THE SAFE HARBOR OF 35 U.S.C. § 271(e)(1): THE COSTLY CONFUSION ABOUT THE SCOPE OF "PATENTED INVENTION"

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I. INTRODUCTION

A. The Problem to be Solved

A patent in the United States conveys an exclusive right over an invention for a limited term,[1] often about seventeen years.[2] During this interval, the patent holder has the right to stop others from making, using, selling, importing, or offering to sell the claimed invention in the United States.[3] This power to exclude had a compounded effect for drug and medical device inventions requiring U.S. Food and Drug Administration ("FDA") approval prior to market entry. Stopping a future competitor from using an FDA-regulated invention throughout the entire patent term also prohibited the competitor from beginning the FDA approval process until the patent expired. Quantitatively, this extended the legal monopoly of the patent holder by between one-and-a-half to six years for the competitor's clinical trials alone.[4]

Meanwhile, the invention owner's path to FDA approval for a regulated drug or medical device was often not without a symmetric grievance. The patent holder commonly obtained FDA approval long after their original patent filing date–the date which started the clock on the twenty-year term. Accordingly, the inventor waited several years for FDA approval to sell the regulated invention, thereby shortening the effective patent term. Unsurprisingly, a patent holder's enjoyment of no competition while a generic sought FDA approval was often deemed warranted by the patent holder's own "regulatory entanglements" on the front end of selling a patented drug.[5] While this rationale may reek of the unsatisfying fallacy that "two wrongs make a right," it nevertheless prevailed during legislative silence. Resolving this symmetric distortion is a subject courts and legislatures have wrestled with for decades.

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1. 35 U.S.C. § 154(a)(2) (2013). The exact term of exclusionary rights over a patented invention begins on the day the associated patent issues and terminates twenty years from its earliest application's filing date.

2. *Id.* The interval over which an inventor may enforce a patent is often around seventeen years because patents often grant two to three years after their earliest filing date.

3. 35 U.S.C. § 154(a)(1) (2013).

4. *Step 3: Clinical Research,* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [https://perma.cc/Z76B-NZEL] (last updated Jan. 4, 2018) (clinical trials are generally the longest phase of FDA approval).

5. Roche Products, Inc. v. Bolar Pharm. Co., 733 F.2d 858, 864 (Fed. Cir. 1984) (prior to §156 of the Hatch-Waxman Act, the filing date started the patent term clock even though the drug was not approved by the FDA and could not be sold).

B. Executive Summary

To understand current problems with the statutory solution to patent term distortions arising from FDA approval, this Note begins with describing the judicial tool most promising to resolve the most contentious distortion–an "experimental use exemption" to patent infringement granted under certain circumstances.[6] After explaining how the experimental use exemption ultimately failed to provide satisfactory results, the Note introduces the responsive legislative solution–the Hatch-Waxman Act ("Act").

The Note then assesses the language of the Act and unfolds the case law developing its most litigated terms. After criticizing the Act's use of undefined statutory terms–which do not secure a preferable symmetry between complementary Sections of the Act–the Note explains how courts now disagree, at least in part, on the scope of what inventions are shielded from patent infringement claims.

After suggesting a legislative amendment to the Act, the Note then focuses on a certain class of inventions commonly known as research tools. These inventions are not themselves subject to FDA approval–though they are consistently used in obtaining FDA approval for other products. Research tools are abundant in a laboratory and include at least mechanical, biochemical, biological, and chemical articles. This Note exposes uncertainty in the status of these tools under the Act and illustrates continued uncertainty after the judiciary's failed attempt to clarify. The Note also briefly assesses the general consequence of this ambiguity.

The Note then illustrates the detrimental effect this uncertainty is having on predictability of litigation by examining two cases, filed on the same day, in different jurisdictions. The cases have materially equivalent facts–the same plaintiff suing for patent infringement based on a similar use of the same patented research tool. While one case has now settled, the jurisdictions still have conflicting precedent on the precise issue which may prove dispositive in future litigation.

The Note concludes by proposing the judiciary adopt a bright-line rule excluding research tools from the purview of the Act's safe harbor. Though legislative action would be preferable, this Note maintains it is not required for a clear interpretation of the statute. Importantly, the judiciary need not fear entering the legislative realm to clarify the uncertainty–and it is in fact the judiciary's duty. Rather, for the judiciary to remain silent while a well-defined industry is subject to unpredictable liability, arising from everyday business decisions, may constitute a dereliction of duty.

C. From the Experimental Use Doctrine to a Statute

Sprouting from a germinate sentence written by Justice Story in 1813, the common law exemption against patent infringement grew into the experimental

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6. Moore U.S.A., Inc. v. Standard Reg., 144 F. Supp. 2d 188, 196 (W.D.N.Y. 2001).

use doctrine.[7] Justice Story recognized a sort of honor in curiosity without monetary gain and thought it was incompatible with the patent laws to punish a purely inquisitive mind.[8] With a subtle boldness, Story asserted "it could never have been the intention of the legislature to punish a man, 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."[9] This became known as the common law exemption to patent infringement. Forty-eight years later this doctrine stated that an "experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement" is not patent infringement–considerably close to Justice Story's own description.[10] In fact, the doctrine departed from its origins for over a century.

Gradually, in applying this doctrine, a distinction resulted in the emergence of two branches of thought within cases. The broadest view maintained experimental use defenses to patent infringement could be honored even when the use was for business purposes–as long as the product was not sold or intended for sale.[11] The public policy rationale was to allow competitors to seek improvements upon another's invention without liability and, in theory, accelerate innovation.[12] The narrower view held the experimental use exemption was to be forfeited as a defense if the patented product was used "in keeping with a legitimate business of the using agency.[13] Thus, courts were divided on whether the experimental use exemption could be used as a means of shielding oneself from liability while actively advancing a business interest. In a fundamental sense, this conceptual divide over public policy and the role of patents is still present today.

In 1984, the broader branch of case law invited a generic drug manufacturer to offer the experimental use doctrine as a defense against patent infringement.[14] In *Roche Products v. Bolar Pharmaceuticals*, the generic manufacturer used a patented drug–prior to the patent's expiration–in seeking its FDA approval.[15] Bolar Pharmaceuticals had imported the patented substance to assess parameters required by the FDA to prove bioequivalence, thus ensuring the generic version

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7. Whittemore v. Cutter, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813).
8. *Id*.
9. *Id*.
10. Poppenhusen v. Falke, 19 Fed. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861).
11. *See* Chesterfield v. United States, 159 F. Supp. 371, 375 (Ct. Cl. 1958) (experimentation with patented steel alloys excused under experimental use *inter alia* because no evidence suggested the manufacture sold or intended it for sale); Dugan v. Lear Avia, 55 F. Supp. 223 (S.D.N.Y. 1944), *aff'd sub nom*. Dugan v. Lear, Inc., 156 F.2d 29 (2d Cir. 1946) (building of a patented device was protected from infringement because, though it was built by a business, it was not sold or intended for sale); Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305 (N.D.W. Va. 1937) (making and using a patented product was protected from infringement because, though it was made and confirmed to work with production equipment, it was not commercially sold).
12. Dugan v. Lear Avia, 55 F. Supp. 223, 228 (S.D.N.Y. 1944).
13. Pitcairn v. United States, 547 F.2d 1106, 1125-26 (Ct. Cl. 1976).
14. Roche Products, Inc., 733 F.2d at 862.
15. *Id*. at 860.

would be market-ready soon after Roche's patent expired.[16] In an unusually forceful opinion, the newly minted[17] Federal Circuit declined to extend the experimental use doctrine to protect generics seeking FDA approval, emphasizing the doctrine was ill-fitted for the circumstances and that the Federal Circuit was not authorized to rewrite patent law.[18]

Thus, while generic drug manufacturers once offered the experimental use exemption with a flicker of hope that it might protect their pursuit of FDA approval in advance of patent expiration, the *Roche* court formally snuffed out exactly that wish. In its stated refusal to act in a legislative manner,[19] the *Roche* court deliberately highlighted the strong public policy rationale for an exemption. The public welfare, in the form of affordable drug prices, depends on price competition as much as protecting the right to profit from a large investment.[20] Without the former, fewer can afford the drugs produced; without the latter, the drugs may never be developed at all. Even so, the court noted the strength of any public policy rationale as immaterial to their task–naming the legislature as the proper forum for such a debate and referencing pending legislation on the very issue.[21] The *Roche* opinion has been interpreted as a "very narrow" experimental use exemption.[22] The often-quoted standard from *Roche* holds the exemption is limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry"– a hermetically sealed version of the *Poppenhusen* wording from the mid-nineteenth century.[23]

Within months of the *Roche* decision, the Drug Price Competition and Patent Term Restoration Act ("the Act" or "the Hatch-Waxman Act") was signed into law in September of 1984.[24] As designed, § 271(e)(1) of the Hatch-Waxman Act,

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16. *Id.*

17. U.S. CT. OF APP. FOR THE FED. CIR., https://cafc.uscourts.gov/home/the-court/about-the-court/ [https://perma.cc/TU97-7D48] (last visited Dec. 17, 2022) (the Federal Circuit formed as an Article III court on October 1, 1982, by the merging of the United States Court of Customs and Patent Appeals and the appellate division of the United States Court of Claims).

