court recognized that §§ 156 and 271(e)(1) produced a "perfect product fit" and a form of statutory symmetry.[93] AbTox argued against Exitron's invocation of the Safe Harbor's infringement defense, stating that since Exitron's patented class II medical device was ineligible for patent term extension under § 156, then the medical device is not of the type of invention that should fall under the Safe Harbor.[94] However, the Federal Circuit was unpersuaded, and instead relied on the Supreme Court's analysis in *Lilly* that "a federal law" includes "an entire statutory scheme of regulation,"

87. *See* Kais, *supra* note 78, at 579–85; *see generally* Cathryn Campbell & R. V. Lupo, *Exemption to Patent Infringement Under 35 U.S.C. Section 271(e)(1): Safe Harbor or Storm A-Brewing*, 5 SEDONA CONF. J. 29 (2004) (discussing twenty years of judicial construction and the questions that remain as to the appropriate application and scope of the Safe Harbor exemption).

88. *See* 21 U.S.C. § 360c(a)(1)(A)–(C) (2023); *see generally* AbTox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997) (discussing whether use of the patented device in question was subject to the Safe Harbor exemption).

89. *Eli Lilly*, 496 U.S. at 671–72 (1990); *see* Davison, *supra* note 86, at 89.

90. *Abtox, Inc.*, 122 F.3d at 1020–21.

91. *Id*. at 1027.

92. *See id*. at 1027–28.

93. *Eli Lilly*, 496 U.S. at 673–74. 35 U.S.C. § 156's patent term extension was applicable to products which face a rigorous premarket approval process; therefore, the *Lilly* Court found that 35 U.S.C. § 271(e)(1) applied to the same products, because had the Safe Harbor not applied, Congress would have left the latter patent term distortion untouched.

94. *See Abtox, Inc.*, 122 F.3d at 1028.

such as the FDCA, which regulates class III, II, and I medical devices.[95]

Accordingly, the *AbTox* court held that the Supreme Court "commands that statutory symmetry is preferable but not required."[96] Under the interpretation of the *AbTox* court, the Safe Harbor provision extended to patented inventions notwithstanding the invention's eligibility for § 156 patent term extension. This holding laid the groundwork for future lines of cases that interpreted the Safe Harbor provision broadly, that is, until the 2009 Federal Circuit decision in *Proveris v. Innovasystems*.[97]

In *Proveris* the Federal Circuit considered whether section 271(e)(1) shields from liability the use of a patented invention "which is used in the development of FDA regulatory submissions, but *is not itself* subject to the FDA premarket approval process."[98] The technology at issue in *Proveris* was an optical spray analyzer ("OSA") which characterized aerosol sprays commonly used in various drug delivery devices, such as nasal spray pumps and inhalers.[99] Innovasystems ("Innova") developed an OSA that Proveris alleged infringed on their patent.[100] The Federal Circuit initially determined that Innova's OSA was not subject to FDA premarket approval, and therefore not eligible for § 156's patent term extension.[101] Next, the Federal Circuit found that Innova's OSA was a product that was free from any of the two pre-Hatch-Waxman Act patent term distortions.[102] The court, therefore, held that Innova's allegedly infringing activities fell outside the

95. *Id.* (quoting *Eli Lilly*, 496 U.S. at 666).

96. *Id.* at 1029.

97. *See* Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265 (Fed. Cir. 2008); *see also* Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., No. 95 Civ 8833, 2001 WL 1512597, at *9 (S.D.N.Y. Nov. 28, 2001) ("[T]he term 'patented invention' means all patented inventions or discoveries, and not merely those that are covered by section 156."); *see generally* Campbell & Lupo, *supra* note 87 (discussing the broad interpretation of the Safe Harbor provision).

98. *Proveris*, 536 F.3d at 1265 (emphasis added).

99. *Id*. at 1258–59.

100. *See generally* U.S. Pat. No. 6,785,400 B1 (describing the Proveris OSA).

