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Piercing the Academic Veil: Disaffecting the Common Law Exception to the Patent Infringement Liability and the Future of A Bona Fide Research Use Exemption After Madey v. Duke University

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PIERCING THE ACADEMIC VEIL: DISAFFECTING THE COMMON LAW EXCEPTION TO PATENT INFRINGEMENT LIABILITY AND THE FUTURE OF A *BONA FIDE* RESEARCH USE EXEMPTION AFTER *MADEY V. DUKE UNIVERSITY*

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Pure academic research. These words conjure images of the noble pursuit of truth and knowledge. Whether cast in the professorial robes of a scientist in a university laboratory or in the bespectacled tinkering of a hobbyist inventor in a home basement, this ideal persists today as a foil to applied research and commercial development. Whether an illusion or anachronism, the presumption that research at institutions of higher learning, or at non-profit and not-for-profit centers, is entirely altruistic in nature is being challenged, at least in the patent law context. One consequence of this scrutiny has been the revelation that even pure academic research may not find safe harbor from patent infringement liability.

In general, any unauthorized conduct involving a patented product or process can establish infringement liability. Of course, allegations of patent infringement may be defeated by successful statutory and equitable defenses relating to the invalidity and unenforceability of the patent. But prevailing on the defense of noninfringement of a patent is a factual determination typically left to the resolution of each specific case with no categorical exemptions as a matter of law.

A statutory exception to the general rule was established in 1984 with the enactment of 35 U.S.C. § 271(e)(1), which provided a limited exemption to patent infringement liability for activity reasonably related to the preparation and submission of an application for federal regulatory approval.[1] No other statutory exemption to patent infringement liability exists. However, a common law exemption to patent infringement liability persists, at least in perception if not reality, with regard to activity done for amusement, to satisfy idle curiosity, or for

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1. 35 U.S.C. § 271(e)(1) (2000).

strictly philosophical inquiry.[2] Since its articulation almost two centuries ago, some in the scientific community came to adopt this common law exemption as a safe harbor for assertedly academic or otherwise noncommercial experimental work.[3] In this manner, the common law exemption was deemed a "research use exemption" to patent infringement liability.[4]

Indeed, many scientists have been guided by a mistaken belief that the scope of this research use exemption to patent infringement was so broadly applicable as to insulate from liability virtually all experimentation performed at universities or non-profit and not-for-profit institutions, among others.[5] The correction of this misperception was a focus of the opinion of the U.S. Court of Appeals for the Federal Circuit in *Madey v. Duke University*.[6] Although the Federal Circuit has not rescinded the common law exemption to patent infringement liability *per se*, the court has clarified that the research conducted at many institutions of higher learning or non-profit and not-for-profit centers for purportedly academic or noncommercial purposes is not immune from patent infringement liability.

This article reviews the patent law jurisprudence pertinent to a research use exemption.[7] In particular, it addresses the statutory experimental use exemption

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2. *See* Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) ("[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1018-19 (1989) ("[T]he courts have long recognized . . . that a purely 'experimental use' of a patented invention, with no commercial purpose, should be exempt from infringement liability.").

3. *See* Brief of Amici Curiae Association of American Medical Colleges, et al. at 4, Duke Univ. v. Madey, 307 F.3d 1351 (Fed. Cir. 2003), *petition for cert. filed*, 71 U.S.L.W. 3475 (Jan. 2, 2003) (No. 02-1007), *available at* http://www.aamc.org/newsroom/pressrel/patentbrief.pdf (last visited Mar. 10, 2003):

The experimental use exemption historically has protected noncommercial research from claims of patent infringement; although prior to this case there had been virtually no litigation with respect to academic scientific research *per se*, the scientific community had every reason to believe that the exemption would protect noncommercial academic research just as it protected other noncommercial research.

