

ARE PATENTED RESEARCH TOOLS STILL VALUABLE? USE, INTENT, AND A REBUTTABLE PRESUMPTION: A PROPOSED MODIFICATION FOR ANALYZING THE EXEMPTION FROM PATENT INFRINGEMENT UNDER 35 U.S.C. § 271(e)(1)

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I. THE HATCH-WAXMAN ACT'S EXEMPTION FROM PATENT INFRINGEMENT AND THE CONCERNS OF RESEARCH TOOL PATENT OWNERS

This paper focuses on the tension between the Hatch-Waxman Act's objectives and the concerns surrounding research tools—particularly in the biotech and pharmaceutical industries. The Hatch-Waxman Act is a statutory exemption from patent infringement claims enacted by Congress to permit a competing researcher to use a patented invention for the purpose of obtaining Food and Drug Administration (“FDA”) approval.¹ The importance of properly applying the Hatch-Waxman Act to research tools is heightened because of the life saving potential of generic drugs and the vital role that research tools play in conducting pharmaceutical research. In relevant part, the Hatch-Waxman Act recites:

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 ge-

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¹ *Drug Price Competition and Patent Term Restoration Act*, H.R. Rep. 98-857 pt. 2 at *4 (1984) as reprinted in 1984 U.S.C.C.A.N. 2686, 2688.

netic 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.²

Generally, the objective of the Hatch-Waxman Act is to stimulate the timely development of competing products by permitting use of a patented invention during the term of a patentee's right to exclude others from using it.³ Although the Hatch-Waxman Act was initially designed to stimulate development of generic drugs, it has been interpreted by courts to have a much broader scope.⁴ This broad interpretation has created concerns surrounding applying the Hatch-Waxman Act to "research tools."⁵

"Research tools" are patented inventions that are used to study other materials or to aid in performing experiments.⁶ "Research tools" are not the end product a researcher seeks to obtain, but devices, products, or methods used to perform experiments or research more efficiently.⁷ "Research tools" allow pharmaceutical research to progress more efficiently, rapidly, and with lower costs.⁸ The concerns about applying the Hatch-Waxman Act to "research tools" include the following: 1) owners of research tool patents may lose revenues from an inability to enforce their patents and be unable to recoup their research and development costs;⁹ 2) there may be a decrease in the development or production of new or improved versions of "research tools";¹⁰ 3) pharmaceutical research and development may be adversely affected by excluding "research tools" from the Hatch-Waxman Act's protection for researchers;¹¹ 4) researchers may be discouraged from undertaking development of competing alternatives or improved versions of patented inventions due to the licensing revenues they

² Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1603 (1984) (codified at 35 U.S.C. § 271(e)(1) (2006)).

³ *Drug Price Competition and Patent Term Restoration Act*, H.R. Rep. 98-857 pt. 2 at *4 (1984) as reprinted in 1984 U.S.C.C.A.N. 2686, 2688.

⁴ *Id.*; *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 670–1 (1990).

⁵ *Integra LifeSciences I Ltd. v. Merck KGaA (Merck I)*, 331 F.3d 860, 868–69 (Fed. Cir. 2003), *amended opinion* at 2003 U.S. App. Lexis 27796 (Fed. Cir. 2003).

⁶ Thomas P. Noud & Paul T. Meiklejohn, *The Developing Law of Pharmaceutical Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 921, 959–61 (2005).

⁷ *Id.* at 963.

⁸ *Id.*

⁹ *Id.* at 964.

¹⁰ *Id.*

¹¹ Brief for the United States as Amicus Curiae at 20, *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193 (2004) (No. 03-1237), 2004 WL 2851214.

would have to pay for the use of “research tools”;¹² and 5) a patentee may have the ability to stifle competition by withholding access to a research tool to protect the market for his patented product.¹³

Some of these concerns favor applying the Hatch-Waxman Act to research tools and others disfavor applying it to research tools. In order to illustrate how these concerns surrounding a possible application of the FDA exemption to research tools arose, this article begins by exploring three distinct stages in the evolution of the Hatch-Waxman Act’s exemption from patent infringement: 1) the genesis of 35 U.S.C. § 271(e)(1) (“the ‘FDA exemption’”); 2) the expansion of the types of “patented inventions” covered by the FDA exemption; and 3) the expansion of the FDA exemption to cover nearly all phases of research involved in obtaining the FDA’s approval. Next, this article will summarize the current form of the analysis used to determine whether or not a potential infringer’s actions are protected from infringement by the FDA exemption.

This article will identify the challenges involved in permitting a potential infringer to use a “patented invention” as a “research tool” and assert the FDA exemption as a defense to infringement claims. Lastly, this article proposes to protect the interests of “research tool” patent holders, without inhibiting the objective of the FDA exemption—permitting researchers to use a patented invention to obtain timely approval of competing products.

II. THREE CRUCIAL STAGES IN THE EVOLUTION OF THE FDA EXEMPTION FROM PATENT INFRINGEMENT

A. *The Federal Circuit creates the need for the FDA exemption from patent infringement by its decision in Roche*

In 1984, Congress enacted the FDA exemption in response to the United States Court of Appeals for the Federal Circuit’s (“Federal Circuit”) decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*¹⁴ In that case, the Federal Circuit held that using a patented invention to perform testing designed to acquire pre-market regulatory approval from the FDA constitutes patent infringement.¹⁵ The *Roche* ruling prevented a researcher from using a “patented invention” to perform experiments designed to obtain FDA approval of a

¹² *Id.* at 19.

¹³ *Id.* at 19–20.

¹⁴ *Merck I*, 331 F.3d at 865; *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, 865–66 (Fed. Cir. 1984).

¹⁵ *Roche*, 733 F.2d at 861.

competing product.¹⁶ In *Roche*, Bolar had sought to begin using flurazepam hydrochloride to perform testing to produce a generic version of Roche's branded sleeping pill called "dalmane."¹⁷ The assignee of U.S. Patent No. 3,299,053 ("the '053 patent"), Roche, sued Bolar for infringement for using flurazepam hydrochloride and lost at the trial court level.¹⁸ Normally, 35 U.S.C. § 271(a) prevents others from using a patented product without a license from the patentee.¹⁹ The district court found for Bolar, because its interpretation of "use" in § 271(a) did not include using a patented compound to perform tests designed to obtain FDA approval for a generic version of "dalmane."²⁰ The Federal Circuit reversed the lower court's decision in *Roche*, and interpreted "use" under § 271(a) to include any "use" of a patented compound, including using a patented compound to gather information for obtaining approval of a generic version of that compound.²¹

1. The Federal Circuit opines that the common law research exemption never permitted commercial enterprises, such as using a patented invention to obtain FDA approval of a competing product

The *Roche* court explicitly held that Bolar's use of Roche's patented drug for obtaining FDA approval of a generic before patent expiration constituted infringement.²² This ruling in effect delayed the introduction of a competing generic drug to the market.²³ In making this ruling, the Federal Circuit created a distinction between the common law experimental use exemption, which had been applied by courts to certain non-commercial infringement, and Bolar's

¹⁶ *Merck I*, 331 F.3d at 865–66.

¹⁷ *Roche*, 733 F.2d at 860.

¹⁸ *Id.* at 860–61.

¹⁹ 35 USC § 271(a) outlines a patent owner's right to exclude others and permits patentees to assert claims for infringement of these rights. Specifically, § 271(a) states, "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

²⁰ *Roche*, 733 F.2d at 860–61.

²¹ *Id.* at 861–62.

²² *Roche*, 733 F.3d at 860–62, 863–65.

²³ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670–1 (1990); *Roche*, 733 F.3d at 860–62, 864–65.

argument for a public policy exception to infringement for the use of a patented drug to acquire information for FDA approval of a generic drug.²⁴

The common law experimental use exemption from patent infringement was created by Justice Story in *Whittemore v. Cutter*.²⁵ The common law experimental use exemption permits research that is performed for “philosophical experiments” or to determine that a claimed invention actually works as described.²⁶ However, the common law experimental use exemption only permits infringing uses where there is no intent to profit from infringement of a patentee’s rights.²⁷ In *Roche*, Bolar conceded that the common law experimental use exemption did not previously include a right to use a patented compound for the purpose of obtaining information for FDA approval of a generic drug.²⁸ Based on the commercial motives for developing generic drugs, the Federal Circuit went on to proclaim that Congress, rather than the courts, should decide whether or not using a patented compound to gather information for FDA approval of a generic drug should be exempt from patent infringement.²⁹

2. Congress responds to Roche by enacting the FDA exemption from patent infringement to enable others to use a patented invention to acquire information for FDA approval of competing generic products

Congress enacted the FDA exemption to ensure that a patent holder’s right to exclude would not be extended by regulatory delays a competitor faced in the FDA’s approval process.³⁰ Around the time *Roche* was decided, the FDA approval process was about seven to ten years long.³¹ Without the FDA exemption, a competitor would face a seven to ten year delay in bringing a competing product to the market, in effect granting the patentee a seven to ten year extension on his patent rights. After the *Roche* decision, Congress enacted two provisions: an extension of the patent term (35 U.S.C. § 156(f)) to offset the delays a

²⁴ *Roche*, 733 F.3d at 862–64.

²⁵ Katherine Strandburg, *What does the public get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 93–94 (2004).

²⁶ *Id.* at 95.

²⁷ *Roche*, 733 F.2d at 863; Robert A. Bohrer, *Between a Rock and a Hard Place: University Research After Merck and Madey and the University of Rochester*, 24 BIOTECHNOLOGY L. REP. 713, 714 n.10 (2005); Strandburg, *supra* note 25, at 93–94.

²⁸ *Roche*, 733 F.2d at 863.

²⁹ *Id.* at 864–66.

³⁰ *Eli Lilly*, 496 U.S. at 670–71.

³¹ *Roche*, 733 F.2d at 864.

pioneer drug manufacturer encountered; and an exemption from infringement (35 U.S.C. § 271(e)(1)) for a generic drug manufacturer seeking to obtain FDA approval for the post expiration sale of generic versions of a patented drug.³²

Courts have struggled with determining the proper scope of the FDA exemption (35 U.S.C. § 271(e)(1)).³³ In particular, the issues have surrounded interpretation of the quoted terms: 1) “patented invention”; and 2) 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.³⁴ As indicated by the court opinions discussed *infra*, however, courts have consistently interpreted the quoted terms broadly in an effort to accomplish the objectives of the FDA exemption.³⁵ This continued trend raises legitimate concerns about research tools becoming ensnared in the broad net of protected activity provided by the FDA exemption.

B. The Supreme Court interprets “patented invention” and “federal law” broadly to include medical devices and expands the reach of the FDA exemption from patent infringement

In *Eli Lilly & Co. v. Medtronic Inc.*,³⁶ the Supreme Court was faced with deciding whether or not using a medical device was protected by the FDA exemption.³⁷ In deciding that the latter includes medical devices, the Court discussed the duality between the 35 U.S.C. § 156(f)³⁸ extension of a patent term and the 35 U.S.C. § 271(e)(1) exemption from patent infringement.³⁹ Congress simultaneously enacted § 156 and § 271(e)(1) to remedy two distortions.⁴⁰

³² *Eli Lilly*, 496 U.S. at 669–71.

³³ *See Merck I*, 331 F.3d at 867–68; *see also Eli Lilly*, 496 U.S. at 669–72; *Roche*, 733 F.2d at 860–63.

³⁴ *See Merck I*, 331 F.3d at 867–68; *see also Eli Lilly*, 496 U.S. at 669–72.