18. Roche Products, Inc., 733 F.2d at 862-65 (the Federal Circuit flags the expansive view of experimental use shielding "experiment" as "*obiter dictum*" and refuses to "rewrite the patent laws").

19. *Id.* at 863-64 ("Parties. . .seem to think. . .we must resolve a conflict between the Federal Food, Drug, and Cosmetic Act. . .and the Patent Act[.] We decline the opportunity here, however, to engage in legislative activity proper only for the Congress.").

20. *Id.* at 865.

21. *Id.* (the Federal Circuit emphasized the fact Congress was actively debating the Drug Price Competition Act of 1983).

22. Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

23. Roche Products, Inc., 733 F.2d at 863; *see also* Madey, 307 F.3d at 1362 (*quoting* Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000)) (consistent reliance on *Roche's* language).

24. *President's Remarks on Signing the Drug Price Competition and Patent Term Restoration Act of 1984 at the White House*, Washington D.C., 20 PUB. PAPERS 39 (Sept. 24, 1984) (Ronald Reagan signed the Hatch-Waxman Act into law on September 24, 1984).

commonly referred to as the "safe harbor" provision, successfully allows a generic drug manufacturer to use a patented drug prior to patent expiration when generating data for FDA submission:

> 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 . . . 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.[25]

When construing the terms of the statute above, it is interesting to consider the judicial interpretation of its sister statute – § 156, relating to extension of a patent term–also part of the Hatch-Waxman Act.[26] In addition to providing a remedy for generics being delayed in market entry, the Hatch-Waxman legislation also sought to remedy the symmetric distortion on the effective start date of a patent term.[27] As introduced above, the patent term would often begin before the FDA had approved the drug for use–reducing the profitable term of the patent on its front end.[28] This reduction in profitable term was not only unpredictable, but out of the inventor's control while the data was with the FDA for review and approval.

Under § 156 of the 1984 Hatch-Waxman legislation, an original drug manufacture can receive a patent term extension if the patent term is triggered prior to receiving regulatory approval.[29] The exact extension is calculated according to the statute.[30] Importantly, this provision is codified using the term "product," to describe those items falling within its ambit.[31] Indeed, the statute explicitly defines "product" to refer to "[a]ny medical device, food additive, or color additive *subject to regulation* under the Federal Food, Drug, and Cosmetic Act."[32] In an unsuspected contrast, and despite the symmetry in function, § 271(e)(1) uses "patented invention" to describe articles within its scope and is internally silent on defining the term.[33] While plot twists are amusing at the cinema, they are good for nothing but a law review article when spotted in legislation.

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25. 35 U.S.C. § 271(e)(1) (2015).
26. 35 U.S.C. § 156(c) (2015).
27. *Id.*
28. Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1261 (Fed. Cir. 2008).
29. 35 U.S.C. § 156(c) (2015).
30. *Id.*
31. § 156(a).
32. § 156(f).
33. 35 U.S.C. § 271 (2015).

II. BACKGROUND: THE STATUS OF JUDICIAL INTERPRETATION

A. A Tale of Two Terms

Though the legislative Act prevented extending a patent monopoly during the delay of FDA approval, it has not alleviated the judiciary's interpretive role. Litigation over the statutory scope of both applicable subject matter and activity has been frequent. Two terms of § 271(e)(1) have received the most attention: the scope of "patented invention," as alluded to above; and the scope of "reasonably related."[34] Debate concerning the former term seeks to characterize eligible inventions by several criteria, which will be explored below, and debate concerning the latter seeks to characterize what FDA approval activity the statute intended to protect.

B. Reasonably Related

Naturally, a 'reasonableness' standard left ripe for judicial interpretation results in substantial case law. This case law has shaped the outer boundaries of the exemptions of § 271(e)(1), but the exact contours form only a blurry line. Where § 156 offered tidy definitions to assist in assessing its reach, § 271(e)(1) has instead relied on the generation of a sizable body of case law.[35]

1. Expansive Scope

What is "reasonably related" to FDA approval is perhaps the best understood, and the least consequential, of the two terms. Reasonably related activity has been held to include: early experimentation where some or even all information may never be submitted to the FDA;[36] experimentation with a patented peptide in hopes of success and eventual FDA submissions for an Investigational New Drug ("IND") application;[37] use of data from clinical study for purposes other than FDA submissions; and activities targeting revision of a drug label.[38] Further, the protection of the safe harbor extends to drug production runs for qualification of processes and equipment under a federal regulation.[39] However, designating some of the resulting product from a qualification run as "commercial inventory," though not decisive, risks forfeiture of the safe harbor.[40] The Supreme Court case of *Merck,* which considered early experimentation, is generally regarded as an inflection point solidifying an expansive view of "reasonably related."[41] *Merck*

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34. § 271(e)(1).

35. 35 U.S.C. § 156(f) (2015).

36. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 206 (2005).

37. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1341 (Fed. Cir. 2007).

38. Classen Immunotherapies, Inc. v. Elan Pharm., Inc., 786 F.3d 892, 899 (Fed. Cir. 2015).

39. Amgen, Inc. v. Hospira, Inc., 944 F.3d 1327, 1339-40 (Fed. Cir. 2019).

40. *Id*. at 1340 (two batches designated as "commercial inventory," one was shielded, and the other was not).

41. Daniel Wobbekind, *Integra Lifesciences I, Ltd. v. Merck KGaA: Re-Examining the Broad*

will be unfolded later in this Note with focus on how its broad language has an inevitable influence on the scope of the patented invention.

2. Not Routine

One judicial limitation on what constitutes "reasonably related" under the safe harbor looks at the type of submission which might be generated from the activity.[42] Specifically, courts distinguish between activity resulting in "routine" and "not routine" submissions to the FDA.[43] Though both types of activities may be related to obtaining or maintaining FDA approval, only activities which are deemed "not routine" are eligible for shielding under the safe harbor.[44] While this requirement receives particular attention with post-approval activity, its waiver should not be assumed simply because a product has not yet received FDA approval. Such an absolute rule might encourage gamesmanship on the part of the manufacturer. For example, production of commercial product prior to FDA-approval would be disallowed afterward while the controlling patent is still in force. Accordingly, the court has allowed discretion on this matter and referred to the American Heritage Dictionary to define "routine" as an activity which is "habitual" or "regular."[45] Hence, the word "reasonable" does not merely convey a degree of relatedness but also a second qualifying quality concerning the activity's output. So, factual relatedness, though necessary, is not alone sufficient to satisfy "reasonably related." The activity must also be non-routine.

As for sample submissions, which do not rise above routine, the Federal Circuit has clarified among them are some activities, which are continued throughout market availability –such as quality control processes and reporting adverse effects of a vaccine when administered according to a patented low-risk method.[46] In contrast, protected "non-routine" FDA reporting has been held to include: (1) submissions to revise a drug label;[47] (2) experimentation which has the potential to result in an FDA submission;[48] and (3) preparation for a mandatory FDA pre-approval inspection.[49]

From a theoretical viewpoint, two characteristics are often used to signify routine. First, as introduced above, the "regularity" of a submission–especially one which would continue throughout market availability–supports the "routine-ness" of the activity used to generate the submission.[50] Second, an activity must

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Scope of the S 271(e)(1) Safe Harbor, 23 BERKELEY TECH. L.J. 107, 138 (2008).

42. *Id.* at 1338.

43. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1343 (Fed. Cir. 2007).

44. Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1358 (Fed. Cir. 2012).

45. Momenta Pharm., Inc. v. Teva Pharm. U.S.A., Inc., 809 F.3d 610, 620 (Fed. Cir. 2015).

46. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1072 (Fed. Cir. 2011); *see also* Momenta Pharm, 809 F.3d at 618.

47. Elan Pharms*,* 786 F.3d at 898.

48. Integra Lifesciences I, Ltd. v. Merck KGaA, 496 F.3d 1334, 1340-48 (Fed. Cir. 2007).

49. Amgen*,* 944 F.3d at 1339-44.

50. Momenta Pharm*,* 809 F.3d at 620.

produce submissions presently required to *obtain* FDA approval – not merely *maintain* FDA approval – for it to succeed at overcoming the bar against routine submissions.[51] The Federal Circuit's use of legislative history affirms this as a minimum.[52] In short, if the alleged infringing activity produces a submission type which continues during market availability, the activity is likely routine, and use of the associated patented invention will likely not be shielded.

B. Patented Invention

Not surprisingly, the generic term "patented invention" of § 271(e)(1) of the Hatch-Waxman Act invariably includes – at the very least[53] – the use of a drug when that use is "reasonably related" to obtaining FDA approval on that same drug.[54] In bounding that scope, the statutory language identifies no obvious limitation to the statute's patented invention. Indeed, § 271 uses "patented invention" throughout to refer to all inventions without regard for their status under federal regulations or otherwise.[55] It is not clear whether the patented invention shielded must be used in connection with its own FDA approval. Further, it is not clear whether the patented invention must be subject to FDA approval at all. By comparison, while the common law exception has the reach of T-rex arms, the Act is linguistically poised with the reach of an orangutang gliding through the treetops. Even so, courts have defined "patented invention" with some particularity.[56] While courts agree the term is not limited to pharmaceutical drugs, a close look reveals courts disagree on whether the patented invention's regulatory status under the FDA is required.

