

Hastings Science & Technology Law Journal

Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools

ALFRED C. SERVER, M.D., PH.D., NADER MOUSAVI, AND
JANE M. LOVE, PH.D.

CITE AS: 1 HASTINGS SCI. AND TECH. L.J. 21

Abstract

A novel, nonobvious Discovery Tool and its use can be the subject of valid patent claims, but patent claims that reach through to cover as-of-yet-undiscovered drug products generally fail to meet the written description and enablement requirements of 35 U.S.C. § 112. Notwithstanding the Supreme Court's broad reading of the scope of the statutory exemption to infringement—under 35 U.S.C. § 271(e)(1)—in *Merck v. Integra*, and the occasionally misapplied common law experimental use exception, valid claims to Discovery Tools and their use are enforceable against unauthorized users. This article analyzes the legality of one form of compensation occasionally sought by Discovery Tool inventors as consideration for the grant of a license to the use of their patented tools: the “reach-through” royalty paid on the sale of a product that is identified by a licensee using a patented Discovery Tool, but is not itself covered by the inventor's tool patent. In addition, this article reviews judicial remedies in patent infringement cases that reach through the infringed patent to burden products and activities of the infringer that are not covered by the infringed patent—remedies that are analogous to a negotiated contractual reach-through royalty obligation. The article concludes that reach-through royalty arrangements between willing licensors and licensees are permissible under U.S. Supreme Court precedent, despite potential patent misuse challenges, and represent a viable method by which the free market for patented Discovery Tools may adequately reward the tool inventor.

Reach-Through Rights and the Patentability, Enforcement, and Licensing of Patents on Drug Discovery Tools

by ALFRED C. SERVER, M.D., PH.D.,* NADER MOUSAVI,** AND JANE M. LOVE, PH.D.***¹

I. Introduction

During the reign of Edward III of England (1327-1377 A.D.), the protection of the sovereign was sought, in the form of the grant of a royal patent, for the invention of a stone that could transform lead into gold, the so-called “philosopher’s stone.” Presumably, the stone’s “inventors” did not possess the mythical object, but they could describe it in terms of its function. In addition, they could describe the utility of the invention and a method for identifying such a stone, namely through the trial and error process of testing each candidate stone for its ability to generate gold from lead. After a favorable review by a royal commission, the King granted the requested patent “apparently upon what we now regard as sound doctrine, that the invention was new and useful.”² The “inventors” thus obtained monopoly rights to the philosopher’s stone, despite the fact that they did not possess it, and with such rights they could exact royalty payments for the stone’s future use or sale, should it later be found by a third party.

* Partner, Wilmer Cutler Pickering Hale and Dorr LLP and an advisor to the Hastings College of the Law LAB (Law and Bioscience) Project, fred.server@wilmerhale.com.

** Partner, Wilmer Cutler Pickering Hale and Dorr LLP, nader.mousavi@wilmerhale.com.

*** Partner, Wilmer Cutler Pickering Hale and Dorr LLP, jane.love@wilmerhale.com.

1. The views expressed here are those of Dr. Server, Mr. Mousavi and Dr. Love and not of Wilmer Cutler Pickering Hale and Dorr LLP. We thank Mr. Peter Singleton for valuable assistance in the preparation of this Article.

2. *McKeever v. United States*, 14 Ct.Cl. 396, 418 (1878) (citing John Coryton, THE LAW OF LETTERS-PATENT 4 n.1 (London, H. Sweet, 1855)).

The royal patent granted for the philosopher's stone has been described as the first known instance of patent protection.³ It may also be the first example of a "reach-through" intellectual property right, in that the so-called "inventor" of the philosopher's stone received monopoly rights to an imagined, but yet-to-be-discovered, object.⁴ Fast forward 650 years to the present, and inventors are still seeking intellectual property protection that "reaches through" that which is known to capture imagined, but undiscovered, inventions. The philosopher's stone of our era, however, is no mythical object, but the elusive blockbuster pharmaceutical product. Today, discovering a single molecule that can safely and effectively be used to diagnose, treat or cure a human disease is worth more than gold. It can improve and save lives, and in so doing, generate billions of dollars in sales, sustain or create tens of thousands of jobs, and change the fortunes of companies. The "critical path"⁵ to these new drugs requires access to biomedical research tools used in the initial stages of drug development to identify new drug candidates—tools which we will refer to in this Article as Discovery Tools. The inventors of these Discovery Tools have sought, and in some cases successfully obtained,⁶ patent rights that reach through their tools and claim drug products that may, someday, be discovered by others using such tools. Meanwhile, pharmaceutical and biotechnology companies that rely on the use of such tools for their drug discovery efforts, and on the revenues that result from the sale of the drug products that such companies identify using such tools, have fiercely defended their rights to their own drug discoveries. The result is a clash of competing interests that has led to recurring disagreements between Discovery Tool inventors and tool users as to the appropriate compensation for use of these tools.

Any discussion of the appropriate compensation for the use of Discovery Tools, however, implicates the longstanding debate regarding the use of biomedical research tools, generally, in the drug development process. At the heart of the debate is a basic policy issue of how best to strike the balance between the rights and

3. *McKeever v. United States*, 14 Ct.Cl. 396, 418 (1878) (citing John Coryton, *THE LAW OF LETTERS-PATENT* 4 n.1 (London, H. Sweet, 1855)).

4. Analogy adapted from that provided by Judge Larimer in *Univ. of Rochester v. G.D. Searle*, 249 F. Supp. 2d 216, 230 (W.D.N.Y. 2003).

5. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS (March 2004).

6. See, e.g., U.S. Patent No. 6,048,850.

interests of tool inventors, tool users and the public. Tool users, among others, argue that the excessive protection of research methods and tools, particularly reach-through protections, stifles downstream drug development efforts to the detriment of the public. The problem is amplified by the sheer number of research tools that are typically employed in the drug development process, requiring the tool user to obtain rights to, and to provide compensation for, the use of each such tool. Tool inventors, on the other hand, argue that the lack of reach-through rights and other protections undercuts their incentive to innovate which, in turn, undermines the discovery and development of critical methods and tools for finding the drugs of tomorrow. In this Article, however, we note, but do not attempt to resolve, the policy debate regarding the use of biomedical research tools. Rather, we take the position that Discovery Tools constitute a special class of research tool, both with respect to the value of their use in the drug development process and their treatment under current law. With respect to these high value research tools, we ask the more limited question of how a Discovery Tool inventor can be compensated for his or her contribution to the drug development process within the existing legal framework? Specifically, we address the following issues: (1) what is the scope of patent protection available with respect to a Discovery Tool and can such protection reach through to an as-yet undiscovered drug candidate (the proverbial philosopher's stone) identified using such tool; (2) if patent rights are available to the Discovery Tool inventor, at least with respect to the use of the tool itself, are these rights enforceable against unauthorized users; and (3) if use of the Discovery Tool requires authorization from the tool inventor with a valid and enforceable patent right, can compensation for such use be in the form of a "reach-through" royalty, a sometimes controversial royalty arrangement whereby the tool inventor obtains a royalty on the sale of a drug product that is found using the Discovery Tool, but is not covered by the tool inventor's patent rights? In addressing these issues, we review recent and significant district court, Federal Circuit and U.S. Supreme Court cases.⁷ The holdings in these cases apply not

7. In 2004, the Court of Appeals for the Federal Circuit in *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004) addressed the question of whether the inventor of a drug discovery method could obtain patent protection for a claimed medical treatment that required the use of a compound that was described only in terms of its function and where the means of finding such a compound required trial and error experimentation using the patented discovery method. In 2002, a Delaware U.S. District Court in *Bayer AG v. Housey Pharmaceuticals*, 228 F. Supp. 2d 467 (D. Del. 2002), *aff'd*,

only to Discovery Tool use, but to significant patent law issues, such as the statutory requirements for patentability under 35 U.S.C. § 112, the scope of the statutory exemption to infringement (35 U.S.C. § 271(e)(1)) and that of the common law experimental use exception, and the current status of the doctrine of patent misuse.

Accordingly, in Part II of this Article we describe the class of Discovery Tools, discuss the special contribution of these tools to the drug development process, and provide background regarding the policy debate on the patenting of research methods and tools generally. In Part III we discuss the District Court and Federal Circuit decisions in *University of Rochester v. Searle*,⁸ and define the permissible scope of patent protection for Discovery Tools and their use in the post-*Rochester* era. We conclude that a novel, nonobvious Discovery Tool and its use can be the subject of valid patent claims, but claims that reach through to cover as-yet undiscovered drug products generally fail to meet the statutory requirements under 35 U.S.C. § 112 for written description and enablement. In Part IV we argue that valid claims to Discovery Tools and their use are enforceable against unauthorized users, notwithstanding the Supreme Court's broad reading in *Merck v. Integra*⁹ of the scope of the statutory exemption to infringement, 35 U.S.C. § 271(e)(1), and the occasionally misapplied common law experimental use exception. Finally, in Part V we discuss one form of compensation occasionally sought by Discovery Tool inventors as consideration for the grant of a license to the use of their patented tools: the "reach-through" royalty, which is a royalty paid on the sale of a product that is identified by a licensee using a patented Discovery Tool but is not covered by the inventor's tool patent. In particular, we focus on the legality of such a royalty obligation in a Discovery Tool patent license agreement. In addition, we review judicial remedies in patent infringement cases that are analogous to a negotiated contractual reach-through royalty obligation, in that the remedies reach through the infringed patent to burden products and activities of the infringer

340 F.3d 1367 (Fed. Cir. 2003), addressed the related question of the legality of a royalty obligation based on the sale of a drug product discovered by the licensee of a patented discovery tool, where the product itself was not covered by the licensed patent. In 2005, the United States Supreme Court, in *Merck v. Integra*, 545 U.S. 193 (2005), rendered an opinion which raised the question of whether any compensation is due the inventor of a Discovery Tool for use of the tool by a third party in the identification of therapeutic compounds that require approval by the Food and Drug Administration.

8. 249 F. Supp. 2d 216 (W.D.N.Y. 2003) *aff'd*, 358 F. 3d 916 (Fed. Cir. 2004).

9. 545 U.S. 193 (2005).

that are not covered by the infringed patent. We conclude that reach-through royalty arrangements between willing licensors and licensees are permissible under applicable law, despite potential patent misuse challenges, and represent a viable method by which the free market for patented Discovery Tools may adequately reward the tool inventor.

II. Discovery Tools

The term “research tool” encompasses a myriad of compositions, apparatuses, and methods useful in experimental research. In the context of biomedical research, the National Institutes of Health (“NIH”) Working Group on Research Tools has broadly defined “research tool” to “include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as “PCR”), methods, laboratory equipment and machines, databases and compute software.”¹⁰ In this Article, however, we focus on the Discovery Tool, whose utility is in the initial identification of a putative drug candidate and, accordingly, whose contribution occurs at an early stage of what the U.S. Food and Drug Administration (“FDA”) has described as the “critical path from laboratory concept to commercial product.”¹¹ As indicated in the Introduction, our focus on Discovery Tools reflects our view that these tools are of particular value in the drug development process and that a discussion of such tools is an effective way to explore the issues that have arisen in recent legal controversies regarding reach-through rights (i.e., the legality of reach-through patent claims and of reach-through royalties). Further, while this Part II is intended to provide the necessary background for our legal analysis of reach-through rights in the context of Discovery Tools, no discussion of research tools is complete without an acknowledgement of the ongoing policy debate regarding the appropriateness of patent protection of all types of research tools used in biomedical research. Accordingly, we conclude this Part II with a brief discussion of some of the relevant policy considerations.

10. NAT’L INST. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS, at 3 (June 1998), <http://www.nih.gov/news/researchtools/index.htm> (last visited Nov. 23, 2008).

11. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS, at ii (March 2004).

A. The Discovery Tool and Its Value in Drug Development

The nature and value of a Discovery Tool is best appreciated in terms of its contribution along the critical path for medical product development. Today's mechanism-based approach to drug development often begins with the identification, in the course of basic research, of a putative drug target (e.g., a cell surface receptor or an intracellular enzyme) that has a role in a disease-related molecular pathway. The target is "validated" by a demonstration that modulation of its activity generates effects that correlate with disease in human beings. The validated target is then configured into an assay that allows for high-throughput screening of a large number of compounds in the search for "hits" that bind to the target and appropriately modulate its activity. The pursuit of hits is intended to select from a library of compounds not known to interact with the validated target, through a process of trial and error, those compounds that are worthy of further investigation. Once a hit is identified, its specificity for the target of interest is assessed by determining its ability to interact with other known drug and toxicity targets. A hit that demonstrates acceptable affinity and specificity for the drug target of interest, and appropriate modulation of such target's activity, is then "optimized" through reiterative chemical modification to generate a lead drug candidate. Such lead is then subjected to preclinical testing necessary for the submission of an application to a regulatory agency for use of the drug in human clinical trials. A drug candidate that is accepted for use in human beings undergoes a series of phased clinical trials in order to evaluate the safety and effectiveness of the drug in the treatment of the relevant disease indication. The final stage of the process for those drugs that have demonstrated the requisite safety and effectiveness in human beings is the submission of an application to the appropriate regulatory authority for marketing approval and product launch.

The Discovery Tool that is the focus of this Article is an assay that embodies a novel putative drug target, is configured for high-throughput screening of compound libraries and is intended for use in the initial identification of hits. The value of such a tool can be demonstrated by application of the two-dimensional research tool characterization suggested by Walsh et al.¹² According to these authors, biomedical research tools can be distinguished in terms of

12. John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 285-340 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

how essential or “foundational” for future innovation they are and the degree to which they are “rival-in-use.” A research tool is essential or foundational if its use is critical for subsequent innovation and the anticipated innovation is of considerable breadth, i.e., “[i]s the research tool a key building block for follow-on research on a specific approach to a specific disease, is the tool key to advance in a broad therapeutic area, or might its application even cut across a range of therapeutic and diagnostic domains?”¹³ A rival-in-use tool is

primarily used to develop innovations that will compete with one another in the marketplace. For instance, in the case of a receptor that is specific to a particular therapeutic approach to a disease, if one firm finds a compound that blocks the receptor, it undermines the ability of another [firm] to profit from its compound that blocks the same receptor.¹⁴

The Discovery Tool qualifies as valuable along both of the dimensions described by Walsh et al. It is more than a so-called “but-for” tool in the causal chain leading from identified hit to marketed drug product. Arguably, access to a Discovery Tool provides the most efficient (in terms of effort expended and costs incurred) method of identifying a drug to treat the medical indication with which the validated drug target embodied in the tool is associated; exclusive access to a novel Discovery Tool can provide the user with a considerable competitive advantage in the marketplace. The special contribution of a Discovery Tool to the drug development process was recognized by Judge Rader of the Federal Circuit in his majority opinion in *Integra v. Merck*.¹⁵ In the words of Judge Rader, “[a] research tool enabling the identification of a drug candidate during high throughput screening . . . may supply more value to the ultimate invention than a research tool used to confirm an already recognized drug candidate’s safety or efficacy.”¹⁶

B. The Controversy

Despite the potential value of access to a novel Discovery Tool, many have expressed concerns with respect to the negative impact of biomedical tool patents in general. Heller and Eisenberg characterized one such concern as “the tragedy of the anticommons”

13. *Id.* at 332.

14. *Id.*

15. 331 F.3d 860 (Fed. Cir. 2003).

16. 331 F.3d at 871.

in biomedical research.¹⁷ According to this view, the proliferation of intellectual property rights covering biomedical research tools can result in underutilization of these valuable resources.

The tragedy of the anticommons . . . arise[s] when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent [that, for example, covers a research tool useful for the discovery or development of a product, but does not cover the product itself] allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.¹⁸

In the case of patented upstream research tools, the consequence of an anticommons effect can be significant transaction costs in collecting the necessary property rights for subsequent innovation, the stacking of excessive royalty obligations to tool patent owners on the products of downstream users, and, in some instances, cessation of promising lines of biomedical research as a result of an inability to identify and collect the fragments of intellectual property rights necessary to proceed.

A second concern, described by Merges and Nelson,¹⁹ results not from a multiplicity of intellectual property rights, but from the grant of a broad patent on a foundational innovation. Such a patent may confer upon the holder the right to exclude downstream innovators from an entire area of investigation. This restricted access problem, resulting from the blocking power of broad patents, is particularly relevant in light of the breadth of patent coverage frequently sought by inventors of upstream foundational drug Discovery Tools.

These concerns are reflected in the policy of the NIH regarding the appropriate protection and licensing of federally-funded tool inventions.²⁰ While acknowledging the need for funding recipients to capture the value of their tool inventions, certain licensing practices, such as demand for reach-through royalties that can contribute to a royalty stacking problem, are considered inconsistent with the NIH's

17. Michael A. Heller, and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998).

18. *Id.* at 699.

19. Robert P. Merges, and Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 *COLUM. L. REV.* 839 (1990).

20. *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, Federal Register Notice*, 64 *Fed. Reg.* 72,090 (Dec. 23, 1999).

goal of wide dissemination of federally-funded tool inventions.²¹ The FDA has also expressed the view that the biomedical research tools necessary to expedite the process of developing new medical products should be publicly available.²² The position of the federal government regarding patent protection of biomedical research tools is reflected in the views expressed in its Amicus Brief submitted to the Supreme Court in *Merck v. Integra*²³ endorsing a broad reading of the scope of 35 U.S.C. § 271(e)(1), the so-called FDA exemption from infringement, which protects the unauthorized use of patented inventions where such use is reasonably related to the development and submission of information to the FDA.²⁴ In the view of the government, a broad statutory exemption would lessen the impact of

21. *Id.* at 72,091 (“In the final policy, the NIH has left considerable discretion to Recipients in determining how to achieve the principle of ensuring appropriate distribution of NIH-funded tools. As articulated by the policy, imposing reach-through royalty terms as a condition of use of a research tool is inconsistent with this principle. When transferring an NIH-funded research tool to a for-profit entity that intends to use the tool for its own internal purposes, Recipients are entitled to capture the value of their invention. Arrangements such as execution or annual fees are an appropriate way for Recipients to do so. Royalties on the sale of a final product that does not embody the tool, or other reach-through rights directed to a final product that does not embody the tool discourage use of tools and are not appropriate in these circumstances. Royalties on the sale of final products are more appropriate to situations where a for-profit entity seeks to commercialize the tool, e.g., by developing a marketable product or service, or incorporating the tool into a marketable product or service.”).

22. FOOD & DRUG ADMIN., U.S. DEPT’ OF HEALTH & HUMAN SERVS., CHALLENGE AND OPPORTUNITY ON THE CRITICAL PATH TO NEW MEDICAL PRODUCTS, p 8 (March 2004) (“The goal of critical path research is to develop new, publicly available scientific and technical tools—including assays, standards, computer modeling techniques, biomarkers, and clinical trial endpoints—that make the development process itself more efficient and effective and more likely to result in safe products that benefit patients. Such tools will make it easier to identify earlier in the process those products that do not hold promise, thus reducing time and resource investments, and facilitating the process for development of medical products that hold the most promise for patients.”).

23. Brief for the United States as Amicus Curiae supporting Petitioner, *Merck v. Integra*, 545 U.S. 193 (2005) (No. 03-1237).

24. In its Amicus Brief supporting the grant of a writ of certiorari, the government decried the narrow reading of the exemption provided by the Federal Circuit in its review of the case in *Integra v. Merck*, 331 F.3d 860 (Fed. Cir. 2003). According to the government, “the affected federal agencies, including FDA and NIH, believe that the court of appeals’ decision is likely to restrict significantly the development of new drugs. Indeed, FDA is aware of anecdotal evidence that the court of appeals’ decision is already adversely affecting the legal advice given to drug researchers regarding their ability to use patented inventions in new drug research.” Brief for the United States as Amicus Curiae On Petition for a Writ of Certiorari to the United States of Appeals for the Federal Circuit at 19, *Merck v. Integra*, 545 U.S. 193 (2005) (No. 03-1237), available at <http://www.usdoj.gov/osg/briefs/2004/2pet/6invt/2003-1237.pet.ami.inv.pdf>.

tool patents on the drug development process to the benefit of the public.

Not all who have reviewed the impact of patent protection of research tools have found a significant reduction in innovation in the pharmaceutical industry. Walsh et al.,²⁵ using interviews and archival data, have concluded that despite the increase in patents on research tools, the discovery of novel drugs has not been significantly impeded. According to the authors,

[n]otwithstanding concerns about the proliferation of IP on research inputs and about the ability of rights holders to limit access to upstream discoveries and promising research targets, the problem was generally considered to be manageable. Firms reported a variety of private strategies and institutional responses that limited the adverse effects of the changing IP landscape. Although negotiations over IP and licensing fees surely affect access, and sometimes choice of projects, our conclusion is that patents on research tools do not yet pose the threat to research projects that they might given the number of patents and diversity of owners.²⁶

The issue of the advisability of patent protection for biomedical research tools remains the subject of considerable debate. As noted in the Introduction, however, we make no attempt in this Article to resolve this policy debate. Our focus is on the validity, enforceability and exploitation, under current law, of patent rights covering Discovery Tools. We conclude that the existing legal framework allows for the enforcement of a valid patent claim to a Discovery Tool and for the compensation of the Discovery Tool inventor in the form of reach-through royalties. At least with respect to this type of high-value, foundational, rival-in-use research tool, such compensation from the tool user may adequately reflect the significant contribution that such a tool can make to drug discovery and, thereby, strike the appropriate balance between the interests of key stakeholders in the drug development process.

III. Patentability of Discovery Tools

As described in Part II above, a Discovery Tool can have an essential role in the development of a pharmaceutical drug product

25. John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 285-340 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

26. *Id.* at 322.

and, accordingly, has the potential for high value in the marketplace. In this Part III of the Article, we discuss the type and scope of patent protection available to a Discovery Tool inventor under U.S. patent law. A patentability analysis of a Discovery Tool is undertaken, which confirms that tools of this type are indeed patentable. In addition, we focus on the legal reasoning underlying our conclusion that patent claims that reach through a screening tool to an as-yet-undiscovered drug candidate (that could be found through the use of such tool) are not patentable. Specifically, we conclude that patent claims to an undiscovered compound or claims to a therapeutic method using that undiscovered compound are invalid (1) where the compound that is necessary to practice the treatment method is described only in terms of its function, and (2) where the only means described by the inventor in the patent application for finding such a compound is the use of the inventor's Discovery Tool in a trial and error process of searching for "hits," i.e., compounds that have the desired functional activity.

A. University of Rochester v. Searle – An Exemplary Case

The holdings of the District Court and the Federal Circuit in *University of Rochester v. Searle*²⁷ provide the basis for our analysis of the type and scope of patent protection available to a Discovery Tool inventor under U.S. patent law. The case involved an allegation by the holder of a patent covering a Discovery Tool (the University of Rochester) that various pharmaceutical company defendants (G.D. Searle & Co., Inc., Monsanto Co., Pharmacia Corp., and Pfizer Inc. ("Searle")) infringed reach-through claims of the patent by the sale of the defendant's drug products.

1. Background

Scientists at the University of Rochester identified the separate functions of two closely related enzymes, PGHS-1 and PHGS-2, and developed a method for screening for drugs that selectively inhibit one of the two enzymes.²⁸ The enzymes are involved in the production of prostaglandins in the body. PGHS-1 is expressed in the gastrointestinal tract, and the hormones produced there protect the stomach lining. PGHS-2 produces prostaglandins responsible for pain and inflammation. Traditional medicines such as aspirin and

27. 249 F. Supp. 2d 216 (W.D.N.Y. 2003), *aff'd*, 358 F.3d 916 (Fed. Cir. 2004).

28. The PGHS abbreviation refers to prostaglandin H synthase enzyme (also known as cyclooxygenase or Cox).

ibuprofen inhibit both enzymes and result in reduced pain and inflammation, along with undesirable side effects such as stomach upset, irritation, ulcers, and bleeding. The Rochester scientists developed a screening assay for use in the identification of compounds that would selectively inhibit PGHS-2, and would not affect the function of PGHS-1, thus avoiding the negative side effects that result from the use of non-specific PGHS inhibitors. A drug that comprised such a selective PGHS-2 inhibitor would reduce pain and inflammation, not affect the stomach lining, and constitute a considerable medical advance.

The university obtained two patents to cover its claimed inventions. The first, U.S. Patent No. 5,837,479 (the '479 patent), was directed to a screening method "for identifying a compound that inhibits prostaglandin synthesis catalyzed by mammalian prostaglandin H synthase-2 (PGHS-2)." Subsequently, Rochester obtained U.S. Patent No. 6,048,850 (the '850 patent) with claims directed to therapeutic methods of treatment using compounds that could be identified using the screen covered in the '479 patent. There were no specific compounds disclosed in either of the Rochester patents. The therapeutic method claims of the '850 patent were the subject of the lawsuit in which the University of Rochester sued Searle for patent infringement. These claims were directed to methods of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host.²⁹ The defendants challenged the validity of the Rochester patent by arguing that the claims were not sufficiently described or enabled by the specification.

The district court in the *Rochester* case granted summary judgment for Searle, holding that the treatment claims of the '850

29. Representative Claim 6 of the '850 patent is as follows: "A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the ability of the non-steroidal compound to selectively inhibit the activity of the PGHS-2 gene product is determined by: a) contacting a genetically engineered cell that expresses human PGHS-2, and not human PGHS-1, with the compound for 30 minutes, and exposing the cell to a pre-determined amount of arachidonic acid; b) contacting a genetically engineered cell that expresses human PGHS-1, and not human PGHS-2, with the compound for 30 minutes, and exposing the cell to a pre-determined amount of arachidonic acid; c) measuring the conversion of arachidonic acid to its prostaglandin metabolite; and d) comparing the amount of the converted arachidonic acid converted by each cell exposed to the compound to the amount of the arachidonic acid converted by control cells that were not exposed to the compound, so that the compounds that inhibit PGHS-2 and not PGHS-1 activity are identified." U.S. Patent No. 6,048,850, col.71-72 (filed Jun. 7, 1995).

patent were invalid as not in compliance with either the written description or the enablement requirement for patentability, as set forth in 35 U.S.C. § 112 ¶ 1. The Federal Circuit affirmed the district court's ruling. A request for an *en banc* rehearing was denied.

2. "Reach-Through" Claims Distinguished

The claims included in the Rochester '479 patent were directed to the use of a screening method for identifying a compound that selectively inhibits PGHS-2 activity, i.e., the use of a Discovery Tool. Access to such a compound was not required to utilize the claimed method since the method could be performed whether or not a specific compound with the desired activity (i.e., the ability to selectively inhibit the function of the PGHS-2 enzyme) was available. In other words, the practice of the screening method of the Rochester '479 patent was not dependent upon the successful use of the method resulting in the identification of a selective PGHS-2 inhibitor; the method could be practiced in the *search* for such a compound. In that sense, the screening claim of the Rochester '479 patent did not depend upon, nor reach through to, a yet-to-be made discovery.

In contrast, the therapeutic method claims of the Rochester '850 patent, which required administration of a yet-to-be discovered selective PGHS-2 inhibitor, are classic reach-through claims. These claims required the use of a compound that was described only by its function (i.e., selectively inhibiting the activity of the PGHS-2 enzyme) and covered a treatment method that could not be practiced without such a compound.³⁰ Simply put, the reach-through claims of the Rochester '850 patent went beyond what had actually been discovered by researchers at the University of Rochester to cover a method of treatment that was dependent upon the successful use, at some point in the future, of Rochester's Discovery Tool.

3. Patent Protection of Discovery Tools Under Rochester

For the purpose of our analysis, we have assumed that the inventions claimed in both Rochester patents and the Discovery

30. While the claims in the Rochester patent were method of treatment claims and not claims to compounds, the cases on written description relied on by the district court in *Rochester* (i.e., *Fiers*, *Eli Lilly* and *Enzo*) each addressed composition of matter claims. The Rochester district court found this difference in the form of the claims irrelevant to its holding, stating that "[v]irtually any compound claim could be transformed into a method claim ... simply by means of wording the claim in terms of a method of using the compound. With respect to the issue before the Court, then, this is little more than a semantic distinction without a difference." 249 F. Supp. 2d 216, 228 (W.D.N.Y. 2003).

Tools under consideration in this Article have met three of the four statutory requirements for patentability under U.S. law, i.e. that the claimed inventions are novel, not obvious, and useful.³¹ In the discussion that follows, we review the requirements for written description and enablement of a claimed invention under 35 U.S.C. § 112 ¶ 1,³² the fourth statutory requirement for patentability. This last requirement establishes the critical criteria for differentiating a valid patent claim from an invalid reach-through claim. The question to be answered is whether an “invention” that is the subject of a reach-through claim can be adequately described by the content of the patent, and whether, on the basis of the information contained in the patent and what is known in the relevant field, one of ordinary skill in such field would be enabled to make and use the invention without undue experimentation. With the above qualifications as to our focus in mind, we turn to the insights provided by *Rochester* regarding the validity of patent claims relating to Discovery Tool invention.