³⁵ *Merck KGaA v. Integra LifeSciences I Ltd. (Merck II)*, 545 U.S. 193, 203–04 (2005); *Eli Lilly*, 496 U.S. at 674–79; *Bristol-Myers Squibb Co. v. Rohne-Poulenc Rorer Inc.*, No. 95 Civ. 8833, 2001 WL 1512597, at *4–5, (S.D.N.Y. Nov. 28, 2001); *Intermedics Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).

³⁶ 496 U.S. 661, 670–1 (1990).

³⁷ *Id.* at 664.

³⁸ In *Eli Lilly*, the Supreme Court refers to 35 USC § 156 as § 201 of the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, and 35 USC § 271(e)(1) is referred to as § 202 of that Act, 98 Stat. 1598. *Eli Lilly*, 496 U.S. at 665.

³⁹ *Id.* at 669–71.

⁴⁰ *Id.* at 670–71.

Congress enacted § 156 to remedy the disincentive caused by regulatory delays pioneering inventors encountered in attempting to commercialize their inventions.⁴¹ Pioneering inventors were limited by the seventeen year (now twenty year) term for their patents, but were unable to commercially exploit their inventions until after meeting the FDA's regulatory requirements.⁴² Congress enacted § 156, granting a pioneering inventor up to a five year extension on the life of his patent.⁴³ This additional five year term is permitted to allow the pioneering inventor to recoup some of the commercial profit of his invention that he was not able to acquire because of a regulatory delay in bringing a commercial embodiment of his invention to the market.⁴⁴ However, the *Eli Lilly* court only discussed § 156 to clarify the breadth of § 271(e)(1) or the FDA exemption.⁴⁵

1. Congress' desire to eliminate the regulatory delay a competitor faced in bringing a competing (generic) FDA approved product to the market

Congress enacted § 271(e)(1) to permit a competitor to make an otherwise infringing use of a patented invention during the term of the patent holder's right to exclude for the purpose of acquiring FDA approval.⁴⁶ Based upon Congress' specific awareness of the two problems created by the FDA's regulatory scheme, the simultaneous enactment of § 156 and § 271(e)(1), and the fact that medical devices were granted an extension under § 156, the Supreme Court interpreted a "patented invention" and "Federal law" under § 271(e)(1) to include medical devices, food and color additives, new and antibiotic drugs, and human biological products.⁴⁷

The Supreme Court opined that it would be illogical for Congress to recognize the regulatory delay for a pioneering inventor of a medical device but ignore the regulatory delay a follow up inventor faced in developing alternative or competing generic versions of the pioneering medical device.⁴⁸ The Supreme Court held that promoting the development of generic drugs might have been

⁴¹ *Id.*

⁴² *Id.* at 672–73.

⁴³ *Id.* at 671.

⁴⁴ *Id.* at 670–71.

⁴⁵ *Id.* at 669–72.

⁴⁶ *Id.* at 671.

⁴⁷ *Id.* at 673–74.

⁴⁸ *Id.* at 672.

the initial impetus for the FDA exemption, but use of the term “Federal law” in the Hatch-Waxman Act indicated that the FDA exception also applied to medical devices under the Food Drug and Cosmetics Act (“FDCA”).⁴⁹ After *Eli Lilly*, the FDA exemption applies to the use of patented medical devices, food and color additives, new and antibiotic drugs, and human biological products for the purpose of acquiring FDA approval.⁵⁰

C. The Federal Circuit interprets “reasonably related” narrowly to protect the interests of research tool patent holders by excluding some phases of research from the FDA exemption’s protection against patent infringement claims

The next major step in the evolution of the FDA exemption was the Federal Circuit’s decision in *Integra LifeSciences I Ltd. v. Merck KGaA*.⁵¹ In *Merck I*, the Federal Circuit made an effort to exclude the upstream phase of research from the protection of the FDA exemption.⁵² “Upstream” and “downstream” respectively refer to earlier and later parts of the research and development process, or “stream” of research.⁵³ The results of an experiment performed early on, or upstream, may be needed in order to make informed decisions about what experiments to perform later, or downstream.⁵⁴ In pharmaceutical research, for example, the large scale initial screening of possible drug candidates in the laboratory would be upstream of later, downstream, pre-clinical⁵⁵ and

⁴⁹ *Id.*

⁵⁰ *Id.* at 673–74.

⁵¹ *Integra LifeSciences I Ltd. v. Merck KGaA (Merck I)*, 331 F.3d 860, 868–69 (Fed. Cir. 2003), *amended opinion* at 2003 U.S. App. Lexis 27796 (Fed. Cir. 2003).

⁵² *Id.* at 866–68.

⁵³ Brendan M. O’Malley, *Merck v. Integra and its Aftermath: A Broader Safe Harbor for the Commercial Use of Biotechnology Research Tools?* 23 *CARDOZO ARTS & ENT. L.J.* 739, 740 n.10 (2006); Brief for the American Intellectual Property Law Association as Amicus Curiae in Support of Neither Party at 20–21, *Merck II*, 545 U.S. 193 (No. 03-1237), 2005 WL 435890.

⁵⁴ *Id.*

⁵⁵ Pre-clinical generally refers to the in vitro, modeling and animal studies that the FDA requires to identify potential risk factors before clinical testing on humans can begin. The pre-clinical studies are often performed to justify undertaking clinical studies. In pharmaceutical research, pre-clinical studies typically involve the pharmacological and toxicological effects of a drug candidate. See Brief for the United States, *supra* note 11, at 20; see generally, Center for Biologics Evaluation and Research, Food and Drug Administration, *Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of*

clinical trials.⁵⁶ The upstream research results are not submitted to the FDA but identify subject matter for subsequent or downstream research.⁵⁷

The Federal Circuit recognized that research tools are frequently used during the upstream phase of research to filter and identify the best drug candidates.⁵⁸ The Federal Circuit was concerned that permitting the FDA exemption to cover research activities in this upstream phase as opposed to the downstream (pre-clinical or clinical activities) phase of research would remove an entire category of research tool patents from patent protection.⁵⁹ Implicitly, the Federal Circuit was attempting to strike a proper balance between the objectives of the FDA exemption and protecting research tool patent owners' incentive to produce more research tools.⁶⁰

In *Merck I*, Dr. Cheresh and Scripps had identified an RGD peptide (tri peptide segment of fibronectin) that was capable of promoting cell adhesion to substrates in culture and in vivo.⁶¹ The RGD peptide interacts with alpha and beta receptors on integrin proteins found on cell surfaces.⁶² Dr. Cheresh discovered that the RGD peptide could be used to prevent the formation of new blood vessels (angiogenesis) by blocking the alpha and beta receptors on integrins.⁶³ Inhibiting angiogenesis could be used to halt tumor cell growth and anti-angiogenic therapies could be used to help treat diabetic retinopathy, rheumatoid arthritis, psoriasis, and inflammatory bowel disease.⁶⁴

Recognizing the value of Dr. Cheresh's discovery, Merck hired Cheresh and Scripps to identify potential drug candidates that might prevent angiogenesis.⁶⁵ Merck then entered into an agreement to fund research necessary to obtain FDA approval.⁶⁶ The agreement contemplated performing clinical trials within

Xenotransplantation Products in Humans, at 34–41 (April 2003), available at <http://www.fda.gov/cber/gdlns/clinxeno.pdf>

⁵⁶ Brief for the American Intellectual Property Law Association, *supra* note 53, at 9–12; O'Malley, *supra* note 53, at 740 n.10.

⁵⁷ Brief for the American Intellectual Property Law Association, *supra* note 53, at 14; O'Malley, *supra* note 53, at 740 n.10.

⁵⁸ *Merck I*, 331 F.3d at 867.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* at 862–63.

⁶² *Id.* at 862.

⁶³ *Id.* at 863.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

three years.⁶⁷ There were tests performed relating to specificity, efficacy, and toxicity for EMD 66203, 85189, and 121974.⁶⁸ In 1997, EMD 121974 was determined to be the best candidate for clinical development.⁶⁹ Integra found out about the Scripps-Merck agreement and initiated licensing negotiations.⁷⁰ The licensing negotiations broke down and Integra sued Cheresch, Scripps, and Merck for patent infringement.⁷¹ The claims against Scripps and Cheresch were dismissed by the district court.⁷² Merck asserted that its activities were protected by the FDA exemption.⁷³ Merck lost at the district court level and appealed to the Federal Circuit.⁷⁴

1. The Federal Circuit incorrectly states that upstream and preclinical activities are too remote from FDA approval to be protected under the Hatch-Waxman Act's defense from patent infringement

In *Merck I*, the Federal Circuit stated that the FDA exemption did not reach all forms of exploratory research designed to identify new drug candidates.⁷⁵ The *Merck I* court framed the issue as whether or not the FDA exemption encompassed pre-clinical research to identify the best potential drug candidate to subject to the FDA approval process.⁷⁶ The Federal Circuit stated that research that does not directly contribute to the generation of information for FDA approval already strained the reasonable relationship contemplated by the FDA exemption and that research to identify the best potential drug candidate is not “reasonably related” to development and submission of information to the FDA.⁷⁷

The Federal Circuit opined that the FDA exemption does not encompass activities that extend far beyond the effort to gather information for FDA ap-

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 867.

⁷⁶ *Id.* at 865–66.

⁷⁷ *Id.* at 866.

proval of a patented pioneer drug already on the market.⁷⁸ For example, the FDA exemption does not encompass all stages for the development of new drugs merely because those new drugs will need FDA approval.⁷⁹ The FDA exemption does not encompass all experimental activity that may, in the distant future, lead to an FDA approval process, and it does not cover exploratory research that forms only a predicate for remote future clinical tests.⁸⁰ The Federal Circuit was concerned that permitting the FDA exemption to apply in both upstream and downstream research activities would strip owners of research tool patents of the ability to derive a commercial benefit from their inventions.⁸¹

Although neither party argued that the RGD peptide was a research tool, the Federal Circuit noted that the RGD peptide could be used as a tool in a laboratory to help discover new drugs or treatments.⁸² The Federal Circuit recognized that some biotechnology patents are tools that help facilitate upstream research to identify new or candidate drugs and also help conduct downstream experiments for FDA approval.⁸³ The Federal Circuit was concerned that since downstream clinical trials were covered by the FDA exemption, the only source of licensing revenues for holders of some biotech research tool patents was licensing during the general or upstream research phase.⁸⁴ The Federal Circuit attempted to protect these interests by distinguishing between general exploratory research and clinical research.⁸⁵ On appeal, however, the Supreme Court disagreed with the Federal Circuit's narrow reading of "reasonably related."⁸⁶

D. The Supreme Court rejects the Federal Circuit's effort to exclude upstream and pre-clinical research activities from the definition of "reasonably related"

In *Merck KGaA v. Integra LifeSciences I Ltd*, the Supreme Court vacated the Federal Circuit's decision, opining that the FDA exemption was broader than suggested by the Federal Circuit's interpretation.⁸⁷ The Supreme

⁷⁸ *Id.* at 867.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 872 n.4.

⁸³ *Id.* at 867–68.

⁸⁴ *Id.*

⁸⁵ *Id.* at 866–68 (emphasis in original).

⁸⁶ *Merck KGaA v. Integra LifeSciences I Ltd. (Merck II)*, 545 U.S. 193, 202 (2005).

⁸⁷ *Id.* at 202 n.6.