4. *See id.*

5. *See* Biotechnology Industry Organization, *Backgrounder on Patenting Gene-Based Inventions*, Genomics, ¶ 8 (Mar. 2000), *at* http://www.bio.org/genomics/genebased.html (last visited Mar. 8, 2003):

A patent has no impact on an academic researcher not engaged in commercial activity. Scientists engaged in academic research are totally free, without any fear of infringement actions, to conduct research on any patented invention. These researchers are protected from a patent infringement action by an 'experimental use' exemption because they are not competitors with a commercial motivation;

National Agricultural Biotechnology Council, *Research Policy Issues*, ¶ 10 (Fall 1995), *available at* http://www.nal.usda.gov/bic/Newsletters/NABC_News/NABCfall95/9Research_Policy_Issues (last visited Mar. 8, 2003) ("[M]any researchers lack an understanding of patent law and operate under the misconception that an overall research exemption exists.").

6. 307 F.3d 1351 (Fed. Cir. 2002).

7. The literature is complemented by several excellent articles regarding the merits of an experimental or research use exemption to patent infringement liability. *See e.g.*, Eisenberg, *supra* note

under 35 U.S.C. § 271(e)(1)[8] and the common law exemption to patent infringement liability that preceded *Madey*. In addition, this article provides a comparative assessment of a research use exemption to similar provisions in foreign laws. This article also considers the merits and feasibility of enacting a *bona fide* research use exemption to patent infringement and the legislative initiatives in that regard. Lastly, the alternative applicability of other laws presently used to shield certain activities performed at universities or non-profit and not-for-profit organizations from patent infringement liability is considered.

I

Patent law provides that "whoever without authority . . . uses . . . any patented invention, within the United States . . . during the term of the patent therefor, infringes the patent."[9] Although the statute plainly addresses all uses, the courts have refrained from construing the term universally.[10] Accordingly, to the extent that not every unauthorized use of a patented invention constitutes infringement, the relevant question is precisely what type of activity is exempt.

Before 1984, no statutory exemption existed with respect to patent infringement liability. Such an exemption, if any, would have been of common law construction. The Federal Circuit decision in *Roche Products, Inc., v. Bolar Pharmaceutical Co.*,[11] prompted Congress to enact 35 U.S.C. § 271(e)(1) as a limited experimental use exemption to patent infringement liability for activity reasonably related to the preparation and submission of an application for federal regulatory approval.

2; Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT'L L. 615 (1994); Gregory N. Pate, *Analysis of the Experimental Use Exception*, 3 N.C. J.L. & TECH. 253 (2002); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243 (1990); Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

8. 35 U.S.C. § 271(e)(1) (2000).

9. 35 U.S.C. § 271(a) (2000).

10. *See* Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 861 (Fed. Cir. 1994), *cert. denied*, 469 U.S. 856 (1984), *superseded on other grounds by* 35 U.S.C. § 271(e) (1984):

> Section 271(a) prohibits, on its face, any and all uses of a patented invention . . . . Because Congress has never defined use, its meaning has become a matter of judicial interpretation. Although few cases discuss the question of whether a particular use constitutes an infringing use of a patented invention, they nevertheless convincingly lead to the conclusion that the word "use" in section 271(a) has never been taken to its utmost possible scope . . . .

11. 733 F.2d 858.

Statutory Experimental Use Exemption – 35 U.S.C. § 271(e)(1)

At present, the only statutory exemption to patent infringement liability exists with 35 U.S.C. § 271(e)(1), which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[12]

Section 271(e)(1) limits this exemption to activity reasonably related to the preparation and submission of an application for federal regulatory approval. Such activity may include experimentation and other data gathering so long as that activity is reasonably related to the Food and Drug Administration (FDA) application. In this regard, § 271(e)(1) can be fairly characterized as an experimental or research use defense, applicable only in the specific context of regulatory compliance.[13] Moreover, the effect of § 271(e)(1) should be measured from the perspective of the overall statutory framework of which it is a part.