The claims included in the Rochester ‘479 patent covering the use of the University’s Discovery Tool were not in dispute in *Rochester* and, accordingly, there was no ruling on the validity of those claims. However, both the district court and the Federal Circuit in their *Rochester* decisions expressed the view that the screening method claims were sufficiently described in the Rochester patents to meet the requirements of 35 U.S.C. § 112 ¶ 1. The district court affirmatively noted that although “detail is lacking” in the description of the compound to be administered in the method of treatment claims in the ‘850 patent, “[t]he patent does describe how to conduct assays ‘for screening of drug actions on both [enzymes].’”³³ According to the Federal Circuit “[t]he only claims that appear to be supported by the specification [of the ‘850 patent] are claims to assay methods, but those claims were already issued in the ‘479 patent.”³⁴ Moreover, the Federal Circuit stated in a closing footnote that “[h]ere

31. The U.S. patent law requires that subject matter of a patent claim be novel (35 U.S.C. § 102 (2000)), be nonobvious in view of what would have been known at the time of filing the patent application by one of ordinary skill in the relevant art (35 U.S.C. § 103 (2000)) and that the claimed subject matter be useful (35 U.S.C. § 101 (2000)).

32. 35 U.S.C. § 112 ¶ 1 requires that patent applications contain “a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.”

33. *Univ. of Rochester v. G.D. Searle & Co.*, 249 F. Supp. 2d 216, 232 (W.D.N.Y. 2003), *aff’d*, 358 F.3d 916 (Fed. Cir. 2004).

34. *Univ. of Rochester*, 358 F.3d at 928.

the patentee has done no more than invent a search method, i.e., a method of identifying a selective COX-2 inhibitor . . .”³⁵ In our view, the language of both the district court and the Federal Circuit in *Rochester* supports the conclusion that a Discovery Tool inventor would be entitled to claims directed to a novel, nonobvious, and useful composition of matter that is a protein target, and to claims directed to the use of that protein target in a novel, nonobvious, and useful method for screening for drug candidates that would specifically interact with that protein target. However, based on the *Rochester* courts’ interpretation of 35 U.S.C. § 112 ¶ 1, a “reach-through” compound claim or method of treatment claim (such as the one of the Rochester ‘850 patent) would be held invalid for a failure to meet the statutory requirements for written description and enablement.³⁶ A review of the reasoning of the *Rochester* courts regarding such reach-through claims is presented in the following sections.

a. Reach-Through Claims and the Written Description Requirement

In assessing the patentability of the therapeutic method claims in the Rochester ‘850 patent, the district court framed the question before it as follows:

[t]he real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for

35. *Id.* at 930 n.10.

36. Our conclusion regarding the validity of patent claims relating to Discovery Tool inventions described in this Part III is consistent with that presented in a comparative study of reach-through claims by the U.S. Patent and Trademark Office, the European Patent Office and the Japanese Patent Office. (THE TRILATERAL CO-OPERATION. MUTUAL UNDERSTANDING IN SEARCH AND EXAMINATION: COMPARATIVE STUDY ON BIOTECHNOLOGY PATENT PRACTICES (TRILATERAL PROJECT B3B) (THE TRILATERAL CO-OPERATION, 2001). http://www.trilateral.net/projects/biotechnology/reach_through_claims/). Each of these offices, based on the applicable law of their jurisdiction, assessed the patentability of claims in a patent application that described a novel protein receptor that was implicated in a disease state. Among the claims assessed were those to the novel receptor, to screening methods for the isolation of compounds that modulate the activity of the receptor, and reach-through claims directed to such compounds and to methods of treatment that required the use of such compounds. All three of the offices concluded, as we do here, that claims to the newly discovered and isolated receptor and claims to a screening method using the receptor were patentable. However, in the absence of working examples of compounds that modulate the activity of the receptor, the reach-through claims were not valid for failure to meet the statutory requirements for patentability (in the case of the U.S. analysis, the written description and enablement requirements under 35 U.S.C. § 112 ¶ 1).

finding such a compound is essentially a trial-and-error process.³⁷

The court relied on recent Federal Circuit precedent in concluding that such a written description does not comply with the requirements for patentability under 35 U.S.C. § 112 ¶ 1.³⁸

In providing its interpretation of the written description requirement, the district court in *Rochester* cited the Federal Circuit's holding in *Vas-Cath Inc. v. Mahurkar*³⁹ for the proposition that a patent application must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. The district court then reviewed the Federal Circuit's holding in *Regents of the University of California v. Eli Lilly & Co.*⁴⁰ In *Eli Lilly*, the Federal Circuit affirmed a district court ruling that certain patent claims were invalid because the specification did not provide an adequate written description of a human DNA encoding insulin. The human sequence was not disclosed, despite the constructive example explaining how to obtain a cDNA encoding human insulin. The application only disclosed the sequence for rat insulin DNA, which was not enough to adequately describe the human DNA sequence. The court ruled that the invention of a gene of one species, e.g., a rat, does not sufficiently describe the gene of another species, e.g., a human. According to the court in *Eli Lilly*, the written description requirement for patentability is intended to ensure that an inventor describe his or her invention in the patent application—and not be permitted to obtain an exclusive right over an invention that has yet to be made.

The *Rochester* district court also cited the Federal Circuit's holding in *Fiers v. Revel*.⁴¹ In that case, where the claims were

37. *Univ. of Rochester*, 249 F. Supp. 2d at 221.

38. The opinions expressed in the Federal Circuit's decision to deny *en banc* review of the *Rochester* case indicated disagreement among the circuit judges regarding whether the written description validity requirement is new and whether it is good law. Judge Lourie, who concurred in the decision, expressed the view of a number of the judges in stating that "there is and always has been a separate written description requirement in the patent law." *Univ. of Rochester v. Searle*, 375 F.3d 1303, 1305 (Fed. Cir. 2004) (Lourie, J., concurring). However, Judges Rader, Gajarsa and Linn, in their dissent, took the position that the written description requirement was only created in 1997 in the *Eli Lilly* case, and, in the words of Judge Rader, is a "new judge-made doctrine [that] has created enormous confusion . . ." *Id.* at 1308 (Rader, J., dissenting).

39. 935 F.2d 1555, 1562-63 (Fed. Cir. 1991).

40. 119 F.3d 1559, 1568 (Fed. Cir. 1997).

41. 984 F.2d 1164, 1171 (Fed. Cir. 1993).

directed to a DNA sequence, the patent application failed to satisfy the written description requirement because the specification did not disclose the complete sequence. Instead, the application only disclosed a method for obtaining the DNA sequence. The court stated that a description of DNA requires “a precise definition, such as by structure, formula, chemical name, or physical properties . . .”⁴² Claiming a DNA sequence that was not described, based on a disclosure of a method for isolating the sequence, was “. . . an attempt to preempt the future before it has arrived.”⁴³

The district court in *Rochester* concluded its review of written description jurisprudence by citing the Federal Circuit’s holding in *Enzo Biochem, Inc. v. Gen-Probe Inc.*,⁴⁴ in which the Federal Circuit adopted the standard set forth in the U.S. Patent and Trademark Office (“PTO”) Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 ¶ 1 “Written Description” Requirement (“Written Description Guidelines”).⁴⁵ According to the Written Description Guidelines, the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics,” including, *inter alia*, “functional characteristics when coupled with a known or disclosed correlation between function and structure”⁴⁶ The Written Description Guidelines, though, do not prohibit patentability without actual, physical production of the invention. An applicant can show possession of the claimed invention by describing the invention with all of its limitations using words, structures, figures, diagrams, and formulas. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. There are no bright lines that set out what is and is not a sufficient written description. The Written Description Guidelines make clear, however, that one cannot validly

42. *Id.*

43. *Id.*

44. 296 F.3d 1316 (Fed. Cir. 2002).

45. *Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 ¶1, “Written Description” Requirement*, 66 Fed. Reg. 1099 (Jan. 5, 2001) (“Written Description Guidelines”). The Guidelines are not binding, but may be given judicial notice to the extent they do not conflict with the statute.

46. 66 Fed. Reg. at 1106.

claim a compound when disclosing only its function in the absence of a known or disclosed structure-function correlation.⁴⁷

After its review of the Federal Circuit's written description requirement, the district court in *Rochester* then applied its interpretation of that requirement to the facts before it. The court acknowledged the significance of the discovery by the Rochester scientists that a selective PGHS-2 inhibitor would constitute an important advance in the treatment of pain and inflammation. However, the therapeutic methods claimed in the '850 patent could not be practiced without such a selective inhibitor and, in the opinion of the court, the Rochester scientists neither isolated such an inhibitor nor described "a process through which one skilled in the art would be directly led to such a compound."⁴⁸ The court's review of the '850

47. The assessment of the correlation is based on facts at the time of filing a patent application. As science and technology advances, so will the understanding of how certain characteristics correlate with structure. For example, antibodies possess a structure that has been accepted by scientists and the courts to correlate with a function of binding to a particular antigen. As noted in *Enzo*,

the PTO would find compliance with § 112, P 1, for a claim to an "isolated antibody capable of binding to antigen X," notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature."

Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) (internal citations omitted).

Thus, the possession of the antigen itself permits one of skill in the art to routinely obtain an antibody to that antigen and, accordingly, a patent claim to the antibody in that circumstance is valid. See *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004) (holding that the characterization of an antibody by its binding affinity to an antigen in the specification of a patent meets the statutory written description requirement if the antigen is adequately characterized by its structure, formula, chemical name or physical properties or by deposition of the antigen in a public depository.) But see *In re Kenneth Alonso*, No. 2008-1079 (Fed. Cir. Oct. 30, 2008) (A claim to a method for treating cancer by administering a monoclonal antibody that binds to a neurofibrosarcoma cell, where only one monoclonal antibody was disclosed, was found invalid because the scope of the genus was found to vary substantially (there was shown to be considerable antigenic heterogeneity of tumors both between patients and metastatic sites within a single patient) and the single antibody disclosed was found to be insufficiently representative to provide adequate written description support.).

With advances in computer modeling and the advent of reliable computer-based screening of virtual small molecule libraries, the definition of routine experimentation in the context of compound screening methods will evolve. Should rational drug design replace trial and error screening in the search for small molecules that modulate drug targets, the scope of valid claims in patent applications that describe and enable the use of drug targets is likely to expand to include yet-to-be-identified small molecule modulators of the targets.

48. *Univ. of Rochester*, 249 F. Supp. 2d at 228.

patent indicated that nowhere in the specification, “is there even any suggestion that the inventors had identified so much as one compound that would be suitable for use in practicing the claimed invention.”⁴⁹ To the extent that any description of the required inhibitor was provided, it was functional in nature and, in the absence of a known or disclosed correlation between function and structure, such a description failed to meet the requirements of the Written Description Guidelines adopted by the Federal Circuit in *Enzo*.⁵⁰ Such failure to identify or adequately describe the required PGHS-2 inhibitor led the court to the following conclusion:

It means little to “invent” a method if one does not have possession of a substance that is essential to practicing that method. Without that substance, the claimed invention is more theoretical than real; it is, as defendants argue, akin to “inventing” a cure for cancer by utilizing a substance that attacks and destroys cancer cells while leaving healthy cells alone. Without possession of such a substance, such a “cure” is illusory, and there is not meaningful possession of the method.⁵¹

The *Rochester* district court opinion also made clear that the disclosure of a trial and error method for the identification of the required PGHS-2 inhibitor is not sufficient to satisfy the written description requirement. Such a method fails to “directly lead” to a compound required for the practice of the therapeutic methods claimed in the ‘850 patent. “Knowing the ‘starting point’ is not enough; that is little more than a research plan. The patent describes how to test compounds to determine whether they work, but it does not set forth any procedure that *will necessarily lead to* discovery of such a compound”⁵² (Emphasis added.)

49. *Id.* at 225.

50. *Id.* at 227 (“*Union Oil* and the other cases relied upon by plaintiff, such as *In re Herschler*, 591 F.2d 693 (C.C.P.A. 1979), and *In re Edwards*, 568 F.2d 1349 (C.C.P.A. 1978), indicate, as this Court has recognized, that it is not always necessary to set forth exact chemical formulas to satisfy § 112, ¶ 1, but they do not hold that a functional description of a chemical compound is necessarily sufficient. Rather, these cases simply reflect the fact that ‘compliance with the written description requirement is essentially a fact-based inquiry that will ‘necessarily vary depending on the nature of the invention claimed.’” *Enzo*, 296 F.3d at 1324 (quoting *Vas-Cath*, 935 F.2d at 1563). In all of those cases, however, the description was found to contain enough information to lead a person skilled in the art to the claimed compound The ‘850 patent is completely lacking in that respect.”).

51. *Univ. of Rochester*, 249 F. Supp. 2d at 228.

52. *Id.* at 229.

The district court in *Rochester* concluded that “without possession, or at least knowledge, of such a compound, or of a method to yield such a compound, the inventors could not have possessed the claimed invention, i.e., a method of treatment using the compound.”⁵³ The court did not require that an exact chemical structure be included in the patent application. Indeed, the court stated that a patent need only “set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed.”⁵⁴ The Rochester ‘850 patent, however, did not do that. In the words of the court,

the patent does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work.⁵⁵

On appeal of the *Rochester* case, the Federal Circuit affirmed the district court’s holding that the ‘850 patent did not comply with the written description requirement of 35 U.S.C. § 112 ¶ 1. In the opinion for the court, Judge Lourie wrote that it was

undisputed that the ‘850 patent [did] not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent’s specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed method [were] disclosed, nor has any evidence been shown that such a compound was known.^{56, 57}

53. *Id.*

54. *Id.* at 227.

55. *Univ. of Rochester*, 249 F. Supp. 2d at 224.

56. *Univ. of Rochester*, 358 F.3d at 927.

57. The Federal Circuit in *Rochester* was clear that in the null case, *i.e.*, where a patent specification provides no examples of a compound necessary to practice the claimed invention, the patentability requirements under 35 U.S.C. § 112 ¶ 1 are not met. But what of the Discovery Tool inventor who uses her tool to identify one or a small number of compounds that modulate the novel target that is embodied in her tool and has been linked to a human disease state? Can she then validly claim *any* compound that modulates the target and a method of treatment using any such compound? The Discovery Tool inventor would be attempting to support a broad genus with some number of species, and the fact-specific question will be whether they are representative.

The Federal Circuit has recently addressed this species/genus issue in relation to the written description requirement in *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115 (Fed. Cir. 2008). The *Carnegie* court held that, based on the facts in that case, one species was not enough to support a broad genus. The court found Carnegie Mellon's patent invalid for failure to meet the written description requirement. The claims were directed to a recombinant plasmid containing a cloned gene isolated from a bacterial source for expression of a polymerase. The patent disclosed *E. coli* as the bacterial source. Carnegie Mellon had filed suit to enforce its patent against Roche in view of the Roche's successful *Taq* polymerase product, which is isolated from another bacteria called *Thermus aquaticus*. In *Carnegie*, the Federal Circuit agreed that the specification only supported claims to *E. coli* bacterial sources, and not *Taq*. There was not a representative number of species described to support a genus of *any* bacterial source.

The Federal Circuit in *Carnegie* relied upon *Lilly* and reiterated that “[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” *Id.* at 1122 (citing *Eli Lilly*, 119 F.3d at 1569). Thus, reading the patent specification, a person of ordinary skill in the art must be able to understand that a genus was invented, not just a species. *Id.* at 1124. As in *Rochester*, the *Carnegie* court endorsed the Written Description Guidelines (see *supra* note 45): “[W]e find [the Written Description Guidelines] to be an accurate description of the law by the agency responsible for examining patent applications, and thus persuasive authority” *Id.* Quoting from the Guidelines, the Court noted that “[s]atisfactory disclosure of a ‘representative number’ depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot be achieved by disclosing only one species within the genus.*” *Id.* Thus, in *Carnegie*, the Federal Circuit held that the disclosure of one species did not support the breadth of a claim to a genus because a single species was not a representative number. The narrow disclosure of the *E. coli* gene was not representative of and did not support the genus. The Federal Circuit set out what is needed to meet the written description requirement in another way: “To satisfy the written description requirement in the case of a chemical or biotechnological genus, more than a statement of the genus is normally required. One must show that one has possession, as described in the application, of sufficient species to show that he or she invented and disclosed the totality of the genus.” *Id.* at 1126.

In *Carnegie*, the court noted that “[w]hether the written description requirement is satisfied is a fact-based inquiry that will depend on the nature of the claimed invention, *Enzo*, 323 F.3d at 963, and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.” *Id.* at 1122. The *Carnegie* court stated “that ‘what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.’” *Id.* at 1126 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005)). The *Carnegie* court recognized, however, that the applicable “knowledge may change as time progresses.” *Id.* at 1122.

There is a constant advance and increase of the knowledge base of any particular technological or scientific field. Therefore, an assessment of the written description requirement will need to be made against a backdrop of the changing state of the art, with consideration of the maturity of the technology, and of the knowledge of a person of ordinary skill in the art in that field. As is currently the case with antibodies, where

Furthermore, according to the court, “the ‘850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art at the relevant time”⁵⁸ At the conclusion of the Federal Circuit’s written description analysis of Rochester’s ‘850 patent, Judge Lourie provided the following observation in a closing footnote:

Although we have treated the issue in this case as one of written description, as it was argued and decided below, underlying that question is the fundamental issue whether Rochester actually invented the subject matter it claimed in the ‘850 patent as required by 35 U.S.C. § 102(f). As the Supreme Court has cautioned, “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” *Brenner v. Manson*, 383 U.S. 519, 536, 16 L.Ed.2d 69, 86 S.Ct. 1033 (1966). Here the patentee has done no more than invent a search method, i.e., a method of identifying a selective COX-2 inhibitor, much less did it invent, as claimed in the ‘850 patent, a method of using any such compound to selectively inhibit COX-2 in humans. Under these circumstances, it might appear that the patentee also failed to satisfy the requirements of section 102(f).⁵⁹

b. Reach-Through Claims and the Enablement Requirement

The *Rochester* district court considered the issue of enablement, in addition to the written description requirement, in assessing the therapeutic method claims in Rochester’s ‘850 patent.⁶⁰ The court began with a restatement of the enablement requirement for patentability as set forth in 35 U.S.C. § 112 ¶ 1. Under the

extensive knowledge in the public domain of the structure and function of these biomolecules allows a party that has characterized a novel biomedical target to validly claim a yet-to-be obtained antibody that binds to such target (*see, supra* note 47), advances in x-ray crystallography, molecular modeling, and bioinformatics may eventually permit a patent applicant who has characterized a novel target and who discloses in her patent application only a limited number of (or even no) small molecule species that interact with the target to validly claim a genus (i.e., all small molecules that interact with the target), in compliance with the requirements of 35 U.S.C. § 112 ¶ 1.

58. *Univ. of Rochester*, 358 F.3d at 929.

59. *Univ. of Rochester*, 358 F.3d at 930 n.10.

60. The Federal Circuit in *Rochester*, basing its affirmation of the district court’s decision on its written description analysis, did not review the lower court’s holding regarding enablement.

enablement requirement, one of skill in the art, after reading the patent specification and in view of what is already known from the prior art literature, must be able to make and use the full scope of the claimed invention without requiring undue experimentation.⁶¹ The court cited Federal Circuit precedent in explaining the meaning of “undue experimentation.” In *PPG Indus., Inc. v. Guardian Indus. Corp.*, the Federal Circuit stated that

[t]he test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.⁶²

In *In re Wands*,⁶³ the Federal Circuit identified the following factors that may be considered in deciding whether the disclosure of a patent would require “undue experimentation”: (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) relative skill of those in the art; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of any working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.⁶⁴ The determination that “undue experimentation” is needed to make and use the claimed invention is a fact-based analysis and requires the careful weighing of multiple factors depending on the circumstances of the particular case.⁶⁵

Applying the enablement standard as developed in Federal Circuit precedent, the *Rochester* district court ruled that the therapeutic method claims of the ‘850 patent did not comply with the enablement requirement of 35 U.S.C. § 112 ¶ 1. The court noted that the ‘850 patent required trial and error to attempt to find a compound that would selectively inhibit the PGHS-2 enzyme, a compound essential to the practice of the patent’s therapeutic method claims. The ‘850 patent, however, lacked the necessary “reasonable detail . . .

61. See, e.g., *In re Angstadt*, 537 F.2d 498, 502-04 (C.C.P.A. 1976).

62. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996) (quoting *Ex Parte Jackson*, 217 USPQ 804, 807 (1982)).

63. 858 F.2d 731 (Fed. Cir. 1988).

64. *Id.* at 737.

65. *Id.* at 736-37.

to enable members of the public to understand and carry out the invention.”⁶⁶ The court concluded that the patent “provides precious little guidance in the way of selecting a particular compound, or even of narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.”⁶⁷ In the words of the court, “[a]t most, [the patent’s] . . . description will enable a person of ordinary skill in the art to *attempt to discover* how to practice the claimed invention.”⁶⁸ Such a description does not satisfy the enablement standard of 35 U.S.C. § 112 ¶ 1.

B. Conclusion

Our analysis of the type and scope of patent protection available to a Discovery Tool inventor under U.S. patent law yields the following conclusion. An inventor who has identified a novel drug target and described a screening method based on the target, but who has yet to identify compounds that modulate the activity of the target, may obtain valid claims to the target itself and to the screening method (the essential aspects of the Discovery Tool). However, the inventor will not be able to reach through to claim yet-to-be-discovered compounds that modulate the activity of the target (our philosopher’s stone) or methods of treating patients through the use of such compounds.

Should the inventor intend to profit from his or her scientific contribution by granting to a third party a right to use the Discovery Tool for the purpose of identifying drug candidates, he or she must be able to enforce such rights against an unauthorized user of the patented tool and to obtain compensation from an authorized user in a form that does not constitute patent misuse. In Part IV of this Article, we address the issue of patent enforcement in the context of Discovery Tool use, reviewing recent case law relating to the statutory FDA exemption under 35 U.S.C. § 271(e)(1) and the common law experimental use exception. In Part V, we discuss the legality of reach-through royalties as a form of compensation of the Discovery Tool inventor for an authorized third party’s use of the tool.

66. *Univ. of Rochester*, 249 F. Supp. 2d at 232 (citing *Genentech v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

67. *Id.* at 233.

68. *Id.* at 235.

IV. Enforceability of Discovery Tool Patents

Given that patents may cover Discovery Tools and their use, we turn our attention to whether and to what extent such patents are enforceable against potential infringers. Enforcement of a patent hinges upon its validity, and that is no different in the case of patents on Discovery Tools. However, Discovery Tools patents have also faced challenges in terms of enforcement based on both a statutory exemption from infringement (35 U.S.C. § 271(e)(1)) directed to the drug development process and the common law experimental use exception to patent infringement liability. In our view, while triggering significant uncertainty and debate on the topic, neither of these potential limitations ultimately undermines the enforceability of Discovery Tool patents.

Since the U.S. Supreme Court's recent decision in *Merck v. Integra*,⁶⁹ in which the breadth of the statutory exemption was addressed, the impact of the Court's holding as applied to research tools has been widely debated. In this Section, we analyze the enforceability of patent claims covering Discovery Tools post-*Merck*, while highlighting the key deficiencies and likely impact of the decision as applied to such tools. We argue that, while *Merck v. Integra* may have significant implications for the enforceability of research tool patents generally, it does not undermine the enforceability of patents on Discovery Tools. Moreover, we argue that such patents are otherwise enforceable notwithstanding the so-called experimental use exception, which the Federal Circuit has interpreted as very narrow in scope in its decision in *Madey v. Duke University*.⁷⁰

A. Statutory Exemption From Infringement (35 U.S.C. § 271(e)(1)) and *Merck v. Integra*

1. Background: *Roche v. Bolar*

A United States patent confers on its holder the right to exclude others during the term of the patent from making, using, selling, offering to sell and importing within the United States those inventions claimed in such patent. Nonetheless, as the Federal Circuit has observed, “[i]t is well-established . . . that the

69. 545 U.S. 193 (2005).

70. 307 F.3d 1351 (Fed. Cir. 2002).

[unauthorized] use of a patented invention, without either manufacture or sale, is actionable.”⁷¹

It was the strict application of this principle in the context of drug development in *Roche Products v. Bolar Pharmaceuticals* that laid the foundation for the enactment of the statutory exemption in 35 U.S.C. § 271(e)(1). In that case, Roche, a pharmaceutical company, owned certain patents covering a chemical compound that was the active ingredient in its successful brand name prescription sleeping pill “Dalmane.” Bolar, a generic pharmaceutical company and potential competitor of Roche, was interested in marketing a generic version of “Dalmane” upon the expiration of the Roche’s relevant patents. Bolar imported and began pre-market testing to obtain the data necessary for the submission of a New Drug Application to the Food and Drug Administration (“FDA”). Roche then sued Bolar for patent infringement and won, overcoming Bolar’s defense that its activity was “experimental” since it was strictly limited to testing and investigation needed to obtain FDA approval. The Federal Circuit found that such activity, while potentially desirable as a policy matter, constituted an unauthorized “use” infringing Roche’s exclusive rights under its patent that was not protected by any applicable exception for experimental activity, and therefore constituted patent infringement.

At least in part as a reaction to the Federal Circuit’s decision in *Roche v. Bolar*,⁷² Congress enacted a statutory exception to patent infringement as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. Under 35 U.S.C. § 271(e)(1),

it shall not be an act of infringement to make, use, offer to sell, or sell within the U.S. or import into the U.S. a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

71. *Roche Prods. v. Bolar Pharms.*, 733 F.2d 858, 861 (Fed. Cir. 1984) (citing *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964); *Coakwell v. United States*, 372 F.2d 508, 510 (Ct. Cl. 1967)) (noting that “the patentee does not need to have any evidence of damage or lost sales to bring an infringement action”).

72. The Supreme Court has noted that “[u]ndoubtedly the decision in *Roche* promoted the proposal of [the exemption]; but whether that alone accounted for its enactment is quite a different question.” *Lilly v. Medtronic*, 496 U.S. 661, 670 n.3 (1990).

While this statute raises numerous interpretive issues, the question raised by § 271(e)(1) for purposes of this Article is whether that statutory safe harbor precludes the enforcement of a patent on a Discovery Tool against an infringing party engaged in drug discovery using that tool.

2. *The Landmark Case: Merck v. Integra*

While there is no U.S. Supreme Court case that specifically addresses this question, the Court's decision in *Merck v. Integra*,⁷³ the leading case on the interpretation of § 271(e)(1), offers significant clues as to the likely answer. In that case, Integra owned certain patents relating to Arg Gly Asp peptides (RGD peptides, in single letter notation) that promote cell adhesion by interacting with certain protein receptors on the cell surface, and that are therefore potentially useful in promoting wound healing and biocompatibility of prosthetic devices. A scientist at Scripps Research Institute discovered that blocking those same receptors using the patented peptide inhibits angiogenesis, the process of generating new blood vessels, which might be useful in treating a variety of diseases, including cancer. Merck entered into an agreement with Scripps to fund experiments using the patented peptide to identify potential drug candidates that might inhibit angiogenesis by interacting with this receptor. Integra learned of this agreement and sued Merck for patent infringement. Merck responded that its activities were protected by § 271(e)(1). The Federal Circuit disagreed on the basis of its narrow reading of the scope of § 271(e)(1). According to the court, "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."⁷⁴ As such, the work fell outside of the safe harbor provided by § 271(e)(1), which was intended to allow for only a "*de minimis* encroachment on the rights of the patentee."⁷⁵

The Federal Circuit went on to note the dire consequence of a broad reading of § 271(e)(1) with respect to the research tool industry. In the words of Judge Rader, writing for the court:

[E]xpansion of § 271(e)(1) to include the Scripps Merck activities would effectively vitiate the exclusive rights of

73. 545 U.S. 193 (2005).

74. *Integra v. Merck*, 331 F.3d 860, 866 (Fed. Cir. 2003).

75. *Id.* at 867.

patentees owning biotechnology tool patents. After all, patented tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs. Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions.⁷⁶

The Federal Circuit concluded by stating that the safe harbor under § 271(e)(1) “does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests,”⁷⁷ and, specifically, that exploratory drug discovery is not protected by § 271(e)(1).⁷⁸ By this interpretation, it was clear that the safe harbor under § 271(e)(1) would not limit the rights of inventors of Discovery Tools to enforce their tool patents against potential infringers.

Merck appealed to the United States Supreme Court, and in a landmark ruling that has had a profound effect on the research tools industry, the Court overruled the Federal Circuit in *Merck v. Integra*.⁷⁹ Finding for Merck, the Court adopted a construction of the FDA exemption that considerably broadens its scope as compared to the interpretation of the exemption provided by the Federal Circuit. The Court acknowledged the Federal Circuit’s view that the safe harbor “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”⁸⁰ Nonetheless, the Court significantly expanded the Federal Circuit’s construction of § 271(e)(1), based on the following four principles:

1. The exemption from infringement provided by § 271(e)(1) is not limited to research conducted in clinical trials; use of patented inventions in preclinical studies is exempted under the statute provided that there is a reasonable basis to believe that the experiment will produce the type of information relevant to an FDA submission.