Court stated that the FDA exemption “extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”⁸⁸ In the Supreme Court’s opinion, upstream activities could be reasonably related to obtaining FDA approval.⁸⁹

1. The Supreme Court states that the FDA exemption does not exclude activities based on the phase of research

The *Merck II* Court clarified that the FDA exemption does not exclude activities based on whether they take place in the pre-clinical or clinical phase of research.⁹⁰ The FDA approval process often requires both pre-clinical and clinical research work; thus the phase of research is not a ground for prohibiting a party from asserting the FDA exemption.⁹¹ The Supreme Court recognized that pre-clinical steps are required before a researcher can reach the clinical testing phase in the FDA approval process.⁹² A necessary pre-cursor to the FDA’s approval process is identifying a drug candidate to be subsequently subjected to clinical tests.⁹³ If a researcher has not identified a drug candidate to subject to the FDA’s clinical tests, then no clinical tests can be performed.⁹⁴

Furthermore, the Supreme Court asserted that because the research and FDA approval processes involve trial and error, often a researcher does not know how much information will be enough to obtain approval or what type of information he will end up submitting to obtain FDA approval.⁹⁵ The Court reiterated that a researcher’s failure to submit the results of his activities to the FDA for approval does not remove his activities from the protection of the FDA exemption.⁹⁶ Although the Supreme Court agreed that basic exploratory research was not covered by the FDA exemption, it held that research done to identify a particular drug candidate or pre-clinical work done for obtaining FDA approval may be covered by the FDA exemption.⁹⁷

⁸⁸ *Id.* at 202.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.* at 202 n.6.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 206.

⁹⁶ *Id.*

⁹⁷ *Id.* at 206–07.

In the Supreme Court's opinion, the key to determining if a "use is 'reasonably related' to the 'development and submission of information under . . . Federal law'"⁹⁸ is whether or not a researcher "has 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."⁹⁹ The Court considered Merck's actions in light of FDA regulations relating to pre-clinical studies, clinical studies, good laboratory practice requirements, permissive variances from the good laboratory practice requirements, industry practices, and Merck's knowledge of the compound being tested and its effects to find that it was reasonable for Merck to believe such activities were necessary to obtain FDA approval.¹⁰⁰

2. The Supreme Court did not address the possibility of applying the FDA exemption to research tools

Since neither party argued that the RGD peptide was a research tool, the Court would not consider whether a narrower construction of the FDA exemption should apply to research tool patents.¹⁰¹ The Supreme Court clarified that the RGD peptide sequence was not a research tool, but the compound being tested.¹⁰² In dictum, the Court alluded to Judge Newman's dissenting remarks as a potential means for deciding whether something is being used as a research tool.¹⁰³ Asking whether or not a patented invention was the object being tested or just an aid for carrying out experiments to develop information for the FDA's regulatory process could be a method for distinguishing between research tools and other patented inventions.¹⁰⁴

Now that we have considered and reviewed the evolution of the FDA exemption, we can consider the current interpretation and the tension in applying the FDA exemption to research tools. Although a few courts have interpreted the FDA exemption narrowly, most courts have continued to interpret the FDA exemption broadly to permit a variety of activities by researchers.¹⁰⁵ The

⁹⁸ *Id.* at 207 (quoting 35 USC § 271(e)(1)).

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 203–08.

¹⁰¹ *Id.* at 205 n.7.

¹⁰² *Id.* at 205.

¹⁰³ *Id.*

¹⁰⁴ *Id.* at 205–06.

¹⁰⁵ *See generally*, cases cited *supra* note 35.

breadth of the FDA exemption seems to be expanding to protect uses of a variety of inventions which arise during almost any phase of research for almost any activities that could conceivably lead to FDA approval.¹⁰⁶ The FDA exemption's expansion may remove all patent protection for some research tools.¹⁰⁷

III. SUMMARY OF THE CURRENT INTERPRETATION OF THE FDA EXEMPTION

At this point, summarizing the current interpretation of “patented invention,” and 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 will help clarify the breadth of the FDA exemption's ability protect researchers from infringement claims.

A. *Court opinions have marginalized the intent requirement by permitting competing researchers to have additional commercial motives*

The Supreme Court has stated that there is a requirement that a researcher's activities are performed for the purpose or with the intent to acquire information reasonably believed to be necessary to obtain FDA approval.¹⁰⁸ Furthermore, a researcher must intend his activities to yield a particular drug or to reasonably believe that the compound will cause the sorts of physiological effects he intends to induce.¹⁰⁹ The research activities should be intended to generate information for FDA approval.¹¹⁰ Many court decisions, however, use language which seems to state that the intent or purpose of the researcher is irrelevant to determining whether or not the FDA exemption applies.¹¹¹ In performing a more scrutinizing review, what these courts hold is that if the intent to obtain FDA approval is established, then additional motives may not necessarily defeat the exemption.¹¹²

¹⁰⁶ *Merck I*, 331 F.3d at 867; O'Malley, *supra* note 53, at 749–56.

¹⁰⁷ *Merck I*, 331 F.3d. at 867; O'Malley, *supra* note 53, at 749–56.

¹⁰⁸ *Merck II*, 545 U.S. at 208.

¹⁰⁹ *Id.* at 207.

¹¹⁰ *Id.* at 208.

¹¹¹ *See, e.g.*, *Abtox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997); *Amgen Inc. v. Hoechst Marion Russell, Inc.*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998); *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991).

¹¹² *Abtox*, 122 F.3d at 1030; *Amgen*, 3 F. Supp. 2d at 108; *Intermedics*, 775 F. Supp. at 1280.

If a researcher meets the threshold intent requirement, then he may have other commercial purposes without losing the protection of the FDA exemption.¹¹³ Some federal court decisions have held that massive preparation for post-expiration sales, including the subsequent use of test results for fundraising, marketing, and obtaining foreign regulatory agency approval, stockpiling of generic products and sale of samples for use in clinical trials or use by FDA clinical investigators is permitted.¹¹⁴

As long as the experiments are initially conducted with the intent to obtain FDA approval, other commercial motives to bring a competing product to market upon expiration of the patent may not defeat the FDA exemption.¹¹⁵ Testing in foreign countries to gather information for the FDA approval process is also permitted.¹¹⁶ On the other hand, making a patented invention and shipping it to foreign regulatory agencies or use of a patented invention solely to obtain foreign regulatory approval may not be covered under the FDA exemption.¹¹⁷ The key is whether or not the circumstances demonstrate intent to use the patented invention to obtain FDA approval in the US.¹¹⁸ If the intent to obtain FDA approval is demonstrated, then additional motives or plans for using the test results will not prevent a party from successfully asserting the FDA exemption.¹¹⁹

B. Phases of research have absolutely no impact on the application of the FDA exemption

The phase of research, upstream, downstream, pre-clinical or clinical, really makes no difference in determining whether or not a researcher will be able to assert the FDA exemption.¹²⁰ Basic research activities, however, without

¹¹³ *Merck II*, 545 U.S. at 206; *Amgen*, 3 F. Supp. 2d at 107–108; *NeoRx Corp. v. Immunomedics Inc.*, 877 F. Supp. 202, 205 (D. N.J. 1994); *Intermedics*, 775 F. Supp. at 1280.

¹¹⁴ *Abtox*, 122 F.3d at 1030; *Intermedics*, 775 F. Supp. at 1282.

¹¹⁵ *Abtox*, 122 F.3d at 1030; *Telectronics Pacing Systems, Inc. v. Ventritex Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992); *NeoRx*, 877 F. Supp. at 205; *Intermedics*, 775 F. Supp. at 1281. *But see* *Biogen, Inc. v. Schering*, 954 F. Supp. 391, 397–98 (D. Mass. 1996).

¹¹⁶ *Intermedics*, 775 F. Supp. at 1284.

¹¹⁷ *Biogen*, 954 F. Supp. at 397 n.1 (distinguishing between making samples and sending the samples to foreign countries as opposed to the testing results, because these samples were never used or intended to be used to obtain FDA approval); *NeoRx*, 877 F. Supp. at 208.

¹¹⁸ *Amgen*, 3 F. Supp. 2d at 108; *Biogen*, 954 F. Supp. at 397–98; *NeoRx*, 877 F. Supp. at 205.

¹¹⁹ *Abtox*, 122 F.3d at 1030; *Telectronics*, 982 F.2d at 1525; *NeoRx*, 877 F. Supp. at 205; *Intermedics*, 775 F. Supp. at 1280.

¹²⁰ *Merck II*, 545 U.S. at 206.

either the intent to acquire a particular drug or a reasonable belief that the compound will cause the physiological effects a researcher desires are not covered by the FDA exemption.¹²¹ Furthermore, there must be a reasonable basis for believing that the experiments will produce the type of information that is relevant to obtaining FDA approval.¹²²

C. “Reasonably related” is interpreted very broadly to permit a variety of activities that may lead to FDA approval

Courts permit a wide scope for trial and error in researchers’ decisions about the types of experiments or activities that may be performed to acquire FDA approval.¹²³ A researcher’s activities do not have to yield results that are ultimately submitted for approval; however, the researcher must demonstrate a reasonable belief that his activities will generate the type of information necessary to obtain FDA approval.¹²⁴ For the most part, courts will rely on the applicable Food Drug and Cosmetics Act (“FDCA”) sections, FDA guidance, in the form of opinions and regulations, as well as industry practices in deciding what types of testing activities are relevant to obtaining approval.¹²⁵ In fact, if there is an acceptable explanation for a variance from the FDA’s good laboratory practice standards, then “reasonably related” may be broad enough to excuse such variances.¹²⁶ “Reasonably related” has been interpreted very broadly to cover almost anything that could conceivably be relevant to obtaining FDA approval.

D. “Patented invention” is interpreted broadly by courts to cover a variety of products for which the FDCA requires approval

The FDA exemption’s definition of “patented invention” has been interpreted broadly to include any type of chemical or device for which FDA approval is required.¹²⁷ Under the broader reading of *Eli Lilly*, patented inventions include medical devices, food and color additives, new and antibiotic drugs and human biological products.¹²⁸ Since research tools are not necessarily a separate

¹²¹ *Id.* at 205, 206.

¹²² *Id.* at 207.

¹²³ *Merck II*, 545 U.S. at 206; *Intermedics*, 775 F. Supp. at 1280.

¹²⁴ *Merck II*, 545 U.S. at 207; *Intermedics*, 775 F. Supp. at 1280.

¹²⁵ *Merck II*, 545 U.S. at 202–03; *Amgen*, 3 F. Supp. 2d at 109.

¹²⁶ *Merck II*, 545 U.S. at 204.

¹²⁷ *Eli Lilly*, 496 U.S. at 672–73; *Abtox Inc. v. Exitron Corp.*, 888 F. Supp. 6, 7 (D. Mass. 1995).

¹²⁸ *Eli Lilly*, 496 U.S. at 674; *Abtox*, 888 F. Supp. at 7.

and distinct category of inventions, they may fall into one of the preceding categories. Many items may have dual uses as research tools and as commercial products or processes; therefore they do not fit neatly into any single category. Whether or not the FDA exemption protects the use of patented research tools is still unclear, however.¹²⁹

More clearly stated, the unanswered question is whether or not the FDA exemption was meant to permit the creation of competing products of patented inventions requiring FDA approval by using other patented research tools. With this understanding of the very wide breadth of the FDA exemption we are ready to consider the pharmaceutical and research tools industries' concerns relating to patented research tools.