1. Not All About Drugs

First, the Supreme Court in *Eli Lilly v. Medtronic* clarified that "patented invention" includes "all inventions, not drug related inventions alone."[57] Unsurprisingly, it is settled that the statute shields the use of patented processes, pharmaceutical manufacturing equipment, medical devices, and pharmaceuticals from infringement when used to approve those technologies under their respective FDA regulations.[58] This holding aligns with the intent to ensure a competitor can introduce a generic product to market immediately upon patent expiration. Notably, the statement in *Eli Lilly* is made without caveat and has

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51. Integra Lifesciences I, 496 F.3d at 1343.

52. Biogen IDEC, 659 F.3d at 1071 (quoting H.R. REP. NO. 98-857(I) at 45 (1984)).

53. Proveris Sci., 536 F.3d at 1263.

54. 35 U.S.C. § 271(e)(1) (2015) (to the author's knowledge, no case has excluded drugs subject to FDA approval from the statutory reach of "patented invention").

55. *Id.*

56. *Id*.

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

58. *See* Amgen Inc., 944 F.3d at 1338-40; Elan Pharm., Inc., 786 F.3d at 898; Proveris Sci., 536 F.3d at 1262.

occasionally been read to suggest a contrast to the "product" of § 156, calling into question whether the "patented invention" must itself be subject to FDA approval.[59]

2. Invention's Status Under Regulation

Following *Eli Lilly*, the next seeming expansion in the scope of what the "patented invention" includes came from the Federal Circuit. In *Abtox v. Exitron*, a defendant used a plasma sterilizer–not itself subject to § 156 or full FDA approval[60], and was granted summary judgement for non-infringement on its motion to dismiss.[61] The *Abtox* court reasoned the Supreme Court in *Eli Lilly* had only indicated statutory symmetry between §156 and § 271 was "preferable but not required."[62] Hence, according to the *Abtox* court's interpretation, the "products" of § 156 need not refer to the same class of inventions as the "patented invention" of § 271–presumably, § 271 including a broader class.[63]

Then, in 2005, the Supreme Court subtly weighed in on the subject in *Merck v. Integra Lifesciences*.[64] Though, *Merck* is often understood to turn on the "reasonably related" term, as discussed above, there is an aspect of *Merck's* holding which is inextricable from the scope of a "patented invention."[65] As an observational matter, a patented compound in the preclinical "twilight zone"–having only hopes of proving therapeutic–is not yet, at the time of experimentation, subject to FDA approval. *Merck* held such a patented compound, not yet subject to FDA approval, was within the ambit of the safe harbor.[66] Public policy motivation for this outcome is centered on encouraging experimentation with potentially useful, but patented compounds. Questions remain whether this holding unacceptably erodes *Eli Lilly's* preference for statutory symmetry.

3. The Standing of the Research Tool

While *Merck* may have been written with the defining of "reasonably related" in mind, it would appear the reader was struck with its profound effect on the "patented invention" term. Specifically, *Merck* held that the safe harbor is not necessarily forfeited when there is "use of patented compounds in experiments

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59. Merck KGaA, 545 U.S. at 208 n.7.

60. Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1029 (Fed. Cir. 1997) (held the sterilizer was a Class II device not eligible for a patent term extension under § 156 because of its status as subject to an abbreviated FDA approval process).

61. *Id.*

62. *Id.*

63. Abtox, 122 F.3d at 1027.

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

65. *Id.*

66. *See* Merck KGaA, 545 U.S. at 206.

that are not ultimately submitted to the FDA."[67] Further, *Merck* interprets *Eli Lilly* to hold § 271(e)(1) "exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs."[68] It is not hard to spot the implications while reading with the court's own emphasis. The patented compounds being used are not necessarily the same compounds receiving, or subject to, the referenced FDA approval.

Merck's broad view of § 271(e)(1) provoked a slew of articles warning the demise of laboratory research tool development under the swelling safe harbor of § 271(e)(1).[69] Anchored in policy animating U.S. patent law, these critical publications argued limited patent enforcement for research tool disclosures would result in fewer patents being made public, less progress in the art by advancements thereupon, and a reduction in related capital investment.[70] Seventeen years later, questions remain whether *Merck* issued an "open season" on the unlicensed use of patented research tools.

It is difficult to say to what extent these fears came to pass. Without a control group (against which a meaningful change could be observed) or a dramatic change in the generation of research tool technology, we can only tentatively say the effects appear to have been minimal across the research tool industry. In contrast, a noticeable effect certainly arose among the courts. A minority of cases have in fact used this language from the Supreme Court in *Merck* to disassociate the submission of FDA approval from the patented invention.[71] Specifically, the safe harbor has been used to protect the use of a patented invention for the generation of data to be submitted pursuant to the FDA approval of a second article.[72] For example, in the 2013 case of *Teva Pharms. v. Sandoz*, the U.S. District Court for the Southern District of New York extended the safe harbor to patented polypeptide markers used to obtain molecular weight characteristics of

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67. *Id.*

68. *Id*.

69. *See* Wolrad Prinz, *Research Tool Patents After Integra v. Merck - Have They Reached a Safe Harbor?*, 14 MICH. TELECOMM. & TECH. L. REV. 367, 445 (2008); *see also* Tara Stuart, *Has The Supreme Court Incorrectly Expanded S 271(e)(1) to Risk a Regulatory Taking?*, 5 J. MARSHALL REV. INTELL. PROP. L. 216, 237 (2006); Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents,* 23 BERKELEY TECH. L.J. 1299, 1365 (2008).

70. *See generally* Daniel Wobbekind, *Integra Lifesciences I, Ltd. v. Merck KGaA: Re-Examining the Broad Scope of the S 271(e)(1) Safe Harbor,* 23 BERKELEY TECH. L.J. 107, 138 (2008) (arguing funds for research will be stifled without patent enforceability); Brendan M. O'Malley, *Merck v. Integra and Its Aftermath: A Safe Harbor for the Commercial Use of Biotechnology Research Tools?,* 23 CARDOZO ARTS & ENT. L. J. 739, 760 (2006) (arguing an immediate financial impact to researchers and long-term impact on public welfare).

71. *See* Teva Pharms. USA, Inc. v. Sandoz Inc., No. 09 CIV. 10112, 2013 WL 3732867 (S.D.N.Y. July 16, 2013).

72. *Id.*

an active ingredient in a drug.[73] The shielded markers are not a drug nor subject to FDA approval.[74] Specifically, these markers are only used to extract data from the marketable drug, data which is then submitted to the FDA for approval of the marketable drug.[75] Hence, the polypeptide markers fall squarely within the research tool class of inventions. Though the *Merck* Court explicitly declined to address the issue of research tools,[76] the *Merck* holding was used in deciding the *Sandoz* case which involved research tools.[77] The Supreme Court's refusal to acknowledge research tools as a distinct class has perhaps inadvertently brought them under the broad principles above and did not foreclose the use of *Merck* in that context.

4. Narrowing at the Federal Circuit

Perhaps in response to a recognized need, or echoing concern for research tool patents, eighteen years after *Eli Lilly*, and three years after *Merck*, the Federal Circuit seemingly carved out a limitation on the statutory "patented invention." In *Proveris v. Innovasystems*, the Federal Circuit held that the use of Innova's laboratory equipment–not itself subject to FDA approval, but used exclusively in producing data for FDA approval–was not shielded by the safe harbor of § 271(e)(1).[78] The Federal Circuit reasoned that since excluding Innovasystems from use of the patented device would not unfairly extend the life of the patent by an approval delay, the purpose of the safe harbor would not be served in applying it in that instance.[79] The Federal Circuit explains this in plain terms:

> 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. For this reason, we do not think Congress could have intended that the safe harbor of § 271(e)(1) apply to it.[80]

In this excerpt, the *Proveris* court underscores key rationale and issues a single result in harmony with this Note's call for a bright-line rule. This decision strengthened the case for a general rule excluding patented inventions not subject to FDA approval from the safe harbor. However, *Sandoz*–decided about five

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73. Sandoz, 2013 WL 3732867, at *1.
74. *Id.* at *2.
75. *Id.*
76. Merck KGaA, 545 U.S. at 205 n.7.
77. Sandoz, 2013 WL 3732867, at *8.
78. Proveris Sci. Corp., 536 F.3d at 1266.
79. *Id.* at 1265.
80. *Id.*

years after *Proveris*–has not been recognized as establishing a binding rule.[81] It would appear this is because of the Supreme Court's unwillingness to concur on such a categorical limitation.

In the face of such binding Federal Circuit guidance, how did *Sandoz* justify a dismissal of patent infringement for use of the patented polypeptide marker? Surprisingly, *Sandoz* does not interpret *Proveris* to narrow, or even consciously impact, the statutory "patented invention."[82] Instead, *Sandoz* emphasizes *Proveris*'s reliance on the statute's requirement that activity is "solely for uses" related to FDA approval.[83] *Sandoz* points out that in *Proveris*, the defendant was "manufacturing and selling a patented device" and argued their "customers' activities"–being in connection with seeking FDA approval–were a basis to grant the defendant shelter under the safe harbor.[84] The defendant wanted to sell a patented product to a customer who would use it in connection with FDA approval.[85] Accordingly, had the defendant in *Proveris* been the one using the patented invention, according to *Sandoz* at least, the safe harbor may very well have applied.[86] To clarify, *Sandoz* expressly concludes that to read *Proveris* to hold that laboratory equipment forms a class of devices generally unprotected by the safe harbor would be to "read *Proveris* too narrowly."[87] In *Sandoz's* view, *Proveris* did not exclude laboratory equipment, a subset of research tools, from the reach of the safe harbor, but rather, the use of a patented invention where the user was not seeking FDA approval.[88] To construct *Proveris* so narrowly is, in this author's opinion, to corrupt the context and conflate the audience with the actors. Regrettably, whether FDA approval was sought concerning the patented invention was left optional.