Although § 271(e)(1) exempts from infringement such activity by the generic drug manufacturer that would otherwise infringe § 271(a). Section 271(e)(2) provides a cause of action for infringement based upon the filing of an application to the FDA for market approval of a generic drug.[14] The statutory scheme thus balances the interests of a patented, brand-name drug manufacturer in enforcing its patent rights and the interests of the public in the availability of a competitively priced generic version of the drug as soon as possible. Given the infringement exemption under § 271(e)(1), § 271(e)(2) essentially authorizes a declaratory

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12. 35 U.S.C. § 271(e)(1) (2000).

13. *See also* Thomas F. Poché, *The Clinical Trial Exemption from Patent Infringement: Judicial Interpretation of Section 271(e)(1)*, 74 B.U. L. REV. 903, 913-14 (characterizing 35 U.S.C. § 271(e)(1) as a "clinical trial exemption").

14. Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829, 835 (Fed. Cir. 1999) (Rader, J., concurring):

Section 271(e)(1) benefits competitors of the patent holder by freeing them from liability for development work reasonably related to securing regulatory approval. By enabling testing to comply with regulatory processes before patent expiration, this section allows competitors to enter the market more quickly after the patent expires, thus limiting what would otherwise amount to an extension of the patent term. Section 271(e)(2), on the other hand, balances the effects of 271(e)(1) to a degree by making it an act of infringement for competitors to file an ANDA if the purpose of the submission is to obtain approval and 'engage in the commercial manufacture, use, or sale' of the drug before the expiration of the patent (citations omitted).

judgment suit by a patentee against a prospective infringer.[15] The otherwise stark infringement exemption under § 271(e)(1) thus serves an important purpose in this regard.

From a business perspective, the pharmaceutical industry arguably feels the greatest impact of the intellectual property laws. However, its members view the federal grants of exclusivity through patents, copyrights, and trademarks from very different perspectives. This disparity is not surprising given that pharmaceutical manufacturers include companies with competing interests on a large scale.[16] In many respects, the distinction of intellectual property ownership separates the haves from the have-nots.

The brand-name drug manufacturer typically undertakes years of research, development and clinical trials at staggering costs to bring a drug to market.[17] With such investment at stake, intellectual property protection provides the relative certainty of market exclusivity upon which a brand-name drug manufacturer depends. Patent rights, for example, can create the opportunity, through an essentially noncompetitive business climate, for a brand-name drug manufacturer to recoup its investments in the patented drug following regulatory approval by the FDA. The commercial success of a patented drug can also help offset the losses incurred by a brand-name drug manufacturer on its drugs that never reached the market due to failed FDA approval or otherwise.

In contrast, the generic drug manufacturer can often bring a generic version of a patented drug to market more quickly and cheaply. Mindful of the brand-name drug patent, a generic drug manufacturer can choose to develop a noninfringing, albeit bioequivalent, substitute during the patented term, or wait until the patent expires to produce copies of the brand-name drug. In either event, the generic pharmaceutical manufacturer can take advantage of a streamlined FDA

15. Novartis Corp. v. Ben Venue Labs., Inc., 271 F.3d 1043, 1047 (Fed. Cir. 2001) ("When a patentee seeks to block FDA approval of an NDA under 35 U.S.C. § 271(e)(2)(A), the infringement inquiry focuses on the hypothetical infringement that would occur if the defendant's NDA were approved and the defendant began to make and sell the drug."); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

16. *See* Lawrence M. Sung, *'Mylan' Presents Setback for Generic Drug Makers*, NAT'L L.J., Jan. 21, 2002, at C8 (describing the aggressive competitive tactics and litigation strategies employed by Bristol-Myers Squibb Co. against Mylan Pharmaceuticals, Inc., the manufacturer of a generic version of Bristol's patented BuSpar drug, which earned over $709 million in sales during the year 2000).