101. *Proveris*, 536 F.3d at 1265–66. The OSA patent at issue could be used to measure the performance of a medical device which is itself subject to FDA premarket approvals, but the OSA is not. *Id.* at 1259; *see* 21 U.S.C. § 360c(a)(1)(A)–(C) (2023).

102. *Proveris*, 536 F.3d at 1265 ("Innova is not a party seeking FDA approval for a product in order to enter the market to compete with patentees. Because the OSA device is not subject to FDA premarket approval, and therefore faces no regulatory barriers to market entry upon patent expiration, Innova is not a party who, prior to enactment of the Hatch-Waxman Act, could be said to have been adversely affected by the second distortion.").

scope of the Safe Harbor because "Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief."[103]

In the three years that followed the *Proveris* decision, the Federal Circuit addressed the issue of "patented inventions" on more than one occasion. First in 2011, in *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit was asked to determine whether Biogen and GlaxoSmithKline's ("GSK") unauthorized use of Classen Immunotherapies' patented method of determining vaccination schedules was protected under Safe Harbor.[104] The Federal Circuit largely resolved the issue using the Hatch-Waxman Act's legislative history, and, in essence, the *Classen* court found that Biogen's alleged infringing activity—the evaluation of an optimal childhood vaccination schedule—is not an activity considered by the Safe Harbor's § 271(e)(1) patent infringement exemption.[105]

One year later in *Momenta Pharms., Inc. v. Amphastar Pharms., Inc*., the Federal Circuit considered whether Amphastar Pharmaceuticals' unauthorized use of Momenta Pharmaceuticals' patented method of characterizing drug products was eligible under Safe Harbor's infringement exemption.[106] After weighing the nature of the infringing activity alleged against Amphastar, and finding it to fall within the Safe Harbor exemption, the Federal Circuit endorsed the Supreme Court's approach in *Lilly* and rejected the dissenting opinion's contention that the Safe Harbor should not be available unless a patent term extension is also available.[107] Unlike in *Proveris* and *Classen*, however, the Federal Circuit here found *Abtox* to be persuasive, and held that statutory symmetry between 35 U.S.C. § 156 and 271(e)(1) was not required, and that Safe Harbor extended to inventions beyond those eligible for patent term extension.[108] Therefore, the *Momenta* court did not view the most recent "patented invention" precedent as persuasive, but instead relied on the Supreme Court's 1990 decision in *Lilly* and the Federal Circuit's 1997 decision in *Abtox*.[109] Even more consequential was the fact that in the span of one year, the Federal

103. *Id.*

104. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1070 (Fed. Cir. 2011).

105. *Id*. at 1070–72.

106. 686 F.3d. 1348, 1351–52 (Fed. Cir. 2012).

107. *Id*. at 1358–61.

108. *Id.*

109. *See id.*

Circuit expounded conflicting views on what types of inventions qualify for the Safe Harbor's noninfringement exemption.

In sum, the Federal Circuit in *Abtox*, *Proveris, Classen,* and *Momenta* applied competing interpretations of the *Lilly* Court's discussion of the "statutory symmetry," what activities qualified for the Safe Harbor's protections, and whether the relationship between §§ 156 and 271(e)(1) should be required or preferred.[110] The Federal Circuit's competing interpretations provide two conflicting but equally controlling lines of precedent. Pharmaceutical and biotechnology litigants are therefore left to craft compelling arguments under either interpretation, but which interpretation a district court or the Federal Circuit may choose to apply remains uncertain. This may appeal to litigation counsel, but not to the real parties at interest, or the public. Further, the question of whether the Safe Harbor's provision includes the use of research tools—patented inventions which are not subject to FDCA regulatory premarket approval but are commonly used in research and development—was left unanswered.