IV. THE PHARMACEUTICAL AND RESEARCH TOOLS INDUSTRIES AND THE CONCERN ABOUT APPLYING THE FDA EXEMPTION TO USE OF RESEARCH TOOLS

In 1999, Americans spent \$125 billion on pharmaceutical drugs.¹³⁰ The pharmaceutical industry is a very large sector of the United States economy, and research tools may be vital to the development of new drugs. In 2002, the average cost to develop a new drug was \$802 million, and the average time period required to bring a new drug to market was about ten to fifteen years.¹³¹ In 2003, the biotech research tool industry had \$200 million in revenues and was expected to grow twenty percent a year.¹³² These numbers indicate that the pharmaceutical industry is a large part of the United States economy. In addition, the growing biotech research tool industry is vital, because it helps to develop new methods of performing pharmaceutical research more efficiently, cheaply, and at an accelerated rate.¹³³ Therefore, meeting the concerns of research tool owners and properly balancing the interests of researchers developing new or competing drugs is necessary to ensure the continued prosperity of both industries. A hypothetical example may illustrate the nature of the concerns surrounding the application of the FDA exemption to research tool patents.

¹²⁹ *Merck II*, 545 U.S. at 206.

¹³⁰ Alison Ladd, *Integra v. Merck: Effects on the Cost and Innovation of New Drug Products*, 13 J.L. & POL'Y 311, 311 (2005).

¹³¹ TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, *Outlook 2002*, <http://csdd.tufts.edu/infoservices/outlookpdfs/outlook2002.pdf>

¹³² Stephen Maebius & Douglas Jamison, *Nanotechnology Law and Business*, 2 NANO-TECHNOLOGY L. & BUS. 220, 220 (September/October 2005).

¹³³ Noud & Meiklejohn, *supra* note 6, at 962–63.

A. Hypothetical use of research tools and the problems with applying the current version of the FDA exemption to the use of research tools

As used in this article, the term “research tool” means a patented invention that is used to study or experiment with other materials, patented inventions, or products. With that understanding, consider a researcher making a generic version of a drug that is known to prohibit angiogenesis in cancerous cells. In order to develop and test the generic (“G1”), a researcher wants to use the following patented inventions: 1) a chemical compound x that identifies cancerous cells; 2) a pipette that can be used to deliver G1 to the isolated cells; 3) a reagent z that is used to activate G1’s reaction with the cancerous cells; and 4) the branded drug (“B1”) that is known to prohibit angiogenesis in cancerous cells to use for determining bioequivalence with G1. Should the researcher be able to use B1, compound x, the pipette, and reagent z without purchasing them or licensing their use? In other words, should the FDA exemption permit the researcher to use all four of these “patented inventions” to obtain FDA approval of G1?

For purposes of this example, let us assume that in the above hypothetical, the researcher intends to use the results to obtain FDA approval for G1. Furthermore, let us assume that the researcher’s activities are reasonably related to acquiring FDA approval. The researcher has a reasonable belief that his activities are likely to generate the type of information necessary for acquiring FDA approval. Under these circumstances, it is clear that use of B1 is currently protected from infringement claims by the FDA exemption. Should the FDA exemption also permit our hypothetical researcher’s use of compound x, the pipette, and reagent z?

Presently, most courts have not opined on the use of a “patented invention” as a tool for performing experiments or studying other material.¹³⁴ In the hypothetical *supra*, compound x, the pipette, and reagent z are being used as tools to assist in performing experiments with other material, patented inventions, or products to develop a generic drug (G1). As argued more fully *infra*, the aforementioned use of compound x, the pipette, and reagent z was not contemplated by Congress.¹³⁵ The FDA exemption was enacted to ensure that our

¹³⁴ *Merck II*, 545 U.S. at 206; *but see* Bristol-Myers Squibb Co. v. Rohne-Poulenc Rorer Inc., No. 95 Civ. 8833, 2001 WL 1512597, at *4–5 (S.D.N.Y. Nov. 28, 2001) (permitting use of a patented intermediate to assist in the creation of a database to use as a tool for identify new drug candidates for FDA approval).

¹³⁵ O’Malley *supra* note 53, at 747–49.

hypothetical researcher could use the branded drug (B1) during the life of its patent for acts designed to acquire FDA approval of a *competing* product.¹³⁶

B. *To permit our hypothetical researcher to use reagent z and the method of producing reagent z may decrease revenues for the patentee*

If researchers are permitted to use the FDA exemption as essentially a free license to use research tools in experiments to obtain FDA approval of a generic drug, then they will not need to purchase or license them from their owners. Our hypothetical researcher could manufacture some of these research tools on his own and use them with complete disregard for the rights of their owners. Now, it may be that our researcher does not manufacture compound x and pipettes on his own because of the costs involved in the manufacturing process or simply a lack of expertise. However, this researcher should be able to manufacture reagent z and other tools similar to reagent z.

Our hypothetical researcher's ability to easily manufacture research tools like reagent z can be readily illustrated, if we assume that reagent z is an enzyme that catalyzes the reaction between G1 and cancerous cells. Assume the following: 1) the genetic code for making reagent z has been isolated; 2) a cloning vector has been created and described; 3) the genetic code for reagent z has been linked to an indigenous gene to ensure that the genetic code for reagent z will be expressed in the transformed bacteria; and 4) working samples of transformed bacteria capable of producing reagent z have been deposited in an appropriate international depository.¹³⁷ All our researcher has to do is acquire a working sample and use it to generate its own miniature bio-chemical factory for producing reagent z. Furthermore, the patentee's disclosure of his method of producing reagent z should enable most pharmaceutical researchers to manufacture these transformed bacteria en masse to produce reagent z with minimal additional costs. Consequently, a pharmaceutical researcher could very easily and cheaply create his own transformed bacteria that produce reagent z.

If the FDA exemption protects such use, then our researcher will not need to license the method of creating reagent z from its owner. The hypothetical *supra* is limited to our researcher's use of research tools in trying to develop a competing generic drug. The same analysis and concerns may apply to use of

¹³⁶ Noud & Meiklejohn, *supra* note 6, at 941–42.

¹³⁷ *In re O'Farrell*, 853 F.2d 894, 896–99 (Fed. Cir. 1988) (providing a detailed description of the technology behind using a transformed bacterium to generate a desired protein or enzyme, like reagent z).

research tools in developing competing medical devices, food color additives, and human biological products. In effect, items like centrifuges, pipettes, cell lines, special assays for screening compounds, monoclonal antibodies, reagents, animal growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, essentially anything that can or in the future may be used to study or identify other substances, would be available for a researcher to use without paying licensing fees.¹³⁸

A researcher may not elect to manufacture all of the abovementioned types of tools on his own. A researcher is likely to manufacture some of these items (similar to reagent z) on his own to decrease his costs of research and development or threaten to manufacture them to negotiate for a lower licensing fee. By applying the FDA exemption to research tool patents we have created a means for researchers to be able to limit the revenues patentees can obtain from licensing or sale of research tools. If the ability to enforce infringement of research tool patents is diminished by the FDA exemption, then the loss of revenues will decrease their value and inhibit their owners' ability to recoup costs and invest in developing additional "research tools."¹³⁹

Under the current interpretation of the FDA exemption, a researcher may be exempt from infringement liability for use of a "research tool" throughout the entire research stream, except for the basic or exploratory stage.¹⁴⁰ To permit the FDA exemption to cover all uses of research tools would drastically decrease markets for research tools and incentives to produce the next generation of research tools.¹⁴¹ In order to ensure that there is an incentive to produce improved versions of reagent z or more efficient alternatives to this type of research tool, the FDA exemption should not protect all uses of such research

¹³⁸ *Integra LifeSciences I Ltd. v. Merck KGaA (Merck I)*, 331 F.3d 860, 871–72 (Fed. Cir. 2003), *amended opinion* at 2003 U.S. App. Lexis 27796 (Fed. Cir. 2003); Robert A. Bohrer, *Between a Rock and a Hard Place: University Research After Merck and Madey and the University of Rochester*, 24 BIOTECHNOLOGY L. REP. 713, 716–20 (2005); Noud & Meiklejohn, *supra* note 6, at 959–60.

¹³⁹ Lawrence B. Ebert, *In Favor of the Federal Circuit Position in Merck v. Integra*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 321, 334 (2005); Stephen B. Maebius & Harold C. Wagner, *Merck v. Integra: The Impact of a Broader "Safe Harbor" Exemption on Nanobiotechnology*, NANOTECHNOLOGY L. & BUS. 254, 258, September/October 2005.

¹⁴⁰ *Merck II*, 545 U.S. 193, 205–06; *Bristol-Myers Squibb Co. v. Rohne-Poulenc Rorer Inc.*, No. 95 Civ. 8833, 2001 WL 1512597, at *4 (S.D.N.Y. Nov. 28, 2001) (permitting use of patented intermediates to assist in the creation of a Structural Activities Database that would be an important tool in developing a new candidate drug.).

¹⁴¹ David A. Kalow & Milton Springnut, *'Integra': A Fatal Blow to Biotechnology?*, 234 N.Y.L.J., at col. 4 (Dec. 27, 2005); Noud & Meiklejohn, *supra* note 6, at 961.

tools to experiment with other patented inventions. The need to protect the incentive to produce pioneering research tools can be better understood by considering the fundamental policies behind granting patents to inventors.

C. *Two fundamental policies drive our patent system, and a disincentive effect is created from applying the FDA exemption to all uses of patented research tools*

The aforementioned loss of revenue creates a disincentive to others contemplating creating an alternative, derivative, improved, or competing version of reagent z. Patentees may not be able to enforce rights to the technology that they invent and may not be able to recoup the costs of commercialization, development, and research.¹⁴² Individuals that develop such technology may choose to maintain the technology as a trade secret to protect their investment in developing it.¹⁴³ Either way, there will be a disincentive to develop and disclose new research tools to the public.

The incentive to invent theory rewards an inventor by granting a patent for his invention to enable him to recoup the costs and efforts he exerts in creating his claimed invention.¹⁴⁴ In order for the inventor to undertake the research and development costs involved in creating his invention, the inventor must be provided some assurance that he will be able to reap the commercial benefits of his invention.¹⁴⁵ If the inventor cannot exclude others from practicing his claimed invention, then individuals that did not incur the research and development costs will be able to undercut the inventor's efforts to reap the commercial rewards of his invention.¹⁴⁶

¹⁴² Noud & Meiklejohn, *supra* note 6, at 961; Maebius & Wagner, *supra* note 139, at 258.

¹⁴³ Kalow & Springnut, *supra* note 141; Maebius & Wagner, *supra* note 139, at 258; Janice E. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exemption to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 40–41, 48 (2001).

¹⁴⁴ Strandburg, *supra* note 25, at 91–93, 105–07; Janice E. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Non Profit Research and Development*, 56 BAYLOR L. REV. 917, 922, (2004).

¹⁴⁵ See sources cited *supra* 143–44.

¹⁴⁶ Ladd, *supra* note 130, at 312–13; Strandburg, *supra* note 25, at 91–93, 105–07.

1. Understanding the need to encourage our hypothetical inventor (“RVTR”) to develop and disclose new research tools and methods of producing them

For example, assume RVTR Inc. (“RVTR”) discovers reagent z¹⁴⁷ and invents the aforementioned method of producing reagent z using transformed bacteria. RVTR’s disclosure contributes and claims a previously undiscovered compound (reagent z) and the method of producing reagent z. A hypothetical researcher comes along, reviews RVTR’s disclosure, and develops copies of the same transformed bacteria or obtains a working sample of RVTR’s transformed bacteria for producing the same reagent z. Next, this researcher proceeds to use RVTR’s claimed method and reagent z to conduct a variety of activities for FDA approval. If RVTR cannot sue this researcher for infringing his patent on reagent z and method of producing reagent z, then the researcher is able to use RVTR’s patent disclosure to avoid the research and development costs RVTR incurred. By avoiding the research and development costs this hypothetical researcher is able to free ride on RVTR’s efforts and create his own supply of reagent z.