76. *Id.*

77. *Id.*

78. It is axiomatic that a drug candidate need only to be discovered once, and once discovered, the method of its discovery has made its most significant contribution.

79. *Merck v. Integra*, 545 U.S. 193 (2005).

80. *Id.* at 205 (citing *Integra*, 331 F.3d at 867).

2. The preclinical studies that can be exempted under § 271(e)(1) are not limited to those that assess the safety of a drug candidate, conducted in accordance with good laboratory practices regulations. Exempted experiments may be designed to assess a drug candidate's efficacy, mechanism of action, pharmacology, or pharmacokinetics and they need not be conducted in accordance with good laboratory practices.
3. The FDA exemption is not limited to experiments on drugs that ultimately form the basis of an FDA submission. If this were not the case, only the testing of a generic drug would provide the certainty *ex ante* that the experiment would fall within the ambit of § 271(e)(1), and the Supreme Court did not read the statute so narrowly as to apply only to the study of generics.
4. The FDA exemption is not limited to experiments that are ultimately included in a submission to the FDA. According to the Court, the scope of § 271(e)(1)'s exemption is sufficiently broad to include studies that may not be submitted to the FDA "as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'" (citation omitted).⁸¹

While the Court effectively broadened the Federal Circuit's narrow interpretation of § 271(e)(1), its holding failed to provide clear guidance as to whether the exemption applies to the unauthorized use of a Discovery Tool. Specifically, the Court did not describe a bright line demarcating the upstream reach of the exemption. Moreover, the opinion did not clearly articulate a test to be used in distinguishing between the research activities on the critical path for drug development that are exempted under the statute and the discovery activities on the critical path that are outside of the ambit of the exemption. As discussed below, a careful reading of the Supreme Court's ruling provides some guidance as to the upstream boundary of 35 U.S.C. § 271(e)(1). However, there remains ambiguity as to the scope of the exemption.

81. *Merck*, 545 U.S. at 208.

In addition, the Court's decision in *Merck v. Integra* failed to address the impact of the holding on the use of biomedical research tools. The only reference by the Court to the research tool issue appears in Footnote 7, as follows:

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 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.⁸²

This language is, at best, unhelpful and, at worst, inaccurate. In the Court's description of the allegedly infringing acts undertaken by Scripps, they referenced one research project in which Scripps used RGD peptides as "positive controls" against which to measure the efficacy of organic mimetics.⁸³ The use of the peptides in this capacity is clearly use as a research tool. This was recognized by the majority in the Federal Circuit decision,⁸⁴ and so it is surprising that the Supreme Court failed to address the tool issue and, thereby, left unanswered the obvious question of whether the principles articulated in its holding regarding § 271(e)(1) apply to research tools.

Nonetheless, if we assume that the principles articulated by the Court apply to research tools in the same way as they do to other patented inventions, and we consider the language of the *Merck* decision in light of the arguments made by Merck in its Petitioner's Brief, we may shed a degree of light on the Court's intended scope of the § 271(e)(1) exemption as applied to Discovery Tools. Two statements in the Supreme Court ruling are particularly instructive for this analysis. The Court indicated that the safe harbor would protect activity "where a drug maker has a reasonable basis for

82. *Id.* at 205.

83. *Merck*, 545 U.S. at 199 ("Scripps also conducted more basic research on organic mimetics designed to block $\alpha_v\beta_3$ integrins in a manner similar to the RGD peptides . . . ; it appears that Scripps used the RGD peptides in these tests as 'positive controls' against which to measure the efficacy of the mimetics . . .").

84. In footnote 4 of the Federal Circuit's opinion, in *Integra v. Merck*, Judge Rader stated the following: "the dissent asserts that Integra's patented RGD peptides are not research tools, 'but simply new compositions having certain uses.' . . . The dissent does not explain why one of those 'certain uses' cannot embrace use of an RGD peptide as a laboratory tool to facilitate the identification of a new therapeutic." 331 F.3d at 872 n.4.

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”⁸⁵ The Court also noted that the safe harbor does not protect “[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce”⁸⁶ In our opinion, these two statements, interpreted in the context of the position expressed by Merck in its Petitioner’s Brief, provide support for the conclusion that the unauthorized use of a Discovery Tool can fall outside of the ambit of § 271(e)(1).

Not even Merck argued that the use of Discovery Tools for high-throughput screening to identify potential “hits” falls within the scope of exempted activity under § 271(e)(1). Rather, like the Court, Merck acknowledged that there are upstream research activities that are clearly beyond the protection of the exemption, such as where a “university scientist conduct[s] basic research on the cause and progression of a disease” or a “researcher who, having learned of a plausible mechanism of a disease, screens compounds whose structures are not known to be (or reasonably suspected of being) likely to affect the disease, in the hopes of finding one that might do so.”⁸⁷ However, unlike the Court, Merck identifies a “critical threshold” in the path of drug discovery at which point the exemption applies. Specifically, Merck argued, that threshold is where “a researcher endures the unpredictable and open-ended process of screening untested structures and emerges with unmistakable evidence that a particular structure shows promise, in a living body, in treating a particular disease through a known mechanism.”⁸⁸ It is only

85. *Merck*, 545 U.S. at 207.

86. *Id.* at 205-206.

87. Brief of Petitioner at 38-39, *Merck v. Integra*, 545 U.S. 193 (2005) (No. 03-1237), 2005 U.S. S. Ct. Briefs LEXIS 162.

88. Brief of Petitioner at 39; *see also* the following excerpt from the Brief at 37-40:

Extending the exemption beyond the clinical phase—to cover preclinical research, or even a few steps before—is not tantamount to insulating all drug research from the patent laws. The FDA graphically illustrated the point in a recent white paper describing the phases of drug development: . . . As this spectrum illustrates, the FDA exemption can “reach back down the chain of experimentation to embrace” preclinical development, and even further back in the “Critical Path” toward drug development—to efforts to optimize the design of promising drug candidates—without embracing “all experimental activity that at some point . . . may lead to an FDA approval process.”

after the researcher has crossed this critical threshold that the exemption provided under § 271(e)(1) can apply to future experiments undertaken to study the identified drug candidate.

The conclusion that emerges from our analysis of the Court's decision in *Merck v. Integra* is that the screening of untested structures, where there is no expectation that such structures will likely affect the particular disease process that is under investigation is not protected by § 271(e)(1) because such activity "is surely not 'reasonably related to the development and submission of information' to the FDA. . . ."⁸⁹ By contrast, research activities that are downstream of this initial discovery effort may fall within the reach of the FDA exemption. While the safe harbor provided by § 271(e)(1), as interpreted by the Court in *Merck v. Integra*, has been applied in protecting the unauthorized use of selected biomedical research tools from infringement claims,⁹⁰ the exemption should not

This spectrum manifests itself in the researcher's shifting orientation. A university scientist conducting basic research on the cause and progression of a disease is unlikely to think of his experiments as directed at the FDA. Nor would a researcher who, having learned of a plausible mechanism of a disease, screens compounds whose structures are not known to be (or reasonably suspected of being) likely to affect the disease, in the hopes of finding one that might do so. These scientists might dream of some day discovering a blockbuster drug, but they are under no delusion in those early years that the FDA is the audience.

Everything changes when a researcher endures the unpredictable and open-ended process of screening untested structures and emerges with unmistakable evidence that a particular structure shows promise, in a living body, in treating a particular disease through a known mechanism. After that point, the researcher may continue to optimize the drug candidate's structure, testing variations to ascertain which shows the greatest promise with the fewest side effects or complications. J.A. 358, 416-20. In fact, the FDA fully expects the scientist to conduct such research on "related drugs," and to include the resulting information in the IND application, if it sheds light on the lead candidate's suitability. 21 C.F.R. § 312.23(a)(5)(v); *infra* at 46. But from that juncture, every experiment that bears on the relationship between the drug candidate or its analogs and the target disease is reasonably viewed as pertinent to the FDA—at least to the extent that the experiment relates to a topic that is of interest to the FDA. While a drug innovator that has crossed this crucial threshold could never be sure *ex ante* that a particular drug candidate will emerge as the candidate for commercial development, or that a specific experiment will necessarily find its way into an IND application, there can be no doubt that the prospect of regulatory approval is very much in the picture

There is, in short, a world of difference between basic exploratory research or screening of untested structures in test tubes and the drug optimization and preclinical research, mostly on animals, that drug innovators conduct with a view toward demonstrating (in an IND application to the FDA) that clinical trials are justified

89. *Merck*, 545 U.S. at 206.

90. In *Classen v. Biogen Idec*, Classen brought an action against a group of biotechnology and pharmaceutical defendants alleging infringement of its patented

method for evaluating the safety of vaccine administration schedules used by the defendants in evaluating their FDA-approved vaccines. 381 F. Supp. 2d 452 (D. Md. 2005). The district court held that the defendants' infringing activities fell within the scope of the § 271(e)(1) exemption, as interpreted by the Supreme Court in *Merck v. Integra*, 545 U.S. 193 (2005). In so holding, the district court applied the exemption to the unauthorized use of a patented method that was employed as a research tool to study the defendants' products. In *Classen v. King*, Classen brought an action against a pharmaceutical defendant alleging infringement of its patented method for identifying new uses of existing drugs. 466 F. Supp. 2d 621 (D. Md. 2006). The district court held that the defendant's "use of the patented process was reasonably related to the submission of information under the FDCA and so is protected under § 271(e)(1)." *Id.* at 625. The district court acknowledged that the U.S. Supreme Court in *Merck v. Integra* failed to address the question of whether the use of a research tool was protected under § 271(e)(1), but concluded that "[a]lthough the Classen process could be considered a "research tool" the Court finds extension of the safe harbor to cover the use of these tools warranted by the language of *Merck* and a plain reading of the statute." *Id.*

Not surprisingly, on remand of the *Integra* and *Merck* case, the Federal Circuit, in applying the Supreme Court's interpretation of the scope of § 271(e)(1), found that all of the challenged actions of Scripps and *Merck* fell within the statutory exemption. *Integra v. Merck* 496 F.3d 1334 (Fed. Cir. 2007). The court focused on the fact that "[a]ll of the work . . . at issue was done after the initial recognition at Scripps of the 'particular biological process' whereby the RGD peptide blocks the cell surface receptors, and the recognition of the 'particular physiological effect' of angiogenesis inhibition," i.e., all of the allegedly infringing activities using the patented invention involved an identified drug candidate. *Id.* at 1339. The court avoided the research tool question by noting that counsel for *Integra*, in a letter to the panel, adopted the following position:

Integra agrees with *Merck* that this is not an appropriate case in which to make new law on the issue of whether patent claims to research tools (however that term may be defined) are excluded from the ambit of Section 271(e)(1). The Supreme Court has ruled that this case does not raise that issue. Hence, its resolution is outside the Supreme Court's mandate. *Integra* has never argued, and does not now contend, that any of its claims at issue belong to a class of patent claims outside the reach of that statutory exemption. *Id.* at 1348.

In a separate opinion in the case, however, Judge Rader objected to the court's reliance on the *Integra* counsel's letter in refusing to address the "research tool exception." According to Judge Rader, "the Supreme Court [in *Merck v. Integra*] extended the exemption back up the experimentation chain to include selection of particular species for FDA approval out of a patented genus. The Supreme Court did not, however, extend the exemption to encompass any method or process or other research tool that might be used in a pharmaceutical laboratory." *Id.* at 1349 (Rader, J., dissenting-in-part and concurring-in-part). Judge Rader lamented that "[b]y treating . . . research tools the same as drugs potentially needing FDA clearance, this court's opinion poses a danger to the entire research tool industry." *Id.*

Judge Rader's concern regarding the research tool industry appears to have registered with the Federal Circuit panel that recently decided *Proveris v. Innovasystems*. 536 F.3d 1256 (Fed. Cir. 2008). In that case, *Proveris* brought an action against *Innova* alleging infringement of its patent claiming an apparatus and system for characterizing aerosol sprays used in drug delivery devices. *Innova*'s allegedly infringing device was not subject to FDA approval, but was used as a research tool by *Innova*'s customers in generating data for FDA regulatory submissions. After determining that *Innova*'s device was covered by valid claims of the *Proveris* patent and that *Innova*'s manufacture and sale

of the device infringed the patent, the court rejected Innova's claim that its activities were exempted under § 271(e)(1). The court based its ruling on its interpretation of the phrase "patented invention" in the § 271(e)(1) safe harbor statute. The court noted that a major goal of the Hatch-Waxman Act, of which § 271(e)(1) and its companion patent term extension provision, § 156, are a part, was "to eliminate two unintended distortions of the effective patent term resulting from the premarket approval required for certain products by the FDCA . . . The first distortion was the reduction of effective patent life caused by FDA premarket approval . . . The second distortion was the de facto extension of effective patent life at the end of the patent term, which also resulted from FDA premarket approval requirements." *Id.* at 1260-61. According to the Federal Circuit panel, however, the invention claimed in the Proveris patent (and embodied in the product manufactured and sold without authorization by Innova) was not of the type that the Hatch-Waxman Act was enacted to address

[b]ecause Proveris's patented product is not subject to a required FDCA approval process, it is not eligible for the benefit of the patent term extension afforded by 35 U.S.C. § 156(f). At the same time, because Innova's OSA device also is not subject to a required FDCA approval process, it does not need the safe harbor protection afforded by 35 U.S.C. § 271(e)(1).

Id. at 1265-66.

The court concluded that the research tool claimed in the Proveris patent and manufactured and sold by Innova is not, for the purposes of § 271(e)(1), a "patented invention," and, accordingly, Innova's infringing activities could not be exempted under § 271(e)(1). While the scope of the *Proveris* holding is currently the subject of considerable debate, it appears that Judge Rader's "research tool exception" to the § 271(e)(1) statutory exemption has been given new life, at least at the Federal Circuit.

The recent District Court and Federal Circuit decisions reviewed in this footnote that relate to the applicability of the § 271(e)(1) statutory exemption to research tool use are of considerable significance for the tool industry. These cases do not, however, alter the conclusion reached in Part IV of this Article regarding the enforceability of Discovery Tool patents. Unlike the research tools at issue in the *Classen* cases, in *Integra* (if one believes that the case involved research tool use) and in *Proveris*, which were used to evaluate drug or device candidates that had already been identified, a Discovery Tool is utilized for the identification of a drug candidate. According to our view of the Supreme Court's interpretation of the scope of § 271(e)(1) in *Merck v. Integra*, the use of a Discovery Tool is outside of the upstream reach of the FDA statutory exemption. Thus, it need not fall within a "research tool exception" to the statute to preserve the Discovery Tool inventor's right to enforce his or her patent on the tool against an unauthorized user.

If the recent cases discussed in this footnote have any impact on the issues addressed in this Article, it is as follows. We have concluded that the unauthorized use of a patented Discovery Tool is an infringement, outside of the ambit of § 271(e)(1), and that the payment of reach-through royalties to the tool inventor is a legal and reasonable form of compensation for the right to use the tool. However, in the absence of a research tool exception to § 271(e)(1), many drug development research tools fall within the scope of the § 271(e)(1) exemption and may be used in the development process without authorization. This undermines the royalty stacking argument frequently raised by research tool users concerned about the mounting royalty burden that could attach to the sale of a pharmaceutical product that is discovered and developed through the use of multiple third party patented research tools. As the number of third party research tools that could be used legally without authorization increases, so too do the drug profits available to share, in the form of reach-through royalties, with the licensor of a foundational, rival-in-use Discovery Tool. If, on the other hand, § 271(e)(1) is read to

preclude enforcement of a Discovery Tool patent where such tool is used in the high-throughput screening of a library of random compounds as discussed in this Article.

B. Common Law “Experimental Use” Exception

A second possible basis for arguing that a patent that claims the use of a Discovery Tool is not enforceable against a potential infringer is the so-called common law “experimental use” exception. The exception was initially created in a decision handed down almost 200 years ago, but debate and, in some cases, confusion as to the scope and application of the exception persist until today.⁹¹ As initially articulated by Justice Story in *Whittemore v. Cutter*, the rationale for the experimental use exception is as follows: “[I]t could never have been the intention of the legislature to punish a man who constructed . . . a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”⁹² By 1861, it was “well-settled . . . that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is

include a research tool exception, tool use in the course of drug discovery and development will require authorization from, and compensation to, the tool inventor. In that circumstance, the royalty stacking argument of tool users against reach-through royalties on research tools carries more weight. This, however, is a policy argument regarding the advisability of such reach-through royalties and does not speak to the legality of this type of payment arrangement.

91. See Judge Newman’s concurring-in-part, dissenting-in-part, opinion in *Integra v. Merck*, 331 F.3d 860, 872-878 (Fed. Cir. 2003); also see Tom Saunders, *Renting Space on the Shoulders of Giants: Madey and the Future of Experimental Use Doctrines*, 113 YALE L. J. 261 (2003); Natalie M. Derzko, *In Search of Compromised Solution to the Problem Arising from Patenting Biomedical Research Tools*, 20 SANTA CLARA COMPUTER & HIGH TECH L. J. 347 (2003-2004); Michelle Cai, *Madey v. Duke University: Shattering the Myth of Universities’ Experimental Use Defense*, 19 BERKELEY TECH. L. J. 175 (2004); Steven P. Caltrider and Paula Davis, *The Experimental Use Defense: Post-Madey v. Duke and Integra Life Sciences I Ltd. v. Merck KGaA*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 1011 (2004); Janice M. 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 (2004); Cristina Weschler, *The Informal Experimental Use Exceptions: University Research After Madey v. Duke University*, 79 N.Y.U. L. REV. 1536 (2004); Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NORTHWESTERN J. OF TECH. AND IP 61 (2005); Jennifer L. Owens, “Not Quite Dead Yet”: *The Near Fatal Wounding of the Experimental Use Exception and its Impact on Public Universities*, 3 J. TELECOM AND HIGH TECH. L. 453 (2005); David G. Swell, *Rescuing Science from the Courts: An Appeal for Amending the Patent Code to Protect Academic Research in the Wake of Madey v. Duke University*, 93 GEO. L. J. 759 (2005); Harold C. Wegner, *Post-Merck Experimental Use and the “Safe Harbor”*, 15 FED. CIR. BJ. 1 (2005).

92. 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

not an infringement of the rights of the patentee.”⁹³ Since that time, the experimental use exception has remained narrow, such that no activity that is in keeping with the “legitimate business” of the accused infringer qualifies for protection from patent infringement, *regardless* of whether such activity is commercial in nature.⁹⁴

This narrow interpretation of this experimental use exception was confirmed by the Federal Circuit in *Madey v. Duke University*,⁹⁵ in which the potential benefit of the defense to patent infringement was denied to a private university in connection with the conduct of basic laboratory research. In that case, Madey was a tenured research professor at Stanford University where he managed an innovative laser research program through which he obtained sole ownership of two laser-related patents. Duke University recruited Madey from Stanford to take a tenured position at Duke. Madey accepted the position and then, for nearly a decade, managed a certain free electron laser research lab at Duke. At that time, a dispute arose between Madey and Duke, and Duke removed him as director of the lab. As a result, Madey resigned. When Duke continued to operate some of the equipment in the lab, Madey sued Duke for infringement of his two laser-related patents practiced by some of the equipment in the lab. In response, Duke asserted the experimental use defense, and the district court agreed on the basis that Duke’s practice of the inventions covered by the asserted patents was solely “for research, academic, or experimental purposes,” and “for experimental, non-profit purposes only.” The Federal Circuit reversed this holding, finding that the district court applied an overly broad interpretation of the very narrow experimental use exception. As indicated by the Federal Circuit:

93. *Poppenhausen v. Falke*, 29 Fed. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

94. In *Pitcairn v. United States*, the Court of Claims stated: “Tests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business of the . . . [alleged infringer]” are infringements for which the experimental use defense is not available. 547 F.2d 1106, 1125-1126 (Ct. Cl. 1976). *See also, Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984), *superseded by statute*, 35 U.S.C. 271(e)(1) (the Federal Circuit held that an alleged infringer’s use of a patented drug for the purpose of obtaining FDA approval did not fall within the experimental use exception, since the “intended ‘experimental’ use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* at 863); *Embrex Inc. v. Service Eng’g Corp.*, 216 F.3d 1343, (Fed. Cir. 2000) (the Federal Circuit held that an alleged infringer’s use of a patented invention in an effort to “design-around” it was not exempt under the experimental use exception despite the contention that the challenged activities were scientific experiments that did not result in the sale of products, since the activities were for commercial purposes.).

95. 307 F.3d at 1351 (Fed. Cir. 2002).

[O]ur precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.⁹⁶

Accordingly, in order to enjoy the benefits of the experimental use exception, the accused infringer must derive virtually no practical benefit from its unauthorized use, since any such benefit could serve its "legitimate business" and therefore preclude the application of the exception.

The narrow scope of the experimental use exception provides little, if any, room for the unauthorized use of Discovery Tools, or any biomedical research tools, for that matter. It is difficult to imagine a realistic factual scenario where a scientist would use a patented research tool for its intended purpose, e.g., identifying or characterizing a drug candidate, without doing so in a manner that is in furtherance of the legitimate business interests of that scientist or his or her sponsoring entity or institution. Even in circumstances where the scientist is using the patented tool solely in order to design around the patented claims covering that tool, that is an infringing use which is actionable.⁹⁷ Further, the use need not be meaningful or substantial to support a claim of infringement. As Judge Rader of the Federal Circuit concluded in his concurring opinion in *Embrex Inc. v. Service Engineering Corp.*, "[b]ecause the Patent Act confers the right

96. *Madey*, 307 F.3d at 1362.

97. In *Embrex Inc. v. Service Eng'g Corp.*, Embrex had patented a method of inoculating chicks against diseases while still in ovo. 216 F.3d 1343 (Fed. Cir. 2000). In its attempt to find a non-infringing method of inoculating chicks, consultants hired by Service Engineering practiced Embrex's patented method. The Federal Circuit confirmed that no experimental use defense was available, since the tests were performed for "expressly commercial purposes." *Id.* at 1349. See also, *Roche v. Bolar*, 733 F.2d 858, 863 (Fed. Cir. 1984) ("Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaptation of the patented invention to the experimenter's business is a violation of the rights of the patentee to exclude others from using his patented invention We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes.").

to preclude ‘use’, not ‘substantial use’, no room remains in the law for a *de minimis* excuse.”⁹⁸ Quoting from a prior case addressing the experimental use exception, he noted that “[d]amages for an extremely small infringing use may be *de minimis*, but infringement is not a question of degree.”⁹⁹

While the narrow scope of the experimental use exception may appear to be well-settled law, it has recently been revisited by Judge Newman in her dissenting opinion in *Integra v. Merck*.¹⁰⁰ In that case, Judge Newman argued that, with respect to the allegedly infringing activities at issue, the experimental use exception was part of a continuum with § 271(e)(1), such that § 271(e)(1) applied where the experimental use exception ceased to do so.¹⁰¹ This position, however, is inconsistent with the majority decision in *Madey v. Duke* and does not stand up to scrutiny when analyzed in the context of the drug development process. The purpose and scope of the two safe harbors are entirely distinct. As discussed above, the experimental use exception does not protect any activity that is in furtherance of a potential infringer’s legitimate business. On the other hand, §

98. *Embrex*, 216 F.3d at 1352 (Rader, J., concurring).

99. *Embrex*, 216 F.3d at 1353 (quoting from *Deuterium Corp. v. U.S.*, 14 U.S.P.Q. 2d 1636, 1642 (Ct. Cl. 1990)).

100. 331 F.3d 860, 872-878 (Fed. Cir. 2003) (Newman, J., concurring-in-part, dissenting-in-part).

101. Judge Newman described her position as follows:

[T]he territory that the Scripps/Merck research traversed, from laboratory experimentation to development of data for submission to the FDA, was either exempt exploratory research, or was immunized by § 271(e)(1). It would be strange to create an intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited. That would defeat the purpose of both exemptions; the law does not favor such an illogical outcome.

Integra, 331 F.3d at 877.

While Judge Newman’s dissenting opinion in *Integra v. Merck* focused primarily on the appropriate interpretation of the common law experimental use exception, she did express disagreement with the majority’s narrow interpretation of § 271(e)(1). She cited *Eli Lilly v. Medtronic*, 496 US 661 (1990), as evidence of the Supreme Court’s broader construction of the statute. She concluded her opinion by stating that:

I do not attempt to resolve, for all technologies and circumstances, the application of the research exception or the point at which research into patented technology loses the immunity that the common law has always provided. However, the basic research here performed was within the common law research exemption, and the development shielded by § 271(e)(1) took up where the research exemption left off. Thus the accused activities were either exempt from or immune from infringement. *Id.* at 878.

271(e)(1) will not apply unless the allegedly infringing activities are solely for uses reasonably related to the practical goal of submitting information to the FDA. If these exceptions were part of a continuous spectrum, one would have to conclude that the activities engaged in by Scripps/Merck that were outside of the scope of § 271(e)(1), yet protected under the experimental use exception, were not in furtherance of Scripps' or Merck's legitimate business interests—a clearly unsupportable premise.¹⁰²

Judge Newman's objection to the majority's infringement holding in *Integra v. Merck* was critically dependent upon her view that none of the uses by Scripps and Merck of the patented peptides was a use as a research tool. In her opinion, "[t]he RGD-containing peptides of the *Integra* patents are not a 'tool' used in research, but simply new compositions having certain biological properties."¹⁰³ As indicated above, this position was adopted by the Supreme Court in

102. Interestingly, as noted in Judge Newman's concurring-in-part, dissenting-in-part opinion in *Integra v. Merck*, 331 F.3d 860, 878 (Fed. Cir. 2003), and in the U.S. Supreme Court's decision in *Merck v. Integra*, 545 U.S. 193, 200 (2004), the district court in the case held that an early Scripps experiment was exempted from infringement liability on the basis of the common law experimental use exception. This holding was never reviewed on appeal either by the majority at the Federal Circuit or the Supreme Court and is clearly inconsistent with the Federal Circuit's ruling in *Madey v. Duke*, 307 F.3d 1351 (Fed. Cir. 2002). In response to Judge Newman's focus in *Integra* on the experimental use exception, Judge Rader speaking for the majority provided the following comment:

In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court's decision in *Madey v. Duke Univ.*, 307 F.3d 1351, 64 USPQ2d 1737 (Fed.Cir.2002). However, the common law experimental use exception is not before the court in the instant case. The issue before the jury was whether the infringing pre-clinical experiments are immunized from liability via the "FDA exemption," *i.e.*, 35 U.S.C. § 271(e)(1). The district court did not instruct the jury on the common law research exemption with respect to the Merck's infringing activities. On appeal, Merck does not contend that the common law research exemption should apply to any of the infringing activities evaluated by the jury. Neither party has briefed this issue to this court. Moreover, during oral arguments, counsel for Merck expressly stated that the common law research exemption is not relevant to its appeal. Judge Newman's dissent, however, does not mention that the Patent Act does not include the word "experimental," let alone an experimental use exemption from infringement. *See* 35 U.S.C. § 271 (2000). Nor does Judge Newman's dissent note that the judge-made doctrine is rooted in the notions of *de minimis* infringement better addressed by limited damages. *Embrex v. Service Eng'g Corp.*, 216 F.3d 1343, 55 USPQ2d 1161 (Fed.Cir.2000) (Rader, J., concurring); *see also Deuterium Corp. v. United States*, 19 Cl.Ct. 624, 631, 14 USPQ2d 1636, 1642 (Cl.Ct.1990) ("This court questions whether any infringing use can be *de minimis*. Damages for an extremely small infringing use may be *de minimis*, but infringement is not a question of degree.").

Integra, 331 F.3d at 864 n.2 (Fed. Cir. 2003).

103. *Integra*, 331 F.3d at 878 (Newman, J., concurring-in-part, dissenting-in-part).

Merck v. Integra, although both the Federal Circuit majority in *Integra v. Merck* and the authors of this Article find this interpretation inconsistent with the facts of the case.¹⁰⁴ Judge Newman concluded that each research use of the patented peptides by Scripps and Merck was intended to study the peptides, and, therefore, was immunized from an infringement claim under the common law experimental use exception, as she interpreted it. Rejecting the “sweeping dictum” in the majority opinion in *Madey v. Duke*, Judge Newman expressed the view that a research investigation into a patented thing has always been permitted under the experimental use exception and the fact that such investigation is in furtherance of a legitimate business interest does not deprive the unauthorized user of the benefit of the exception.¹⁰⁵ What the experimental use exception does not protect is a research investigation using a patented thing as it is intended to be used. This, according to Judge Newman, is what occurred in *Madey v. Duke*, and is the reason for her agreement with the holding in that case.¹⁰⁶ Interestingly, had Judge Newman been convinced that the RGD peptides were used by Scripps and Merck as research tools, she would not have found the experimental use exception available to shield certain activities of the defendants from an infringement claim. In her own words, “[u]se of an existing tool in one’s research is quite different from study of the tool itself.”¹⁰⁷

Unlike the RGD peptides in the *Merck* case, which could be studied as candidate products or used as tools to characterize other compounds, the Discovery Tool discussed in this Article is used only as a research tool. Whether one adopts the Federal Circuit’s “legitimate business” test or some version of Judge Newman’s “use as intended” test to exclude the application of the common law experimental use exception, the use of a Discovery Tool falls outside of the ambit of this exemption. Accordingly, just as we concluded with respect to § 271(e)(1), the common law experimental use exception does not compromise the ability of owners of Discovery Tool patents to enforce claims of infringement against unauthorized users.