IV. THE AMBIGUITY SURROUNDING RESEARCH TOOLS

The applicability of the Safe Harbor to patented inventions categorized as research tools has provided a bounty of litigation amongst pharmaceutical and biotechnology companies.[111] Generally, a research tool may be viewed as a resource that aids in the development of a final product, such as Proveris' OSA, or Momenta's characterization method.[112]

110. *See generally* Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1265–66 (Fed. Cir. 2008); AbTox, Inc. v. Exitron Corp., 122 F.3d 1019, 1029 (Fed. Cir. 1997); Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1071 (Fed. Cir. 2011); *Momenta*, 686 F.3d at 1361 (highlighting the conflicting interpretations).

111. *See generally* Teva Pharms. USA, Inc. v. Sandoz Inc., No. 09 Civ. 10112, 2013 U.S. Dist. LEXIS 99121 (S.D.N.Y. July 15, 2013); Regenxbio Inc. v. Sarepta Therapeutics, Inc., No. 20-1226-RGA, 2022 U.S. Dist. LEXIS 1945 (D. Del Jan. 4, 2022); Allele Biotechnology & Pharms., Inc. v. Pfizer, Inc., No. 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. May 4, 2021); PSN Ill., LLC v. Abbott Labs. & Abbott Bioresearch Ctr., Inc., No. 09cv5879, 2011 U.S. Dist. LEXIS 108055 (N.D. Ill. Sept. 20, 2011); Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012); Momenta Pharms., Inc. v. Teva Pharms. USA Inc., 809 F.3d 610 (Fed. Cir. 2015); Classen Immunotherapies v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011); Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., No. 95 Civ. 8833, 2001 U.S. Dist. LEXIS 19361 (S.D.N.Y. Nov. 28, 2001) (describing the litigation regarding the applicability of the Safe Harbor to research tools).

112. *See Proveris*, 536 F.3d at 1259–60; *Momenta*, 686 F.3d at 1349–52.

According to the National Institutes of Health (NIH), a "research tool" is a "unique research resource that encompass[es] a full range of tools that scientists use in the laboratory, including: cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."[113] Due to the incomplete and ever expanding list of "research tools," it is added by the NIH that when determining whether a resource is a research tool, factors to consider include whether the resource is (1) "primarily a tool for discovery rather than an FDA-approved product or an integral component of such a product"; (2) "is a broad, enabling invention that will be useful to many other users, rather than a project or product-specific resource"; and (3) "is readily useable or distributable as a tool, as opposed to an instance where private sector involvement is either a necessary means or the most expedient means for developing or distributing the resource."[114]

In the context of a Safe Harbor dispute, a research tool may be viewed as a patented invention that enables discovery of another invention's qualities or characteristics. For example, Allele Biotechnology Inc. ("Allele") is the patentee of the fluorescent protein technology, mNeonGreen, which provides researchers with the means to test efficacy of antibody and vaccine candidates in a laboratory setting.[115] Allele markets the product to pharmaceutical or biotechnology researchers, presumably for its use during the purchasers' research activities. However, in 2021, Allele filed suit alleging patent infringement of its mNeonGreen technology against both Pfizer Pharmaceuticals-BioNTech and Regeneron Pharmaceuticals for the unlicensed and infringing use of mNeonGreen in both companies' COVID related technology.[116] Specifically, Allele alleged that Regeneron used mNeonGreen without a license throughout Regeneron's research of Regeneron's now marketed REGEN-COV drug therapy.[117]

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113. *Research Tools Policy*, NAT'L INSTS. OF HEALTH, https://sharing.nih.gov/other-sharing-policies/research-tools-policy (last visited Oct. 12, 2023).

114. *Id*.

115. Brief of Defendant at 3, Allele Biotechnology and Pharms., Inc. v. Regeneron Pharms., Inc., No. 7:20-cv-08255 (S.D.N.Y. Aug. 20, 2021).