D. Summary of Uncertainty Concerning Research Tools

Today, all these factors have produced uncertainty concerning the safe harbor's effect on the species of patented invention, commonly referred to as research tools.[89] Generally, research tools are not subject to FDA approval, though they are often required to generate data demanded by FDA submissions. *Sandoz* is a district court decision in which a research tool was brought under the safe harbor, but *Sandoz* is in the minority on this holding.[90] *Proveris*, on the other

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81. Sandoz, 2013 WL 3732867, at *8.

82. *Id.* at *7.

83. *Id.* at *8.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. Merck KGaA, 545 U.S. at 208 n.7.

90. To this author's knowledge, *Sandoz* is the only district court which has explicitly included in the scope of "patented invention" drugs not themselves subject to FDA approval – many district courts have remained silent on the issue.

hand, is a Federal Circuit decision in which a research tool was excluded from the safe harbor.[91] Though the Supreme Court has used broad terms to define the safe harbor's "patented invention" and expressly avoided answering the question of whether a research tool is shielded under § 271(e)(1), at least two district courts have read *Proveris* to categorically exclude research tools as a "patented invention" under § 271(e)(1).[92]

In contrast, the *Sandoz* decision from the Southern District of New York above dismissed multiple patent infringement claims arising from the use of patented polypeptide markers to measure the molecular characteristics of a generic drug seeking FDA approval.[93] Characteristic of most research tools, the polypeptides were themselves not subject to FDA approval.[94] Interpreting *Abtox*, the district court in *Sandoz* firmly asserted that "[i]n construing that all classes of medical devices fell within the scope of the safe harbor (not just those subject to FDA approval), the Federal Circuit relied upon the language of the statute and the Supreme Court's broad language in *Eli Lilly*."[95] With the Supreme Court holding a broad view of which inventions fall under the safe harbor, the Federal Circuit now construing that precedent narrowly, and district courts landing on both sides and in-between, some enterprising innovators have been willing to risk litigation rather than seek licensing on crucially important technologies.

III. USE NOW, LITIGATE LATER

A. Two Controversies

Two patent infringement lawsuits, one still pending, highlight the uncertainty around research tools under the safe harbor. Allele Biotechnology & Pharmaceuticals Inc. filed suit against two defendants in two different Federal District Courts on the same day.[96] Allele filed against Regeneron in the United States District Court for the Southern District of New York on October 5, 2020,[97] and against Pfizer in the United States District Court for the Southern District of California.[98] The lawsuits both allege infringement of the same patented

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91. Proveris Sci. Corp., 536 F.3d at *1261.

92. Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347, at *12 (S.D. Cal. May 4, 2021).

93. Teva Pharma. USA, Inc. v. Sandoz Inc., 2013 WL 3732867, *2 (S.D.N.Y. 2013).

94. *Id.*

95. *Id.* at *7.

96. Regeneron has its principal place of business, maintains its registered office, and is incorporated in the State of New York. Complaint, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharm., Inc., No. 20-cv-08255, 2021 WL 2880694, at *1 (S.D.N.Y. Apr. 8, 2021). Thus, venue was proper and easy to attain in the Southern District of New York.

97. Complaint, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharm., Inc., No. 20-cv-08255, 2021 WL 2880694, at *1 (S.D.N.Y. Apr. 8, 2021).

98. Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347, at *1 (S.D. Cal. May 4, 2021).

technology expressly identified as a research tool. Further, the alleged activity of the defendants did not materially differ. Both defendants, among other alleged activity, used mNeonGreen in neutralization assays which inserted a gene chimera from Allele's fluorescent protein into the SARS-CoV2-19 viral genome for purposes of tracking its proliferation and related behavior.[99] The choice to file in two different jurisdictions, though perhaps essential to easily ensure proper venue, may prove to highlight a particular uncertainty in the law on an integral issue.

Four subjects will be considered briefly. First, the prospect of the remaining case going to trial, and its suitability for appeal and clarification of an unresolved issue of the safe harbor's interpretation will be addressed in this section. Second, this section will consider whether the relevant analysis offered by the court so far is legally satisfying. Third, this section will provide a brief consideration of the possible outcomes. Lastly, a bright-line rule will be proposed which aims to resolve statutory ambiguity.

1. Patent at Issue

Prior to the spread and discovery of SARS-CoV2-19, Allele had developed and patented mNeonGreen – a monomeric fluorescent protein – as United States Patent No. 10,221,221.[100] Such a protein is useful as a biomarker to track or identify certain molecules and, among other applications, gives researchers a window into the effectiveness of therapeutics designed to generate antibodies.[101] In an effort to enhance the standing of its cases against Regeneron and Pfizer, Allele argued mNeonGreen is the best fluorescent protein available and has been referred to objectively by third-parties as the "[k]ing of fluorescent proteins."[102]

2. Accused Activity

Before Pfizer, or any other therapeutic developer was directly involved, a university used mNeonGreen to develop the "gold standard" COVID-19 assay for evaluating vaccine effectiveness and differentiating between which therapeutic was most and least effective.[103] Allele alleges Pfizer and BioNTech then used this assay, along with the patented florescent protein, for commercial testing, development, and ultimately selection of their mRNA prophylactic COVID-19 vaccine during clinical trials.[104] By testing antibody levels of patients during clinical trials, Pfizer selected a winning vaccine from among several BNT162

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99. AmendedComplaint at 4, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. Feb. 25, 2021).

100. *Id.* at 2.

101. *Id.* at 4.

102. *Id.* at 6.

103. *Id.* at 2.

104. *Id.*

mRNA candidates.[105] Similarly, Allele alleges Regeneron Pharmaceuticals used mNeonGreen to detect a pseudoparticle reporter indicating the presence of SARS-CoV-2 neutralizing antibodies.[106] In sum, Allele alleged both Pfizer and Regeneron emerged as front runners in the race to a vaccine precisely because of their unlicensed use of mNeonGreen.[107] Noting mNeonGreen is not itself subject to premarket approval under any federal law, Allele argued against applying the safe harbor.[108]

3. Legal Issue: Complaint and Defense

Allele, in both complaints alleging infringement of the 221 patent, specifically identify mNeonGreen as a research tool.[109] In addition to denying nearly all of Allele's allegations, asserting Allele's patent is invalid, and asserting non-infringement of the patent, Pfizer raised § 271(e)(1) as an affirmative defense against patent infringement.[110] Accordingly, Pfizer filed a motion to dismiss the lawsuit, arguing its use of mNeonGreen was sheltered by the statutory safe harbor.[111]

Similarly, Regeneron filed a motion to dismiss under Federal Rules of Civil Procedure 12(b)(6), arguing Allele had failed to state a claim upon which relief could be granted.[112] As expected, Regeneron filed its support to this motion on August 20, 2021.[113] Unsurprisingly, it ardently pointed out that *Sandoz* expressly included research tools in the safe harbor: emphasizing *Sandoz's* found that "'[t]he statutory safe harbor is clear' and 'patented invention' is defined by 35 U.S.C. § 100(a) to broadly mean 'invention or discovery.'"[114] Further, Regeneron argues that whatever *Proveris* stated concerning the term "patented invention,"

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105. *Id.* at 10-11.

106. Amended Complaint at 9, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharm., Inc., No. 20-cv-08255, 2021 WL 2880694 (S.D.N.Y Apr. 8, 2021).

107. AmendedComplaint at 11, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. Feb. 25, 2021); *see also* Second AmendedComplaint at 10, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. Feb. 25, 2021).

108. *Id.* at 7.

109. *Id.* at 11; *see also* AmendedComplaint at 12, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. Feb. 25, 2021).

110. Answer at 34, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. June 3, 2021).

111. Motion to Dismiss at 1, Allele Biotechnology and Pharmaceuticals, Inc. v. Pfizer Inc., 20-cv-01958-H-AGS, 2021 WL 2774550 (S.D. Cal. April 23, 2021).

112. Notice of Motion at 1, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharmaceuticals, Inc., No. 20-cv-08255, 2021 WL 2880694 (S.D.N.Y Aug. 20, 2021).

113. Reply Memorandum of Law at 2, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharmaceuticals, Inc., No. 20-cv-08255, 2021 WL 2880694 (S.D.N.Y Aug. 20, 2021).

114. *Id.* at 2 (*quoting* Teva Pharm's USA, Inc. v. Sandoz, Inc., 2013 WL 3732867, at *7 (S.D.N.Y. 2013)).

and a dependence on it being subject to FDA approval, was mere dicta because *Proveris* itself did not turn on that holding.[115] Rather, Regeneron argues, *Proveris* rejected application of the safe harbor "because the defendant's use was not related to generating data for FDA submission."[116] Asserting *Proveris* offered only dicta on the scope of "patented invention" appears to be bold, and in the minority view. However, the case has been filed in a jurisdiction which has shown favor to that vary approach and the litigation remains pending.