104. Note that on remand of the *Integra* case after the Supreme Court’s decision in *Merck v. Integra*, the Federal Circuit majority took the position that research tool use was not at issue in the case. *Integra v. Merck*, 496 F.3d 1334, 1347-48 (Fed. Cir. 2007); *supra* note 90.

105. *Integra*, 331 F.3d at 878 (Newman, J., concurring-in-part, dissenting-in-part).

106. *Id.*

107. *Id.*

V. Reaping Value From Discovery Tool Patents: The Legality of Reach-Through Royalties

In Part III of this Article, we established that, post-*Rochester*, a Discovery Tool inventor is unlikely to obtain valid patent claims that reach through the tool to claim yet-to-be-discovered drugs that may be found using that tool. Rather, the patent rights of the tool inventor will generally be limited to the tool itself. Nonetheless, Discovery Tool inventors may still reap potentially significant economic value from their research tool inventions. As previously discussed, U.S. patent law allows claims that cover the Discovery Tools and their uses, and the patents covering such tools are not subject to any categorical exceptions to enforceability. Further, if the tool is in the critical path to the development of a drug in a market of any significance, as would certainly be the case for some Discovery Tools, the demand is likely to be equally significant. On this basis, we conclude that the inventor of a Discovery Tool is afforded adequate opportunity to reap a financial return commensurate with the value generated by that tool, even in the absence of reach-through patent claims.

In this Part V, we discuss one form of compensation occasionally sought by a Discovery Tool inventor as consideration for the grant of a license under the inventor's patent rights covering the tool: a reach-through royalty.¹⁰⁸ We begin with a brief explanation of this type of royalty arrangement and note some of the possible advantages and disadvantages associated with its use in a license agreement. We then assess the legality of reach-through royalties with a particular focus on the potential for patent misuse in the licensing of the Discovery Tool patent rights. In addition, we review judicial remedies in patent infringement cases that are analogous to a negotiated contractual reach-through royalty obligation, in that these remedies reach through the infringed patent to burden products and activities of the infringer that are not covered by the infringed patent. We conclude that a reach-through royalty arrangement between a willing licensor and a willing licensee is permissible under applicable law and represents a viable method by which the free market for patented Discovery Tools may adequately reward the tool inventor.

108. Alternative compensation arrangements for the license of rights to a Discovery Tool include a fixed fee determined at the time the license is granted, usage-based pricing that is keyed to the frequency of use of the tool by the licensee, and milestone payments based on the developmental and commercial success of a drug product discovered through the use of the tool.

A. Reach-Through Royalties

In a typical patent license, a royalty is consideration paid on the sales of a product that is covered by the licensed patent, where the royalty is usually a percentage of such sales.¹⁰⁹ In the case of the license of a Discovery Tool patent, however, the royalty is occasionally a percentage of the sales of the drug product found using the patented tool. This is a so-called “reach-through” royalty, since the royalty is not based on sales of the patented tool, but rather, “reaches-through” to the sales of the drug product found by the licensee using the tool, notwithstanding the fact that the Discovery Tool patent does not cover such drug sales.

Unlike a reach-through claim, which a Discovery Tool patentee would be able to assert against any infringing party who uses her tool without authorization, a reach-through royalty obligation would only apply where a licensee specifically agreed to its terms. Where so agreed, the reach-through royalty would provide a tool licensor with a direct contractual claim to a percentage of potentially significant revenues generated from drug sales. The ability to share in that upside may be important to the prospects, research programs, and financial viability of the tool inventor. In other words, a reach-through royalty may be a method of accommodating the limits in the patent system, while preserving some degree of the incentive for innovation with respect to those research tools that are essential to the drug development process.

Moreover, some commentators have argued that reach-through royalties also provide a fair and accurate method of valuing a license of a Discover Tool patent.¹¹⁰ Consider the variety of possible

109. See Brian G. Brunsvold and Dennis P. O'Reilley, *DRAFTING PATENT LICENSE AGREEMENTS* (Fifth Edition 2004), p. 113.

110. See Thomas J. Kowalski and Christian M. Smolizza, *Reach-Through Licensing: A US Perspective*, 6 J. COM. BIOTECH. 349 (2000) (“Despite criticism, reach-through licensing creates a license the value of which can be measured, and thus solves the problem of valuing basic research *per se*. Indeed, the value of basic research may not be known at the time of the license and is usually not known until after production of the end product. Thus, reach-through licensing may be necessary to compensate for use of a basic research invention . . .” (footnote deleted)); Janice M. Mueller, *No “Dilettante Affair”*: *Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L.R. 1, 61-62 (2001) (“Reach-through royalty payments continuing beyond the expiration date of an underlying research tool patent more accurately recognize the value of the patented research tool, which cannot be definitively established during the enforceable life of the patent. . . . The premise underlying reach-through royalties is that the true value of the patented research tool will be determined by the ultimate marketplace success of the new product developed through use of the tool.”); See also Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration*

compensation arrangements for licensing such a research tool. In the simplest case, the tool licensor and licensee could, at the time the license is granted, agree upon a fixed price, payable as a lump sum or in installments. That price would represent the parties' assessment of the risk-adjusted net present value of the right to practice under the research tool patent. Alternatively, pricing may vary based on mutually agreed upon factors, including the amount or character of the use (e.g., number of assays) or the size of the research and development budget of the applicable licensee. In each of these cases, the price is fixed *ex ante* based on the anticipated value of the research tool (i.e., the likelihood of identifying a drug candidate and potential market value of that drug), rather than the actual value generated by its use (i.e., whether such a drug candidate is in fact identified, developed and ultimately sold and the actual amount of those sales). Given the highly uncertain nature of drug discovery, pricing based on the anticipated value of a Discovery Tool may result in an inaccurate measurement of realized value, and may even be wildly inconsistent with such realized value. A reach-through royalty, by contrast, values the use of the tool based on its actual success in generating drug sales.¹¹¹ If the tool user does not identify any drug

on *License Agreements*, 65 J. PAT. OFF. SOC'Y, 297, 303 (1982), discussing post-expiration patent royalties ("But the trouble with any flat royalty arrangement is that it measures that patentee's reward by the level of success which the parties *expect* the licensed product to achieve, and that may turn out to be much greater or much less than is actually achieved in the future. The great virtue of a royalty based on sales, as compared to a flat royalty, is that it automatically expands or contracts as the future unfolds.").

111. See Thomas J. Kowalski and Christian M. Smolizza, *Reach-Through Licensing: A US Perspective*, 6 J. COM. BIOTECH., 349, 352 (2000) ("Consider . . . that in reach-through licensing the value of the enabling technology is based on the end product. If there is never any end product, there is no reach-through royalty. Similarly, if the end product does not enjoy an enormous market, the reach-through royalty may not amount to sums . . . [that in our hypothetical, where the research tool user discovers a blockbuster drug, are in the range of tens to hundreds of millions of dollars] . . . [T]he measure of value of a basic research tool is not merely the costs for developing and patenting the basic research tool; but rather the extent to which the basic research tool enables the development of further products and the value of those products; namely, market-place forces. . . . [T]he developer of the basic research tool developed the research tool and it solved problems the drug developer either could not afford or did not find profitable to solve, or did not timely solve first; and the research tool—the enabling technology—played a pivotal role in developing the end product. Simply, without the basic research tool, the end product would not have been produced. . . . The value of the patented research tool is thus reflected in the value of the end product. Therefore, a reach-through royalty may not necessarily be inequitable or excessive compensation, despite the fact that at first sight it may seem shocking to possibly receive . . . [tens to hundreds of millions of dollars] for an investment in research and patenting that may have been only several hundred thousand to a few million dollars. But, such returns are contingent on the end product being a blockbuster . . .").

candidates using the tool, or if a drug candidate is identified that never reaches the market, then no reach-through royalty would be payable. On the other hand, if a blockbuster drug is discovered, reach-through royalties could be significant. In either case, the royalty is arguably proportionate to the value it generates.

As noted in Part II, however, “reach-through” royalties have generated significant controversy as to whether they are an appropriate compensation arrangement. The leading concern is that such royalties constitute an excessive economic burden on the downstream development and commercialization of drug candidates discovered using a patented Discovery Tool and, thereby, undermine incentives for developing drugs. The NIH has adopted this view and issued a non-binding, but influential, policy statement that generally discourages the use of reach-through royalties in the licensing of federally funded research tool inventions, in order to minimize potential obstacles to drug development.¹¹²

Thus, the debate continues with respect to the advisability of reach-through royalties in the context of licensing a Discovery Tool patent. Nonetheless, our purpose is not to advocate the use of this type of royalty arrangement, nor to suggest that such royalties are appropriate in any specific case. Rather, it is to determine whether reach-through royalties are a lawful option that willing tool licensors and licensees may, under circumstances that they deem to be appropriate, elect to employ.

Some have argued that reach-through royalties are not legal under applicable patent law, or alternatively, that applicable law is sufficiently ambiguous so as to raise questions as to the lawfulness of such royalties.¹¹³ At first blush, this may seem surprising, if one presumes that willing licensors and licensees may under general principles of freedom of contract agree to any royalty arrangement that suits their needs and circumstances. However, because reach-through royalty arrangements impose a financial burden on drug products that are not covered by the licensed Discovery Tool patent, they may expose the tool inventor to a claim that the royalty

112. See Footnotes 19 and 20.

113. Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 443 (2003) (“The legal status of Reach-Through Royalties is unclear. There are few judicial or administrative pronouncements available, and the ones that exist are in conflict. . . . In recent Congressional hearings, one industry expert noted the need for clarification on whether Reach-Through Royalties create antitrust or patent misuse problems, arguing that clear approval or disapproval would be better than the current uncertainty.”).

constitutes an unlawful extension of the patent monopoly.¹¹⁴ So are reach-through royalties a lawful pricing method for the licensing of patents on Discovery Tools? For the balance of this Section, we focus on the answer to this question, and in particular whether such a reach-through royalty constitutes patent misuse.¹¹⁵ Ultimately, if the royalty obligation is properly negotiated and appropriately qualified, we conclude that reach-through royalties are not patent misuse and are lawful. Prior to beginning our analysis, though, we will briefly review the development and rationale for the patent misuse doctrine.

B. Patent Misuse Primer

1. Background

Patents derive from the authority of Congress under the U.S. Constitution “[t]o promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.”¹¹⁶ Consistent with this constitutional mandate, a patent is a limited exclusive right. Regardless of its subject matter, the grant of a U.S. patent confers upon its holder the right during the patent term to exclude others from making, using, selling, offering to sell and importing in the U.S. the process, apparatus, or combination claimed therein.¹¹⁷ Accordingly, the right to exclude under a U.S. patent is limited both in scope (of the inventions claimed) and in time (the 20-year term of the patent).

Patent misuse is an affirmative defense to a claim of patent infringement.¹¹⁸ Analogous to the equitable doctrine of “unclean

114. By contrast, if reach-through claims were valid, then a Discovery Tool inventor would have the right to exclude unauthorized parties from making and selling a drug product identified using the tool, as well as from using the tool itself. This would enable the tool inventor to exact royalties on drug sales pursuant to a patent right. In that circumstance, there would be no question of patent misuse, since the royalty would be paid on the sale of a drug product that is within the scope of the patent.

115. We assume that: (1) no license is granted to know-how/trade secrets; and (2) use of the tool and sale of the product occur in the U.S.

116. U.S. Const. art. I, § 8, cl. 8.

117. 35 U.S.C. § 271(a).

118. Patent misuse itself is not actionable. See, e.g., *Transition Electronic Corp. v. Hughes Aircraft Co.*, 47 F. Supp 885 (D. Mass. 1980), *aff'd*, 649 F.2d 871 (1st Cir. 1981) (holding that “patent misuse of itself is not an actionable tort”) (cited in *Chisum, Defenses*, § 19.04[4], n2); *Foseco, Inc. v. Consolidated Aluminum Corp.*, 10 USPQ2d 1632, 1633 (E.D. Mo. 1988) (“An allegation of misuse is generally set up as a defense to an infringement claim, and is not itself an actionable tort serving as grounds for affirmative relief.”) (cited in *Chisum, Defenses*, § 19.04[4], n3); *Medtronic, Inc. v. Eli Lilly & Co.*, 15 USPQ2d 1465, 1468 (D. Minn. 1990) (“The federal patent laws do not provide for

hands,” the purpose of the misuse doctrine is to prevent the impermissible exploitation of the patent monopoly. The misuse defense was created in a series of early Supreme Court cases directed to curbing abusive tying practices by patent holders.¹¹⁹ In these early cases, “the Supreme Court relied on public policy found in the ends and means of the patent laws themselves [where] [a]dvancement of the useful arts is the end, and [the] grant of a limited monopoly the means of the patent laws.”¹²⁰ Tying and other arrangements that “extend” the economic impact of the patent beyond the area actually claimed or the statutory period of monopoly “upset the careful balance between monopoly and free usage.”¹²¹ Since these early cases, courts have applied the misuse doctrine to a variety of potentially abusive practices involving patents, but with inconsistent results in some cases.¹²²

compensatory damages or injunctive relief for proof of misuse.”) (cited in *Chisum, Defenses*, § 19.04[4], n3).

119. The doctrine of patent misuse originated as a defense against contributory infringement in a series of Supreme Court cases in the early 1900s. See, e.g., *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917); *Carbice Corp. of America v. American Patents Development Corp.*, 283 U.S. 27 (1931); *Leitch Mnf. Co. v. Barber Co.* 302 U.S. 458 (1938); see, generally, *Chisum, Defenses*, § 19.04[1]. The Supreme Court first applied the doctrine of patent misuse in a case of direct infringement in 1942. *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942); *B.B. Chemical Co. v. Ellis*, 314 U.S. 495 (1942); *Chisum, Defenses*, § 19.04[1][b]. Prior to the establishment of the misuse doctrine, improper use of a patent was not a defense to a claim of infringement. *Chisum, Defenses*, § 19.04[1]. Rather, the patent holder retained the action and remedies of patent infringement even if the holder had utilized its patent as part of anticompetitive practices to monopolize a market or extended its patent monopoly into unpatented products or components. *Id.* These cases deemed infringement of a patent to be tantamount to trespass upon property. *Id.* (citing *Strait v. National Harrow*, 51 F. 819, 820-21 (N.D.N.Y. 1892) (“[I]n a suit brought for the infringement of a patent by the owner, any . . . inquiry [into the proprietary of the actions of the patent holder], at the behest of the infringer, would be as impertinent as one in respect to the moral character or antecedents of the plaintiff in an ordinary suit for trespass upon his property. Even a gambler, or the keeper of a brothel, cannot be deprived of his property because he is an obnoxious person or a criminal; and it is no defense to the trespass upon it . . . that it was used in carrying out the unlawful occupation.”)).

120. *Chisum, Defenses*, 19-440, § 19.04[2].

121. *Transitron Electronic Corp. v. Hughes Aircraft Co.*, 487 F. Supp. 885, 893 (D. Mass. 1980) (“Patent misuse was developed as an equitable doctrine to provide an equitable defense, analogous to the clean hands defense, against an infringement action.”).

122. *Chisum, Defenses*, § 19.04[3]. As *Chisum* observes: “Because courts have failed to adopt a general theory as to the proper limitations on the exploitation of the patent monopoly, it is necessary to assess a given practice in the light of precedent, custom and history, and the treatment of closely analogous practices.” *Id.*

2. *Legal Standard*

As a general matter, “[t]he right to a patent includes the right to market the use of the patent at a reasonable return.”¹²³ The central inquiry of patent misuse is whether the patentee has wielded her patent monopoly in order to violate the antitrust laws¹²⁴ or to extend the physical or temporal scope of the patent beyond the statutory grant.¹²⁵ If a court has determined that the patentee’s conduct does not constitute patent misuse, it will have necessarily concluded that the conduct does not violate the antitrust laws.¹²⁶ However, the court will also have determined that the patentee has not engaged in conduct that falls short of an antitrust violation but still constitutes patent misuse.¹²⁷

In a series of rulings,¹²⁸ the Federal Circuit has developed an analytical framework for deciding whether conduct by a patentee

123. *Automatic Radio Mfg. Co. v. Hazeltine Research Co.*, 339 U.S. 827, 833 (1950) (citing 46 Stat. 376., 35 USC § 40; *Hartford-Empire, Co. v. United States*, 323 U.S. 386, 417 (1945), 324 U.S. 570, 574 (1945)).

124. *Hartford-Empire, Co. v. United States*, 323 U.S. 386, 415 (1945) (“so long as the patent owner is using his patent in violation of the antitrust laws, he cannot restrain infringement of it by others”).

125. *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 343 (1971) (“the Court has condemned attempts to broaden the physical or temporal scope of the patent monopoly”).

126. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 873 (Fed. Cir. 1997) (“conduct that is insufficient to support a misuse defense cannot support an otherwise flawed antitrust judgment. Accordingly, because we determine that the conduct underlying the allegations of misuse does not amount to patent misuse, the same conduct cannot support a judgment that VP’s conduct violated the Sherman Act.”); *Monsanto Company v. Homan McFarling*, 363 F.3d 1336, 1343 (Fed. Cir. 2004) (“However, because we have found McFarling’s allegations insufficient to present a genuine issue of material fact concerning whether Monsanto’s licensing restrictions went beyond the boundaries of its patent grant, McFarling’s antitrust counterclaim also fails. *Cf., In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1327-28 (Fed. Cir. 1999) (concluding that an antitrust claim “does nothing to limit the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant”) . . . In this instance, the anticompetitive effect of which McFarling complains is part and parcel of the patent system’s role in creating incentives for potential inventors).

127. *C.R. Bard v. M3 Systems*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) (“misuse may arise when the conditions of antitrust violation are not met.”) *See also Chisum, Defenses*, § 19.04[2] (“Use of a patent to violate the antitrust laws will constitute misuse. However, conduct which in some respect falls short of an antitrust violation may still constitute misuse.”).

128. *Windsurfing Int’l v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860 (Fed. Cir. 1997); *C.R. Bard, Inc. v. M3Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998); *Monsanto Company v. Homan McFarling*, 363 F.3d 1336 (Fed. Cir. 2004).

qualifies as patent misuse.¹²⁹ First, it must be determined whether the challenged practice is one of those identified by the Supreme Court as per se misuse. Examples of per se misuse include: (1) tying, whereby a patent holder conditions a license under a patent upon the purchase of a separable, staple good or component,¹³⁰ (2) conditioning the grant of a license under a patent on the payment of royalties on unpatented products or components,¹³¹ or (3) requiring the payment of royalties that accrue based on the use of a patented invention after the

129. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (“Patent misuse is an affirmative defense to an accusation of patent infringement, the successful assertion of which ‘requires that the alleged infringer show that the patentee has impermissibly broadened the ‘physical or temporal scope’ of the patent grant with anticompetitive effect.’ *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001, 228 USPQ 562, 566 (Fed. Cir. 1986) (quoting *Blonder-Tongue Lab., Inc. v. University of Ill. Found.*, 402 U.S. 313, 343, 91 S. Ct. 1434, 1450, 28 L.Ed.2d 788, 169 USPQ 513, 525 (1971); see also *USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505, 510, 216 USPQ 959, 963 (7th Cir. 1982) (“[I]n application, the doctrine [of patent misuse] has largely been confined to a handful of specific practices by which the patentee seemed to be trying to ‘extend’ his patent grant beyond its statutory limits.”) . . . When a practice alleged to constitute patent misuse is neither *per se* patent misuse nor specifically excluded from a misuse analysis by § 271(d), a court must determine if that practice is ‘reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims.’ *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708, 24 USPQ2d 1173, 1179-80 (Fed. Cir. 1992). If so, the practice does not have the effect of broadening the scope of the patent claims and thus cannot constitute patent misuse. *Id.*, 976 F.2d at 708, 24 USPQ2d at 1180. If, on the other hand, the practice has the effect of extending the patentee’s statutory rights and does so with an anticompetitive effect, that practice must then be analyzed in accordance with the ‘rule of reason.’ *Id.* Under the rule of reason, ‘the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.’ *State Oil Co. v. Kahn*, 522 U.S. 3, 10, 118, S.Ct., 275, 279, 139 L.Ed.2d 199 (1997) (citing *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 343 & n. 13, 102 S.Ct. 2466, 2472 & n. 13, 73 L.Ed.2d 48 (1982)).”) See also, *U.S. Phillips Corp. v. International Trade Commission*, 424 F.3d 1179 (Fed. Cir. 2005) for an example of the application of the Federal Circuit’s analytical framework for determining patent misuse.

130. See, e.g., *Morton Salt Co. v. G. S. Suppiger*, 314 U.S. 488 (1942). But see 35 USC § 271(d)(5), precluding a patent misuse defense based on tying in the absence of patentee market power (“[n]o patent owner otherwise entitled to relief for infringement . . . of a patent shall be . . . deemed guilty of misuse or illegal extension of the patent right by reason of his having: . . . conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.”). See also *Scheiber v. Dolby*, 293 F. 3d 1014, 1020 (7th Cir. 2002). (“The 1998 amendment [to the patent statute which resulted in 35 U.S.C. §271(d)(5)] limited the tying doctrine, in cases in which the tying product is a patent, to situations in which the patentee has real market power, not merely the technical monopoly (right to exclude) that every patent confers.”).

131. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969).

expiration of the licensed patent covering that invention.¹³² If a practice is found to constitute *per se* misuse, no further misuse analysis is necessary. If no *per se* violation is identified, the analysis will continue as described below.

Second, it must be determined whether the practice falls within a statutory exemption to patent misuse set forth under 35 U.S.C. § 271(d).¹³³ Section 271(d) statutorily limits the scope of the patent misuse defense, and in particular, limits misuse based on tying only to those situations in which the licensor has market power in the relevant market for the tying patent or product.

Third, assuming that the practice is not determined to be *per se* misuse and is not exempt from misuse under § 271(d), the court must determine whether the practice has the effect broadening the scope of the patent.¹³⁴ As a general rule, no “broadening” of a patent will be found where the challenged practice is “reasonably within the patent grant,” and where “it relates to subject matter within the scope of the patent claims.”¹³⁵ If the challenged practice is found to be within the subject matter of the patent grant, that conclusion ends the misuse inquiry. No misuse will be found,¹³⁶ because a patent misuse defense cannot prevail where the patentee is merely exploiting the value of his patent, and a patentee does not commit misuse by maximizing that value within its lawful bounds.

If, on the other hand, the practice has the effect of extending the patent beyond the subject matter claimed therein, then a fourth step in the misuse analysis is required. The question, then, is whether the practice “impermissibly broadened the ‘physical or temporal scope’ of the patent grant with anticompetitive effect.”¹³⁷ In this inquiry, anticompetitive effects alone do not themselves require a finding of misuse. Rather, such anticompetitive effects must be found to

132. *Brulotte v. Thys Co.*, 379 U.S. 29 (1964).

133. See 35 U.S.C. § 271(d), which identifies acts of patent owners that shall not be deemed patent misuse; See *supra* note 130.

134. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860 (Fed. Cir. 1997).

135. *Id.* at 869 (quoting *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992)).

136. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d at 708 (holding that a prohibition on the buyer’s reuse of a patented medical device was enforceable under patent law if the restriction was within the patent grant). See also, *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938); *Monsanto Company v. Homan McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004); *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997); *B.Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426-27 (Fed. Cir. 1997).

137. *Windsurfing International, Inc. v. AMF, Incorp.*, 782 F.2d 995, 1001 (Fed. Cir. 1986).

outweigh any procompetitive benefits of the challenged practice, based on an analysis conducted under “conventional antitrust principles, in particular the rule of reason.”¹³⁸ For a finding of patent misuse in this circumstance, a factual determination must reveal that “the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint’s history, nature, and effect.”¹³⁹

It is noteworthy that the Federal Circuit’s analytical framework for identifying patent misuse has been the object of criticism by commentators.¹⁴⁰ The view generally expressed is that, in contrast to Supreme Court precedent, the Federal Circuit has conflated the “antitrust type” of patent misuse and the “extension of monopoly type” of patent misuse, such that from the Federal Circuit’s prospective “no misuse of any kind can be found unless the patent infringement defendant proves that the alleged misuse had ‘anticompetitive effect not justifiable under the rule of reason.’”¹⁴¹ The Federal Circuit’s interpretation of the patent misuse doctrine, which appears to ignore the pure “extension of monopoly type” misuse, raises the threshold for a showing of patent misuse and, according to some, reflects that court’s antipathy to the doctrine in

138. ABA SECTION OF ANTITRUST LAW, *ANTITRUST LAW DEVELOPMENTS*, (6th ed. 2007), at 1143 (summarizing *USM Corp. v. SPS Technologies, Inc.*, 694 F.2d 505 (7th Cir. 1982)). See also *Mallinckrodt, Inc. v. Medipart, Inc.* 976 F.2d at 708 (“Anticompetitive effects that are not *per se* violations of law are reviewed in accordance with the rule of reason.”)

139. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997); (quoting *State Oil Co. v. Kahn*, 552 U.S. 3, 10 (1997) (citing *Arizona v. Maricopa County Med. Soc.*, 457 U.S. 332, 343 & n. 13 (1982))).

140. Robert J. Hoerner, *The Decline (And Fall?) Of The Patent Misuse Doctrine In The Federal Circuit*, 69 ANTITRUST L.J. 669 (2001) (arguing that the Federal Circuit has departed from Supreme Court precedent by requiring a showing of “anticompetitive effect,” which analysis is derived from the antitrust rule of reason, in order to sustain a patent misuse defense); Patricia A. Martone and Richard M. Feustel, Jr., *The Patent Misuse Defense-Does it Still have Viability*, in INTELLECTUAL PROPERTY ANTITRUST, 213, 250 (2002) (noting that, contrary to Supreme Court precedent, the Federal Circuit has required “antitrust-type findings” to support an “attempt to extend the scope of monopoly”-type patent misuse defense); Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 418-31 (2003) (arguing that the Federal Circuit’s inconsistent effort “to change patent misuse doctrine so that it tracks antitrust doctrine” has resulted in “a confusing tangle that distorts both antitrust and misuse doctrine.” *Id.* at 430-31).

141. Robert J. Hoerner, *The Decline (And Fall?) Of The Patent Misuse Doctrine In The Federal Circuit*, 69 ANTITRUST L.J. 669, 683 (2001).

keeping with its pro-patent bias.¹⁴² In light of the increasing activity of the Supreme Court in reviewing and reversing Federal Circuit positions regarding the rights of a patentee,¹⁴³ any perceived discrepancy between Supreme Court precedent and Federal Circuit jurisprudence, as has been suggested with respect to patent misuse, must be given serious consideration when advising patentees as to their rights in exploiting their patents. As will be shown in the sections of this Article that follow, however, the conclusion that we reach regarding the enforceability of a properly negotiated and appropriately qualified reach-through royalty obligation for Discovery Tool use does not depend on the Federal Circuit's heightened threshold for a finding of patent misuse, which some scholars believe may not survive Supreme Court review (if the Court should take such a case). Instead, our conclusion that a reach-through royalty obligation is legal is based on our applying principles articulated in the leading Supreme Court cases evaluating royalty arrangements that are analogous to a reach-through royalty.

3. *Consequences*

Upon a finding of patent misuse, regardless of the basis for that finding, courts will refuse to enforce affected license agreements against the licensees victimized by the misuse, and will refuse to enforce the misused patents against any person, including third parties who are not individually affected by the conduct that gave rise to the misuse.¹⁴⁴ In other words, a single act of patent misuse results

142. *Id.* at 683.

143. See *Merck v. Integra*, 545 U.S. 193 (2005) (reversing the Federal Circuit's restrictive interpretation of 35 U.S.C. § 271(e)(1), which exempts from infringement liability the unauthorized use of patented inventions in the drug development process) (see section IV.A.2, *supra*); *Ebay v. Mercexchange*, 547 U.S. 388 (2006) (overturning the Federal Circuit's special rules regarding the granting of injunctions in patent infringement cases; rather, requiring the court to apply traditional principles of equity to the determination of whether to grant or deny injunctive relief); *MedImmune v. Genentech* 549 U.S. 118 (2007) (overturning the Federal Circuit's holding that a patent licensee must breach the license contract before there would be a constitutionally sufficient case or controversy to establish standing for a declaratory judgment action seeking a finding that the licensed patent is invalid); *Microsoft v. AT&T*, 127 S. Ct. 1746 (2007) (reversing the Federal Circuit's holding that selling a copy of a master software disk outside the U.S. as a component in a computer, which master disk had originally been produced in and sent abroad from the U.S., gave rise to infringement liability under 35 U.S.C. § 271(f)); *Quanta Computer v. LG Electronics*, 128 S. Ct. 2109 (2008), (overturning the Federal Circuit's rule that the doctrine of patent exhaustion does not apply to method patents, and interpreting the scope of the doctrine more broadly than did the Federal Circuit).