116. *See generally* Allele Biotechnology and Pharms., Inc. v. Regeneron Pharms., Inc., No. 20-CV-08255, 2022 U.S. Dist. LEXIS 219036 (S.D.N.Y. Dec. 5, 2022); Allele Biotechnology and Pharms., Inc. v. Pfizer, Inc., No. 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. May 4, 2021) (alleging infringing use of mNeonGreen).

117. *See* Complaint at 10–11, Allele Biotechnology and Pharms., Inc. v. Regeneron Pharms., Inc., No. 7:20-cv-08255 (S.D.N.Y. Oct. 5, 2020).

Regeneron filed a motion to dismiss on the grounds that Regeneron's alleged conduct and research use of mNeonGreen was protected under the section 271(e)(1) Safe Harbor.[118] Regeneron argued that the Supreme Court's decision in *Merck KGaA* grants a "wide berth" for the uses of patented inventions, including research tools, provided that such uses be "reasonably related to the development and submission of any information" to the FDA.[119] Further, Regeneron pointed out that the same jurisdiction decided a very similar case in 2013, where an alleged infringer used a competitor's patented multiple sclerosis drug throughout its research as a comparator-marker and the Southern District held the alleged infringer's activities fell under the Safe Harbor.[120] Despite support from the Federal Circuit's holding in *AbTox*, and the Southern District's prior decision in *Teva Pharms. USA, Inc. v. Sandoz Inc.*, the court denied Regeneron's motion to dismiss and ordered both parties to proceed to discovery.[121]

The *Allele* case highlights a contemporary instance where ambiguity around Safe Harbor's inclusion of research tools has immense monetary and technological ramifications.

V. A SOLUTION TO THE AMBIGUITY OF RESEARCH TOOLS UNDER THE SAFE HARBOR

Whether research tools qualify for the Safe Harbor noninfringement exemption is a blind spot in the mirrors of pharmaceutical and biotechnology companies attempting to produce cost-effective drugs for the public. Such ambiguity may, however, be resolved in favor of including research tools as "patented inventions" for three reasons.

First, tenets of statutory interpretation favor this plain reading of the Safe Harbor provision and support finding that Congress's use of the phrase "patented invention" includes research tools. Additionally, the Safe Harbor provision does not stand alone without safeguards. A litigant's attempted Safe Harbor defense may be viewed by courts as embarking on a two-part inquiry. First, the court must assess and characterize what type of "patented invention" is at issue—whether the

118. Allele Defendant Brief, *supra* note 118, at 1.

119. *Id.* at 8 (quoting Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005)).

120. *See generally* Teva Pharms. USA, Inc. v. Sandoz Inc., No. 09 Civ. 10112, 2013 U.S. Dist. LEXIS 99121, at *3, 25 (S.D.N.Y. July 16, 2013) (holding defendant's use of plaintiff's patented drug fell under the Safe Harbor provision).

121. Allele Biotechnology and Pharms., Inc. v. Regeneron Pharms., Inc., No. 7:20-cv-08255 (S.D.N.Y. Mar. 2, 2022) (order denying motion to dismiss).

patent is subject to premarket approval, a research tool, et cetera.[122] Second, the court would evaluate the context of use—whether the alleged infringer's unauthorized use of the patented invention was solely for uses reasonably related to the creation of information required under the FDCA. Lastly, public policy supports the inclusion of research tools because the genesis of the Safe Harbor provision was designed to alleviate the negative economic effects of high drug prices that face consumers.

A. Statutory Interpretation & Public Policy Warrant the Inclusion of Research Tools in the Phrase "Patented Invention"

A fundamental principle behind statutory construction is that words will be interpreted as taking their "ordinary, contemporary, common meaning" before considering extrinsic factors like the statute's legislative history or social policy.[123] The Supreme Court in *Lilly* recognized the lack of clarity in Congress's word choice in the Safe Harbor provision.[124] Without further definition from Congress, the phrase "patented invention" should include research tools, but only when unauthorized use was "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[125]

In fact, the *Lilly* court observed that "'patented invention' in [the Safe Harbor provision] is defined to include *all* inventions, not drug-related inventions alone."[126] Moreover, Title 35 of the United States Code, the same title to which the Safe Harbor provision belongs, defines "invention" broadly to mean an "invention or discovery."[127] Under this context, and lack of Congressional input, limiting what

122. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 672–73 (1990).