As a result, RVTR would lose the sales or licensing revenues it could have obtained from our hypothetical researcher or have to supply reagent z at a lower price to entice this researcher to buy reagent z, instead of making reagent z. If multiple researchers or consumers of reagent z can force RVTR to supply reagent z at a lower price, then RVTR would not be able to reap all the commercial benefits of his invention.¹⁴⁸ In effect, RVTR may be unable to recoup the costs of its research and development. Its consumers (researchers) will be able

¹⁴⁷ Assume that RVTR’s method produces a highly concentrated solution of reagent z. It catalyzes reactions between G1 and cancer cells more efficiently and rapidly than any other solutions of reagent z found in nature. In essence, this concentrated solution of reagent z cannot be found in nature, it was invented by RVTR’s process of using the transformed bacteria to create reagent z. Consequently, there are no questions about patentability or validity of RVTR’s claims to this concentrated solution of reagent z or the method of producing it. Use of the terms “reagent z” throughout the remainder of this paper refers to this highly concentrated solution of reagent z.

¹⁴⁸ Although the incentive to invest and disclose theories are traditionally used to justify the granting of patent protection in the first instance, they also provide justification for ensuring that the FDA exemption is not used too broadly to remove patent protection for research tools. Mueller, *supra* note 143, at 40–41 (discussing how the incentive functions of a patent right may be removed by an overly broad experimental use exemption); Strandburg, *supra* note 25, at 90–93 (arguing for a broader experimental use exemption, but keeping it narrow enough to protect a patent’s ability to promote invention and disclosure.).

to create their own supplies of reagent z for use in their experiments or compel a reduced price for RVTR's reagent z. In this context, applying the FDA exemption to all uses of reagent z will discourage RVTR from undertaking the effort involved in creating transformed bacteria capable of producing reagent z. Therefore, the public would lose out on a pioneering inventor (RVTR) and associated follow up inventors that may develop a competing method of producing reagent z in greater quantity with lower costs.

Because of the aforementioned scenario, sometimes RVTR will not undertake the effort to develop transformed bacteria capable of producing reagent z. Other times, RVTR will undertake the effort to develop transformed bacteria capable of producing reagent z, but protect its invention as a trade secret.¹⁴⁹ In this latter scenario, the incentive to disclose theory provides a greater justification for granting a patent to RVTR. The incentive to disclose theory is premised on the belief that in order for an inventor to share his invention with the world, he must be provided a patent right.¹⁵⁰ As long as the invention cannot be reverse engineered, the inventor can continue to commercially exploit his invention and maintain it as a trade secret.¹⁵¹

In our hypothetical, RVTR can sell reagent z and still maintain the method of producing it using transformed bacteria as a secret. Since sale of reagent z does not enable others to reverse engineer RVTR's method of producing reagent z, RVTR needs an incentive to disclose this method to the public. If RVTR is granted a right to exclude others from using the transformed bacteria to produce reagent z, then it will be less motivated to keep it a secret. Granting RVTR a patent permits it to commercially exploit the method of using transformed bacteria to produce reagent z in return for developing and disclosing the method to the public.¹⁵²

2. Protecting the incentive to produce research tools is particularly important to the pharmaceutical industry, because it uses them to conduct research

“Research tools” play a vital role in the pharmaceutical industry by allowing cheaper, more efficient, and accelerated research.¹⁵³ Within the pharmaceutical industry, patented research tools often facilitate general research to

¹⁴⁹ Strandburg, *supra* note 25, at 105–07.

¹⁵⁰ *Id.* at 105.

¹⁵¹ *Id.* at 105–06.

¹⁵² Ladd, *supra* note 130, at 312–13.

¹⁵³ Noud & Meiklejohn, *supra* note 6, at 963–64.

identify candidate drugs as well as downstream safety-related experiments on those new drugs.¹⁵⁴ These research tools are often used to aid in performing tests and basic research on thousands of compounds in the drug discovery process.¹⁵⁵ In the short run, allowing use of research tools may have some initial stimulus for the development of competing or derivative pharmaceutical goods; however, in the long run the disincentive to produce a new generation of pioneering research tools will hurt the industry.¹⁵⁶

Because most innovation builds upon prior invention, without these pioneering research tools, there will also be a decrease in the development of follow up research tools.¹⁵⁷ An overly broad exemption from patent infringement can cause more harm for the pharmaceutical industry, because it may lead to a decrease in the development of research tools it needs to efficiently develop pharmaceutical products.¹⁵⁸ Now, that we recognize the need to protect the incentive to discover and disclose research tools, including methods of making research tools (like reagent z), we are ready to consider Congress' objective in enacting the FDA exemption.

D. Congress enacted the FDA exemption to stimulate the development and sale of FDA approved products that compete with patented inventions that are the subject of a researcher's FDA related experiments

The legislative history behind § 271(e)(1)¹⁵⁹ indicates that Congress intended to permit others to use the patented product to perform experiments for obtaining FDA approval of competing goods, so that they could be brought to the market without encountering a regulatory delay.¹⁶⁰ In *P.L. 98-417*, entitled

¹⁵⁴ *Merck I*, 331 F.3d 860, 867–8. See *Bristol-Myers Squibb Co. v. Rohne-Poulenc Rorer Inc.*, No. 95 Civ. 8833, 2001 WL 1512597, at *4 (S.D.N.Y. Nov. 28, 2001) (A research tool in the form of a Structural Activities Database was created to track information on thousands of compounds during basic research).

¹⁵⁵ *Bristol-Myers Squibb*, 2001 WL 1512597, at *4 (permitting use of patented intermediates to assist in the creation of a Structural Activities Database that was used to collect and gather information on the structural activities relationship on more than 1000 compounds during basic research).

¹⁵⁶ Noud & Meiklejohn, *supra* note 6, at 964.

¹⁵⁷ *Id.* Mueller, *supra* note 132, at 40–41; Strandburg, *supra* note 144, at 105–07.

¹⁵⁸ Mueller, *supra* note 132, at 40–41.

¹⁵⁹ 35 U.S.C. § 271(e)(1) (2006) (referred to within the bill as section 202).

¹⁶⁰ *Intermedics Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1276–77 (N.D. Cal. 1991); Noud & Meiklejohn, *supra* note 6, at 941–42.

“Drug Price Competition and Patent Term Restoration Act,” Congress specifically states that it was concerned about the anti-competitive effects of the FDA’s post-1962 drug approval process.¹⁶¹ Congress further expressed dissatisfaction over a practical extension of the patented drug owner’s right to exclude competing generic drugs.¹⁶²

In fact, Congress explicitly stated that § 271(e)(1) was enacted to permit competing generic manufactures to obtain a supply of a patented drug product to perform equivalency tests during the term of a patent holder’s right to exclude.¹⁶³ Congress was attempting to avoid a practical extension of a patentee’s right to exclude because of the regulatory delays a researcher encountered in bringing a competing version of a patentee’s invention to the market.¹⁶⁴ The FDA exemption was never intended to be a complete license to use any patented invention that may be useful in performing experiments on other patented inventions.¹⁶⁵

Interpreting the FDA exemption to permit *only* a competing researcher to use a patentee’s invention preserves Congress’ desire to prevent unwarranted extensions of a patentee’s rights. Hypothetically assume that patented invention (“P1”) is subject to FDA approval requirements. Now, hypothetically assume that P2 is not subject to FDA’s approval requirements. In this part of the discussion, P1 refers to a branded patented invention that is subject to FDA ap-

¹⁶¹ *Drug Price Competition and Patent Term Restoration Act*, H.R. Rep. 98-857 pt. 2 at *4 (1984) as reprinted in 1984 U.S.C.C.A.N. 2686, 2688. As Congress discussed in the background on FDA Approval Process: “The FDA rules on generic drug approval for drugs after 1962 have had serious anti-competitive effects. The net result of these rules has been the practical extension of the monopoly position of the patent holder beyond the expiration of the patent.”

¹⁶² *Id.*

¹⁶³ *Id.* at *5. In discussing the purpose of the FDA exemption, Congress stated:

A generic manufacturer may submit an application for approval to the FDA before the so called pioneer drug goes off patent. The generic may submit data establishing bio-equivalency during this time period. In order to complete this application the generic manufacturer must conduct certain drug tests. In order to facilitate this type of testing, section 202 of the bill creates a general exception to the rules of patent infringement. Thus, a generic manufacturer may obtain a supply of a patented drug during the life of the patent and conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.

Id.

¹⁶⁴ *Lilly*, 496 U.S. at 671–72; Thomas J. Friel Jr. and Chad T. Nitta, *Patent Infringement: The 35 USC § 271(e)(1) Safe Harbor Exemption*, 34 AUG. COLO. LAW. 103, 104 (2005)

¹⁶⁵ O’Malley, *supra* note 40, at 755.

proval. P1 is the invention for which a researcher is seeking to develop an alternative, derivative, generic, or improved competing product. P2 refers to another patented invention that a researcher wants to use as a research tool—to study or aid in performing experiments for developing an alternative, derivative, generic, or improved competing version of P1.

In this scenario, the justification behind the FDA exemption cannot support use of P2 as a research tool to study or aid in performing research for the development of a competing version of P2 or P1. Since creating an alternative, derivative, or improved competing version of P2 is not subject to FDA regulations, it would not be subject to a regulatory delay. Therefore, the P2 owner would not be able to obtain an undesirable extension of his patent rights. If P2 is not subject to FDA approval, then the justification behind the FDA exemption that was described in the legislative history for § 271(e)(1) and discussed in *Eli Lilly* cannot be used to apply the FDA exemption to P2.

As explained in *Eli Lilly*, Congress enacted the FDA exemption to offset a regulatory delay by permitting a competing researcher to use P1 during the term of the patent on P1.¹⁶⁶ The FDA exemption's objective was to permit a *competing* researcher to use P1, which is subject to FDA regulations; because otherwise the P1 owner would acquire an unwarranted extension of his patent rights.¹⁶⁷ Congress was specifically concerned with encouraging the development of products that compete with P1—it never intended to permit use of any patented invention (P2) to study or aid in performing experiments on P1.¹⁶⁸

Now, hypothetically assume that P2 is subject to FDA approval. Even if P2 is subject to FDA approval, Congress could not have intended for the FDA exemption to permit use of P2 to study or aid in performing research to develop an alternative competing version of P1. Congress enacted the FDA exemption in direct response to the *Roche* opinion. That opinion, the legislative history for § 271(e)(1), and the Supreme Court's opinion in *Eli Lilly* all indicate that the justification behind it was to offset a regulatory delay a *competing* researcher would face in developing an alternative, derivative, or improved competitor to P1 for post patent expiration sales.¹⁶⁹ The concern was that without the FDA exemption, the P1 owner would be able to prevent a *competing* researcher from using P1 and acquire an unwarranted extension of his patent right because of

¹⁶⁶ *Lilly*, 496 U.S. at 671 (referring to 35 USC § 271(e)(1) the Supreme Court stated: "This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.").

¹⁶⁷ *Lilly*, 496 U.S. at 671–672

¹⁶⁸ *Id.*; O'Malley, *supra* note 40, at 755.

¹⁶⁹ *Lilly*, 496 U.S. at 671–72.; Noud & Meiklejohn, *supra* note 6, at 941.

this regulatory delay.¹⁷⁰ Since, a researcher using P2 to aid in the development of an alternative, derivative, or improved version of P1 is not *competing* with the owner of P2; he is not the intended beneficiary of the FDA exemption.

Based on this reasoning, at first glance, it may seem that research tools should be excluded completely from the FDA exemption. However, creating a broad category of research tools that are excluded from the FDA exemption's protection may inhibit research. In fact, it is the vital role of research tools in the development of pharmaceutical products that raises concerns about inhibiting the progress of research and development. A complete exclusion of all uses of patented research tools from the FDA exemption raises a concern about a research tool owner withholding his research tool from a competing researcher in order to block the development of a product that competes with a different patented invention owned by that same tool owner.