144. The rationale for this harsh consequence is that to allow an infringement suit by a patentee who has misused [his] patent "would be to extend the aid of a court of equity in

in the denial to a patent holder of all judicial remedies related to the misused patent.¹⁴⁵ It is not necessary that that defendant asserting the misuse defense has been—or would be—directly injured by the misuse.¹⁴⁶ This is because the misuse of a patent, a monopoly which was granted by the government in furtherance of an express public policy originating in the U.S. Constitution for the advancement of “science” and other “useful arts,” is deemed to be a harm to the public as a whole. For example, if a patent license provision is deemed to constitute misuse, the consequences would include the following: (1) the offending contractual provision is rendered unenforceable as against the licensee, and (2) the misused patent itself is rendered unenforceable such that the patent holder is precluded from remedy in an infringement action under that patent, (a) even if the remedy is otherwise wholly within the patent’s lawful scope (e.g., a fee on the use of the patented tool itself and/or royalties for pre-expiration use), and (b) not only against the “victim” of the misuse, but against any third party infringer.¹⁴⁷

Despite these potentially harsh consequences, misuse of a patent does not affect the validity of the patent itself and does not subject the patentee to a claim for damages.¹⁴⁸ It is only an affirmative defense to patent infringement. As soon as a patentee has “purged”

expanding the patent beyond the legitimate scope of its monopoly.” *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944); *Hensley Equipment v. Esco Corp.*, 383 F.2d 252, 260 (5th Cir. 1967) (“One who attempts to exploit a patented invention beyond the scope of the patent monopoly may be the subject of a judicially-imposed disability to enforce the patent.”).

145. For example, in the classic tying arrangement, a patent holder would be precluded from obtaining a remedy for breach of the tying agreement with respect to amounts due not only the unpatented components that were improperly “tied,” but also on the patented components themselves. Moreover, the misused patents would be rendered unenforceable against any third party infringer.

146. “It is the adverse effect upon the public interest of a successful infringement suit in conjunction with the patentee’s course of conduct which disqualifies him to maintain the suit, regardless of whether the particular defendant has suffered from the misuse of the patent. . . . The patentee, like those other holders of an exclusive privilege granted in the furtherance of public policy, may not claim protection of his grant by the courts where it is being used to subvert that policy.” *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492-495 (1942).

147. Chisum, *Defenses*, § 19.04. As Chisum observes, “If . . . misuse is found, the courts will withhold any remedy for infringement or breach of a license agreement—even against an infringer who is not harmed by the abusive practice.” *Id.*

148. On the other hand, if a patentee’s conduct is found to constitute misuse (whether *per se* or under the rule of reason), that same conduct may also be the basis for an antitrust claim against the patentee, which if found, may result in antitrust remedies in addition to the consequences that result from a finding of patent misuse alone.

the misuse, the patent will become enforceable once again.¹⁴⁹ In other words, patent misuse suspends, but does not forever preclude, the patent holder's right to recover for patent infringement or breach of a patent license.¹⁵⁰ However, in order to regain the right of relief, (1) the patent holder must completely abandon the abusive practice, and (2) the consequences of that abusive practice must be fully dissipated.¹⁵¹ As to the first requirement, a patentee may abandon misuse arising from a license provision by either canceling the license¹⁵² or by canceling the offending license provision.¹⁵³ However, non-enforcement of an offending provision, alone, is insufficient to constitute abandonment.¹⁵⁴ Accordingly, if a patent license provision were found to constitute misuse, an effective purge would require the patent holder to fully and effectively waive that provision with respect to all of its licensees of the subject patent. The second requirement of a purge, which is that the consequences of the misuse have been fully dissipated, requires another fact-based inquiry. Where the misuse had no adverse consequence, some lower courts have held that

149. See *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493 (1942) ("Equity may rightly withhold its assistance from such a [mis]use of the patent by declining to entertain a suit for infringement, and should do so at least until it is made to appear that the improper practice has been abandoned and that the consequences of the misuse of the patent have been dissipated.").

150. See *United States Gypsum v. Nat'l Gypsum*, 352 U.S. 457, 465 (1957) ("It is now, of course, familiar law that courts will not aid a patent holder who has misused his patents to recover any of their emoluments accruing during the period of misuse or thereafter until the effects of such misuse have been dissipated or 'purged'"); *Senza-Gel Corp. v. Seiffhard*, 803 F.2d 661, 668 n.10 (Fed. Cir. 1986) (a "successful patent misuse defense results in rendering the patent unenforceable until the misuse is purged"); *Id.* at 668 ("All that a successful defense of patent misuse means is that a court of equity will not lend its support to enforcement of a mis-user's patent.").

151. Chisum, *Defenses*, 19-323, § 19.04[4] (citing, *inter alia*, *Morton Salt* and *Gypsum*).

152. *Id.*

153. See, Chisum, *Defenses*, 19-538, § 19.04[4] n.15 (citing *Berlenbach v. Anderson & Thompson*, 329 F.2d 782 (9th Cir. 1964) ("Although we have said that nonenforcement and voluntary relinquishment of an illegal clause will overcome the defense of patent misuse, . . . we know of no case permitting an infringement suit where the clause remains in effect but unenforced."); *In re Yarn Processing Patent Validity Litigation*, 472 F. Supp. 180 (S.D. Fla. 1979) ("To establish purge, the law requires the patent holder [to] engage in clear and unequivocal affirmative action in abandoning the misuse. . . . Mere non-enforcement of the illegal provision is itself insufficient abandonment under the law of purge.").

154. See *supra* note 152. Chisum also points out "that the licensor may simply annul a provision inserted for his benefit without obtaining the consent of the licensees." Chisum, *Defenses*, 19-538, § 19.04[4] n.16 (citing *Automatic Radio Mfg. Co. v. Hazeltine Research Co.*, 339 U.S. 827, 835 (1949) ("Since this provision of the agreement was made for the benefit of respondent, it could voluntarily waive the provision.")).

abandonment alone is sufficient to affect a purge.¹⁵⁵ In any case, once the misuse is purged, the remedies of patent infringement and the right to enforce the affected patent license are revived with respect to infringing acts occurring after the abandonment and dissipation.¹⁵⁶

Accordingly, patent misuse doctrine sets certain limits on the way a patentee can exploit his or her patent, and places boundaries on lawful patent licensing practice. Specifically, lawful licensing practice is limited by the physical and temporal scope of the patent itself, each of which is subject to analysis under a distinct line of cases addressing patent misuse. We start with a discussion of physical scope.

C. Physical Scope

In this section, we will analyze a reach-through royalty arrangement in terms of whether it constitutes an unlawful extension of the “physical” scope of a patent. The “physical” scope of each patent consists of the items or methods that fall within the subject matter of its claims. While such claims cannot themselves be extended by a patentee, a licensing practice—such as a reach-through royalty—may have an analogous and therefore impermissible effect by imposing an economic burden on an item or method outside of the subject matter of such claims. Our focus is on whether it is lawful to license a Discovery Tool patent in consideration for a royalty on the sales of a drug found using that tool, where the drug itself is not covered by the licensed patent.

To address this question, we review the leading Supreme Court cases and their Federal and Regional Circuit progeny that have addressed closely analogous fact patterns. Based on this analysis, we conclude that a reach-through royalty, if properly negotiated, is not an impermissible extension of the physical scope of a patent and may be a lawful arrangement.

155. Chisum, *Defenses*, 19-538-539, § 19.04[4]; Chisum notes that “[a] number of lower court decisions indicate that abandonment alone is sufficient where it is not shown that the misuse had any actual adverse consequences.” *Id.* n.17 (citing *White Cap Co. v. Owens-Illinois Glass Co.*, 203 F.2d 694, 698 (6th Cir. 1953) (“Under such circumstances it was unnecessary for the plaintiff to prove that the consequences of the misuse had been dissipated because it was not shown that the misuse had illegal consequences.”)).

156. Chisum, *Defenses*, 19-538, § 19.04[4]; As Chisum noted, “[i]n *Gypsum [United States Gypsum v. National Gypsum]*, 352 U.S. 457 (1957), the Court seemed to assume that a patent owner could not, even after complete abandonment and dissipation, recover monetary relief for infringing acts occurring prior to such dissipation.”

1. *Leading “Total Sales” Royalty Cases: Automatic Radio and Zenith*

Neither the Supreme Court nor any federal appeals court has ruled specifically on whether a reach-through royalty constitutes patent misuse.¹⁵⁷ Substantial jurisprudence exists, however, on an analogous royalty arrangement that also involves an extension of the “physical scope” of a patent. This type of royalty arrangement is commonly referred to as a “total sales” royalty. A total sales royalty involves the grant of a patent license where royalties are calculated not only on the sales of the product covered by the patent, but also on the sales of products or components that are not covered by the licensed patent. In this section, we analyze the leading total sales royalty cases, and argue that the rules and reasoning of those cases should also govern the analysis of the legality of a reach-through royalty arrangement.

a. *Automatic Radio*

The seminal case in total sales royalty jurisprudence is the Supreme Court’s decision in *Automatic Radio Manufacturing Co., Inc. v. Hazeltine Research, Inc.*¹⁵⁸ In this case, a radio research organization (Hazeltine) licensed 570 patents and 200 patent applications covering inventions relating to the manufacture of radio broadcasting receivers in return for a small percentage of all of the licensee’s (Automatic Radio’s) sales of radio broadcasting receivers. It was clear that some of the receivers on which a sales royalty was to be paid would not be covered by any of Hazeltine’s patents or patent applications, although with respect to any individual receiver it was not clear, without a significant tracking effort, whether its manufacture and sale fell within the scope of any of the licensed patents or patent applications. Hazeltine sued Automatic Radio to recover royalties under their license agreement. Automatic Radio asserted a defense of patent misuse. Rejecting the misuse defense and affirming the appellate court’s judgment for Hazeltine, the Supreme Court held that “in licensing the use of patents to one engaged in a related enterprise, it is not *per se* a misuse of patents to

157. *But see Bayer v. Housey*, 228 F. Supp. 2d 467 (D. Del. 2002), *aff’d*, 340 F.3d 1367 (Fed. Cir. 2003), the only federal district court case of which we are aware that addressed the legality of reach-through royalties in the context of a Discovery Tool patent license, discussed in section V.C.3., *infra*.

158. 339 U.S. 827 (1950).

measure the consideration by a percentage of the licensee's [total] sales."¹⁵⁹

In reaching its holding, the Court in *Automatic Radio* rejected three main arguments by the defendant, each of which, as we will discuss, is relevant in terms of analyzing a reach-through royalty arrangement. First, the Court dismissed as inapposite *Automatic Radio*'s argument that the total sales royalty constituted per se misuse and, possibly, an antitrust violation on the basis that it was an unlawful tying arrangement or "identical in principle" thereto.¹⁶⁰ As stated by the Court, the "tie-in" cases "have condemned [practices] requiring the purchase of unpatented goods for use with the patented apparatus or process, . . . prohibiting production or sale of competing goods, . . . and conditioning the grant of a license under one patent upon the acceptance of another different license."¹⁶¹ These actions are deemed to be unlawful because they involve the use of patent leverage to create another monopoly or restrain trade.¹⁶² However, the Court found that none of those elements are present in the case of a total sales royalty. Solely at issue in *Automatic Radio* was a method of calculating royalties for the licenses granted. As stated by the Court:

That which is condemned as against public policy by the "Tie-in" cases is the extension of the monopoly of the patent to create another monopoly or in restraint of competition—a restraint not countenanced by the patent grant. . . . The principle of those [tie-in] cases cannot be contorted to circumscribe the instant [total sales royalty]. This [total sales] royalty provision does not create another monopoly; it creates no restraint of competition beyond the legitimate grant of the patent. The right to a patent includes the right to market the use of the patent at a reasonable return.¹⁶³

As such, the Court concluded that the "tie-in" cases do not "on their facts" control the total sales royalty in *Automatic Radio*.¹⁶⁴

159. 339 U.S. at 834.

160. This represents the first prong of the Federal Circuit's analytical framework for determining patent misuse.

161. *Id.* at 830-31; *See supra* note 130.

162. *See, e.g., Mercoind Corp. v. Mid-Continent Inv.t Co.*, 320 U.S. 661, 665-666 (1944); *Morton Salt Co. v. Suppiger Co.*, 314 U.S. 488 (1942); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456 (1940).

163. *Automatic Radio*, 339 U.S. at 832-833; *see also Hartford-Empire Co. v. United States*, 323 U.S. 386, 417 (1945).

164. *Id.* at 830-833.

Second, the Court distinguished *United States v. U.S. Gypsum*,¹⁶⁵ which Automatic Radio had relied upon to argue that the total sales royalty constituted an antitrust violation under the Sherman Act. *Gypsum* also involved a total sales royalty. In that case, a licensor entered into numerous license agreements—in aggregate, with substantially all of the parties in the relevant market—that based royalties on sales of both patented and unpatented products (i.e., a total sales royalty) with the understanding that only patented goods would be sold. The Court held that this practice violated the Sherman Act, since it constituted a conspiracy between the licensor and its licensees to restrict production and fix prices of unpatented goods, and to eliminate competition in the market for such goods. In *Gypsum*, “[i]t was held that the license provisions, together with evidence of an understanding that only patented [products] would be sold, show a conspiracy to restrict the production of unpatented products which was an invalid extension of the area of the patent monopoly.”¹⁶⁶ The holding in *Gypsum* therefore relied on a combination of incriminating facts that demonstrated a concerted effort by the defendants “to restrain commerce in an entire industry under patent licenses in order to organize the industry and stabilize prices.”¹⁶⁷ However, no such facts or conspiracy were present in *Automatic Radio*, nor would the Court imply such a conspiracy merely on the basis that a total sales royalty provision was utilized. Accordingly, no antitrust violation was found.

Third, the Court rejected Automatic Radio’s argument that a total sales royalty otherwise constituted an unlawful extension of Hazeltine’s patent monopoly. In its reasoning, the Court established the principle of mutual convenience—a cornerstone of our analysis in this Article. The Court explained that “there is in this [total sales] royalty provision no inherent extension of the monopoly of the patent.”¹⁶⁸ Rather,

since it would not be unlawful to agree to pay a fixed sum for the privilege to use patents, it was not unlawful to provide a variable consideration measured by a percentage of the licensee’s [total] sales for the same privilege... Sound business judgment could indicate that such a [total sales royalty]

165. 333 U.S. 364 (1948).

166. *Automatic Radio*, 339 U.S. at 832 (citing *United States v. U.S. Gypsum*, 333 U.S. at 397).

167. *United States v. U.S. Gypsum*, 444 U.S. at 401.

168. *Automatic Radio*, 339 U.S. at 834.

payment represents *the most convenient method of fixing the business value of the privileges granted by the licensing agreement*.¹⁶⁹ (emphasis added).

As such, the Court in *Automatic Radio* established the principle that a “total sales” royalty entered into for the mutual convenience of the parties is permissible even if it obligates the licensee to pay royalties on the sales of products that are not covered by the licensed patents.¹⁷⁰ In essence, the Court found that a “total sales” royalty that is mutually agreed upon is lawful, and does not constitute per se, or any other form of, patent misuse.¹⁷¹

b. Zenith

The Supreme Court’s decision in *Automatic Radio* was not, however, an unqualified endorsement of total sales royalty arrangements. In *Zenith Radio Corporation v. Hazeltine Research Inc.*,¹⁷² the Supreme Court again addressed the legality of total sales royalties, and in doing so, defined the limitations of the mutual convenience doctrine of *Automatic Radio*. Zenith, a radio and television manufacturer, obtained rights under a license agreement to use all of Hazeltine’s domestic radio and television patents in return for a payment of royalties on Zenith’s total radio and television sales. Upon the expiration of the license, Zenith declined to accept Hazeltine’s offer to renew it, but continued to practice under the previously licensed patents. Hazeltine sued Zenith for patent infringement. Zenith argued in response that Hazeltine’s claims were unenforceable under the patent misuse doctrine. The Supreme Court agreed, holding that “*conditioning* the grant of a patent license upon payment of royalties on products which do not use the teaching of the patent does amount to patent misuse.”¹⁷³ (Emphasis added). Conditioning, in this case, was found where Hazeltine had a “policy of insisting upon the acceptance of its standard five-year package license agreement, covering 500-odd patents . . . and reserving

169. *Id.* at 833-834.

170. What is unclear from the facts of *Automatic Radio* is whether, despite mutual convenience, a “total sales” royalty will be found to constitute misuse unless there exists a significant administrative burden in determining whether a product sold by a licensee is covered by a licensed patent.

171. In this case, although a total sales royalty imposes an economic burden on the sale of unpatented products (thereby extending the economic impact of the patent), the Court did not engage in any formal rule of reason analysis.

172. 395 U.S. 100 (1969).

173. 395 U.S. at 135.

royalties on the licensee's total radio and television sales, irrespective of whether the licensed patents were actually used in the products manufactured."¹⁷⁴ The Court explained that conditioning is "where the patentee refuses to license on any other basis and leaves the licensee with the choice between a license . . . providing [royalties on at least some unpatented products] and no license at all."¹⁷⁵ The Court distinguished *Automatic Radio* on the grounds that no conditioning was evident in the facts of that case, and limited the holding in *Automatic Radio* approving total sales royalties to circumstances in which no conditioning exists. The fact that the parties enter into an agreement with a total sales royalty is not, alone, sufficient to demonstrate that such royalty was not coerced by the licensor.¹⁷⁶ On the other hand, conditioning should not be implied by virtue of the mere presence of a total sales provision in a license agreement. A total sales royalty may be permissible

even if, as things work out, only some or none of the merchandise employs the patented idea or process, or even if it was foreseeable that some undetermined portion would not contain the invention. It could easily be . . . that the licensee as well as the patentee would find it more convenient and efficient . . . to base royalties on total sales than to face the burden of figuring royalties based on actual use. . . . If the convenience of the parties [as in *Automatic Radio*] rather than patent power [as in *Zenith*] dictates the total-sales royalty provision, there are no misuse of the patents and no forbidden conditions attached to the license. . . . But we do not read *Automatic Radio* to authorize the patentee to use the power of his patent to insist on a total-sales royalty and to override protestations of the licensee that some of his products are unsuited to the patent or that for some lines of his merchandise he has no need or desire to purchase the privileges of the patent.¹⁷⁷

Accordingly, a total-sales royalty—if not obtained through coercion—will be deemed lawful even if "as things work out only

174. *Id.* at 134.

175. *Id.* See also *id.* at 139 ("We also think that misuse inheres in a patentee's insistence on a percentage-of-sales royalty, regardless of use, and his rejection of licensee proposals to pay only for actual use. Unquestionably, a licensee must pay if he uses the patent. Equally, however, he may insist upon paying only for use, and not on the basis of total sales, including products in which he may use a competing patent or in which no patented ideas are used at all.").

176. See *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 420 F.2d 319, 321 (2d Cir. 1970) ("The mere fact of agreement is not determinative.").

177. *Zenith Radio Corporation v. Hazeltine Research, Inc.*, 395 U.S. 100, 138-39 (1969).

some or none” of the products sold are covered by the licensed patents. However, if a total-sales royalty is obtained through coercion, it will be deemed to be *per se* patent misuse.

2. *Application of Automatic Radio and Zenith to a Reach-Through Royalty Arrangement*

Our view is that the reasoning of the Supreme Court in *Automatic Radio* and *Zenith* should apply to an analysis of the legality of a reach-through royalty arrangement in the context of the license of a Discovery Tool patent. Like a total sales royalty, a reach-through royalty is a method of calculating the consideration for a licensed patent based on the sales of products that are outside of the subject matter (i.e., outside of the physical scope) of the licensed patents. If a reach-through royalty is deemed by a willing licensor and a willing licensee to be a mutually convenient method of calculating that consideration, and it is not coerced by the licensor within the meaning of *Zenith*,¹⁷⁸ then it too should be found to be lawful.¹⁷⁹

Automatic Radio and *Zenith* set forth the basic principles of patent misuse law with respect not only to total sales royalties, but also, as we discuss below, more generally with respect to methods of calculating patent royalties based on products or components entirely outside of the subject matter of the licensed patent claims, including reach-through royalties. In the course of our analysis, we address three potential jurisprudential objections to the application of *Automatic Radio* and *Zenith* to a reach-through royalty arrangement in the context of the license of a Discovery Tool patent.

178. To avoid a finding of coercion, a Discovery Tool licensor could offer the licensee economically viable options of paying only for actual use of the patented tool, in addition to the option of a reach-through royalty. For example, tool-based options might include a reasonable upfront, fixed payment for the right to use the tool or reasonable variable payments based on the amount or character of tool usage. If the licensee then elected to pay based on the reach-through royalty arrangement, the arrangement should qualify as one entered into for the mutual convenience of the parties, and therefore be deemed lawful under *Automatic Radio* and *Zenith*.

179. See section V.C.2.a., *infra* (discussion of *Engel*). In the case of *Automatic Radio* and *Zenith*, the total sales royalty was calculated based on the licensee’s sale of televisions and radios, whether patented or unpatented. More generically, the total sales royalty may be described as a royalty that accrues on the sale of products, both patented and unpatented, that are generally of a similar type.

a. Do *Automatic Radio* and *Zenith* Apply Beyond “Total Sales” Royalty Cases?

A first potential objection is that *Automatic Radio* and *Zenith* are limited to facts involving royalties that are based on “total sales,” and a reach-through royalty is not a total sales royalty.

As demonstrated in *Automatic Radio* and *Zenith*, a “total sales” royalty is a royalty that is based on sales of products of the same general type, some of which are or may be covered by the licensed patents, and some of which are not. Like a total sales royalty (at least in part), a reach-through royalty is calculated based on the sales of products that are not covered by the licensed patents, and in that way, also represents an extension of the physical scope of the licensed patent. However, there are several important distinctions between total sales royalties and reach-through royalties. A reach-through royalty, paid in consideration for the license of a Discovery Tool patent, does not involve the license of rights to a product that is sold by the licensee to generate revenue, but rather, the license of an upstream research tool used in the hopes of discovering a drug product that may, in turn, be sold. Accordingly, reach-through royalties are not calculated based on the “total sales” of licensed and unlicensed products of the same general type, but rather, on sales of a product (the drug) that (1) without question is not covered by the licensed patent (which claims only the Discovery Tool) and (2) is likely different in character (a composition of matter) from the licensed tool (a screening method) used to discover it.¹⁸⁰

This highlights yet another, albeit more subtle, distinction. While *Automatic Radio* and *Zenith* expressly acknowledge that allowing a total sales royalty may mean that royalties are calculated based on product sales where an individual product may not, in fact, be covered by the licensed patent, those cases also presume that, at the time the license is granted, at least some of the products sold *may* be covered. With respect to a license of a Discovery Tool patent, it is known from the outset that the licensed patent covers only the research tool, and that the royalty will be calculated based only on the sale of a drug that is not, never was, and never will be, covered by the licensed patent. One may fairly argue, then, that a reach-through royalty “physically” extends the royalty base for a licensed patent in a

180. *Cf.*, *Zenith*, 395 U.S. at 138 (the Court acknowledged that a total sales royalty was lawful “even if, *as things work out*, only some or none of the merchandise employs the patented idea or process, or even if it was foreseeable that some undetermined portion would not contain the invention.”) (emphasis added).

manner that is fundamentally different from that of a total sales royalty.

Despite these factual differences, case law interpreting *Automatic Radio* supports the conclusion that its holding should apply beyond total sales royalty cases to include reach-through royalty arrangements. In *Engel Industries, Inc. v. Lockformer Company*,¹⁸¹ the Federal Circuit relied on *Automatic Radio* to uphold a royalty that was not based on total sales, but rather, was based on distinct, unpatented components (corner connectors) that were sold with and used in connection with the patented products (sheet metal duct sections). *Engel* involved the grant of a license under a patent with apparatus and method claims covering a system for connecting the ends of sheet metal duct sections. In order to use these sheet metal duct sections as intended (forming an integral frame), there was a need to utilize certain unpatented “corner connectors.” For each unpatented corner connector produced by the licensee or purchased by the licensee from another party (other than the licensor), the licensee was required to pay a royalty. If the licensee elected to purchase the unpatented corner connector from the licensor, no royalty would be payable. While this royalty applied to unpatented products (the corner connectors), and therefore represented an extension of “the physical scope” of the licensed patent, the arrangement was not a royalty based on the “total sales” of patented and unpatented products, as in *Automatic Radio* and *Zenith*. Nonetheless, the Federal Circuit in *Engel* cited *Automatic Radio* and *Zenith* for the proposition that “royalties may be based on unpatented components if that provides a convenient means for measuring the value of the license,”¹⁸² and found that the arrangement was “voluntarily agreed to” by the parties, and, therefore, lawful.

The decision in *Engel* represents an important application of the holdings of *Automatic Radio* and *Zenith*. In the “total sales” royalty jurisprudence starting with *Automatic Radio* and *Zenith*,¹⁸³ the royalty base included a category of products, at least some of which might be covered by the licensed patents, “even if, as things work out, only some or none of the merchandise employs the patented idea or

181. 96 F.3d 1398 (Fed. Cir. 1996).

182. *Engel Industries*, 96 F.3d at 1408.

183. See also *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 299 F. Supp. 278 (S.D. New York 1969), remanded in 420 F.2d 319 (2nd Cir. 1970) (toilet tank covers); *Plastic Contact Lens Company v. Young Contact Lens Laboratories, Inc.*, 175 U.S.P.Q. 573 (D. Mass. 1972) (contact lenses).

process.”¹⁸⁴ By contrast, in *Engel*, it was clear at the time the license was granted that the basis for calculating the royalty (the making or buying of corner connectors) was a convenient measure of the value of the licensed rights, but that those corner connectors were not, never had been, and never would be, covered by the licensed patents. The reach-through royalty arrangement under consideration in this Article can be similarly described. As a convenient measure of the value of the grant of a license to a Discovery Tool patent, royalties are calculated and paid based on the licensee’s sales of drugs found using that tool, despite the fact that such drugs are not, never were, and never will be, covered by the tool patent. The royalty arrangement in *Engel* and the reach-through royalty arrangement under analysis here, each represents an extension of the physical scope of a licensed patent since it burdens an activity of the licensee (whether the making or buying of corner connectors in *Engel* or the sale of a drug discovered using a research tool) that falls outside of the scope of the licensed patent. If *Automatic Radio* and *Zenith* allow a royalty to accrue upon the licensee’s making or purchase of a product (a corner connector) that is not covered by the licensed patent, so too should they allow a royalty calculated upon the sale of a product (a drug) identified using a patented research tool, as long as the royalty arrangement is not coerced and is otherwise determined by the parties to be a convenient measure of the value of the licensed rights.

Accordingly, Federal Circuit precedent suggests that *Automatic Radio* and *Zenith* are not limited to facts involving total sales royalties, but rather apply more generally to cases involving other types of royalty arrangements, including reach-through royalties, that contractually extend the physical scope of a licensed patent.

b. Must the extent of the royalty base be difficult to determine?

A second potential objection to the application of *Automatic Radio* and *Zenith* to a reach-through royalty arrangement is that those cases justify a non-coerced royalty obligation on the sale of unpatented products *only* where it is difficult to determine whether an individual product is covered by the licensed patent(s). Such difficulty may arise when a large patent portfolio is licensed to a party that sells a number of closely related products, not all of which are

184. *Zenith*, 395 U.S. at 138.

necessarily covered by the licensor's patents.¹⁸⁵ In that circumstance, determining the royalty base for the calculation of a royalty payment can present a significant administrative burden if it requires tracking the sales of only those products that are covered by the licensed patents. Confronted with the possibility of such a burden, the parties may well agree that extending the royalty obligation to include the sales of products that may not be covered by a licensed patent is necessary as a practical matter.