123. *See* Perrin v. United States, 444 U.S. 37, 42 (1979); Patricia Nussle, Eli Lilly & Co. v. Medtronic, Inc.*: A Case of Statutory Interpretation,* 53 OHIO ST. L.J. 645, 654 (1992); *see also* 2A NORMAN J. SINGER, SUTHERLAND'S STATUTES AND STATUTORY CONSTRUCTION § 47.07 (6th ed. 2000) ("If it is expected that a particular term would be defined in the body of the statute, but is not, then the word will be assumed to have its ordinary and popularly understood meaning."); Microsoft Corp. v. I4I Ltd. P'ship, 564 U.S. 91, 103 (2011) (quoting Standard Oil Co. of N.J. v. United States, 221 U.S. 1, 59 (1911)) ("[W]here words are employed in a statute which had at the time a well-known meaning at common law . . . they are presumed to have been used in that sense.").

124. *Eli Lilly*, 496 U.S. at 669.

125. 35 U.S.C. § 271(e)(1).

126. *Eli Lilly*, 496 U.S. at 665.

127. 35 U.S.C. § 100(a) (2023).

qualifies as a patented invention to exclude research tools would exceed judicial review and wade into the realms of legislative action. The Supreme Court in *Diamond v. Chakrabarty*, restated that "courts 'should not read into patent laws limitations and conditions which the legislature has not expressed,'" largely due to Congress's authority "[t]o promote the progress of the . . . useful arts" by necessary and proper means.[128]

Precluding "research tools" from qualifying for Safe Harbor's noninfringement exemption raises the essential question—what is a research tool? As a guiding principle by the NIH, a research tool may include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones, methods, laboratory equipment and machines.[129] However, this list is not exhaustive and qualifying a piece of technology as a research tool, or not, may lie in the eye of the beholder. For example, in *Merck KGaA v. Integra*, the technology at issue was a RGD peptide which interacted with cell-surface receptors to disrupt blood supply through a process called angiogenesis.[130] The Court did not address the nature of the technology or whether the peptide was a research tool, in fact that was not even included in briefs. Without clearer guidance, it inevitably seems that what may be considered a drug or medical device in one instance, may next be viewed as a research tool in another.

Furthermore, including research tools as a member of the class of patented inventions which qualify for the Safe Harbor noninfringement exemption is supported by sound public policy. First, the Hatch-Waxman Act was proposed to mitigate rising drug prices and "balance the need to stimulate innovation against the goal of furthering the public interest."[131] Restricting Safe Harbor's qualifying inventions to those subject to pre-market approval restriction would increase overhead for pharmaceutical and biotechnology innovators.[132] This would be in large part due to increased overall expenditures due to license negotiation, which may slow or stall research and development, and

128. Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (citing United States v. Dubilier Condenser Corp., 289 U.S. 178, 199 (1933)); U.S. CONST. art I. § 8, cl. 8.

129. Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090, 72092 n.1 (Dec. 23, 1999).

130. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 197 (2005).

131. H.R. REP. NO. 98-857, *supra* note 56, at 30.

132. Erin M. McKibben, Proveris Scientific Corp. v. Innovasystems, Inc. *Sinks Safe Harbor Protection for Research Tools*, 8 J. MARSHALL REV. INTELL. PROP. L. 452, 469 (2009).

increased litigation costs for claims of patent infringement. To that end, lesser-known research tool patentees, or alternatively and in a class of their own, patent trolls, may utilize research tool patents in a generally anticompetitive manner—licensing exclusively to some medical innovators, while precluding others from accessing novel tools—ultimately at the expense of the public. In such an event, biotechnology companies may fail to use critical research tools due to a patentee's right to exclude others from the tools' use, thereby forcing companies to alternatively develop or abandon a potential drug product all together.