17. *See* Robert Pear, *Research Cost for New Drugs Said to Soar*, N.Y. TIMES, Dec. 1, 2001 at C1 ("A new round in the national debate over prescription drugs opened today with a study from researchers at Tufts University estimating that the average cost of developing a new drug has more than doubled since 1987, to $802 million."); Posting of James Love, love@cptech.org, to pharm-policy@lists.essential.org, *at* http://lists.essential.org/pipermail/pharm-policy/2000-May/000201.html (May 25, 2000) (last visited May 19, 2003) ("[T]he costs of good clinical practice trials (the type used for US FDA approval) were almost always in the range of $2,000 to $7,000 per patient.").

approval process for its generic drug by filing an abbreviated new drug application (ANDA) that greatly relies on the information known about the brand-name drug.[18]

Still, generic drug manufacturers serve a vital public interest by making generic drugs available to consumers at reduced prices compared to the brand-name drug.[19] In turn, such competition typically motivates the brand-name drug manufacturer to lower its price as well.[20] This public benefit was a focus of the congressional intent behind the Drug Price Competition and Patent Term Restoration Act of 1984,[21] better known as the Hatch-Waxman Act. This statutory framework recognizes the importance of facilitating generic drug approval by the FDA well in advance of the expiration of the brand-name drug patent so that the first day after patent expiration can reflect a competitive market as much as possible.[22]

The Hatch-Waxman Act thus exempts from patent infringement liability certain activity reasonably related to the submission of an ANDA by a generic while the brand-name drug patent is still in force. To the extent a generic pharmaceutical manufacturer states in an ANDA "Paragraph III" certification that it does not intend to market its generic drug until the brand-name drug patent expires, the generic can enjoy a safe harbor for conduct that would otherwise constitute infringement under patent law.[23] In the alternative, a generic

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18. *See* Poché, *supra* note 13, at 913 ("The Act allowed generic drug manufacturers to file Abbreviated New Drug Applications ('ANDA's), which are much less expensive and time-consuming than full NDAs.") (citations omitted); James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 458 (1986) ("ANDAs must contain information showing: . . . that the generic is bioequivalent to, and bioavailable to the same extent as, the pioneer; [and] a certification that approval of the ANDA will not violate a patent held by the maker of the pioneer.") (internal footnote omitted).

19. *See* H.R. REP. NO. 98-857, pt. 1, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (estimating a consumer cost savings of $920 million in the twelve years following enactment of the Hatch-Waxman Act).

20. *See* Jaclyn L. Miller, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 93 (2002) ("In focusing on the pharmaceutical industry, many legislators felt lower prices for pharmaceutical drugs could be obtained by increasing competition between generic manufacturers and brand name manufacturers.").

21. Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 (2000)).

22. *See* Ned Milenkovich, *Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751, 764 (1999) ("[T]he Hatch-Waxman Act . . . enables a generic drug maker to market on the first day of patent expiration by having FDA requirements satisfied in a timely manner.").

23. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III) (2000) (setting forth ANDA "Paragraph III" certification provision); *see also* M. Howard Morse, *Settlement of Intellectual Property Disputes in the Pharmaceutical and Medical Device Industries: Antitrust Rules*, 10 GEO. MASON L. REV. 359, 385 n.147 (2002):

If the applicant makes a certification under Paragraph III (i.e., if a valid patent is in force and would be infringed), the FDA may approve the ANDA effective on the date that the applicant certifies that the patent will expire. The Hatch-Waxman Act . . . authorizes use of patented drugs to develop and

pharmaceutical manufacturer can assert in an ANDA "Paragraph IV" certification that it intends to commercialize the generic drug before expiration of the brand-name drug patent.[24] Such a statement must be accompanied by the allegation that the brand-name drug patent is invalid, unenforceable, or would not be infringed by the generic drug.[25] In response to notice of a "Paragraph IV" certification by a generic, the brand-name drug manufacturer may sue for patent infringement.[26] In addition to seeking the adjudication of the brand-name drug manufacturer's patent rights, the filing of the patent infringement suit suspends any FDA approval of the generic drug for up to 30 months.[27]

The Hatch-Waxman Act thus seems to strike an equitable balance between the need for reliable patent enforcement by brand-name pharmaceutical manufacturers and the need for generic pharmaceutical manufacturers to begin the FDA approval process before the brand-name drug patent expires. Moreover, the public interest appears well served by maintaining the incentives for brand-name drug manufacturers to develop pioneering drugs, and by facilitating public access to competitively priced drugs as soon as possible.