The avoidance of just such an administrative burden was certainly a factor in justifying the total sales royalty arrangement in *Automatic Radio*, where the license agreement at issue was a "package" license that included hundreds of patents and patent applications. In that case it would have been a significant and costly administrative burden to track which products made or sold in fact used the claimed inventions.¹⁸⁶ Likewise, *Zenith* involved the license

185. Both *Automatic Radio* and *Zenith* involved the licensing of large patent portfolios to licensees that manufactured and sold closely related electronic products. See also *Plastic Contact Lens Company v. Young Contact Lens Laboratories, Inc.*, 175 U.S.P.Q. 573 (D. Mass. 1972) for a case that involved difficulty in determining whether a product is covered by a licensed patent, outside of the context of a package license. (The total sales royalty arrangement was used as a necessary convenience in light of the fact that it was "difficult for manufacturers to determine, because the applicability of a particular patent depends largely on the physical relationship of the lens to the surface of the cornea of the eye, which ordinarily is not known by the manufacturer but only by the physician or other person qualified to fit or prescribe the lens which will fit a particular eye." *Id.* at 573. The parties agreed that "for the convenience of all concerned, royalties would be based upon total sales at a substantially reduced royalty rate per lens." *Id.* at 574. An alternative arrangement remained available to manufacturing licensees in which royalties were charged only for lenses manufactured under the patent.)

186. Package royalty jurisprudence subsequent to *Automatic Radio* has followed the principle that a package royalty provision is lawful provided that the arrangement was uncoerced and the royalty obligation terminates upon expiration of the last-to-expire licensed U.S. patent. See *McCullough Tool Co. v. Well Surveys, Inc.*, 343 F.2d 381, 410 (10th Cir. 1965) (relying on *Automatic Radio* to uphold a package license that was "purely voluntary"); *Well Surveys, Inc. v. Perfo-Log, Inc.*, 396 F.2d 15, 18 (10th Cir. 1968) (adhering to the decision in *McCullough* and holding that "[t]he relative importance of patents has no significance if a licensee is given the choice to take a patent alone or in combination on reasonable terms. Freedom of choice is the controlling question."); *Hull v. Brunswick Corporation*, 704 F.2d 1195, 1202 (10th Cir. 1983) (upholding a royalty that "does not on its face call for royalty payments to continue after the time that no unexpired patents are being used."); *Beckman Instruments, Inc. v. Technical Development Corp.*, 433 F.2d 55, 61 (7th Cir. 1970) (relying on the reasoning in *McCullough Tool* to conclude that "a package license agreement, voluntarily entered into, which requires the payment of royalties beyond the expiration of some, but not all, of the licensed patents is valid."); *Hensley Equipment Co. v. Esco Corp.*, 383 F.2d 252, 265 (5th Cir. 1967) (upholding a package royalty where the arrangement was not coerced and the royalty terminated upon the expiration of the last patent in the package). But see, *Rocform Corp. v. Acitelli-Standard Concrete Wall, Inc.*, 367 F.2d 678, 681 (6th Cir. 1966) ("[W]e deal with a licensing

of a large patent portfolio and a reliance on a total sales royalty arrangement to avoid a significant administrative royalty tracking burden (although, as discussed above, in that case the royalty arrangement was held to be illegal because it was *a condition of the license* and not agreed to for the convenience of the parties).

By contrast, a reach-through royalty obligation included in a Discovery Tool patent license agreement presents no administrative royalty tracking burden. The licensed product (a research tool) is not sold by the licensee to generate revenues, but is used by the licensee to identify a drug product. The royalties to be paid by the licensee are calculated on the sale of the identified drug and it is known, *ab initio*, the drug is not covered by the licensed Discovery Tool patent (since no patent claims reach through the tool to cover the discovered drug). In the absence of any tracking problems, a reach-through royalty may be a mutual convenience, but it is not necessary as a practical matter. Simply put, if *Automatic Radio* and *Zenith* were limited to their respective facts, and the need to avoid a potential administrative royalty tracking burden was a required element of those holdings, those decisions would not support the legality of a reach-through royalty arrangement.

This proposition, however, is not supported by applicable case law as it has evolved since the decisions in *Automatic Radio* and *Zenith* were first handed down. Jurisprudence subsequent to *Automatic Radio* and *Zenith* suggests that the need to avoid a potential administrative burden is not required in order to justify a royalty on unpatented products; rather, mutual convenience alone will suffice. This point was clearly illustrated by the reversal and remand by the Second Circuit Court of Appeals of a decision of the U.S. District Court for Southern District of New York in *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*¹⁸⁷ This case involved a licensee's challenge, on patent misuse grounds, of a total sales royalty that was based on the licensee's sales of toilet tank covers, where only some of those sales were covered by the licensed patent. In contrast to *Automatic Radio* and *Zenith* (each of which involved the license of a large number of patents as a package), *Glen* involved

arrangement where one important patent (about to expire) is grouped with others of longer duration for 'leverage'" and "we believe such a contract, when it contains no diminution of license fee at the expiration of the most important patent and contains no termination clause at the will of the licensee, constitutes, in effect, an effort to continue to collect royalties on an expired patent.").

187. 299 F. Supp. 278 (S.D. New York 1969), remanded in *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 420 F.2d 319 (2d. Cir. 1970).

the license of a single U.S. patent that covered a single, uncomplicated product.¹⁸⁸ As noted by the district court, upon any sales of the toilet tank cover, it could be readily determined, without any administrative burden, whether such product utilized the teachings of the licensed patent. The district court held that the royalty arrangement constituted patent misuse, and it based that decision on a narrow reading of *Automatic Radio*, as follows:

[*Automatic Radio*] did little more than establish a reasonable method of calculating royalties in a situation where it was virtually impossible to determine whether each product manufactured by the licensee embodied any of the 570 patents or 200 patent applications for electronic apparatus. Because of the complexities involved in the patents and the difficulty in determining whether the patented devices were used in the licensee's products, the court permitted the royalty structure in question. The [*Automatic Radio*] rationale is, therefore, an exception to the general rule requiring a strict, limited royalty structure; it is by no means the standard in a case such as the present where the patented item involved is a single, simple, uncomplicated object.¹⁸⁹

Accordingly, the district court held that, in the absence of a potential administrative burden, a total sales royalty constitutes patent misuse (presumably as a contractual arrangement that impermissibly extends the physical scope of the licensed patent), irrespective of whether the license was conditioned. Where there is no difficulty in determining whether a product is covered by the licensed patent, the *Glen* district court required that royalties be calculated solely on the basis of the sales of the covered product.

The Second Circuit reversed. Relying on the Supreme Court's decision in *Zenith*, which was handed down just one week after the district court's decision in *Glen*, the Second Circuit held that conditioning—rather than the presence or absence of a potential administrative burden—was the critical factor in determining whether a total sales royalty constituted misuse. In the view of the Second Circuit, the district court had applied the wrong legal standard. Accordingly, the Second Circuit remanded the case for further findings on the key issue of conditioning, as articulated in *Zenith*. The fact that the *Glen* case was remanded is significant to our

188. While there was also a license of a Canadian patent in the *Glen* case, the existence of that license did not enter into the court's analysis, and is irrelevant for our purposes.

189. 299 F. Supp. 278, 285 (1969).

analysis, since it dispelled any notion that *Automatic Radio* is limited to circumstances where it is difficult to determine whether the licensee's product sales are covered by a licensed patent. If *Automatic Radio* had required difficulty in determining whether a product sold by a licensee is covered by the licensed patent in order to avoid a finding of misuse, the Second Circuit in *Glen* would have had no need to remand the proceedings. Rather, the lack of such difficulty in *Glen* would have alone been sufficient to justify a finding of misuse on the basis of the total sales royalty arrangement without any need to remand to determine whether the license was conditioned. Nonetheless, the Second Circuit in *Glen* did remand the case to the district court. Therefore, the procedural history in *Glen* suggests that, under the Second Circuit's interpretation of *Automatic Radio*, an non-coerced total sales royalty arrangement is not patent misuse when entered into for the "mutual convenience" of the parties, despite the fact that there is no difficulty in determining whether or not a royalty-bearing product is covered by the licensed patent. The Federal Circuit decision in *Engel* also supports this conclusion, where it was clear that the royalty-bearing corner connectors were not covered by the licensed patent.¹⁹⁰

Accordingly, the presence or absence of difficulty in calculating or applying a royalty is not an essential element in determining the legality of a reach-through royalty arrangement. It follows, then, that any attempt to reject such a payment arrangement as unlawful based on a reading of *Automatic Radio* and *Zenith* as requiring such a difficulty would likely fail.

c. Do *Automatic Radio* and *Zenith* Require a Nexus Between the Licensed Patent and the Royalty Base?

If the holdings in *Automatic Radio* and *Zenith* apply generally to "physical" extensions of a royalty base of a patent license to unpatented products, may willing licensors and licensees agree to patent royalties that are calculated based on products or activities that are wholly unrelated to the licensed patents? In other words, does the law of patent misuse require any nexus between the licensed patent and the royalty base? The answer is likely yes. As a practical matter, rational licensors and licensees negotiating an arms-length, non-coerced agreement would presumably only enter into a patent license with a royalty base that reflected a measure of the value received or generated by the licensee from its exploitation of the

190. See *infra* section V.C.2.a.

licensed patent. Nonetheless, as a doctrinal matter, commentators have acknowledged that “[t]he criteria used to establish the royalty rate may raise antitrust or misuse issues where the royalty calculation is unrelated to the licensee’s utilization of the patent.”¹⁹¹ Thus, it would seem that the principle of “mutual convenience” established in *Automatic Radio* is likely premised on an assumption that some nexus must exist between the subject matter of the licensed patent and the royalty base. The question, then, is whether the nexus between a licensed Discovery Tool and the drugs found using that tool (whose sales constitute the base used to calculate the royalties) is sufficient to allow the application of *Automatic Radio* and *Zenith*? We think so. As long as a reach-through royalty arrangement is not coerced and is otherwise determined by the parties to a license to be a convenient method of measuring the value of licensed rights (i.e., the royalties accrue based on sales of drugs found using the licensed tool and not on the sales of unrelated drugs or products), our view is that the misuse doctrine likely does not preclude such reach-through royalties.

In *Automatic Radio*, *Zenith* and *Glen*, the royalty base was comprised of sales of products of the same type as those covered by the licensed patents (i.e., radios and televisions or toilet tank covers). However, as *Engel* made clear, a component or peripheral (corner connectors) that is not covered by the licensor’s patent but is consistently used with the licensed product (sheet metal ducts) may constitute a convenient measure of value, and therefore, a lawful royalty base. By contrast, in the reach-through royalty arrangement under consideration in this Article, the royalty base is comprised of sales of drugs found using (rather than used or sold with) the licensed tool patent. As the Federal Circuit recently acknowledged, its “case law has not addressed in general terms the status of . . . restrictions placed on goods made by, yet not incorporating, the licensed good under the patent misuse doctrine.”¹⁹² This statement applies equally to goods discovered by a licensed method.

Nonetheless, we would argue that the nexus between a Discovery Tool and a drug discovered using that tool is at least as close as, and as rationally connected as, the nexus found in other cases where mutual convenience has justified royalties on unpatented products. In *Automatic Radio*, *Zenith* and *Glen*, the patented and unpatented

191. ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 1108 (6th ed. 2007).

192. *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1343 (Fed. Cir. 2004); see *supra* note 126.

products included in the royalty base were connected only in the sense that they were all sold by the same licensee and were generally the same type of product (i.e., radios and televisions or toilet tank covers). By contrast, in the Discovery Tool context, the tool and the drug are categorically distinct products. In *Engel*, the royalty base was comprised of a corner connector that was used every time the licensee used the licensed product, and therefore the use of the unlicensed corner served as a measure of the value derived by the licensee from the licensed product. Drug discovery, however, does not involve any such contemporaneous use of tools and drugs. Rather, drug discovery is serial in nature. The Discovery Tool gives rise to data, and that data is used to identify and then develop drug candidates. Despite these factual distinctions, the essential point is that, arguably, drug sales are the best measure of the value created by the use of a Discovery Tool. The purpose of using the Discovery Tool is to identify drug candidates, and if successful, such drug sales are directly enabled by the use of the Discovery Tool. Accordingly, drug sales certainly can represent a convenient measure of the value of the licensed rights, and for that reason, are sufficiently related to such rights to allow the application of *Automatic Radio* and *Zenith*.

For all of the reasons discussed above, *Automatic Radio* and *Zenith* should apply to an analysis of the legality of a reach-through royalty, and any Discovery Tool licensor wishing to avoid a finding of misuse when entering into a patent license containing such a royalty arrangement would need to comply with the principles of those decisions. On the basis of these Supreme Court holdings, we conclude that where a reach-through royalty is offered together with an economically viable alternative to pay only for actual use, and the licensee elects to pay a percentage of the sales of drugs found using the licensed Discovery Tool, the arrangement does not constitute patent misuse and is lawful.

3. Bayer v. Housey

Our conclusion regarding the legality of a reach-through royalty arrangement in the context of the license of a Discovery Tool patent is consistent with the only federal district court decision that addresses this issue.¹⁹³ Applying the principles established in

193. While we have searched the extant case law, it is of course possible that we have missed a federal case, and we certainly have not exhaustively searched state case law. Nonetheless, it is clear that as the time of the drafting of this Article, that there is only one significant federal case addressing the legality of reach-through royalties of the sort contemplated by this Article, and the district court in that case reached the same

Automatic Radio, Zenith and Engel Industries, the district court in *Bayer AG v. Housey Pharmaceuticals, Inc.*¹⁹⁴ held that a non-coerced reach-through royalty is not an impermissible extension of the physical scope of a licensed patent and, therefore, is a lawful arrangement.¹⁹⁵ In that case, Bayer AG, a pharmaceutical company, filed an action seeking a declaratory judgment that certain patents held by Housey Pharmaceuticals were invalid, unenforceable and not infringed by Bayer. In response, Housey filed a counterclaim of infringement against Bayer. The patents at issue covered a Discovery Tool. Specifically, the patents claimed certain methods of screening

conclusion as this Article has regarding the required analysis, and ultimate legality, of such a royalty arrangement.

194. 228 F. Supp. 2d 467 (D. Del. 2002), *aff'd*, 340 F.3d 1367.

195. The royalty obligation in *Bayer* differs from the reach-through royalty arrangement under consideration in this Article only in the fact that in the *Bayer* case, the patented research tool was used outside of the United States, thereby implicating an interpretation of 35 U.S.C. § 271(g) that ultimately decided the case on appeal. The Federal Circuit's holding in *Bayer v. Housey*, 340 F.3d 1367 (Fed. Cir. 2003) is important, not only for its interpretation of the scope of 35 U.S.C. § 271(g) but also because it effectively capped the potential value of a U.S. Discovery Tool patent. According to the Federal Circuit's decision in that case, the act of importing the "fruits" of the extraterritorial use of the inventor's Discovery Tool (*i.e.*, data and information) into the U.S. does not constitute infringement under United States patent law. At issue in the case specifically was a statutory provision, 35 U.S.C. § 271(g), that provides in pertinent part:

Whoever without authority imports into the United States or offers to sell, sells or uses within the United States a *product which is made by* a process patented in the United States shall be liable as an infringer. (Emphasis added).

The plaintiff inventor argued that this prohibition captures the importation of data and information which is generated in the use of a "process patented in the United States." The Federal Circuit disagreed, holding that "in order for a product to have been 'made by a process patented in the United States' it must have been a *physical article that was 'manufactured,'* and that the production of information is not covered." *Bayer*, 341 F.3d at 1377 (emphasis added).

Accordingly, tool users may freely use Discovery Tools that are patented in the U.S. in non-U.S. jurisdictions where the patentee has no patent coverage, without the threat of U.S. patent infringement, and then import the resulting data and information into the U.S. for use in drug discovery. Since § 271(g) is designed to protect tangible products (rather than data), and is limited to the infringement of manufacturing process patents (rather than discovery methods), the "fruits" of Discovery Tools are not protected by the statute. This undoubtedly represents a set-back for tool inventors, and a potential loophole in the patent laws for the protection of Discovery Tools.

While the practical impact of this decision remains to be seen, it effectively caps the value of U.S. Discovery Tool patents at approximately the cost of performing the same research in a non-U.S. jurisdiction without similar patent protection. Presumably, potential licensees would not be willing to pay significantly more than the cost of conducting the discovery work outside of the U.S. in a jurisdiction where no patent protection for the tool exists, since under *Bayer*, they can freely import and use the results.

for active compounds useful in order to generate data used to identify and develop new drugs, but did not claim such compounds or drugs themselves.¹⁹⁶ Housey licensed these patents to over 30 companies under a licensing program that included two payment options for potential licensees. The first type of license required the licensee to make a significant, upfront, lump sum payment based upon the size of the licensee's research and development budget. The second type of license required the licensee to pay small license fees as well as reach-through royalties on the sales of drug products discovered using the licensed methods. Housey had offered both types of licenses to Bayer, but the parties did not reach an agreement. Instead, Bayer filed its declaratory actions seeking to invalidate the Housey patents. Among its several arguments, Bayer asserted that Housey had committed patent misuse by offering a patent license that would impose royalties on products and activities (i.e., drugs and drug sales) that were not covered by Housey's Discovery Tool patents. Rejecting Bayer's misuse argument, the district court held that Housey had not committed patent misuse since it had not conditioned the grant of a patent license upon the payment of royalties on drug products, but rather had offered such a royalty arrangement as an option that the licensee could elect to take at its discretion.

While not a binding precedent, the *Bayer* decision is of significance not only for its holding (that a non-coerced reach-through royalty arrangement in the context of a Discovery Tool patent license is legal) but, for the purpose of our analysis, for the following three reasons: First, like the *Engel* court, the district court in *Bayer* applied the principles of *Automatic Radio* and *Zenith* to a royalty arrangement that falls outside of the limited definition of a total sales royalty. Second, consistent with *Automatic Radio*, *Zenith* and *Glen*, the *Bayer* court did not require that there be the potential for an administrative royalty tracking burden in order to justify a royalty on a product that is not covered by the licensed patent, as long as the royalty arrangement was entered into for the mutual convenience of the contracting parties for determining the value of the licensed rights. And, finally, the court in *Bayer* concluded that the nexus between a licensed Discovery Tool patent and the product found using the tool (and whose sales constitute the royalty base) was

196. 228 F. Supp. 2d 467, 468 (D. Del. 2002), *aff'd*, 340 F. 3d 1367 (Fed. Cir. 2003). The patents, which were initially assigned to Housey under its former name of ICT Pharmaceuticals, claimed a "Method of Screening for Protein Inhibitors and Activators" and included United States patent numbers 4,980,281, 5,266,464, 5,688,655 and 5,877,007.

sufficient to support the legality of a reach-through royalty on the sale of the product.

D. Temporal Scope

In our analysis thus far, we have assumed that all royalties on drug sales accrue during the term of the licensed Discovery Tool patent. If most or all of such drug sales were likely to occur during that period, no further analysis would be necessary. However, due to the realities of the drug development process, that is not the case. Discovery Tools are often invented and patented long before the discovery of any drug using that enabling technology. And, even after the discovery of a candidate drug, it typically takes many years to complete the pre-clinical drug development and the clinical trials necessary to market the drug.¹⁹⁷ As a result, if a reach-through royalty accrues only during the term of the relevant Discovery Tool patent, a tool licensor will be precluded from sharing in at least some, and perhaps all, of the royalty base comprised of sales of drugs discovered using his or her enabling tool. Simply put, the practical utility of a reach-through royalty obligation whose term does not overlap with the period in which the royalty base is generated through drug sales is nil from the perspective of the tool inventor.

The question arises, then, whether a Discovery Tool licensor may lawfully obtain a reach-through royalty on drug sales for a period that extends—at least for some time—past the expiration of the tool patent. With respect to this potential extension of “temporal scope,” we begin our analysis with the specific question of whether a reach-through royalty that extends beyond the expiration of the licensed tool patent, even if mutually agreed-upon and absent coercion, constitutes per se misuse.¹⁹⁸ In *Brulotte et al v. Thys Company*,¹⁹⁹ the Supreme Court held that a post-expiration royalty for post-expiration use of a previously patented invention is per se unlawful. In the

197. Note that a typical user of a Discovery Tool—a drug development company—is likely to obtain its own patent protection for drugs found using a licensed tool that extends past, perhaps significantly, the expiration of the patent covering the tool itself. Once the drug development company identifies its drug candidate, that company would commonly obtain patent protection for that drug candidate and potentially for its relevant therapeutic uses. These patent claims may be worth potentially hundreds of millions or billions of dollars since they read directly on the revenue-generating drug and its use in the treatment of a disease.

198. That is, even if willing parties agree for their mutual convenience that patent royalties are payable for post-expiration use, that agreement will be deemed to be a misuse of the licensed patent.

199. 379 U.S. 29 (1964).

remainder of this section, we analyze the ruling in *Brulotte* and its applicability to a reach-through royalty arrangement in the context of the license of a Discovery Tool patent. We conclude that *Brulotte* is not only inconsistent with analogous decisions, but more importantly, does not preclude the inclusion of a reach-through royalty obligation in a Discovery Tool patent license agreement.

1. *Leading “Post-Expiration Royalty” Case: Brulotte v. Thys*

Brulotte v. Thys stands for the proposition that royalties that accrue based on the post-expiration use of a previously patented invention are per se unlawful. In *Brulotte*, Thys Company, an owner of various patents relating to a method of hop picking, sold a machine incorporating those patents for a flat sum and issued a license for its use to various licensees, including to Walter C. Brulotte. The license required licensees to pay a minimum royalty equal to the greater of \$500 for each hop-picking season or \$3.33 per 200 pounds of dried hops harvested by the machine both during and *after* the term of the licensed patents. The licenses also prohibited removal of the machines from the licensee’s initial place of business (Yakima County) both before and after expiration of the licensed patents. Upon the expiration of all of the licensed patents, the licensee refused to pay royalties due under the license agreement. Thys Company, the seller and licensor, brought suit to collect those royalties. Thys prevailed in the trial court, defeating the licensees’ argument that the royalty arrangement constituted patent misuse. The Supreme Court of Washington upheld the post-expiration royalty arrangement on the basis that “the period during which royalties were required was only ‘a reasonable amount of time over which to spread the payments for the use of the patents.’”²⁰⁰

The U.S. Supreme Court reversed the Supreme Court of Washington’s holding that the post-expiration royalty payments were a lawful means of spreading payments for “use of the patents,” since there was “intrinsic evidence that the agreements were not designed with that limited view.”²⁰¹ The U.S. Supreme Court held that “the judgment below must be reversed in so far as it allows royalties to be collected which accrued after the last of the patents incorporated into the machines had expired.”^{202, 203} Justice Douglas, writing for the

200. *Brulotte*, 379 U.S. at 30 (quoting *Thys Co. v. Brulotte*, 382 P.2d 271, 275 (Wash. 1963)).

201. *Id.* at 31.

202. *Id.* at 30.

majority, affirmed the basic principles that (1) after the expiration of a patent, the exclusive rights conferred thereunder become public property;²⁰⁴ and (2) “any attempted reservation or continuation in the patentee . . . of the patent monopoly, after the patent expires . . . runs counter to the policy and purpose of the patent laws.”²⁰⁵

Applying these principles, the Court relied on several key facts as the “intrinsic evidence” that the royalty arrangement in *Brulotte* unlawfully projected the patent monopoly after the expiration of the licensed patents, rather than “spreading” royalty payments for pre-expiration use of the patented invention into the post-expiration period. First, the royalty payments for use of the machine accrued annually, both before and after expiration of the patents, for the then-current year of use. Therefore, the royalty expressly accrued based on the post-expiration use of the previously patented machine rather than a deferred payment for use during the term of the patents.²⁰⁶ The same royalty rates and terms and conditions applied after expiration of the licensed patents as before that expiration, in what the Supreme Court refers to as a “bald attempt to exact the same terms and conditions for the period after the patents have expired as they do for the monopoly period.”²⁰⁷ Second, the Court indicated that the continuity in terms and conditions was “peculiarly significant in this case in view of other provisions of the license agreements.”²⁰⁸ Specifically, the agreement prohibited assignment or removal from Yakima County of the machines covered by the licensed patents both before and after the expiration of the licensed patents. The Court indicated that “[t]hose restrictions are apt and pertinent to protection of the patent monopoly; and their applicability to the post-expiration period is a telltale sign that the licensor was using the licenses to project his monopoly beyond the patent period.”²⁰⁹ Moreover, such restrictions “forcefully negate the suggestion that we have here a bare arrangement for a sale or a lease at an undetermined price, based on

203. The issue of patent exhaustion upon the sale of the hop-picking machine was not addressed in *Brulotte*, but is worthy of consideration, especially in light of the U.S. Supreme Court’s recent holding regarding the doctrine in *Quanta v. LGE*.

204. *Brulotte*, 379 U.S. at 31 (citing *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169 (1896); *Kellogg Co. v. Nat’l Biscuit Co.*, 305 U.S. 111 (1938)).

205. *Id.* (quoting *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945)).

206. *Id.* (quoting *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945)).

207. *Id.* at 32.

208. *Id.* at 31-32.

209. *Id.* at 32.

use.”²¹⁰ Based on these considerations, the Court concluded that the challenged royalty arrangement constituted a royalty for use of the patented machines after the expiration of the applicable patents that was obtained through the leverage of the patent monopoly in a manner analogous to tying,²¹¹ and therefore held the post-expiration royalty was unlawful *per se*.²¹²

In reaching that holding, the Court also declined to extend the ruling in *Automatic Radio*. The Court properly acknowledged that *Automatic Radio* found that royalties accruing based on the licensee’s total sales were lawful, even where “no patents were used.” However, the royalties claimed in *Automatic Radio* were not, as the Court pointed out, “for a period when all of them had expired.” By contrast, in *Brulotte*, even after all patents had expired, royalties continued to accrue based on post-expiration use. In the view of the Court, to find that the royalty arrangement in *Brulotte* was lawful would effectively “project the patent monopoly” past its statutory term. The Court refused to do so.

Although *Brulotte* remains good law today,²¹³ commentators and even a recent decision of a U.S. Court of Appeals have criticized its holding as flawed. The leading decision that applies *Brulotte* while questioning its legal reasoning and economic effects is the decision of the Seventh Circuit Court of Appeals in *Scheiber v. Dolby*

210. *Id.*

211. *Brulotte*, 379 U.S. at 33 (“But to use that leverage to project those royalty payments beyond the life of the patent is analogous to an effort to enlarge the monopoly of the patent by tying [*sic*] the sale or use of the patented article to the purchase or use of unpatented ones.”).

212. Justice Douglas, writing for the majority in *Brulotte*, used the terminology “unlawful *per se*,” rather than “*per se* patent misuse” in the Court’s opinion. It is clear, however, that the holding is based on the principles of patent misuse. A possible source of confusion in post-expiration royalty cases is the fact that, after the patent expires, there is no patent in effect to misuse. However, the misuse arises from the act of exerting leverage at the time of the grant of the patent license in order to extract a commitment from the licensee to pay post-expiration royalties. Moreover, the remedy for misuse in post-expiration royalty cases is necessarily limited. Upon a finding of patent misuse, the royalty provision that requires a payment for use of the patented invention, following expiration of the licensed patent, is held invalid and unenforceable. However, since the licensed patent has already expired, the additional consequence of a finding of patent misuse—that is, that the misused patent is no longer enforceable—is irrelevant.

213. See *Zenith Radio Corporation v. Hazeltine Research, Inc.*, 395 U.S. 100, 136-37 (1969); *Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313, 344 n.40 (1971); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264-65 (1979) (the Court distinguished but did not overrule *Brulotte*). See also *Scheiber v. Dolby Laboratories, Inc.*, 293 F.3d 1014, 1019 (2002) (“the reaffirmation of *Brulotte* in *Aronson* tells us that the Court did not deem the cases inconsistent, and so, whether we agree or not, we have no warrant for declaring *Brulotte* overruled”).

Laboratories.²¹⁴ In *Dolby*, Judge Posner affirmed as patent misuse an agreement that required the payment of royalties based on U.S. sales past the expiration of the last-to-expire U.S. patent in a package patent license. Scheiber, a holder of U.S. and Canadian patents on the audio system known as “surround sound,” granted Dolby rights under those patents in exchange for its promise to pay royalties on U.S. and Canadian sales covered thereby. During negotiations, Dolby requested a lower royalty rate on its U.S. and Canadian sales in exchange for its agreement to pay that lower rate on both U.S. and Canadian sales until the last-to-expire Canadian patent expired, which did so approximately two years after the last-to-expire U.S. patent. Dolby indicated that it wished to have this reduction in the royalty rate so that it could pass on this savings to its customers; and Scheiber agreed. However, when the last U.S. patent in the package of U.S. and Canadian patents expired, Dolby refused to pay further royalties on U.S. sales, even though it had expressly agreed (pursuant to its own suggestion) to pay for an additional two years until the expiration of the last Canadian patent in the package. Scheiber sued to enforce the express terms of the patent license agreement. Dolby’s principal defense was that the license agreement was per se unenforceable under *Brulotte*.