Increased research and development costs resulting from these expenses would likely be reflected at the hospital or pharmacy. To effectuate the legislature's original intent and mitigate effects of rising drug prices, it is the role of Congress, not the courts, to modify, amend, or supplement the terminology within the Safe Harbor provision to exclude research tools. Until then, the courts should construe the term "patented invention" to include "*all inventions*" as Supreme Court precedent demands.[133]

B. Safeguarding Safe Harbor: The "Reasonably Related" Requirement

The Safe Harbor provision provides necessary boundaries for the broad construction of "patented invention" argued here. The Safe Harbor does not provide a broad, unqualified license to infringe on a patented invention for commercial or noncommercial use. Rather, the provision requires that the use of a patented invention be "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs."[134]

The Supreme Court addressed what qualifies as "reasonably related" in *Merck KGaA v. Integra Life Sciences*.[135] The Court stated that the Safe Harbor exemption does not embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.[136] Rather, it is required that the activity be "reasonably related" at the time of initiating the experiment.[137] Under the Court's

133. *Id.* at 458.

134. 35 U.S.C. § 271(e)(1) (2023).

135. *See* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202–03 (2005); *see also* Scripps Clinic & Rsch. Found. v. Genentech, Inc., 666 F. Supp. 1379, 1395–97 (N.D. Cal. 1987).

136. *Merck*, 545 U.S. at 205–06.

137. *Id.*

construction, the Safe Harbor provision provides limitation. Specifically, in the context of pharmaceutical manufacturers, alleged infringers must have a "reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is 'reasonably related' to the 'development and submission of information under . . . Federal law.'"[138]

On remand, the Federal Circuit conducted a fact-sensitive inquiry to determine Merck's basis for conducting experiments using Integra's patented technology. Specifically, the Federal Circuit conducted a thorough and detailed review of the purpose of each of sixteen enumerated categories of accused experiments that were conducted over two years.[139] The Federal Circuit evaluated "extensive" trial testimony regarding "how and why all of these experiments were performed," the type of information generated by each experiment, and the type of information required by the specific FDA regulations at issue.[140] Effectively, the Supreme Court, and Federal Circuit on remand, demonstrated that to qualify for the Safe Harbor provision's noninfringement shield, the otherwise infringing party would need to invest significant time and money with a clearly plausible idea of the outcome and its relation to requirements under Federal law—merely stating what could occur is insufficient to sail into the Safe Harbor.

CONCLUSION

The research dependent pharmaceutical and biotechnology industries rely on the availability of innovative research tools to accomplish efficient creation of new and affordable drugs. Congress's enactment of the Hatch-Waxman Act was the first step towards meeting the demand of lower-drug prices for consumers while balancing the need for ensuring patent rights for inventors.

Since the Hatch-Waxman Act's passage, the Supreme Court has recognized that without a congressional mandate, the term "patented inventions" includes all inventions.[141] Some decisions of the Court of Appeals for the Federal Circuit have paradoxically upheld the Supreme Court's broad proclamation while others limit the scope of the

138. *Id.* at 207 (quoting § 271(e)(1)).

139. *See* Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1342–43 (Fed. Cir. 2007).

140. *Id.* at 1344.

141. *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 665 (1990).

Supreme Court's ruling. Federal Circuit precedent has failed to provide district courts with clear direction on the proper construction of the Safe Harbor provision, in part because of the fact-sensitive nature of patent infringement cases, but also because there has been no conclusive decision on whether research tools qualify as a patented invention under Safe Harbor.

To alleviate the lingering ambiguity, it may be time to include research tools as the type of patent inventions to which the Hatch-Waxman Act's Safe Harbor provision applies.