E. The potential for a patentee to use a research tool patent to defeat the FDA exemption's objective of stimulating development of competing products

Once again, consider the above hypothetical—assume RVTR owns B1, the patents on reagent z, and the method of producing reagent z. Without reagent z, our hypothetical researcher will be unable to catalyze his generic—G1's reaction with cancerous cells.¹⁷¹ By preventing our hypothetical researcher from accessing reagent z, RVTR can prevent him from carrying out experiments to develop G1 to a stage where it can obtain FDA approval. Although the FDA exemption grants our researcher access to B1, his efforts cannot progress further, because of his inability to acquire reagent z. Consequently, our hypothetical researcher will not be able to experiment with G1, until RVTR's patent on reagent z and the method of producing it expire.

RVTR has blocked our hypothetical researcher's access to reagent z, and the risk of a patent infringement suit will deter him from manufacturing reagent z on its own and from using it to perform tests to develop G1. Using this technique, RVTR can effectively prevent our researcher from taking advantage of the FDA exemption and delay the sale of an FDA approved version of G1. By creating an exception from the FDA exemption for all uses of "research tools," we have permitted RVTR to prevent our hypothetical researcher from

¹⁷⁰ *Lilly*, 496 U.S. at 671–72; Noud & Meiklejohn, *supra* note 6, at 941.

¹⁷¹ This discussion is premised on the assumption that there are an insufficient number of alternatives to reagent z for catalyzing G1's reaction with cancerous cells and that there are an insufficient number of known alternative methods for producing RVTR's version of reagent z.

obtaining timely FDA approval of B1's competitor, G1. In essence, we have permitted RVTR to utilize a technique that reintroduces the regulatory delay that was removed by the enactment of the FDA exemption.

When RVTR is blocking a researcher from developing a competing product, it is appropriate to allow the FDA exemption to protect our researcher's use of reagent z for experiments related to FDA approval of G1. Otherwise, the incentive to produce better research tools would be protected to the detriment of Congress' desire to permit use of patented inventions for conducting pre-patent expiration experiments relating to FDA approval. The FDA exemption was designed to offset the regulatory delay by enabling our hypothetical researcher to use B1 to provide G1 immediately, upon the expiration of the patent on B1. RVTR should not be able to circumvent the FDA exemption's objective by limiting access to reagent z in order to protect its market for B1. Therefore, any exception that we create for excluding the use of a "research tool" must take into account RVTR's ability to defeat the FDA exemption's objective by blocking access to the research tool (reagent z).

The remaining question is whether the FDA exemption can be interpreted to balance both the research tool patent holder's concern and the need to provide timely post-expiration sale of competing versions of a patented invention subject to FDA approval? Included *infra* is a proposed analysis that provides a fairly good balance between the need to protect the incentive to develop pioneering research tools and the FDA exemption's objective. Although it is not a perfect solution, it provides some protection to both sides and is flexible enough to be modified on a case-by-case basis.

V. A PROPOSAL FOR MODIFYING THE FDA EXEMPTION ANALYSIS TO PROTECT THE INCENTIVE TO PRODUCE RESEARCH TOOLS AND TIMELY DEVELOP COMPETING FDA-APPROVED PRODUCTS

The proposed analysis applies a combination of use, intent, a rebuttable presumption, and the existing FDA exemption analysis. The proposal is as follows: 1) after the FDA exemption is raised as a defense, the patentee gets an opportunity to assert that his invention is being used as a research tool; 2) next, the court applies the Use As a Research Tool ("UART") factors to determine if a patentee's invention is actually being used as a research tool; 3) based on the UART factors, the court determines if the patentee's invention is being used as a research tool and whether it will raise a presumption against a researcher's ability to assert the FDA exemption; 4) if the court finds that this presumption should apply, then a researcher can rebut it by establishing that the patentee is blocking the development of a competing product; and 5) finally, if the presumption is rebutted by the researcher or if the presumption does not apply, the

court will need to apply the current FDA exemption analysis, as described under part III of this paper, to the researcher's activities.

To determine whether a patentee's invention is being used as a research tool, the court should consider if the patentee's invention is the subject of a researcher's experiments. In fact, both the Supreme Court (in dictum) and Judge Newman professed that distinguishing between the subject being tested and the object being used to study or aid in performing experiments may be an appropriate method of identifying research tools.¹⁷² In essence, there is a difference between using an existing tool for research and studying the tool itself.¹⁷³

This proposal takes this basic distinction and expands upon it to create a working method for identifying when a patented invention is being used as a research tool. Applying this distinction, we can create a rule that when a patented invention itself is being studied or is the object being tested, it is not being used as a research tool. On the other hand, when a patented invention is not being studied and is used to study or aid in performing experiments with other material, then it is being used as a research tool. The court will need a method of filtering out the real cases from false ones, where a patented invention is being used as a research tool.

¹⁷² *Merck II*, 545 U.S. at 205 n.7.

The Court of Appeals also suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called 'research tools' of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not. See [*Merck I*, 331 F.3d 860, 878 (Fed. Cir. 2003)] (Newman, J., dissenting) ('Use of an existing tool in one's research is quite different from study of the tool itself'). We therefore need not—and do not—express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of 'research tools' in the development of information for the regulatory process.

Id. See also *Merck I*, 331 F.3d at 877–78 (Newman, J., dissenting).

There is a fundamental distinction between research into the science and technology disclosed in patents, and the use in research of patented products or methods, the so-called 'research tools' Use of an existing tool in one's research is quite different from study of the tool itself. . . . The RGD-containing peptides of the Integra patents are not a 'tool' used in research, but simply new compositions having certain biological properties. The Scripps/Merck syntheses and evaluations of new RGD peptides were not use of the Integra products as a research tool.

Id.

¹⁷³ *Merck II*, 545 U.S. at 205 n.7; *Merck I*, 331 F.3d at 877–78; Noud & Meiklejohn, *supra* note 6, at 960–61.

A. *Protecting against false assertions of a patented invention being used as a research tool or the subject of experimentation*

Courts should be mindful that creating a category for use of patented inventions called “research tools” and excluding it from the protection of the FDA exemption may create two undesirable incentives. First, patentees may sometimes be motivated to strengthen their infringement claims by falsely asserting that their patented inventions are being used as research tools so that they can overcome an asserted FDA exemption defense. A patentee that is able to successfully demonstrate that a researcher is using his patented invention as a research tool will get the benefit of the presumption that the FDA exemption does not apply. With the benefit of this presumption, a patentee may be more likely to prevail on his infringement claim against a researcher.

Second, researchers will be motivated to falsely assert that they are studying a patentee’s invention or that it is the subject of their tests to avoid the presumption that their activities fall outside the protection of the FDA exemption. If a researcher successfully asserts that he is studying a patentee’s invention or that it is the subject of his tests, then the court will not presume that his activities fall outside the boundaries of the FDA exemption. By avoiding this presumption, a researcher can more easily assert the FDA exemption as a defense to a patentee’s infringement claim. To protect against these undesirable assertions, the proposal creates the UART factors to assist a court in filtering out these potentially false assertions by patentees and researchers.

1. Using the UART factors to determine if a patented invention is being used as a research tool

When considering whether a patented invention is being used as a research tool, the initial inquiry should be whether the patented invention is the subject of the testing or if it is an object being used to perform the research. In making this determination, courts should perform a qualitative and quantitative analysis of a researcher’s use of a patentee’s invention to determine if it is used as a research tool. In performing this analysis, the court should consider the following UART factors:

- 1) the existence of recorded data or test results on the patented invention;
- 2) whether the patented invention is used to facilitate a step, process, or other objective in the experiment;
- 3) the number or percentage of different tests performed on the patented invention claimed to be used as a research tool compared to the num-

- ber or percentage of tests performed on other patented inventions that are claimed to be the subject of the experiments;
- 4) the timing of the tests on the patented invention claimed to be used as a research tool in relation to the researcher's other activities;
 - 5) whether the type of testing that is performed on the patented invention conforms to applicable industry standards or regulations;
 - 6) how the industry predominately uses the patented invention claimed to be used as a research tool;
 - 7) whether the patentee markets and sells his invention for studying or assisting in performing steps or processes in experiments;¹⁷⁴ and
 - 8) the manner in which the results of the tests on the patented invention are used.

Certainly, there is a distinction between a patented invention that is the subject of tests and a patented invention that is used to study or aid in performing experiments with other materials. In close cases, however, these UART factors can help the court to distinguish between scenarios where a patented invention is the subject of the researcher's experiments and where a patented invention is used to study or aid in performing experiments with other materials (i.e., being used as a research tool). The reader should note that this is merely an illustrative list and no single factor should be considered more important than another. In fact, all of the UART factors do not have to be considered in every case; instead, courts should decide which particular factors are relevant on a case-by-case basis. To demonstrate how a court could use the UART factors, we return to our hypothetical researcher's use of B1, G1, and reagent z.¹⁷⁵

2. Applying the UART factors to our hypothetical researcher's use of reagent z to determine if a research tool is being used

In order to apply the UART factors, assume the following arguments and evidence are before the court: 1) the researcher claims to have performed ten tests on reagent z but only has recorded results for five tests; 2) the researcher has performed twenty tests each on B1 and G1 and has recorded results for eighteen of the tests; 3) the researcher's testing on B1 and G1 began on or about January 1, 1997; 4) the researcher's testing on reagent z began on or about November 30, 2005; 5) the patentee for reagent z filed a complaint alleging pat-

¹⁷⁴ See Bohrer, *supra* note 27, at 716.

¹⁷⁵ See *supra* Part IV-A.

ent infringement against our researcher on or about February 15, 2006; 6) the researcher has used reagent z as a catalyst for G1's reaction with cancerous cells in all twenty of his tests on G1; 7) the patentee has asserted that the researcher is using reagent z as a research tool to study G1 or to aid in performing experiments to develop G1; and 8) the researcher has asserted that reagent z is the subject of his experiments or that he is studying reagent z. With this additional information, we are ready to apply the UART factors to determine if our hypothetical researcher is using reagent z as a research tool.

In our example, because there are tests being performed on B1, G1, and reagent z, this may not be an easy case. Reagent z could be the subject of the testing or just an aid in performing experiments with other material. Therefore, the court should turn to the UART factors to see if they can assist in determining whether our researcher is using reagent z as a research tool. The court should elect to disregard factors that are inapplicable, however.

For example, there is no evidence of how the industry predominately uses reagent z or how the patentee markets reagent z; thus, factors six and seven cannot be applied effectively by the court. Also, there is no evidence about industry standards; thus, factor five cannot be applied effectively by the court. Therefore, in analyzing our hypothetical researcher's use of reagent z, the court should disregard factors five, six, seven, and eight because there is no evidence to properly apply them. There is sufficient evidence to properly apply factors one through four, however. As such, we will apply factors one through four to our example and perform a general discussion of factors five through eight.

a. UART factor one: the existence of recorded data or test results on the patented invention

If a patented invention is the subject of the experiments, then there should be records for the results of the tests performed on it. A lack of records may help filter out a false assertion about a patented invention being the subject of the experiments. On the other hand, if there are records of tests on the patented invention claimed to be used as a research tool, then it is more likely to be the subject of a researcher's experiments. Although our hypothetical researcher claims to have performed ten tests on reagent z, he has only recorded results for five of the claimed tests. The lack of recorded results for the alleged tests on reagent z indicates that it is not the subject of this researcher's experiments.