While directly questioning the rationale and logic of *Brulotte*, the Seventh Circuit accepted Dolby’s argument, depriving the patentee (Scheiber) of its claim for damages. Characterizing the decision in *Brulotte* as a “free-floating product of a misplaced fear of monopoly,” Judge Posner rejected the notion that post-expiration royalties have the effect of extending the patent beyond the term fixed in the patent statute.²¹⁵ On the contrary, “charging royalties beyond the term of a patent does not lengthen the patentee’s monopoly; it merely alters the timing of royalty payments.”²¹⁶ As Judge Posner explained:

After the patent expires, anyone can make the patented process or product without being guilty of patent infringement. . . . For a licensee in accordance with a provision in the license agreement to go on paying royalties after the patent expires does not extend the duration of the patent either technically or practically, because, as this case demonstrates, if the licensee agrees to continue paying royalties after the patent expires the royalty rate will be lower. The duration of the patent fixes the

214. 293 F.3d 1014 (7th Cir. 2002) (Posner, J.).

215. *Scheiber*, 293 F.3d at 1018.

216. *Id.*

limit of the patentee's power to extract royalties; it is a detail whether he extracts them at a higher rate over a shorter period of time or a lower rate over a longer period of time.²¹⁷

Most commentators who have addressed this topic, including the authors of this Article, fully agree with this critique.²¹⁸ Nonetheless, as Judge Posner acknowledges in his opinion, the Seventh Circuit has “no authority to overrule a Supreme Court decision no matter how dubious its reasoning.”²¹⁹ Since the agreement at issue in *Dolby* clearly required payment on U.S. sales of products that occurred after the expiration of the last-to-expire U.S. patent, and that payment obligation accrued based on post-expiration use of the previously patented invention, it fit squarely within the per se prohibition of *Brulotte*. The express agreement of the parties that such payments should continue during that period in exchange for a lower royalty overall was effectively disregarded.

As the decision in *Scheiber* illustrates, *Brulotte* has been interpreted and applied in such a manner so as to nullify the contractual intent of the parties, on the basis of a rule intended to limit the abuse of patents. As a result, willing parties are prohibited from agreeing to royalties that accrue based on post-expiration use, even if that royalty structure is mutually agreed (a) without any coercion by the licensor, (b) as the most convenient method of measuring the value of the licensed rights, and (c) in exchange for a lower royalty rate overall. The *Brulotte* decision, in effect, “requires

217. *Scheiber*, 293 F.3d at 1017.

218. See Harold See and Frank M. Caprio, *The Trouble With Brulotte: The Patent Royalty Term and Patent Monopoly Extension*, 1990 UTAH L. REV. 813, 814 (1990) (“The *Brulotte* rule incorrectly assumes that a patent license has significance after the patent terminates. When the patent term ends, the exclusive right to make, use or sell the licensed invention also ends. Because the invention is available to the world, the license in fact ceases to have value. Presumably, licensees know this when they enter into a licensing agreement. If the licensing agreement calls for royalty payments beyond the patent term, the parties base those payments on the licensees’ assessment of the value of the license during the patent period. These payments, therefore, do not represent an extension in time of the patent monopoly.”); Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, 64 J. PAT. OF. SOC’Y 297, 302 (1982) (“licensees will not normally be willing to pay a royalty, after patent expiration, for what their competitors can then obtain without charge ... They only pay what they must in order to use the invention during the time when the patent would otherwise bar their way.”); Mark A. Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CAL. L. REV. 1599, 1630 (1990). (“agreements that extend royalty terms simply are not anticompetitive. A licensee will pay a fixed amount for a license, and the courts should not care whether the licensee pays that amount up front, in ten years, or in a hundred years”).

219. 293 F.3d at 1018.

the licensor and licensee to amortize the present value for the license fee over the remaining years of the patent term, rather than over a longer period of years, even if a longer amortization period is optimal for the parties.”²²⁰

2. *Reconciling Total Sales Royalty Jurisprudence and Brulotte*

Can the decision with respect to an extension of the temporal scope of a patent in *Brulotte* be harmonized with the decisions with respect to an extension of the physical scope of a patent in *Automatic Radio* and *Zenith*? The answer, ultimately, is no. Each of these cases addresses a circumstance in which a patent royalty is calculated based on the sale of a product that is not, at the moment of sale, covered by the licensed patent. However, a sale of an unpatented product which occurs during the term of a patent (i.e., an “in-term” expansion of physical scope as in *Automatic Radio* and *Zenith*), and a sale of a product that was once, but is not longer, covered by a patent (i.e., an extension of temporal scope as in *Brulotte*), are analyzed and ultimately decided based on fundamentally different policy models.²²¹ *Automatic Radio* and *Zenith* rest on the doctrine of contractual intent. In the nomenclature of these cases, the analysis of “mutual convenience” is a judicial inquiry into whether the final written agreement represents the true intent of the parties. Where the final agreement is the product of coercion, as in *Zenith*, its terms can no longer be relied upon as an accurate representation of the contractual intent of the parties, and therefore, the royalty on unpatented products is held to be *per se* misuse. *Brulotte*, by contrast, categorically disregards the intent of the parties by holding that any post-expiration royalty for post-expiration use is *per se* misuse, even in the absence of any coercion.²²² In other words, while contractual intent governs where royalties are paid on products that are not covered by the licensor’s patent during the term of a licensed patent

220. Harold See and Frank M. Caprio, *The Trouble With Brulotte: The Patent Royalty Term and Patent Monopoly Extension*, 1990 UTAH L. REV. 813, 814 (1990).

221. Compare the reasoning of the U.S. Supreme Court in *Automatic Radio* and *Zenith*, as discussed *supra* in section V.C.1., with that of the Court in *Brulotte*, as discussed *supra* in section V.D.1. See also Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, 64 J. PAT. OFF. SOC’Y 297, 297-314 (1982) for a discussion of the interplay between “the contractual intent approach” and “the statutory policy approach” in analyzing the *Brulotte* holding.

222. One commentator has aptly referred to the result in *Brulotte* as the “ultimate victory of the statutory policy approach over the doctrine of contractual intent.” Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, 64 J. PAT. OFF. SOC’Y 297, 308 (1982).

(a physical extension), that intent is overridden immediately upon patent expiration if a royalty is for post-expiration use (a temporal extension).

These different models and results in seemingly analogous circumstances invite the conclusion that these cases are simply irreconcilable, and ultimately, we believe that that conclusion is correct. However, a closer analysis of the reasoning behind the original holdings and subsequent evolution of these cases provides some insight into the how the case law arrived at these contrasting outcomes. Consider the rationale for the decisions in *Automatic Radio* and *Zenith*. As discussed above,²²³ each of these cases involved a package license, whereby the licensor granted a license under numerous patents, some of which may cover the products sold, and some of which may not.²²⁴ While it was clear that these patent packages covered an electronic apparatus used in radios, televisions and phonographs, it would have been difficult or practically impossible to determine—on a unit-by-unit basis—precisely which radios, televisions and phonographs sold by the licensee were in fact covered by one or more of the patents in the package.

In this context, the justification for upholding a total sales royalty as a “practical necessity” was born. Because actual patent usage was difficult or practically impossible to determine,²²⁵ the parties mutually agreed upon, and the Supreme Court upheld, a total sales royalty calculated as a percentage of the licensee’s sales of all radios, televisions and phonographs, notwithstanding the fact that there may have been products within that product grouping that (1) had once been, but were no longer covered by a patent in the package at the time of sale, or (2) were never covered by a patent in the package. This is the interpretation of *Automatic Radio*—as a narrow, necessity-based exception to a general rule requiring that patent royalties accrue strictly upon items covered by the licensed patents—that was initially articulated by the district court in *Glen*.²²⁶ For as long as there is a single active U.S. patent, the difficulty in determining

223. See *supra* sections V.C.1. and V.C.2.b.

224. For other package licensing cases, see *McCulloch Tool Company, Well Surveys, Inc.*, 343 F.2d 381 (10th Cir. 1965); *Hull v. Brunswick*, 704 F.2d 1195 (10th Cir. 1983); *Beckman Instruments, Inc. v. Technical Development Corp.*, 433 F.2d 55 (7th Cir. 1970); *Hensley Equipment Co. v. Esco*, 383 F.2d 252 (5th Cir. 1967). But see, *Rocform Corp. v. Acitelli-Standard Concrete Wall, Inc.*, 367 F.2d 678 (6th Cir. 1966). See also 35 U.S.C. § 271(d)(5).

225. See *supra* sections V.C.1. and V.C.2.b.

226. See *supra* section V.C.2.b. and note 188.

whether a particular product sold is covered by a patent could—at least in theory—persist. However, upon the expiration of the last patent in the package, the rationale of “practical necessity” that justified the extension of the royalty base to products not covered by the licensed patent no longer applies, since the problem of determining patent usage only continues as long as there are active patents within the package. On the basis of this narrow “necessity” rationale, *Automatic Radio* and *Zenith* may be reconciled with *Brulotte*. That is, while “necessity” can justify an in-term extension of a royalty to products not covered by the licensed patent (as in *Automatic Radio* or *Zenith*), it can never justify a post-expiration royalty on previously patented products (as in *Brulotte*).²²⁷

Notwithstanding this potential basis for harmonization, as discussed in section V.C.2.b. *supra*, *Automatic Radio* has been interpreted and applied in cases where there was no difficulty in determining whether a product was covered by the licensed patent (e.g., the toilet tank covers in *Glen* and the corner connectors in *Engel*), including in cases where there was a single licensed patent (no package license)²²⁸ and a single and uncomplicated product.²²⁹ This more liberal application of *Automatic Radio* has replaced the notion that a total sales royalty must be “necessary” due to difficulty in determining patent usage with a flexible standard requiring only that a royalty on unpatented products is “mutually convenient” for the contracting parties in determining the value of the licensed patent rights.²³⁰ With the more forgiving inquiry of “mutual convenience” as the critical requirement, the restriction of *Brulotte* no longer makes sense. While a post-expiration royalty could never be “necessary” in order to avoid difficulty in calculating royalties, it certainly could be a

227. Perhaps this is the underlying reason why *Brulotte* declined to extend *Automatic Radio* to reach post-expiration royalties. In *Brulotte*, the Court “decline[s] the invitation to extend [the holding of *Automatic Radio*] so as to project the patent monopoly beyond the 17 year period” and distinguished *Automatic Radio* on the basis that although “some of the patents under that license [in *Automatic Radio*] apparently had expired, the royalties claimed were not for a period when all of them had expired.” *Brulotte*, 379 U.S. 33.

228. *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 299 F. Supp. 278 (S.D. New York 1969), remanded in 420 F.2d 319 (2d. Cir. 1970); *Engel Industries, Inc. v. Lockformer Company*, 96 F.3d 1398 (Fed. Cir. 1996). See also *supra* note 185.

229. See *Engel Industries, Inc. v. Lockformer Company*, 96 F.3d 1398 (Fed. Cir. 1996) (corner connectors); *Glen Manufacturing, Inc. v. Perfect Fit Industries, Inc.*, 299 F. Supp. 278 (S.D. New York 1969), remanded in 420 F.2d 319 (2d. Cir. 1970) (toilet tank covers); *Plastic Contact Lens Company v. Young Contact Lens Laboratories, Inc.*, 175 U.S.P.Q. 573 (D. Mass. 1972) (contact lenses).

230. See *supra* section V.C.2.b.

“mutually convenient” method of measuring the value of the licensed rights.²³¹

As a result, *Brulotte* cannot be reconciled with *Automatic Radio* as that holding was interpreted by the Federal Circuit in *Engel* and the Second Circuit in *Glen*. Absent additional facts showing an attempt to extend the monopoly,²³² there would appear to be no reasoned difference between agreeing to a royalty arrangement that required payment of a royalty on the sale of (1) a product that was never covered by the licensed patent for as long as the licensed patent survives (the royalty obligation in the patent license agreement in *Engel*); (2) a product that was once covered by at least one of the patents included in a package license but is no longer covered, for as long as at least one of the licensed patents survives (as might occur under the total sales royalty obligation in the package license agreement in *Automatic Radio*); and (3) a product that is no longer covered following the expiration of the last-to-expire patent (the post-expiration royalty for post-expiration use in *Brulotte*). In each case, the parties to the contract would have agreed to pay a royalty on the sale of a product that was not covered by the licensed patent. However, while the first two royalty arrangements are permitted and enforceable as long as they are not coerced (i.e., contractual intent governs),²³³ the last is illegal per se without regard to contractual intent (i.e., statutory policy overrides contractual intent).²³⁴

The foregoing analysis confirms that *Brulotte* is anomalous when considering analogous cases where a royalty base has been extended to unpatented products, particularly when the parties freely agree upon that approach as the most convenient and appropriate method of measuring the value of the licensed patent. Nonetheless, as *Scheiber* confirms, *Brulotte* remains the law today. With that admonition in mind, we turn to an assessment of the applicability of

231. As many commentators have noted and Judge Posner forcefully expressed in *Scheiber*, post-expiration royalties are merely a method of financing the value received by the licensee during the patent term, since upon expiration of the patent, the patentee has nothing of value left to offer in exchange. Following the expiration of the patent, no one can be excluded from exploiting the previously patented invention, and licensees presumably know this fact when they negotiate the royalty terms of their license.

232. See, e.g., *Brulotte*, 379 U.S. 29 (clear evidence that royalties accrued on post-expiration use of the previously patented invention, and post-expiration restrictions on assignment and prohibition on removal of the previously patented invention from Yakima County). See also *supra* section V.D.1.

233. See *supra* sections V.C.1. and V.C.2.a. and note 220.

234. See *supra* section V.D.1. and note 220.

Brulotte to a reach-through royalty arrangement in the context of a Discovery Tool patent license.

3. *Is A Post-Expiration Reach-Through Royalty Unlawful Per Se Under Brulotte?*

While neither the U.S. Supreme Court nor any federal appeals court has ruled on whether a post-expiration reach-through royalty obligation in a Discovery Tool patent license agreement is lawful, we believe that a careful analysis suggests that it is. Indeed, the holding in *Brulotte* need not even be disturbed in order for us to reach this conclusion. The reason is that, while *Brulotte* clearly prohibits post-expiration royalties that accrue based on post-expiration use of a previously patented invention, *Brulotte* implicitly allows for deferred payments for pre-expiration use. The license agreement in *Brulotte* included a royalty that expressly accrued based on post-expiration use, i.e., on an annual basis each year both before and after patent expiration. Under those facts, deferred payment for pre-expiration use was not at issue. However, the Court suggested *in dicta* that a deferred payment arrangement “would present wholly different considerations” than those presented by the unlawful royalty arrangement addressed in *Brulotte*.²³⁵ The implication is clear: The holding in *Brulotte* should not be read to prohibit a circumstance where a payment accrues for the pre-expiration use of a patent, but is paid after its expiration on a deferred basis.

This interpretation is supported by later descriptions by the Supreme Court itself of its holding in *Brulotte*. In *Zenith*, the Court described its holding in *Brulotte* as follows:

Recognizing that the patentee could lawfully charge a royalty for practicing a patented invention prior to its expiration date and that the payment of this royalty could be postponed beyond that time [*i.e.*, following expiration], we noted that the post-

235. *Brulotte*, 379 U.S. at 32. Note that while the Court used the “wholly different considerations” phrase in its discussion of deferred payments for unpatented machines, its opinion in *Brulotte* suggests that the phrase is equally applicable in the context of a deferred payment for a patented invention. The Court spent considerable effort in distinguishing the unlawful post-expiration-payment-for-post-expiration-use royalty arrangements in *Brulotte* from a presumably lawful one in which the royalty obligation extended beyond the expiration of the licensed patent only because it represented “a reasonable amount of time over which to spread the payments for the use of the patents” *Id.* at 31 (quoting the Supreme Court of Washington’s holding in the *Brulotte* case (62 Wash. 2d 284, 291 (Sup. Ct. Wash. 1963)). See section V.D.1. *supra*. *Zenith*’s subsequent interpretation of the Court’s decision in *Brulotte*, provided in this section, supports this view.

expiration royalties were not for prior use but for current use, and were nothing less than an effort by the patentee to extend the term of his monopoly beyond that granted by law. *Brulotte* thus articulated in a particularized context the principle that a patentee may not use the power of his patent to levy a charge for making, using, or selling products not within the reach of the monopoly granted by the Government.²³⁶

Brulotte does not, therefore, stand for the proposition that the payment of any royalty after the expiration of the licensed patent is, without more, unlawful. Rather, as other commentators have observed,²³⁷ *Brulotte* stands for the proposition that royalties are unlawful to the extent that they are based on the licensee's use of a previously patented invention after expiration of the last licensed patent. This view is consistent with the holdings in *Brulotte* and *Scheiber*, since the royalties held to be unlawful in both of those cases arose from the licensee's use of the licensed inventions (hop-picking machines and surround sound, respectively) after the expiration of the applicable last-to-expire U.S. patent. The most reasonable interpretation of *Brulotte*, therefore, is that "[i]t is not the time of payment, but the time of the use to which the payment is properly allocated, which should be determinative."^{238, 239}

236. *Zenith*, 395 U.S. at 136-37.

237. Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, 64 J. PAT. OFF. SOC'Y 297, 309 (1982) ("The real point of *Brulotte* may be that payments are properly considered to be illegal royalties if they are dependent upon the extent of the licensee's use of the invention in the period following expiration of the last relevant patent.").

238. *Id.* at 309-10.

239. A pair of rulings of a New York district court provides further support for the conclusion that a post-expiration payment obligation for pre-expiration patent use is lawful. These so-called "stock on hand" cases involved the royalty obligation of a patent licensee that manufactured a product under the licensed patent during its term, but did not sell the product until after the patent expired. See *Studiengesellschaft Kohle v. Novamont Corp.*, 532 F. Supp. 234 (S.D.N.Y. 1981) (*SGK*); *Forbo-Giubiasco v. Congoleum Corp.*, 1985 WL 1827 (S.D.N.Y., 1985) (*Forbo*). The District Court of the Southern District of New York that decided these cases held that a licensee must honor its obligation to pay royalties on the sale of products following the expiration of the licensed patent on the theory that such payments were for pre-expiration use of the licensed patent in the manufacture of the products sold. In *SGK*, the court noted that relieving the licensee of its obligation to pay post-patent expiration royalties would permit "a licensee anticipating a patent's expiration . . . [to] freely produce vast quantities of . . . [the product] prior to the expiration of that patent, but wait until after the expiration date for sale, and thereby avoid payment for material produced during the period of the patent's validity, pursuant to the license agreement." *Studiengesellschaft Kohle v. Novamont Corp.*, 532 F. Supp. 234, 236-237 (District Court S.D.N.Y. 1981). In *Forbo*, the court evaluated essentially the same fact pattern as in *SGK* and rejected the licensee's claim that the *SGK* holding should not

This conclusion is consistent with the decision in *Bayer v. Housey*, in which the district court held that a post-expiration reach-through royalty obligation on a product identified through the use of a patented Discovery Tool was not an impermissible temporal extension of the scope of the tool patent.²⁴⁰ In its decision, the court based its ruling in part on the following interpretation of *Brulotte*:

In *Brulotte*, the Supreme Court held that patent misuse occurs when a licensing agreement “allows royalties to be collected which accrued after the last of the patents [has] expired.” [citing *Brulotte*] In the case at bar, the royalties to be paid after the expiration of the patent are for the use of the subject invention prior to the expiration of the patent. Royalties are collected based on later pharmaceutical sales, but the royalties are being accrued as the invention is practiced during the research phase. Collecting royalties after the expiration of the patent has expired is not *per se* patent misuse as plaintiffs assert. Indeed, the Supreme Court has recognized that a patentee may

be followed since it violated the Supreme Court’s decision in *Brulotte*. The court held that there was no violation of *Brulotte* in obligating a licensee to pay post-expiration royalties on products manufactured prior to patent expiration. According to the court:

In the case at hand, . . . [licensee] is not asked to pay royalties for use of . . . [licensor’s] patented process after the patent expiration date but only for goods manufactured while the patents remained in effect. The stock of goods manufactured by . . . [licensee] was produced pursuant to a patented process granted to . . . [licensor] for a limited period of time. There exists no inequity in permitting . . . [licensor] to recover the benefits of its invention over the life of the patent.

Only if . . . [licensee] was obliged to pay royalties on product manufactured after September of 1984, the time of expiration of . . . [licensor’s] . . . patent, might the royalty provision in the . . . licensing agreement be per se unlawful. This conclusion is not inconsistent with the concern voiced in *Brulotte*, that the free market envisioned for a formerly patented product which has entered the public domain upon the expiration of the patent not be subjected to monopoly influences by the former patent holder, . . . because . . . [licensee] is and has been free to sell product without payment of royalties for all product manufactured since September, 1984. Accordingly, we hold that . . . [licensee] is obligated to pay royalties to . . . [licensor] on all product manufactured before the date of expiration of . . . [licensor’s] . . . patent.

Forbo-Giubiasco v. Congoleum Corp., 1985 WL 1827, *7 (S.D.N.Y., 1985) (It should be noted that the patent involved in *Forbo* was a Swiss, and not a U.S. patent. The extraterritorial application of U.S. patent misuse jurisprudence by the district court in the case is open to question, especially in light of the Supreme Court’s recent holding in *Microsoft v. AT&T*, 127 S. Ct. 1746 (2007), in which the Court confirmed the limited extraterritorial reach of U.S. patent law, albeit in another context. See footnote 142).

240. *Bayer AG v. Housey Pharmaceuticals*, 228 F. Supp. 2d 467 (D. Del. 2002), *aff’d*, 340 F.3d 1367 (Fed. Cir. 2003)). For further discussion of the district court’s decision in this case and the holding of the Federal Circuit on appeal, see *supra* section V.C.3. and note 195.

collect royalties post-expiration without violating *Brulotte*. . . . The problem arises when “the post-expiration royalties were not for prior use but for current use, and were nothing less than an effort by the patentee to extend the term of his monopoly beyond that granted by law.” [citing *Zenith*]²⁴¹

Accordingly, although not binding precedent, at least one district court decision has applied the principle of deferred payments to conclude that a post-expiration reach-through royalty on a drug identified through the use of a patented Discovery Tool was lawful and did not constitute misuse under *Brulotte*. While the Federal Circuit did not rule on this issue on appeal,²⁴² we believe that—as long as the royalty is agreed without coercion and for the mutual convenience of the licensor and licensee in determining the value of the licensed patent rights—the district court came to the correct conclusion.

Under our analysis, then, the inclusion of a non-coerced, post-expiration, reach-through royalty obligation in a Discovery Tool patent license agreement is permissible under *Brulotte* and, in fact, under patent misuse doctrine generally. However, the royalty obligation must be appropriately qualified. Consider the following examples: In using a licensed Discovery Tool, a licensee generates data and information that may provide a critical clue to the identification of a new drug. Certainly, if the Discovery Tool is used after the expiration of the licensed patent covering it, then it is without doubt that any data or information generated or drug candidates discovered cannot give rise to any royalty payments without running afoul of *Brulotte*. Such a royalty would arise from the post-expiration use of a previously patented invention (the Discovery Tool). By contrast, consider a circumstance in which, during the life of the tool patent, the licensee discovers a new drug using the tool and that, once the drug product is identified, the licensee does not re-use the enabling tool. In this case, the use is solely within the patent term, and that “in-term” use serves its purpose and delivers its critical value to the licensee entirely during the patent term. That same “in-term” use also fixes the licensee’s royalty obligation, which attaches to the sale of drugs discovered using the patented tool during the term of the licensed tool patent. Regardless of when those royalties are ultimately paid, they are (and

241. *Bayer*, 228 F. Supp. 2d at 472-73.

242. *Bayer*, 340 F.3d 1367 (Fed. Cir. 2003); *See supra* note 195.

indeed, under these facts, can only be) made in consideration of the “in term” use of the tool.

Nonetheless, even if a royalty arises only from the pre-expiration use of the licensed Discovery Tool, some may fairly argue that *Brulotte* never envisioned a deferred payment of the type contemplated in our example of “in-term” tool use. A classic deferred payment would be an amount that accrues, and is fixed and determined, during the life of a licensed patent, but is paid later. For example, suppose a licensor and licensee agree upon a \$100,000 license fee accruing in full upon the grant of the license, but in order to accommodate the licensee’s limited cash flow, that \$100,000 fee is payable in regular installments for a 30-year period starting from the date that the patent issues. In this arrangement, since there is no doubt that the \$100,000 is payable solely for the use of the patent during its statutory term, the post-expiration payments are clearly deferred payments for prior use.

In our example of “in-term” Discovery Tool use, however, neither the amount nor the timing of payment is fixed and determined at the time of the license grant or even prior to the expiration of the licensed patent. Since future drug sales are unknown and variable (i.e., they may be zero or significant), the amount and timing of the royalty—which is calculated as a percentage of those sales—is also unknown and variable. A reach-through royalty therefore defers a payment obligation for pre-expiration use, but that obligation is variable and contingent at the expiration of the licensed patent.²⁴³ As a result, while the obligation to pay the royalty is determined based only on the pre-expiration use of the tool, the payment amount will vary depending on sales occurring pre- and post-expiration. This fact raises the specter of per se misuse under *Brulotte*, since, on its face, royalties are “accruing” based on post-expiration sales. However, while the royalty may vary based on post-expiration sales, that royalty is still a deferred payment for pre-expiration use of the licensed Discovery Tool as long as the royalty attaches only to drug candidates identified from the use of the licensed tool during the life of the licensed tool patent.

Moreover, upon the expiration of the Discovery Tool patent, the licensee may freely use the previously patented tool to identify new drugs, and its sale of such drugs would not give rise to any payment

243. While linking payments to post-expiration sales raises the risk that a court may view these payments as improperly accruing after the patent expires, the fact remains that there is no post-expiration use with respect to which those royalties accrued.

obligation to the tool patentee. In other words, upon expiration of the patent, the former licensee is appropriately placed in the same position as every other member of the public—each is entitled to freely practice, without obligation or charge, the previously patented tool inventions that have been contributed to the public domain.

As discussed above, a running royalty has the virtue of representing a measure of the actual value created (in the form of drug sales) by using the licensed Discovery Tool. And, as the Court in *Automatic Radio* concluded in an analogous circumstance, since “it would not be unlawful to agree to pay a fixed sum for the privilege to use patents, it was not unlawful to provide a variable consideration measured by a percentage of the licensee’s sales for the same privilege.”²⁴⁴ One commentator has aptly posed the issue as follows: “[d]oes it make sense to allow post-expiration patent royalty payments if the parties merely guess at the probable success of the licensed product (that is to say, if they commit themselves in advance to a predetermined total royalty pay-out), but to take the option of post-expiration payments away from them just because they relate the total royalty pay-out in some reasonable fashion to post—expiration sales?”²⁴⁵ Irrespective of how one answers this question, we believe that *Brulotte*, if viewed as a decision where the timing of use to which the payment is allocated is determinative, does not require such an, arguably, economically irrational result.

Accordingly, we conclude that a non-coerced, post-expiration, reach-through royalty obligation in the context of the license of a Discovery Tool patent is not *per se* patent misuse under *Brulotte*, nor even an extension of the temporal scope of the licensed tool patent, *provided that* all royalty payments are based solely on the pre-expiration use of the patented tool.²⁴⁶ For the reasons presented

244. *Automatic Radio*, 339 U.S. at 833.

245. Louis Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, 64 J. PAT. OFF. SOC’Y 297, 312 (1982).

246. Even if such a royalty is lawful in principle, is it otherwise subject to any restrictions in terms of its implementation? Since that question is fact-based and no jurisprudence exists on the issue, any particular implementation of a post-expiration, reach-through royalty remains subject to risk of a finding of patent misuse. Nonetheless, commentators have identified and in some cases evaluated several potential forms of such a royalty, although none of these alternatives have (other than in *Bayer*) been endorsed by a court. While we do not endorse a particular implementation of a reach-through royalty obligation (nor, for that matter, any use of a reach-through royalty obligation, since it is a decision to be made by the contracting parties), options cited by commentators have included arrangements where, with respect to sales of drugs that are identified in the pre-expiration use of the licensed tool, the royalty obligation extends past the expiration of the licensed tool patent(s):

1. A royalty obligation without a fixed term of years, but up to a maximum amount of royalties that is fixed at the time of the grant of the Discovery Tool license or otherwise during the term of the tool patent (e.g., \$1 million license fee, payable only upon drug sales, at a rate of 1% thereof); See Altman, *Is There an Afterlife? The Effect of Patent or Copyright Expiration on License Agreements*, J. PAT. & TRADEMARK OFF. SOC'Y (1982). ("One might then suggest that a flat total royalty figure be agreed on, but, in deference to the licensee's cash flow problems, it could be paid out in installments extending over a period of, say 25 years from the date of a patent issuance. Presumably no court can find fault with that arrangement solely because the pay-out period extends beyond the life of the patent. If it is clear that the royalty is being paid only for the use of the invention *during* the patent term, then the length of the pay-out period, or the fact that it survives the patent, should be of no concern from the standpoint of any policy underlying the patent statute. It is merely a matter of financial strategy or convenience for the parties. See also Deehr and Fiengold, *Drafting Around Post Patent Expiration Royalties*, THE METROPOLITAN CORPORATE COUNSEL (2002) ("the parties might . . . consider a more risky – but perhaps defensible – provision which sets forth the full amount of the royalty payments due during the life of the U.S. patent, along with an agreement by the patent holder to defer receiving a portion of those payments until after the patent has expired. The withheld portion of the royalties would be payable by the licensee after the patent expires through a continuing series of payments, that include a premium (e.g., interest) to take into account the value of the deferred payments (which might be analogized to a loan)).
2. A royalty obligation for a fixed term of years (e.g., 10 years from the first commercial sale of the first drug discovered using the tool or for period equal to the term of the patents covering the drug discovered using the tool), without any dollar cap. See Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001) ("this Article argues for a broadened rule of 'development use' that would permit scientists to use certain patented research tools without prior authorization, but require that the research tool patent owner be paid an ex post royalty based on the ultimate commercial success of the new drugs or other products developed through the use of the tool. This 'reach-through' royalty approach maintains incentives for the development and patenting of new research tools, but alleviates the access restrictions and up-front costs currently associated with their acquisition and use. . . . Reach-through royalty payments are prima facie reasonable so long as the total time period over which they are paid is no longer than the term of the underlying tool patent, i.e., a period of twenty years less the patent application's pendency. . . . This Article proposes that reach-through royalties be paid beginning with the date of the first sale of the product developed through use of the patented tool, whenever that sale occurs, and ending eighteen years thereafter. The recovery period of eighteen years has been time-shifted to correspond with the period of sales of the new product.").
3. A royalty obligation for as long as the discovered drug is sold, without any limit in terms of years or maximum amount of royalties payable. See Lemley, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CALIF. L. REV. 1599 (1990) ("[A]greements that extend royalty terms simply are not anticompetitive. A licensee will pay a fixed amount for a

above in this Part V, we are of the opinion that such a royalty arrangement is lawful.