B. Status of Pfizer Litigation

1. Motion to Dismiss Denied

The action against Pfizer was filed with the United States District Court for the Southern District of California. Prior to resolution by settlement on January 5th, 2022, three orders on motions were issued from Judge Marilyn L. Huff.[117] Two related to motions to dismiss and compel, respectively, and are of little import to the safe harbor issue.[118] Of particular interest, in May 2021, the Court denied Pfizer's motion to dismiss under Federal Rules of Civil Procedure 12(b)(6) on the theory that, as a matter of law, Allele had failed to state a claim upon which relief could be granted.[119]

According to Pfizer, even if the patent was valid and Pfizer's activity constituted elements of infringement, as Allele alleges, the activity was shielded under the safe harbor of § 271(e)(1) and, as such, Allele was never entitled to any of the relief it requested.[120] In denying this motion, the Court noted that two Federal District Courts have held research tools, which are not subject to FDA approval, are not shielded under the safe harbor.[121] Though the legal standard for a successful 12(b)(6) favors the plaintiff,[122] the U.S. District Court for the

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115. *Id.*

116. *Id.* at 1-2.

117. *See* Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 37287 (S.D. Cal. Feb. 26, 2021). *See also* Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 174654 (S.D. Cal. Sep. 13, 2021).

118. *Id.*

119. Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347, at *3 (S.D. Cal. May 4, 2021).

120. *Id.* at *5.

121. *Id.* at *11. *See also* Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 11CV02214, 2012 U.S. Dist. LEXIS 134107, 2012 WL 4111157, at *4 (S.D. Cal. Sept. 19, 2012) ("The Safe Harbor does not apply, however, when a biological compound is used to perform 'basic scientific research' or as a 'research tool.'"), *and* PSN Ill., LLC v. Abbott Labs. & Abbott Bioresearch Ctr., Inc., No. 09 C 5879, 2011 U.S. Dist. LEXIS 108055, 2011 WL 4442825, at *5 (N.D. Ill. Sept. 20, 2011) ("Proveris excluded research tools from the purview of the safe harbor exemption.").

122. Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., 20-cv-01958-H-AGS, 2021 U.S. Dist. LEXIS 85347, at *4 (requiring all questions of fact to be resolved in favor of the non-moving party).

Southern District of California suggested, in its refusal to dismiss the action against Pfizer, that it reads *Eli Lilly* and *Proveris* to teach research tools are outside the scope of the "patented invention" of § 271(e)(1).[123]

Interestingly, discussion of the Supreme Court case of *Merck*–a case which contains what some have viewed as expansive language suggesting research tools rest within the ambit of § 271(e)(1)–is limited to one paragraph and avoided entirely in the court's analysis section.[124] Aside from several quotes unanchored by meaningful context, the Court reports *Merck's* broadest statement only in parentheses and removes the Supreme Court's emphasis. Indeed, the Court's lack of focus on *Merck* suggested it would not extend *Merck's* sweeping principles to research tools.[125] Notably, *Merck* was seemingly replaced with a discussion easily distinguishing *Classen v. Elan Pharms* in the Court's brief analysis and subsequent rejection of Pfizer's motion to dismiss.[126] Perhaps *Merck's* direct refusal to address research tools has been taken by some courts to relieve its application of the general statements therein.[127] The appropriateness of this maneuver will be considered later.

Though not excepted by all courts, the U.S. District Court for the Southern District of California made it clear, as a matter of law, the safe harbor would not shield Pfizer's activity.[128] Since juries generally favor patent holders, the parties could assess their chances of success and the outcome of the jury trial which was set for late 2022. This proved enough information to settle. It is safe to say the terms of the settlement were in Allele's favor–favor obviously dependent on the Court's refusal to apply the safe harbor.

2. Status of Regeneron Litigation

A similar motion to dismiss was filed by Regeneron on August 8, 2021, with the Southern District of New York, which was dismissed on March 2, 2022.[129] A status update from Allele on December 13, 2021, indicated Regeneron had ceased all use of mNeonGreen in its current research and development of next generation antibody cocktails and notified Allele.[130] Allele has accordingly withdrawn

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123. *See* Santaris Pharma A/S Corp., U.S. Dist. LEXIS 134107, at *4 ("The Safe Harbor does not apply, however, when a biological compound is used to perform 'basic scientific research' or as a 'research tool.'"), *and* Abbott Labs. & Abbott Bioresearch Ctr., Inc., U.S. Dist. LEXIS 108055, at *5 ("Proveris excluded research tools from the purview of the safe harbor exemption.").

124. *Id.*

125. *Id.* at *8.

126. Elan Pharm., Inc., 786 F.3d at 896-97 (the court states the defendant's reliance on Elan Pharm. is misplaced because the issue relates strongly to the nature of the activity instead of the invention being used).

127. Allele Biotechnology & Pharm., Inc., 2021 U.S. Dist. LEXIS 85347, at *15.

128. Elan Pharm., Inc., 786 F.3d at 896-99.

129. Status Update at 1, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharmaceuticals, Inc., No. 20-cv-08255, 2021 WL 2880694 (S.D.N.Y Apr. 8, 2021).

130. *Id.*

associated allegations of continued use of their patented technology, but has retained other allegations.[131] While Regeneron's move is difficult to legally construe, it could be an indication both parties are also likely to negotiate a settlement.

3. Settlement of Trial: Jury or Bench

With about 96 percent of patent infringement lawsuits settled before trial,[132] it is statistically unlikely that an individual case would receive a written opinion from a judge on appeal, though a case is slightly more likely to be resolved on a granting of summary judgment.[133] With some lawsuits being dismissed or abandoned, only about 1.5 percent of filed patent infringement lawsuits are litigated to a conclusion.[134] Of these, however, an increasing number are being submitted to a jury for deliberations.[135] Though jury trials significantly increase both the chances a patent holder wins and their corresponding average award,[136] they are the costliest form of resolution.[137] For a jury trial to advance, both parties must sharply disagree on what damages, if any, will restore the interests of the plaintiff. For cases of ordinary circumstances–where damages from comparable lawsuits are readily available–settlement is likely in the best interest of both plaintiff and defendant. Time and resources consumed by trial are often not worth the statistically larger award.

Allele, however, filed a case against Pfizer which was not average in several respects. It was arguably worth an extraordinary reward. When viewed as a single industry, biotech and pharmaceuticals garner infringement damages which dwarf those of other industries.[138] Further, Pfizer has made a veritable fortune from the vaccine.[139] If Allele had been left to convince a jury Pfizer was first to an effective therapeutic because of a deliberate and unauthorized use of mNeonGreen, Allele would have also happily asked that jury to consider exactly

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131. *Id.*

132. Branka Vuleta, *25 Patent Litigation Statistics-High-Profile Feuds About Intellectual Property*, LEGALJOBS (Aug. 6, 2021), https://legaljobs.io/blog/patent-litigation-statistics/#:~:text=A%3A,year%20in%20the%20United%20States [https://perma.cc/W59F-XZ7H].

133. *Id.*

134. *Id.*

135. *Id.*

136. Landan Ansell et al., *2018 Patent Litigation Study*, PRICE WATERHOUSE COOPERS 1, 6-7 (May 2018), https://www.ipwatchdog.com/wp-content/uploads/2018/09/2018-pwc-patent-litigation-study.pdf [https://perma.cc/8HN5-33CQ].

137. Vuleta, s*upra* note 132.

138. Ansell et al., s*upra* note 136 (in a 20-year study where the median damage award over all industries was $5.9 million, the Biotech/Pharma industry had a median award per case exceeding $20 million).

139. Zachary Brennan, *Moderna's Covid-19 Vaccine Sales to Trail Pfizer's Total Significantly in 2021 and 2022,* ENDPOINTS NEWS (Aug. 5, 2021), https://endpts.com/modernas-covid-19-vaccine-sales-to-trail-pfizers-total-significantly-in-2021-and-2022/ [https://perma.cc/A8J4-33EB].

what part of Pfizer's projected $33 billion in 2021 revenue belongs to Allele.[140] Though Pfizer has settled, an analogous consideration applies against Regeneron with respect to the wide use of its antibody cocktail–including the high-profile treatment of then-President Donald Trump, after he contracted the illness prior to vaccine availability.

Pleadings in both cases force an answer on the research tool question–an unresolved conflict which has garnered much attention. Though Allele has resolved Pfizer's case without option to refile, it is conceivable that amicus briefs and similarly interested parties would aptly vie for resolution on this issue. This factor suggests Regeneron's case may be ripe for escalation to higher courts. High-profile players produced a product which has become a household name on a global scale–largely due to the significance of the COVID-19 outbreak.[141] The accompanying money, motive, and resources may help extrude a final answer to the research tool question.