Additionally, our hypothetical researcher has testing results for thirty-six of the forty total tests he has performed on B1 and G1. The researcher's meticulous recording of results on B1 and G1 indicates that B1 and G1 were really the subjects of his experiments. Because the researcher does not have records of each test on reagent z, and he has records of almost every test on B1 and G1,

factor one should weigh against a finding that reagent z is the subject of this researcher's experiments. Instead, this factor should favor the patentee's assertion that reagent z is being used as a research tool.

b. UART factor two: whether the patented invention is used to facilitate a step, process, or other objective in the experiment

If the patentee's invention does not facilitate a step or process in the experiments, then a researcher is more likely to be using it as the subject of his experiments. If the patented invention helps facilitate a step or process in a researcher's experiments, then a researcher is more likely to be using it as a research tool. Applying the second factor to our hypothetical, the court should note that reagent z has been used by the researcher in all thirty-six of his experiments with G1 and B1 to help catalyze G1's and B1's reaction with cancer cells. Reagent z has been used by the researcher to help facilitate this process of his experiments with G1 and B1. Consequently, the second UART factor should weigh in favor of finding that the researcher is using reagent z as a research tool.

c. UART factor three: the number or percentage of different tests performed on the patented invention claimed to be used as a research tool versus the number of tests performed on other patented inventions claimed to be the subject of the experiments

If the number of tests performed on the patented invention claimed to be used as a research tool is small in comparison to the number of tests performed on other materials or other patented inventions, then it is more likely that the patented invention at issue is being used as a research tool. If the number of tests performed on the patented invention claimed to be a research tool is equal to, greater than, or marginally smaller than the number of tests performed on other material or other patented inventions, then it is more likely to be the subject of a researcher's experiments.

In our hypothetical case, the researcher claims to have performed ten experiments on reagent z but has performed twenty experiments each on B1 and G1. Typically, a researcher will perform more experiments upon the subject of his experiments than something that is used as a research tool. Therefore, the third UART factor favors a finding that reagent z is being used as a research tool. Now, it may be that in some cases a factor is neutral—the factor may not weigh in favor of either finding. For example, if our hypothetical researcher had

performed sixteen experiments on reagent z, then this factor may be deemed neutral. Sixteen experiments on reagent z would be almost equal to the twenty tests on G1 and B1, individually (total of forty on both); thus in this case, the number of tests would not provide much insight.

With respect to the percentage analysis, the parties have not provided statistical information about the testing on B1, G1, and reagent z, thus the court may choose not to consider the percentage portion of the analysis. However, since the actual numbers of experiments on reagent z (ten), B1 (twenty), and G1 (twenty) are provided to the court, it may elect to calculate the percentages on its own or ignore them. Let us assume the court elects to consider that the researcher has performed fifty percent more tests upon B1 and G1; this factor should then weigh in favor of finding that reagent z is being used as a research tool.

d. UART factor four: the timing of the tests on the patented invention claimed to be used as a research tool in relation to the researcher's other activities

If the timing of the tests on the patented invention claimed to be used as a research tool indicates that they were performed just before the patentee asserted his patent infringement claim, then it is probably an attempt to avoid the finding that the patentee's invention is being used as a research tool. If the timing of the tests on the patented invention occurred within the normal course of research and development, then a researcher is less likely to be making an effort to strengthen his FDA exemption defense. Our hypothetical researcher began testing on reagent z in November 2005 but initiated testing upon B1 and G1 in January 1997. The researcher did not begin testing on reagent z until about two and a half months before the patentee filed a suit for infringement.

In this scenario, our hypothetical researcher's testing upon reagent z is more likely an effort to strengthen his ability to assert the FDA exemption. If reagent z was truly the subject of the testing, then the researcher would not have waited so long to begin his experiments on it. Thus, this factor should weigh in favor of finding that reagent z is being used as a research tool. If our hypothetical researcher had knowledge of the patentee's impending claims for infringement and based on that knowledge initiated the testing on reagent z, then this factor would even more strongly favor the finding that reagent z is being used as a research tool.

Now, before deciding what the court's finding should be with respect to our hypothetical researcher's use of reagent z, we will briefly discuss UART factors five through eight for illustrative purposes.

3. How UART factors five through eight may be applied by courts

a. UART factor five: whether the type of testing that is performed on the patented invention conforms to applicable industry standards or regulations.

If a researcher's tests on the patented invention do not conform to industry standards, then it may be an improper effort to avoid a finding that he is really using the patented invention as a research tool. Conversely, if a researcher's tests on the patented invention conform to industry standards, then it is likely that he is really not using it as a research tool. This factor really goes to the legitimacy of the tests to determine if a patented invention is the subject of a researcher's experimentation. If the court is provided more detailed evidence about the researchers tests on reagent z and industry practices, it could use UART factor five to determine whether reagent z is being used as a research tool.

b. UART factor six: how the industry predominately uses the patented invention claimed to be used as a research tool

If the industry typically does not use the patented invention to aid or facilitate experiments, then it is less likely to be used as a research tool. If the industry predominantly uses the patented invention to aid or facilitate steps in research, then it is more likely to be used as a research tool. The court should consider evidence of the invention's sales revenues and the type of consumers that use it. If more than fifty percent of the sales revenues are from use of the patented invention to aid or facilitate research, then it is likely to be used as a research tool. If the majority of the consumers for the patentee's invention are individuals or entities that perform research, then it is likely to be a research tool.

If, however, the consumers for the patentee's invention are not researchers, and less than fifty percent of the sales revenues are from use of the patented invention to facilitate steps in experiments, then the industry does not predominately use it as a research tool. If the industry does not predominately use the patentee's invention as a research tool, then it is less likely to be used as a research tool by a researcher. With appropriate evidence, UART factor six could be used by a court to determine if reagent z is being used as a research tool.

c. UART factor seven: does the patentee market his invention for studying or assisting in performing steps or processes in experiments with other materials?

If a patentee markets his invention for use in studying or assisting in performing steps in experiments with other material, then it is more likely to be used as a research tool. The court should consider the advertising and market focus of the patentee to determine the intended consumers and recommended uses of the patented invention. If a patentee does not market his invention for use in studying or assisting in performing experiments with other materials, then it is less likely to be used as a research tool. On the other hand, if a patentee markets his invention to researchers and recommends using it to assist in experimenting with other materials, then it is more likely to be used as a research tool. If the court had evidence of the advertising and market focus of reagent z's owner, then UART factor seven might be useful to the court.

d. UART factor eight: the manner in which the results of the tests on the patented invention are used

If a researcher uses the results of the tests on the patented invention to compare or demonstrate equivalency with an alternative or competing product, then it is more likely to be the subject of a researcher's experiments. If a researcher submits the test results to the FDA, then it is more likely to be the subject of a researcher's experiments. Conversely, if a researcher just stores the results of the tests on the patented invention, without using them for any other purpose, then it is more likely to be a research tool in a researcher's experiments. Once again, evidence of how our hypothetical researcher used the results from the tests on reagent z would allow the court to apply this UART factor.

Although UART factors five through eight are not applicable to our hypothetical researcher's use of reagent z, as illustrated *supra*, they could be useful to courts in other situations to determine whether a patented invention is being used as a research tool. In fact, if UART factors five through eight were applicable to our hypothetical, they might cause a different outcome. With this general understanding of how to apply UART factors five through eight, let us briefly return to our hypothetical researcher to further understand if he is using reagent z as a research tool.

4. Our hypothetical researcher is using reagent z as a research tool, thus the court should presume its activities are beyond the FDA exemption's protective sphere

Returning to our hypothetical, although this is may have appeared to be a close case, UART factors one through four indicate that the court should find that our researcher is using reagent z as a research tool. Indeed, all four UART factors favored a finding that our hypothetical researcher was using reagent z as a research tool. Based on the finding that our hypothetical researcher is using reagent z as a research tool, the court should invoke a presumption that his use of reagent z falls outside the protection of the FDA exemption.¹⁷⁶ If we were to continue to use our hypothetical researcher, the next step would be whether our researcher could rebut the presumption that his activities are outside the scope of the FDA exemption. The manner of performing the analysis for rebutting the presumption will be discussed without using our hypothetical researcher, however, because he is no longer crucial to understanding the modification.

Any researcher should be permitted to rebut this presumption by demonstrating that the owner of the research tool patent is limiting access to the research tool to delay a legitimate effort to bring a competing FDA approved product to the market. An effort to block a researcher is likely when a single individual or entity owns both the patent on the research tool and the patented invention that is the subject of the researcher's experiments. The following part of the analysis considers objective evidence of the patentee's intent.

B. A researcher's ability to rebut the presumption that his activities fall outside the scope of the FDA exemption by demonstrating that the research tool patent owner is blocking his efforts to develop a competing product

The research tool patent ("RTP") owner's intent is reviewed to determine if he is withholding access to a research tool to prevent a researcher from

¹⁷⁶ Alternatively, if the court believed that portions of reagent z may legitimately have been the subject of our hypothetical researcher's tests, instead of an effort to avoid liability for patent infringement, then it could apply the presumption for those activities. For example, the court could find that reagent z was the subject of the researcher's study for the five experiments that he has recorded results. For the remainder of the researcher's use, the court could find that he used reagent z as a research tool. Consequently, the researcher would have to rebut the presumption that his activities were outside the scope of the FDA exemption for all of his use of reagent z, except for those five experiments.

being able to undertake development of a competing version of a different patented invention. A key inquiry will be ownership of the RTP and the “branded patented invention” (“BPI”).¹⁷⁷ Generally, a researcher will be trying to create a competing or derivative version of the BPI that meets FDA approval.

The court should simply determine if there is a commonality of an interest to exclude by evaluating the ownership of the RTP and the BPI. If the owner of the RTP is different from the owner of the BPI, then there is minimal concern of a successful effort to block a researcher’s attempts to obtain FDA approval of a competing product. Therefore, a court should consider ownership or a commonality of an interest to exclude to determine if the RTP owner is engaging in an effort to prevent a researcher from bringing a competing product to the market.

In the ownership analysis, the court should consider the following: 1) a parent company relationship between the owners of the BPI and RTP; 2) a subsidiary relationship between the owners of the BPI and RTP; 3) a holding company relationship between the owners of the BPI and RTP; and 4) exclusive licensee relationships between the owners of the BPI and RTP. The purpose is to determine whether the owners of the BPI and RTP have a common interest in excluding others from being able to use their technologies. If a researcher demonstrates a parent, subsidiary, holding company, or exclusive licensee relationship between the RTP and BPI owners, then the court should find that a commonality of an interest to exclude has been demonstrated.

1. Finding a commonality of an interest to exclude a researcher from the market for the BPI should lead the court to consider evidence of collusion or overreaching

If a researcher is able to demonstrate that there is a commonality of an interest to exclude, then the court may consider evidence of actual collusion or overreaching during licensing negotiations. Within the context of the collusive or overreaching efforts arguments, the court should consider the availability of alternative tools or patented inventions that a researcher may substitute for the BPI and RTP owners’ inventions. Such evidence is considered in determining if the BPI and RTP owner(s) is/are engaging in an effort to prevent the researcher from bringing a competing product to the market. Courts should be mindful that

¹⁷⁷ I am using the term “branded patented invention” to refer to the object of the study. Generally, this is a successful patented product and others are seeking to duplicate that success by creating an alternative or derivative version to compete with this product.

permitting a collusive efforts argument in every case may defeat the presumption's ability to protect research tool owners. Thus, the collusive efforts argument should not be permitted in every case. If a researcher does not demonstrate a commonality of an interest to exclude, then the collusive or overreaching efforts argument should not be permitted.