E. Application of the Legal Standard

Having reviewed the case law on physical and temporal extensions of patent scope, it would be instructive to apply the Federal Circuit's analytical framework for identifying patent misuse, described in section V.B.2. *supra*, to a non-coerced reach-through royalty arrangement in the context of a Discovery Tool patent license. The first question to answer is whether the royalty arrangement is one that the U.S. Supreme Court has specifically condemned as per se illegal (e.g., a tying arrangement (as in *Morton Salt Co.*²⁴⁷), a coerced total sales royalty (as in *Zenith*²⁴⁸) or a post-expiration royalty for post-expiration use (as in *Brulotte*²⁴⁹). Applying the reasoning of the Court in *Automatic Radio* in assessing a total sales royalty, an analogous royalty obligation that also extends the physical scope of a patent (*see supra* section V.C.1.a.), we conclude that a reach-through royalty is not a tie-in. Judge Posner in *Scheiber* came to the same conclusion with respect to a royalty obligation that extends the temporal scope of a patent,²⁵⁰ although (as we argued above in section V.D.3. *supra*, relying on *Brulotte* as interpreted in *Zenith*) the post-expiration phase of a properly qualified reach-through royalty obligation in a Discovery Tool patent license agreement is a deferred payment for pre-expiration use and not a temporal extension of the patent.

license, and the courts should not care whether the licensee pays that amount up front, in ten years, or in a hundred years.”).

These options present different methods of sharing risk and allocating return between a tool licensor and tool licensee, and they may also present varying degrees of risk in terms of whether a court would likely view them as a legitimate deferred payment consistent with the ruling in *Brulotte*. In each of these examples, the volume of drug sales will determine the amount of royalties, if any, to be paid. In that way, each royalty is a mechanism for sharing the risk and rewards for the actual value generated by using the tool patent. As long as those royalties are mutually agreed without coercion and are tied only to sales of drugs identified using the licensed tool during the term of the patent covering that tool, we do not believe that *Brulotte* nor patent misuse doctrine generally should preclude a reach-through royalty that continues past the expiration of the licensed patents, even if the royalty rate continues undiminished for a reasonable time under the circumstances.

247. *Morton Salt*, 314 U.S. 488.

248. *Zenith*, 395 U.S. 100.

249. *Brulotte*, 379 U.S. 29.

250. *Scheiber*, 293 F.3d at 1020-1021.

Having assumed that the reach-through royalty arrangement under consideration in this Article is non-coerced, any concern under *Zenith* with respect to per se misuse as a result of conditioning is eliminated. Moreover, because we view the post-expiration phase of the reach-through royalty obligation as a deferred payment, such an arrangement does not run afoul of *Brulotte's* prohibition of post-expiration royalties for post-expiration patent use. Accordingly, we conclude that a reach-through royalty arrangement in the context of a Discovery Tool patent license has not been previously condemned as *per se* illegal by the U.S. Supreme Court.

The second question to answer is whether the royalty arrangement is “specifically excluded from a misuse analysis by 35 U.S.C. § 271(d).”²⁵¹ The only potentially relevant provision of 35 U.S.C. § 271(d) is subsection (d)(5), but, as noted by Judge Posner in *Scheiber*,²⁵² the statutory limitation of a defense to infringement provided in § 271(d)(5) is limited explicitly to tying and, as we discussed above, a reach-through royalty obligation is not a tying arrangement.

The next question is whether the royalty arrangement is “reasonably within the patent grant,”²⁵³ i.e., does the licensee’s payment obligation accrue with respect to a product that falls within the scope of the patent claims? If this question is answered in the affirmative, the arrangement “does not have the effect of broadening the scope of the patent claims and thus cannot constitute patent misuse.”²⁵⁴ As to this inquiry, the weight of the evidence presented in this Article suggests that a reach-through royalty arrangement does extend the patentee’s statutory rights (i.e., it is an extension of physical scope, but not, according to our deferred payment interpretation, an extension of temporal scope) requiring the continuation of the patent misuse analysis.

The final question, therefore, is whether a reach-through royalty arrangement impermissibly broadens the scope of the patent grant

251. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997).

252. 293 F.3d at 1021 (“There just is no evidence that Congress in the 1988 amendment [to the patent statute which resulted in 35 U.S.C. §271(d)(5)] wanted to go or did go beyond tying. Had it wanted to, it would have chosen different words. We are not literalists, but there must be *some* semantic handle on which to hang a proposed statutory interpretation, and there is none here . . .”).

253. *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 869 (Fed. Cir. 1997) (quoting *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992)).

254. 133 F.3d at 869.

with anticompetitive effect.²⁵⁵ As discussed in section V.B.1. *supra*, “impermissibly,” in this context, means that the practice broadens the scope of the patent claims (i.e., is an extension), has an anticompetitive effect, and such anticompetitive effect outweighs any procompetitive benefit of the practice, based on a rule of reason analysis conducted through application of conventional antitrust principles. While the exact nature of this type of analysis remains open to some debate, the evidence presented in this Article provides ample support for the conclusion that a reach-through royalty arrangement in the context of a Discovery Tool patent license is lawful (and, therefore, not patent misuse, including patent misuse in the form of an antitrust violation) under the principles articulated in *Automatic Radio* (as qualified by *Zenith*, distinguished by *Brulotte*, and interpreted in *Glen* and *Engel*).

As noted above, some commentators have challenged the Federal Circuit’s analytical framework for identifying patent misuse because it ignores the pure “extension of monopoly type” of misuse recognized by the Supreme Court. This challenge, however, does little to undermine the validity of our conclusion in this Part V that a properly qualified, non-coerced, reach-through royalty arrangement in the context of a Discovery Tool patent license is legal, since our analysis is based upon the direct application of the principles articulated in relevant Supreme Court precedent (i.e., *Automatic Radio*, *Zenith* and *Brulotte*).

F. Damages Jurisprudence

Damages jurisprudence provides another vantage point in assessing the legality of reach-through royalties in the context of a Discovery Tool patent license. As discussed in this section, courts have imposed damages awards that include reach-through royalties in a variety of decisions.²⁵⁶ The statutory framework to patent damages forms the basis for these decisions. Upon a finding of patent infringement, courts are required under the Patent Act to award “damages adequate to compensate for the infringement, but in no

255. *Windsurfing International, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986).

256. As aptly stated by Mueller (Janice M. Mueller, *No “Dilettante Affair”*: *Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 60 (2001)) and documented by Ware (Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267 (2002)), “[r]ecent liberalization of the Federal Circuit’s damages jurisprudence provides additional support for the legitimacy of a reach-through royalty approach.”

event less than a reasonable royalty for the use made of the invention by the infringer.”²⁵⁷ As commentators have noted, “[i]f there is an established royalty rate for patented inventions in the applicable field, that rate is generally deemed to be the best measure of reasonable compensation.”²⁵⁸ However, more commonly—especially in the field of biotechnology—there is no established royalty rate for the patented invention. In that case, the reasonable royalty is calculated on the basis of a “hypothetical, arm’s length license negotiation between a willing licensor and a willing licensee at the time the infringement began.”²⁵⁹

Consistent with our analysis of patent misuse doctrine generally, in this section we analyze damages jurisprudence relating both to the imposition of damages on an object not covered by the infringed patent (an extension of physical scope), and the imposition of a remedy that burdens an activity after the relevant patent has expired (a potential extension of temporal scope). These judicial infringement remedies are analogous to a negotiated contractual reach-through royalty obligation in that they both reach through the infringed patent to burden objects and actions of the infringer not covered by the infringed patent. We conclude that damages jurisprudence provides further support for our conclusion that a non-coerced reach-through royalty in the context of a Discovery Tool patent license is a legal payment arrangement.²⁶⁰

257. 35 U.S.C. § 284 (2000).

258. Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267 (2002).

259. *Id.* at 281 (“In applying the hypothetical negotiation method for determining a reasonable royalty, courts continue to cite the range of factors identified in the district court case that first articulated the method, *Georgia Pacific Corp. v. United States Plywood Corp.* The overriding goal, as the court there explained, is to determine: The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.”).

260. No analysis of damages jurisprudence in the context of reach-through royalties is complete without a discussion of the relationship between court-sanctioned reasonable royalties for infringement and actual licensing practices in an industry. The relationship with respect to the licensing of research tools is succinctly summarized by Ware (Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267, 282-83 (2002)) in the following excerpt:

How then, will courts . . . determine the amount of a reasonable royalty for infringement of a research tool patent? And, in particular, to what extent are the

1. “Reach-Through” Damages that Extend the Physical Scope of the Infringed Patent

Courts have fashioned reach-through remedies that extend the “physical” scope of a patent in a variety of patent infringement cases. In each of these cases, the infringer is burdened (in the form of a required payment of damages to the holder of the patent right) with respect to, or on the basis of, sales that (1) are either lost by the patent holder (in computing lost profits) or made by the infringer (in computing reasonable royalties) as a result of the alleged infringement, and (2) include items or components, at least some of which are not covered by the infringed patent.²⁶¹ As stated by the Federal Circuit in *King Instruments Corp. v. Perego*, “[a]s long as the patentee receives a proper economic return on its investment in the acquisition of a patent, the [Patent] Act does not require that return to come from the sale [or loss thereof] of patented products.”²⁶²

For example, in both *Minco v. Combustion Engineering*²⁶³ and *Ajinomoto v. Archer-Daniels-Midland*,²⁶⁴ the Federal Circuit affirmed rulings of district courts that awarded reasonable royalties in the form of reach-through royalties to patentees whose patented technologies

courts likely to impose reach-through royalties that extend to revenues generated by a successful drug whose discovery, development, or production is facilitated, at least in part, by a research tool patent?

To a great extent, the answer will turn on empirical evidence and will be driven by the marketplace. Over time, the research institutions, molecular biology laboratories, developmental biotech companies, and large pharmaceutical companies will determine, through their licensing negotiations, what are reasonable licensing terms for research tools.

If reach-through royalties become the licensing norm, then courts can be expected to factor that into their determinations of reasonable royalty damage awards. If reach-through royalties become the exception in the marketplace, courts ought not to assume otherwise in the name of ‘adequate’ compensation.

The point is that court-sanctioned reach-through royalties are more than an affirmation of the legality of such a royalty arrangement; they are a reflection of what is, or could reasonably be, industry licensing practice. It is likely that the Federal Circuit’s holding in *Bayer v. Housey* will affect the damages awards for reasonable royalties by courts for the infringement of Discovery Tool patents in the U.S. Those awards are intended to fix a reasonable royalty based on a hypothetical negotiation between the parties. Post-*Bayer*, it is difficult to imagine circumstances in which a licensee would not consider in that negotiation the cost of a non-U.S. development effort in a jurisdiction where the Discovery Tool could be freely used.

261. See *Central Soya Company v. Geo. A. Hormel & Co.*, 723 F.2d 1573 (Fed. Cir. 1983); *Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109 (Fed. Cir. 1996); *Ajinomoto Co. v. Archer-Daniels-Midlands*, 228 F.3d 1338 (Fed. Cir. 2000).

262. *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995).

263. 95 F.3d 1109 (Fed. Cir. 1996).

264. 228 F.3d 1338 (Fed. Cir. 2000).

were infringed. In *Minco*, the patent holder brought an infringement action against a competitor, alleging infringement of its patent for a rotary furnace used to fuse minerals. Although the patent did not cover the fused minerals themselves, the district court awarded both lost profits and a reasonable royalty calculated on the basis of the sales of fused silica that were not covered by the asserted patent. As noted by the court:

The assessment of adequate damages under section 284 does not limit the patent holder to the amount of diverted sales of a commercial embodiment of the patented product. Rather, the patent holder may recover for an injury caused by the infringement if it “was or should have been reasonably foreseeable by an infringing competitor in the relevant market, broadly defined.” *Rite-Hite*, 56 F.3d at 1546; *accord Perego*, 65 F.3d at 950. In this case, the invention produced marketable fused minerals. Both CE and Minco used the invention to compete in that market. Therefore, CE should have reasonably foreseen that infringement of the ’462 patent would harm Minco’s sales in the fused silica market. This court accordingly upholds the trial court’s determination to use that measure of damages.²⁶⁵

In *Ajinomoto*, the Federal Circuit affirmed a ruling of a district court that had awarded reach-through royalties to a patentee based on the infringement of its patented method of modifying bacterial genetic structure in order to produce an amino acid in increased quantities. In that case, the district court had entered a judgment for damages assessing a royalty (\$1.23 per kilogram) on the alleged infringer’s sales of an amino acid that itself was not covered by the patentee’s patent, but was made (without authorization) using the patented method. While the appellant in *Ajinomoto* did not dispute the patentee’s theory of damages,²⁶⁶ the Federal Circuit refused to “disturb” the district court’s assessment of that damages award.

Similarly, in *Central Soya Company v. Geo. A. Hormel & Co.*,²⁶⁷ the Federal Circuit awarded “reach-through” lost profits damages, based on the sale of a product that was made, but not covered, by an infringed process patent. In that case, the infringed patent claimed a “method of making a food product in the form of a patty,” which, in

265. *Minco*, 95 F.3d at 1118.

266. See Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267, 283-84 (2002) for a discussion of *Ajinomoto*.

267. 723 F.2d 1573 (Fed. Cir. 1983).

its commercial application using pork loin, was used to make pork loin fritters. However, the patent covered only the process for making pork loin fritters, and not the fritters themselves. In upholding the damages award, the Federal Circuit rejected the infringer's argument that an award of damages based on sales of products (pork loin fritters) that were not covered by the plaintiff's patents (covering only the process for making such fritters) was an "improper extension of the rights granted under the [the process] patent."²⁶⁸ The Federal Circuit found that such an argument confused "the measure of damages with the issue of infringement [since the] proper measure of damages is that amount which will compensate the patent holder for his pecuniary loss attributable to the infringing acts."²⁶⁹ Finding those damages not to be clearly erroneous, the court affirmed.

In each of these Federal Circuit cases, the court approved a damages award based on the sale of an unpatented object (fused silica in *Minco*, an amino acid in *Ajinomoto*, and pork loin fritters in *Central Soya*) as compensation for the infringement of a patented machine or method. These cases demonstrate that the Federal Circuit has found that a reach-through royalty arrangement is, at least in certain instances, both a legal and an appropriate reasonable royalty remedy for patent infringement.²⁷⁰

268. *Id.* at 1579.

269. *Id.*

270. The Federal Circuit has sanctioned three additional damages theories, each of which can be viewed as an extension of the physical scope of the patent monopoly. The first, known as the "entire market value rule," was articulated by the United States Supreme Court in *Garretson v. Clark*, 111 U.S. 120, 121 (1884). According to the Federal Circuit in *King Instruments Corp. v. Luciano Perego and Tapematic*:

[t]he 'entire market value rule' recognizes that the economic value of a patent may be greater than the value of the sales of the patented part alone. Under this rule, courts have allowed recovery of lost profits or a reasonable royalty based not only on the profit from the patented part, but also on non-patented parts. (See, e.g., *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580, 12 USPQ.2d 1026, 1031 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 1022, 110 S.Ct. 725, 107 L.Ed. 2d 744 (1990)).

65 F.3d 941, 950 n.4 (Fed. Cir. 1995).

Such an extension is permitted, however, only upon a showing by the infringed party "that the profits and damages are to be calculated on the whole machine [including the non-patented parts], for the reason that the entire value of the whole machine, as a marketable article, is properly and legally attributable to the patented feature." *Westinghouse Elec. & Mfg. Co. v. Wagner Elec. & Mfg. Co.*, 225 U.S. 604, 615, 32 S.Ct. 691, 694, 56 L.Ed. 1222 (1912) (quoting *Garretson v. Clark*, 111 U.S. 121, 28 L.Ed. 371, 4 Sup.Ct. Rep. 291 (1884)).

In *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*,²⁷¹ a district court case in which the alleged infringement of a Discovery Tool was at issue, the jury returned a verdict in favor of the patentee and awarded damages of \$18 million.²⁷² This award was likely based on a calculation of reasonable royalties on the anticipated sale of a drug product that might be discovered through the use of the Discovery Tool.²⁷³ As stated by Ware, the *Sibia* decision demonstrates that “at least some district courts are prepared to consider awards of reach-through royalties for infringement of patented drug discovery tools,”²⁷⁴ providing further support for the legality of this type of royalty arrangement in the context of a Discovery Tool patent license.

The second damages theory was articulated by the Federal Circuit in *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538 (Fed. Cir. 1995) (*en banc*), *cert. denied*, 516 U.S. 867, 116 S.Ct. 184, 133 L.Ed.2d 122 (1995), and again applied in *King Instruments Corp. v. Luciano Perego and Tapematic.*, 65 F.3d 941 (Fed. Cir. 1995). According to the so-called *Rite-Hite* damages theory, damages for an injury that results from an infringement can include payments by the infringer (in the form of lost profits damages) as compensation for sales lost by the patent holder of a product that competes with the infringing product but is not covered by the infringed patent.

The third damages theory, the anticipated collateral sales rule, was sanctioned by the Federal Circuit in *Deere & Co. v. Int'l Harvester Co.*, 710 F.2d 1551, 1559 (Fed. Cir. 1983), and subsequently in *Trans-World Mfg. Corp. v. Al Nyman & Sons, Inc.*, 750 F.2d 1552, 1568 (Fed. Cir. 1984). According to this rule, in determining a reasonable royalty award for the infringement of a patent based upon a hypothetical negotiation between a willing licensor and willing licensee, the Court can “take into account the impact of anticipated collateral sales of an admittedly non-infringing product line on the respective bargaining positions of the parties engaged in the theorized licensing negotiations.” (*Deere* at 1559).

271. No. 96-1231-IEG(POR), 1999 WL 335544683 (S.D. Cal. 1999).

272. Note that at the appellate court level the patent on the tool was found to be obvious and therefore invalid, resulting in reversal of the district court decision without an evaluation of the \$18 million damages award.

273. See Donald R. Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267 (2002). Note that in the *Sibia* case, the basis for the jury’s \$18-million “reasonable royalty” damages award was not disclosed. However, the expert testimony and jury instructions provided in the case (as summarized in various post-trial motions), upon which the jury likely relied in making its damages determination, suggest that the \$18-million award was a reach-through royalty based upon the anticipated sale of a drug product that might be discovered through the infringing use of the patented research tool (a permissible extension of the physical scope of the patent). This is the interpretation of the award expressed by Ware and we agree with this interpretation.

274. 30 AIPLA Q.J. at 287.

2. “*Reach-Through*” Damages That Burden Infringer Activity Following the Expiration of the Infringed Patent

In each of the Federal Circuit cases described above, the damage award was calculated for the duration of the infringement only,²⁷⁵ and, accordingly, the issue of a potential extension of the temporal scope of the infringed patent right was not addressed. For evidence of the courts’ affirmation, in the form of sanctioned damages awards, of the legality of at least certain types of post-patent expiration royalties, one must look to other cases. Specifically, one must consider those cases in which courts have held that infringement of a patent before its expiration justifies some form of post-expiration relief, whereby a burden (either an injunction or a payment obligation) is placed on the infringer’s post-expiration activity.

Early cases demonstrating the willingness of courts to fashion judicial remedies that place a burden on the infringer’s post-expiration activities involved the infringement of patents on the manufacture of products. In these cases, the product itself was not covered by the infringed patent, and therefore its sale, whether before or after the expiration of the patent, would not infringe the manufacturing claims of the patent at issue. Rather, while the infringement was limited to the unauthorized use of a manufacturing apparatus²⁷⁶ or of a method for making the product,²⁷⁷ the judicial remedy (which in these early cases was an injunction against the sale of the manufactured product) burdened the infringer’s activity following the expiration of the apparatus or method patent. The product was burdened because it was made, without authorization, using a patented apparatus or method, and (according to the court) to allow its free exploitation—even post-expiration—would be to allow the infringer to reap the “fruits of a poisonous tree.” As the Sixth Circuit in *Fulton v. Bishop & Babcock* explained:

275. See *Minco, Inc. v. Combustion Eng’g, Inc.*, 95 F.3d 1109, 1115 (Fed. Cir. 1996) (“this court affirms the trial court’s decision to permit recovery of damages for the full period of infringement”); *Ajinomoto Co. v. Archer-Daniels-Midland*, 228 F.3d 1338, 1351 (Fed. Cir. 2000) (“[a]lthough we do not disturb the district court’s assessment of damages for the period before entry of judgment [of infringement], for the period after entry of judgment ADM is entitled to raise the defense of non-infringement”); *Central Soya Company v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1579-80 (Fed. Cir. 1983) -although the meaning of the following is somewhat less clear- (“[the trial court] awarded Central Soya lost profits . . . based on 90% of Hormel’s sales of its infringing breaded pork loin fritters [or - more accurately stated - fritters made using the infringed process.]”).

276. *Motion Picture Patents v. Centaur Film*, 217 F. 247 (D.N.J. 1914).

277. *Fulton v. Bishop & Babcock Co.*, 17 F.2d 1006 (6th Cir. 1927).

[I]t is fairly well settled that the patent upon an article will be enforced by forbidding sales, after the patent expires, of infringing articles made before the expiration We see no reason why the same rule does not apply where the article has come into existence through infringing the monopoly of manufacture given by the process patent as well as when the infringement has been of the monopoly of manufacture given by the article patent. In the latter case, no violation of the patent law comes merely from selling the article after the patent expires; the violation is indirect; *the basic reason of the result is that the article itself came into existence in violation of law. Its conception and birth were tainted.* To permit it to be sold [either at all or absent a damages remedy] would be to impair the patent grant by shortening its term. (emphasis added).²⁷⁸

In another, more recent, line of cases (referred to as “accelerated reentry” cases),²⁷⁹ the courts have fashioned damages remedies to compensate for the ability of a past infringer to reenter the market of the patent holder at an enhanced or accelerated level (as a result of the prior infringement) upon expiration of the relevant patent. As the theory goes, such accelerated reentry would provide the infringer with a competitive advantage that would be absent, but for the prior infringement. The courts in these cases have awarded the patentee a post-patent expiration remedy in the form of royalties or lost profits based on the post-expiration sale by the infringer of the then-unpatented product. In *Amsted Industries Incorporated v. National Castings, Inc.*,²⁸⁰ the defendant, National, infringed upon Amsted’s patent for two and one-half years prior to the expiration date, thereby gaining “a foothold in the market for center plates [for railway freight cars] which it would not otherwise have enjoyed had it waited until the patent expired to begin its sales.”²⁸¹ Amsted sought damages for the infringement, including recovery based on National’s sales following the expiration of the Amsted patent to compensate for the economic impact of National’s “accelerated reentry” into the market. National argued, in its defense, that post-expiration, accelerated reentry damages were unlawful because they violated the rule set forth in *Brulotte*. The district court rejected this argument, and

278. *Id.* at 1006-07.

279. See *BIC Leisure Prods., Inc. v. Windsurfing Int’l, Inc.*, 687 F. Supp. 134 (S.D.N.Y. 1988), and *Amsted Indus. v. Nat’l Castings, Inc.*, 16 U.S.P.Q. 2d 1737 (N.D. Ill. 1990).

280. 16 U.S.P.Q. 2d 1737 (N.D. Ill. 1990).

281. 16 U.S.P.Q. 2d at 1752.

instead adopted the reasoning of *BIC Leisure Products v. Windsurfing International*²⁸² that had upheld such damages, since:

Accelerated reentry damages of the type approved in *BIC Leisure* are not the equivalent of a royalty which extends beyond the expiration of the patent. In other words, reentry damages are not based upon an assumption that the plaintiff's statutory monopoly on the market should be extended or that all of the defendant's post-expiration sales should be deemed wrongful *per se*. What *BIC Leisure* allows are damages based only upon those post-expiration sales which the defendant would not have made but for its wrongful conduct before the patent expired. [See 687 F. Supp. at 138.] Implicit in *BIC*, therefore, is the recognition that the plaintiff has no entitlement to damages based upon the post-expiration sales which the defendant would have made even had it not engaged in pre-expiration infringement. So clarified, the holding *BIC Leisure* in no way conflicts with *Brulotte*.²⁸³

The remedy fashioned in these accelerated reentry cases is the judicially sanctioned equivalent of a contractually agreed-to post-expiration reach-through royalty in the context of a Discovery Tool patent license, where the royalty is paid on the post-patent expiration sale of a drug identified by a licensee using the tool prior to the expiration of the tool patent. Both the judicial remedy and the contractual royalty obligation are examples of a post-expiration payment for pre-expiration use of a patent that do not violate the U.S. Supreme Court's holding in *Brulotte*.

3. *Infringement Remedies Support the Legality of Reach-Through Royalties*

The judicial infringement remedies discussed in this section are analogous to a negotiated contractual reach-through royalty in that they both reach through a patent to burden an object not covered by the patent and that burden can persist following the patent's expiration. Conceptually, a damages award in the form a reach-through royalty places the patent holder and an infringer in the same position as that of a willing licensor and a willing licensee who elect to enter into such a royalty arrangement by contract, *ab initio*. The fact that courts have continued to fashion reach-through royalty patent infringement remedies undermines the argument that such a payment

282. 687 F. Supp. 134 (S.D.N.Y. 1988).

283. *Amsted Indus. v. Nat'l Castings, Inc.*, 16 U.S.P.Q. 2d 1737, 1754 (N.D. Ill. 1990).

arrangement is an impermissible extension of the scope of a patent. It would be unreasonable to preclude willing parties from entering into a contractual payment arrangement *ex ante* in the form of a license agreement that is the economic equivalent of a payment obligation that a court may fashion *ex post* in the form of a patent infringement remedy. While a reliance on damages jurisprudence does not settle the question of whether a reach-through royalty arrangement in the context of a Discovery Tool patent license is advisable, it certainly provides additional persuasive evidence that such an arrangement is lawful.

VI. Conclusion

In this Article, we described the class of Discovery Tools, discussed the special contribution of these tools to the drug development process, and provided background regarding the policy debate on the patenting of research methods and tools generally. We next discussed the district court and Federal Circuit decisions in *University of Rochester v. Searle*, and defined the permissible scope of patent protection for Discovery Tools and their use in the post-*Rochester* era. We concluded that a novel, nonobvious Discovery Tool and its use can be the subject of valid patent claims, but claims that reach through to cover as-of-yet-undiscovered drug products generally fail to meet the statutory requirements under 35 U.S.C. § 112 for written description and enablement. We then argued that valid claims to Discovery Tools and their use are enforceable against unauthorized users, notwithstanding the Supreme Court's broad reading in *Merck v. Integra* of the scope of the statutory exemption to infringement, 35 U.S.C. § 271(e)(1), and the occasionally misapplied common law experimental use exception. Finally, we analyzed the legality of one form of compensation occasionally sought by Discovery Tool inventors as consideration for the grant of a license to the use of their patented tools: the "reach-through" royalty that is paid on the sale of a product that is identified by a licensee using a patented Discovery Tool, but is not itself covered by the inventor's tool patent. In addition, we reviewed judicial remedies in patent infringement cases that are analogous to a negotiated contractual reach-through royalty obligation, in that the remedies reach through the infringed patent to burden products and activities of the infringer that are not covered by the infringed patent. We concluded that reach-through royalty arrangements between willing licensors and licensees are permissible under applicable U.S. Supreme Court precedent, despite potential patent misuse challenges, and represent a

viable method by which the free market for patented Discovery Tools may adequately reward the tool inventor.

* * *