IV. ANALYSIS

A. On The Denial of Motions for Summary Judgement

1. Right Outcome

It is helpful to understand the significance of the denial to grant Pfizer's motion to dismiss. Pfizer asserted a motion to dismiss because of Allele's alleged "failure to state a claim upon which relief can be granted."[142] For this motion to succeed against the plaintiff, the pleadings must not contain "enough facts to state a claim to relief that is plausible on its face."[143] In determining this, the court may ignore naked assertions and legal conclusions, amounting to formulaic recitations of the elements of the cause of action–but only when they are lacking further factual enhancement.[144] The burden of establishing a facially plausible claim rests with the plaintiff and factual disagreement is to be resolved in favor of the non-moving party.[145] After a conforming Rule 8 pleading is submitted by the plaintiff, the burden then shifts to the defendant to show, even if the alleged facts are true, the plaintiff would not be positioned to collect any remedy.[146] Here, Pfizer's argument rested principally on the safe harbor for protection to bar Allele from any recovery. With the scope of the safe harbor being one of contention and the

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140. *Id.*

141. *Id.*

142. FED. R. CIV. P. 12(b)(6).

143. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007).

144. *Id.* at 557, 564.

145. Daniel C. Cooley & Justin E. Loffredo, *A Refresher on the Standards of Pleading Direct Patent Infringement,* IP LITIGATOR (Dec. 2020), https://www.finnegan.com/en/insights/articles/a-refresher-on-the-standards-of-pleading-direct-patent-infringement.html [https://perma.cc/497Y-HDWR].

146. *Id.*

precedent of the Southern District of California, denial of a motion to dismiss was not surprising. Even so, the scope of the safe harbor will likely be questioned again in the Southern District of California. Similarly, and relying on similar rationale, the March 2nd denial of Regeneron's motion to dismiss will likely not be the last time the scope of the safe harbor is at issue in the Southern District of New York.[147] Indeed, it may be raised again in later proceedings involving this same litigation.

Whether the § 271(e)(1) safe harbor applies is a mixed question of law and fact. As to law, it depends on the definition of the "patented invention" of § 271(e)(1). As to fact, it depends on what mNeonGreen is and where it falls in relation to the judicially endorsed definition. Whether these questions coincide in the law-fact continuum remains a mystery, and so, it is no surprise the court ultimately dismissed both defendant's motions for summary judgement. Based on variation between courts, it is difficult to say whether mNeonGreen, though it be a research tool, falls under the purview of the safe harbor. It is important to note that the court only stated Pfizer had "failed to demonstrate that the facts alleged in the [complaint] establish that the allegedly infringing activity is exempted" under the safe harbor.[148] The court may be alluding to an answer turning on *activity* instead of subject matter contemplated by the "patented invention" of the safe harbor.

2. Limited Rationale

The court, in its denial to dismiss the case against Pfizer, points out that the defendant's reliance on *Sandoz* is unpersuasive and ineffectual because it is a non-binding district court opinion.[149] However, this same rationale disembowels its own reliance on two district courts who have interpreted *Proveris* to categorically exclude items not subject to FDA approval from the "patented invention" of § 271(e)(1).[150] The court resorts to 'cherry picking' of lateral, non-binding interpretations of *Proveris* exactly because its binding precedent–the Federal Circuit and Supreme Court–have not yet enunciated the bright-line rule it seeks. Federal District Courts have been criticizing each other's interpretation of their mutually binding precedent. This silence to-date by the Federal Circuit and Supreme Court raises questions of unacceptable ambiguity for those who innovate in the field of research tools.

The court, in Allele's case against Pfizer, quotes from *Proveris* to purportedly show a rule requiring an invention be subject to FDA approval to receive safe

147. *See* Cooley & Loffredo, *supra* note 145.

148. Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347, at *18 (S.D. Cal. May 4, 2021).

149. *Id.* at *17.

150. *Id.* at *12; *see also* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 665, 672 (1990) (to state "all inventions, not drug related inventions" are within the ambit of § 271(e)(1) formally marks at least one aspect of asymmetry between § 156 and § 271).

harbor protection.[151] After noting Proveris' patented device is not eligible for § 156 patent term extension because it is not subject to FDA approval, the *Proveris* court added that "because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1)."[152] The Court relies heavily on this quotation. While it is true *Proveris* goes on to treat subjection to FDA approval as a requirement to be under the safe harbor, the last word on that subject from the Supreme Court was only that such symmetry be "preferable."[153] Was *Proveris* wrong to add a limitation the Supreme Court did not? Was this language mere dicta, as *Sandoz* surmised? Such a reading of *Proveris* may conflict with the holding in *Merck*, where the patented peptides only had hopes of producing material for FDA submissions but were nonetheless protected.[154] Is the rule *potential* subjection to FDA regulation? Further, *Abtox*, the Federal Circuit decision, where a non-FDA regulated plasma sterilizer was shielded by the safe harbor, has not been overruled.[155] In sum, whether a district court should require a product be subject to FDA approval for application of the safe harbor is a matter reasonable interpretations of current case law can (and do) differ on.

Further, three times throughout the denial of the motion to dismiss, the California district court emphasizes the 'perfect "product" fit' described in *Eli Lilly*.[156] While the symmetry between § 156 and § 271 is dependent on an invention itself being subject to FDA approval, *Eli Lilly* used this fact to explain why § 271(e)(1) extended to a patented medical device, refusing to limit its scope to drugs, to maintain this symmetry. This maneuver by some was regarded as expanding a term once presumptively limited to drugs. Though the connection is perfectly logical, *Eli Lilly* is not the latest binding precedent a district court must reconcile before arriving at a conclusion. *Merck* was decided in 2005 and builds on *Eli Lilly* to extend–not limit–the scope of § 271(e)(1) inventions. Referring to *Eli Lilly*, *Merck* states it is "apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA."[157] Whether "any information" signifies that the information need not relate to approval of the subject patented invention has not been answered by the Supreme Court, and as we have already seen, is a subject of disagreement in lower courts.[158]

It has been over fifteen years since this textualistic statement of the statute concerned holders of research tool patents. Admittedly, the context is principally

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151. *Id.* at *9.

152. Proveris Sci. Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1266 (Fed. Cir. 2008).

153. Eli Lilly & Co., 496 U.S. at 666.

154. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 208 (2005).

155. Abtox, 122 F.3d at 1029.

156. Allele Biotechnology & Pharm., Inc., 2021 U.S. Dist. LEXIS 85347, at *11, *13, *17.

157. Merck KGaA, 545 U.S. at 202.

158. *See* Teva Pharms. USA, Inc. v. Sandoz, Inc., No. 09 CIV. 10112, 2013 WL 3732867, at *6-7 (S.D.N.Y. July 16, 2013).

aimed at defining the "reasonably related" phrase in the statute.[159] However, in the same way *Merck* (primarily concerned with the scope of reasonably related) harmonizes with *Eli Lilly* (primarily concerned with the scope of patented invention), a more fulsome explanation must bound the broad principles in *Merck* as limited to the context of reasonably related activity and not conflicting with a yet to be articulated general rule concerning research tools. Again, the scope of "reasonably related" has not been defined in isolation: courts can and have woven themes of reasonably related into analysis evaluating research tools as patented inventions.[160] With the significance of the patented invention's subjection to FDA approval formally left open for the lower courts, Allele presents a high-profile opportunity where an unlicensed use of a patented research tool may be analyzed to provide clarity on that point.[161]

3. Final Outcome

Inconsistency between courts on this matter is not a distant obscurity. A student of the subject need only assess the probable outcome of these two cases based on each jurisdiction's precedent. As illuded to above, prior to settlement, Allele's complaint in the Southern District of California survived a motion to dismiss and the jurisdiction has recent precedent categorically excluding patented inventions not subject to FDA approval from the safe harbor. Collectively, this suggests the Southern District of California is unlikely to extend the safe harbor to immunize the future use of patented research tools. Indeed, this is not the first time, or the last time, the Southern District of California has articulated a narrow reading of *Proveris*.[162]

In contrast, the Southern District of New York, in which Allele has filed suit against Regeneron, has a recent case where the use of so-called research tools was shielded under the safe harbor. Therefore, it once appeared two cases alleging similar use of the same patented invention were queued up for different outcomes. However, on March 2, 2022, Regeneron's motion to dismiss, a motion analogous

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159. Justice Scalia is known for strict textualistic reading of statutes and was often skeptical of using legislative history to interpret statutes. He argued it could often support both sides and may have been produced to yield an interpretation not voted on by Congress. *See* Merck KGaA, 545 U.S. at 202, 206, 208 (in each passage Scalia refuses to impose a limitation on "patented invention" which was not introduced by the statute's text).

160. *See* Teva Pharms. USA, Inc., 2013 WL 3732867, at *6 (*quoting* from *Merck* specifically when assessing whether the patented invention used must itself be subject to FDA approval). *See also* Allele Biotechnology & Pharm., Inc., 2021 U.S. Dist. LEXIS 85347, at *7 (reconciling *Merck* with its narrower application of the safe harbor in the context of "patented invention").

161. Merck KGaA, 545 U.S. at 208 n.7 (footnote 7 in *Merck* states that though the Court of Appeals argued limiting § 271(e)(1) was appropriate to protect patents on research tools, the Supreme Court explicitly declined to "express a view about whether, or to what extent," research tools should fall under the safe harbor).

162. *See* Isis Pharms., Inc. v. Santaris Pharma A/S Corp., No. 11-cv-02214, 2012 U.S. Dist. LEXIS 134107, at *11 (S.D. Cal. Sept. 18, 2012).

to Pfizer's motion, was similarly denied. As of July 31, 2022, both parties are preparing for a jury trial, the outcome of which will likely raise the research tool question again on appeal. Whether on appeal in this case, or in future cases with arguably distinguishable facts, the contradictory case law will be advanced, and the judge will resolve each case. This scenario is contrary to the desire for consistency in the law and raises questions related to forum shopping, equity, and predictability of the patent laws.