After considering evidence of collusion or overreaching, if a court finds that a researcher is unable to demonstrate that the RTP owner is using his patent to block efforts to develop a competing or derivative version of a BPI, then the presumption remains and the researcher's effort to assert the FDA exemption as an affirmative defense should fail.¹⁷⁸ On the other hand, if a researcher demonstrates that a RTP owner used his patent rights effectively to block the researcher's effort to develop an alternative or derivative version of a BPI, to compete with then he has rebutted the presumption. If a researcher successfully rebuts the presumption, then the court should proceed to apply the existing version of the FDA exemption analysis summarized under part III of this paper. Alternatively, if the court had found that the invention claimed to be infringed was the subject of a researcher's experiments instead of a research tool, then it should skip the presumption portion of the proposed modified analysis and move directly to the current version of the FDA exemption analysis summarized under part III of this paper.

C. If the court finds that the patented invention is the subject of the researcher's experiments, then the traditional FDA exemption analysis should apply

If a researcher is performing tests upon the patented invention or it is the subject of the experiments performed to obtain FDA approval of a competing product, then it is not being used as a research tool. As discussed *supra*, this type of activity is exactly what the FDA exemption was designed to promote—activities that lead to the FDA's approval of competing versions of patented inventions for immediate post-patent expiration sales. In this context, the RTP holder's concern is outweighed by Congress's objective. Even if a patented invention is something that could be used as a research tool, when it is the subject of the experiments, it is not being used as a research tool.

Under these circumstances, because such a researcher is using the patented invention as the subject of his experiments to develop a product that competes with the RTP owner's product, he is the intended beneficiary of the FDA

¹⁷⁸ The FDA exemption is an affirmative defense. *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1281–82 (S.D. Fla. 2005).

exemption. Consequently, there is no need to presume that such a researcher's activities are outside the scope of the FDA exemption. The RTP owner's interest is outweighed by Congress's desire to avoid an unwarranted extension of his patent term by delaying the development of a competing research tool product.

If a researcher has to wait until the patent on the research tool expires to begin the process of obtaining FDA approval of a competing version of the research tool, then the RTP owner will get a practical extension of his right to exclude due to the regulatory delay. In this context, a RTP owner is no different from any other owner of a patented invention that must go through the FDA's approval process to practice his claimed invention. When a patented invention is the subject of the researcher's experiments, whether it is normally a research tool or not, the court should proceed to apply the current version of the FDA exemption analysis as described in part III of this paper.

D. Allocating burdens of proof and production in the proposed modification for applying the FDA exemption to meet the concerns of the research tool holders and the pharmaceutical industry

Since the FDA exemption is an affirmative defense, the burden of proof to establish that a researcher's activities are reasonably related to obtaining FDA approval should always be upon the researcher.¹⁷⁹ The burden of proof with respect to whether something is being used as a research tool should be on the patentee attempting to assert that his patented invention is being used as a research tool. The burden of proof for rebutting the presumption that the FDA exemption does not apply to his activities will be upon the researcher.

The burden of producing evidence will also vary at different stages of the proposed modification of the FDA exemption analysis. The burden of producing evidence of how the patented invention is used will be upon the researcher, because he has this type of evidence. The burden of producing evidence about the ownership should be upon the owners of the BPI and RTP, because they have access to this type of evidence. The burden of producing evidence demonstrating that a researcher's use of a patented invention is reasonably related to obtaining FDA approval will be upon the researcher. Allocating the burdens of proof and production, as described *supra*, will further help to ensure that the court has accurate information to use in balancing the RTP owner's interest with the FDA exemption's objective.

¹⁷⁹ *Id.*

E. The flexibility and nuance provided by the proposed modification to the FDA exemption analysis make it a better solution than a bright line test for the pharmaceutical industry

In this uncertain legal arena, the flexibility of the proposed test provides the additional advantage of adapting to the needs of the research tool owner, the researcher, and the court. Despite the illusory attractiveness of precise rules, “nuanced and flexible standards are generally more appropriate for the dynamic innovation environment confronted by the Federal Circuit.”¹⁸⁰ Although the modified analysis will exclude the use of a patented invention as a research tool from the FDA exemption, it will also give the industry the option of creating a competing research tool to reduce impediments to research and development of new or competing products. Furthermore, owners of research tool patents are still encouraged to invent and disclose their inventions because they will be able to enforce their right to exclude the use of their patented invention as a research tool.

The proposed modification is not a bright line test; instead it is nuanced and better suited to the needs of the pharmaceutical industry. Bright-line legal tests help provide certainty and predictability, but in the pharmaceutical industry’s rapidly changing area of technological research, a bright line rule is likely to result in unfairness and over and under inclusiveness.¹⁸¹ A static definition of research tools would be unable to adapt to the changing needs of the pharmaceutical industry. Something that is a research tool today may not be used as a research tool tomorrow. There may be patented inventions that can be used as research tools in some situations but not in others; these inventions may fall on the wrong side of the research tool definition.

In addition to the over and under inclusiveness concerns, a bright line may not serve the goals of the FDA exemption. Employing a static definition of research tools and excluding them completely from the scope of the FDA exemption may provide a RTP owner a means to block a researcher’s effort to develop competing versions of the BPI. A complete exclusion of all uses of a patented invention based on a pre-defined category of research tools may defeat the FDA exemption’s objective of permitting pre-expiration approval activities of research tools that require FDA approval.

At this time, due to the lack of empirical studies supporting either side of the issue, a judicially or legislatively carved out exception for all uses of research tools is too drastic a remedy. In fact, the Solicitor General’s amicus brief

¹⁸⁰ Mueller, *supra* note 144, at 965.

¹⁸¹ *Id.*

in the *Merck II* decision indicates that excluding the pre-clinical phase from the FDA exemption had an immediate adverse impact on the research and development of new drugs.¹⁸² Consequently, taking the drastic step of creating a pre-defined category of research tools and excluding all uses of this category of research tools may result in a similar decrease in research and development.

1. An empirical analysis may be unrealistic because of the difficulty in obtaining accurate and complete data. Therefore, the modified proposal's flexible and nuanced approach is more appropriate than decisive legislative action

In order to perform an empirical analysis we would need the following type of information: 1) how researchers are using different patented inventions; 2) how often they are using a patented invention to study or aid in performing experiments; 3) what types of patented inventions researchers generally use as research tools; 4) whether a patented invention that is used as a research tool has a narrow range of alternative uses; 5) to what extent would a market for a patentee's invention be decreased by permitting researchers to use his invention as a research tool; and 6) whether a patentee's ability to recoup the costs of research and development would be nullified because of a loss in revenues from sales or licensing of a patented invention that is used as a research tool. As argued *infra*, the general interests of researchers and patentees do not favor providing the aforementioned type of information to perform an empirical analysis.

Many researchers would be unwilling to disclose their use of research tools or techniques, unless their uses are already protected from claims of patent infringement. By disclosing their uses of research tools and techniques, disclosing researchers may open themselves to infringement claims. Without first being assured that they would be able to raise the FDA exemption defense for their use of a patented invention as a research tool, many researchers would be reluctant to provide complete and accurate accounts of their potentially-infringing use. Conversely, if use of research tools were already protected from infringement claims by the FDA exemption, then RTP owners would be concerned about limiting the perceived value of their claimed inventions.

A RTP owner that asserts that his patented invention should be treated as a research tool, because it has a very limited range of uses, may incur a perceived decrease in the value of his invention. This particular concern of RTP owners is heightened by the potential for a perceived decrease in value of their

¹⁸² Brief for the United States, *supra* note 11, at 19.

claimed inventions in the eyes of company shareholders.¹⁸³ Company shareholders will be concerned about any admissions from a RTP owner about a potential loss of markets, revenues, or ability to recoup research and development costs. Thus, trying to get accurate and complete information from RTP owners about what may be a research tool is not only difficult, but it may be unrealistic.

Finally, the difficulty in performing an empirical analysis disfavors new legislative action. As discussed *supra*, the modification to the current FDA exemption analysis does not require any new legislative action. This creates an added benefit because the proposed modification will not incur legislative delays or additional interpretation issues created by new regulations or statutes. Creating a legislative proposal without having empirical studies on both sides of the issue may be akin to using a bulldozer to knock down a single tree. The proposed modification interprets the FDA exemption to allow a researcher to make products that compete with a patented invention by using the same patented invention to obtain FDA approval. This interpretation is consistent with Congress' intent and prior court decisions stating the need to enable competitors to come to the market without undue delay.¹⁸⁴ Furthermore, the proposal merely creates a rebuttal presumption as a procedural effort by courts to balance the varying interests of RTP owners and researchers. In this uncertain arena, the flexibility and nuance provided by the modified proposal and the associated ability to make a case-by-case determination about whether the FDA exemption should apply to the use of a patented invention as a research tool seems to be a better approach.

VI. CONCLUSION

The expanding reach of the FDA exemption threatens to prevent research tool patent owners from recovering the costs and investments in developing the research tool. To ensure that research tool patent owners have sufficient incentive to develop and disclose their inventions, I have proposed an exclusion of research tools from the FDA exemption. The proposal is simply to analyze the use of the patented invention to determine if it is the subject of a researcher's experiments or if it is an aid in carrying out other objectives of the experiments.

¹⁸³ Noud & Meiklejohn, *supra* note 6, at 961.

¹⁸⁴ *Lilly*, 496 U.S. at 671–72. (referring to 35 USC § 271(e)(1) the Supreme Court stated: “This allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.”); *Intermedics Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) (permitting a competitor to engage in a variety of pre-approval activities to prepare for selling a competing version of a patented product upon patent expiration); *see supra* notes 161–63.

To assist the judge in making this determination the proposal provides the UART factors to filter for legitimate instances where a researcher is using a research tool.

Creating a blanket exclusion for research tools may enable research tool patent owners' efforts block the development of products that compete with their other inventions. Since research tools often aid in conducting pharmaceutical experiments more cheaply, efficiently, and quickly, a blanket exclusion could thwart a variety of legitimate research efforts. Consequently, my proposal creates a presumptive exclusion that can be rebutted by a researcher seeking to develop competing products. This nuanced and flexible approach should effectively balance the interests of research tool patent owners, researchers, and Congress' objective in creating the FDA exemption.

In summary, the proposed modification is as follows:

- 1) first, a patentee will assert claims of infringement against a researcher;
- 2) next, a researcher will assert the FDA exemption as a defense to the claims of infringement;
- 3) at this stage, the modified proposal would permit a patentee to assert that a researcher is using his patented invention as a research tool;
- 4) the court would then decide if a researcher is using the patented invention as a research tool (the court may elect to use the applicable UART factors to aid its decision);
- 5(a) if the court finds that a researcher is using the patentee's invention as a research tool, then it will presume that this researcher's activities are outside the protection of the FDA exemption;
- 5(b) if the court finds that a researcher is not using the patentee's invention as a research tool, then it will bypass the presumption and skip to step eight;
- 6) a researcher may rebut the presumption that his activities are outside the protection of the FDA exemption by demonstrating: (a) a commonality of an interest to exclude between the patentee asserting infringement and the owner of the branded patented invention and (b) collusion or overreaching in the form of an effort to block the researcher from developing a product that competes with the branded patented invention;
- 7) if the researcher rebuts this presumption, then the court proceeds to step eight; if the researchers does not rebut the presumption, then he

cannot raise the FDA exemption as a defense to a patentee's claim of infringement; and

- 8) the court applies the current or existing version of the FDA exemption¹⁸⁵ to determine if a researcher's activities are reasonably related to obtaining FDA approval.

¹⁸⁵ See *supra* Part III for a detailed summary of the current FDA exemption analysis.