B. The Future of the Controversy

1. An Important Opportunity

Several factors unique to Allele's case against Regeneron make it a candidate to solidify the status of research tools under § 271(e)(1). First, there is no dispute as to the nature of mNeonGreen—it is squarely a research tool and used as such in the allegedly infringing activity. Relatedly, it is not itself subject to FDA approval. Second, though the *Proveris* holding will almost certainly be considered relevant, the aerosol spray analyzer in that case was not in fact used for *research* by the defendant.[163] Rather, it was used for measuring data from a fully designed consumer product—the data required by the FDA before sale.[164] Further, the aerosol spray analyzer in *Proveris* was being sold by the defendant to third parties who would use it for obtaining data for FDA submissions. In other words, Innova was making the device to sell it for a direct profit, not conduct research themselves—potentially more scandalous than in-house use of a molecular compound. Notably, mNeonGreen is used for research of promising compounds, in identifying one which may be advanced and eventually require submission to the FDA. In that sense, there are factual similarities with *Merck*.[165] Though it is not the actual compound with hopes of FDA submissions being directed at it, as in *Merck*, mNeonGreen appears to have been genetically integral to those very compounds for the purposes of research.[166] In short, *Proveris* may be distinguishable, as mNeonGreen is the quintessential research tool.

Thirdly, the financial stakes could scarcely be higher. Though the parties are not financial equals, both have adequate access to funding to fully litigate the matter.[167] Alleles technology was powerful. To illustrate, mNeonGreen assisted

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163. Proveris Sci. Corp., 536 F.3d at *1264.

164. *Id.*

165. Merck KGaA, 545 U.S. at 193 (*Merck* states "§ 271(e)(1) exempts from infringement the use of patented compounds in preclinical research, even when the patented compounds do not themselves become the subject of an FDA submission.").

166. Amended Complaint at 4, Allele Biotechnology & Pharm., Inc. v. Pfizer, Inc., No. 20-cv-01958-H, 2021 U.S. Dist. LEXIS 85347 (S.D. Cal. Feb. 25, 2021).

167. ALLELE BIOTECHNOLOGY AND PHARMACEUTICALS INC., https://www.allelebiotech.com [https://perma.cc/74UK-M7UV] (last visited Oct. 24, 2021); *see also* Pfizer Gross Profit 2006-2021 | PFE, MARCOTRENDS, https://www.macrotrends.net/stocks/charts/PFE/pfizer/gross-profit [https://perma.cc/JJA7-RL8T] (last visited Nov. 14, 2021) (Allele is a private corporation with $18M in

Pfizer in being first to market in the vaccine race—allowing it to immediately secure $400 million in grants,[168] an immediate multi-billion-dollar sales contract with the U.S. Department of Health and Human Services and the Department of Defense,[169] and maintain leading revenues in continued vaccine sales.[170]

Likewise, Regeneron used Allele's mNeonGreen to be beat competitors to an effective antibody therapeutic for those infected with SARS-CoV-2, helping it capture over $2.59 billion in antibody-related revenue alone in just the second quarter of 2021.[171] Assigning a monetary value to that advantage may prove difficult. If successful securing a verdict for infringement, Allele hopes to task a jury with just such a difficult determination. What share of Regeneron's profits belong to Allele? As such, Regeneron is strongly motivated to secure a non-infringement verdict. With the non-infringement so far denied, settlement negotiations will surely be considered. However, if negotiations are unsuccessful, the safe harbor issue is sure to arise again on appeal.

2. Benefit Of A Bright-Line Rule

In a word, the benefit of having a bright line rule in law is commonly noted as predictability.[172] In the same way detailed statutes and case law on corporations offer value to business ventures seeking to organize as a corporation, a clear interpretation of § 271(e)(1)'s "patented invention" would offer research tool users and developers value. This clarity would add predictability to respective liabilities and inform disputes prior to the cost of judicial involvement. Information concerning liability, or the lack thereof, for use of research tools will influence how researchers allocate resources for research and development. The

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total funding from three investors while Pfizer regularly reports annual profits in excess of $30 billion).

168. Rebecca Tapscott, *Regeneron, Pfizer and BioNTech Accused of Infringing Allele Patent in Connection with COVID-19 Technologies*, IPWATCHDOG (Oct. 7, 2020), https://www.ipwatchdog.com/2020/10/07/regeneron-pfizer-biontech-accused-infringing-allele-patent-connection-covid-19-technologies/id=126017/ [https://perma.cc/A9VD-58HG].

169. *Pfizer and BioNTech Announce an Agreement with U.S. Government for Up to 600 Million Doses of mRNA-Based Vaccine Candidate Against SARS-CoV-2,* BUSINESSWIRE (July 22, 2020), https://www.businesswire.com/news/home/20200722005438/en/ [https://perma.cc/M4AF-2Z2D].

170. Kevin Dunleavy, *Pfizer, Moderna Will Rake in a Combined $93 Billion Next Year on COVID-19 Vaccine Sales: Report*, FIERCE PHARMA (Oct. 18, 2021), https://www.fiercepharma.com/pharma/pfizer-moderna-will-rake-a-combined-93-billion-next-year-covid-19-sales-says-analytics-group [https://perma.cc/JJ6V-DX9S].

171. Kevin Dunleavy, *Surprise COVID-19 Antibody Sales of $804M Help Regeneron Trounce Expectations in Third Quarter*, FIERCE PHARMA (Nov. 4, 2021), https://www.fiercepharma.com/pharma/surprise-antibody-sales-804-million-help-regeneron-exceed-revenue-expectations-third-quarter [https://perma.cc/3UJW-872X].

172. *Bright-Line Rule*, CORNELL L. SCH., https://www.law.cornell.edu/wex/bright-line_rule [https://perma.cc/W5XA-WLL4] (last visited Oct. 23, 2021).

clearer the rule, the more efficient the outcome. The interpretation of § 271(e)(1) needs a bright-line rule.

3. Danger Of A Bright-Line Rule

Why has the court been so reluctant to provide a bright-line rule on the status of research tools under the safe harbor provision of § 271(e)(1)? First, bright-line rules are often deemed mechanical, objective, and invariant. When applied across all cases, mitigating factors or extenuating circumstances may be silenced, underemphasized or ignored entirely–thus violating a sense of fairness in a given outcome.[173] Second, courts do not like to tie their own hands. A clear rule will demand an outcome given some triggering fact pattern–regardless of an unforeseen nuance the court would have rather weighted more heavily. Third, and most relevant in the present instance, issuing a bright-line rule limiting statutory language which appears broad to a judge requires reading more than the words of the legislature–it often requires supposing intent of the legislature–anathema to a strict textualist.[174]

4. A Conflict Between Courts

Another obstacle to the adoption of a bright line rule is the furthering of a controversial influence of the Supreme Court on the country's patent laws. Of course, the Supreme Court has general subject matter jurisdiction and is superior to the Federal Circuit. However, the Federal Circuit was specifically created to resolve patent disputes and provide better predictability in patent law.[175] To what extent the Supreme Court should assert itself in reviewing the court specifically designated to resolve patent disputes has been, and will continue to be, debated.

The Supreme Court has a habit of reversing the Federal Circuit on patent cases, and has become increasingly active in doing so over the last twenty years–reversing twenty two out of twenty seven cases between 2005 and 2015.[176] With the vast majority of reversals favoring an alleged infringer, it is not surprising the Supreme Court is considered hostile to patent holders; the Federal Circuit is notably more likely to uphold the validity of a patent.[177] Though the Supreme Court is the highest authority in United States patent law, it has a

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173. *Id.*

174. *See* Merck KGaA, 545 U.S. at 202, 206 (Justice Scalia's aversion to "read narrowly" where the statutory text "provides a wide berth" is both illustrative in general and captures the issue in the context of this exact statute).

175. CONG. RESEARCH SERV., PATENT LAW AND INNOVATION: THE CREATION, OPERATION AND A TWENTY-YEAR ASSESSMENT OF THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT 1 (2003).

176. OSHA BERGMAN WATANABE BURTON, *Why Does the U.S. Supreme Court Keep Reversing the Federal Circuit?* (Mar. 31, 2017), https://www.obwbip.com/newsletter/why-does-the-u-s-supreme-court-keep-reversing-the-federal-circuit [https://perma.cc/9XB3-QJE2].

177. *Id.*

limited docket for reviewing patent cases and the Federal Circuit generally has the final word on all but a handful[178] of the roughly 450 cases decided annually.[179] As such, though speculation often erupts with any Supreme Court decision perceived as threatening the enforceability of patents, as in *Merck*,[180] concern is generally quelled shortly thereafter by the less rigid and more patent-holder-friendly, application by the Federal Circuit. With a practical limit on case-by-case enforcement, the threat of undesirable rigidity, and a tendency for the federal circuit to ameliorate resultant rules, might a bright line rule from the Supreme Court quickly become blurry? To answer this question with any persuasiveness will require unfolding the proposed rule–which will now be explained quite simply.

5. The Proposed Resolution

The Supreme Court, potentially in response to these cases, should enunciate a rule ensuring the enforceability of patents directed at research tools. The defining characteristic of this class of inventions is that they are not themselves subject to FDA approval. Hence, the safe harbor of § 271(e)(1) should not apply to research tools and strict symmetry between § 156 and § 271(e)(1) should be an unambiguous requisite for shielding under the safe harbor.

It is this author's position that a bright line rule from the Supreme Court on this issue would not be subject to typical vulnerabilities or ineffectual application in the lower courts. Initially, with respect to the rigidity of the rule, the concern surrounding a harmful mechanical application is quelled due to the nature of the players in this industry. Those made subject to liability after any narrowing of the safe harbor are largely sophisticated players with a close eye on this very topic. A word of warning would spread rapidly through a tight community of highly skilled research professionals. This warning would allow them to quickly license their use of equipment belonging to a now emboldened patent holder or seek an alternative technology. Those affected know they are affected and generally have suitable resources to respond.

Beyond the parties affected, a second factor strongly supporting the success of a bright line rule in this case relates to the nature of the rule itself. Formally recognizing the criteria of FDA approval calls for an objective test which is resolved through a purely factual inquiry. There is no heavy lifting required by courts to expand upon the 'reasonableness' standard.

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178. Devin Salmon, *A Sign of the Times? A Brief Look at the Trend of Patent Cases Before the US Supreme Court*, IP.COM, https://ip.com/blog/a-sign-of-the-times-a-brief-look-at-the-trend-of-patent-cases-before-the-us-supreme-court/ [https://perma.cc/G8NT-LHJH] (last visited Oct. 22, 2021) (though the Supreme Court has averaged just one or two patent cases per year over the last 80 years, it has roughly tripled this average over the last 10 years).

179. Dan Bagatell, *Fed. Cir. Patent Decisions in 2019: An Empirical Review*, LAW360 (Jan. 9, 2020), https://www.law360.com/articles/1232623/fed-circ-patent-decisions-in-2019-an-empirical-review [https://perma.cc/E8TY-F9JA].

180. *See supra* note 26 and accompanying text.

A third factor forecasting the success of the rule relates to the dynamic between the Supreme Court and the Federal Circuit. Simply put, the rule would generally support patent enforceability and be favored in its most simple form at the Federal Circuit. Further, if a desire to alter the rule arose, there is little nuance to leverage.

With two recent controversies emerging in jurisdictions having uncertain precedent, historical revenues at stake, and plenty of interested money available for advocacy, the Supreme Court should consider resolving these cases with a landmark decision of clarity. As far as the safe harbor is concerned, there is disagreement and ambiguity on specialized doctrine. Whether research tools fall under the safe harbor is a matter lower courts can manipulate by selective use of precedent. This yields uncertainty, expense, and potentially fosters bad faith in competition.

Alternatively–and indeed the most direct means of clarification–would be for the legislature to take unilateral action. A sufficient action from the legislature would consist of merely an exchange of the term "patented invention" in § 271 for the § 156 "product" and it's associated definition.[181] With decades of this debate as context, and § 156's explicit definition of "product"–being limited to articles subject to FDA approval[182] –this would result in a clear understanding and virtually immediate predictability among courts.

C. The Scope Of Relevance

1. Illustrative Importance of Research Tools

i) MOLECULAR BIOMARKERS

Much of the litigation discussed centers on this class of research tools, but why are they important? As has been explained, mNeonGreen and other fluorescent proteins are considered "marker" or "indicator" proteins. In the case of vaccine research, they annunciate the existence of antibodies successfully produced during clinical trials of vaccines or similar activities. More generally, molecular biomarkers are used to "diagnose disease, monitor disease progression and response to therapy, and are targets for development of new drugs."[183] Generally, these biomarkers are not subject to FDA approval since they are not administered to patients. A lack of patent protection for molecular biomarkers would allow uncompensated use and copying in a majority of their applications–reducing both the value of the inventions and investment in the technology.

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181. § 156(f).

182. *Id.*

183. KECK GRADUATE INST., *About the Center for Biomarker Research*, https://www.kgi.edu/faculty-and-research/centers-initiatives/center-for-biomarker-research/ [https://perma.cc/TLF3-7Y5Q] (last visited Oct. 24, 2021).

ii) MEDICAL LABORATORY DEVICES

Medical devices used as research tools are more intuitive and are indeed ubiquitous. From laboratory microscopes to centrifuges, this class of tools is interacted with in a high-school science classroom and the occasional visit to the general practitioner. Some of these devices are subject to FDA approval, such as a cardiac defibrillator, and in that sense, do not fall within the typical definition of a research tool. Generally, devices used in laboratory settings are not subject to FDA approval and would be at risk of losing patent protection if research tools were widely included in the ambit of § 271(e)(1). A loss of commercial value in the development of new and improved laboratory equipment, by the unencumbered copying by competing manufacturers, would diminish the investment in this industry and reduce published technological advances.

iii) ARTIFICIAL INTELLIGENCE

One technology often classified as a research tool is artificial intelligence (AI). For AI to be patentable it must do more than perform mathematical formulas, mental processes, or organize ordinarily human activity.[184] Even so, thousands of AI related patents have met that burden and have been granted. The growth of AI patents in the medical industry has experienced rapid acceleration since 2011 due to a significant increase in big data analytics and improvements in computing power.[185] Patents on AI research tools–especially those mining and predicting usefulness of the astronomical number of uncharted chemical compounds–will become increasingly contentious as the space gets crowded.[186] For prospective investors, it will be increasingly important to understand the issue of AI as research tools under patent protection prior to entering into this new era. AI is particularly vulnerable to copying as it is often, in large part, code which is run on a supercomputer.

2. Importance Of Patent Protection

Whether the right to exclude extends to lawfully patented research tools must be clearly answered in the affirmative to secure current investment, and promote future investment, in the above industries of public import. If a patented research tool, requiring a large capital investment, can be used without compensation

184. Andrew Rapacke, *Are Machine Learning Algorithms Patentable?,* RAPCKE L. GRP. (Jan. 27, 2020), https://arapackelaw.com/patents/softwaremobile-apps/are-machine-learning-algorithms-patentable/ [https://perma.cc/JAX2-VY5V].

185. Yang Xin et al., *The Development Trend of Artificial Intelligence in Medical: A Patentometric Analysis,* (1) A.I LIFE SCI. 100006 (2021).

186. Sam Lemonick, *Exploring Chemical Space: Can AI Take Us Where No Human Has Gone Before?,* CHEM. & ENG'G NEWS (Apr. 6, 2020), https://cen.acs.org/physical-chemistry/computational-chemistry/Exploring-chemical-space-AI-take/98/i13 [https://perma.cc/2WTZ-2MAE].

under a negotiated licensing agreement, why should companies like Allele invest in producing fluorescent proteins capable of accelerating the development of future vaccines? Though Allele could use the technology internally, Allele generates a large part of its revenue from producing and selling cutting edge technology for clinical and therapeutic use and develops an array of research tools.[187]

A second consequence of limiting enforceability of research tool patents is that fewer patents will be issued on research tools commonly used in generating data for FDA approval. This will discourage public disclosure of available technology for research tools and preclude possible advancements thereupon. Rather, developers of research tools may elect for keeping trade secrets. Protecting the trade secrets may needlessly complicate experiments required to generate data for the FDA or limit where the experiments may be conducted. These outcomes would slow the progress of valuable technologies.

Some may argue an exception should be carved out for the case where a patented research tool is the exclusive option for obtaining specific data required for FDA approval. If the holder of the patent on the research tool and the patent on the drug are one and the same, the owner could conceivably delay FDA approval by withholding the required patented research tool, thus extending their monopoly. This reasoning is not persuasive and fails to consider existing processes and procedures. Such an exception is not required because the research tool may be properly licensed by the generic. If the holder is unwilling, a case for mandatory licensing may be considered under those rare circumstances. Nullifying the patent amounts to taking property rights promised by the Constitution[188] and otherwise does not advance the state of science.

IV. CONCLUSION

Any ambiguity in a statute is properly presumed a legislative failure. As such, the duty to remove alternative readings and denounce misconceived case law rests first with the legislature. Adopting symmetric language and definitions between § 156 and § 271 of the Act would resolve the ambiguity faced by Federal District Courts and prospective litigants. While an amendment from the legislature is the preferable solution, the Supreme Court must not be idle while opposing interpretations leave an issue essentially without law.

If the remaining Allele case is eventually appealed to the Supreme Court, the Court should enunciate an interpretation of *Merck* and § 271 which explicitly excludes patented inventions not themselves subject to FDA approval. The Supreme Court should clarify that research tools are not within the purview of § 271(e)(1) and clarify that the "product" of §156 has the same scope as the "patented invention" of § 271. While the judiciary is not licensed to write laws, and the nation admires judicial humility, the duty to interpret is of particular

187. Second Amended Complaint at 4, Allele Biotechnology & Pharm., Inc. v. Regeneron Pharm's, Inc., No. 20-cv-08255, 2021 WL 2880694 (S.D.N.Y Apr. 8, 2021).

188. U.S. CONST. art. I, § 8 cl. 8.

importance when ambiguity has resulted in inconsistent application of the patent laws. Poorly worded statutes need not beget murky interpretations. Whether a particular use of a patented invention in the United States is patent infringement should not depend on which federal district one lives within.