The Federal Circuit has addressed the operation of § 271(e) on numerous occasions.[28] Although the patent infringement claim in an ANDA litigation derives from a specific statutory authority, the infringement analysis under

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submit information to the FDA to obtain premarketing approval, without infringing patents, to ensure generic drugs are ready for market as soon as relevant patents expire (citations omitted).

24. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000) (setting forth ANDA "Paragraph IV" certification provision).

25. *See id.* (requiring the ANDA applicant to certify "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted").

26. *See id.* § 355(j)(5)(B)(iii) ("If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received.").

27. *See id.* "If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action . . . .") *Id.*

28. *See e.g.*, Warner-Lambert Co. v. Apotex Corp, No. 02-1073, 2003 U.S. App. LEXIS 594 (Fed. Cir. Jan. 16, 2003); Bayer AG v. Biovail Corp., 279 F.3d 1340 (Fed. Cir. 2002); Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323 (Fed. Cir. 2001); Bayer AG v. Elan Pharm. Res. Corp., 212 F.3d 1241 (Fed. Cir. 2000); Merck & Co., Inc. v. Mylan Pharms., Inc., No. 99-1044, 1999 U.S. App. LEXIS 21395 (Fed. Cir. Sept. 3, 1999); Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d 829 (Fed. Cir. 1999); Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997); Hoechst-Roussel Pharms., Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997); Bio-Tech. Gen. Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996); Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130 (Fed. Cir. 1995); DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397 (Fed. Cir. 1995); Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992).

§ 271(e)(2) proceeds similarly to the otherwise routine inquiry under § 271(a).[29] In any event, the unique circumstances of patent infringement under § 271(e) have prompted the Federal Circuit to provide a fairly detailed primer on the statutory framework. In *Mylan Pharmaceuticals., Inc. v. Thompson*,[30] the Federal Circuit said at length:

> [A] pharmaceutical company seeking to manufacture a new drug is required to file a New Drug Application ("NDA") for consideration by the FDA. Preparing an NDA is frequently a time-intensive and costly process, because among other things, it must contain detailed clinical studies of the drug's safety and efficacy. The NDA must also include a list of patents which claim the drug:
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> > The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. . . . Upon approval of the application, the Secretary shall publish information submitted under [this section].
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> If the FDA approves the NDA, it publishes a listing of the drug and patents on the drug's approved aspects in *Approved Drug Products with Therapeutic Equivalence Evaluations,* otherwise known as the "Orange Book." Because an applicant may not receive original approval for all aspects of the drug as described in the original NDA submission, once the NDA is approved, the applicant must amend the patent submission to list only the patents that meet the listing criteria for the approved drug product.
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> Under the Drug Price Competition and Patent Term Restoration Act of 1984, a pharmaceutical manufacturer seeking approval to market a generic version of a previously approved drug may submit an abbreviated new drug application ("ANDA") to the FDA. An ANDA offers an expedited approval process for generic drug manufacturers. Instead of filing a full NDA with new safety and efficacy studies, in an ANDA a generic manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic product's bioequivalence with the previously approved drug. These provisions of the Hatch-Waxman Amendments "emerged from

29. *See* Glaxo Group Ltd. v. Ranbaxy Pharms., Inc., 262 F.3d 1333, 1337-38 (Fed. Cir. 2001) ("The inquiry under 35 U.S.C. § 271(e)(2) is a standard infringement test. 'The only difference . . . is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved.'").

30. 268 F.3d 1323 (Fed. Cir. 2001).

Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Thus, Title I of the Act was intended to "make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." Title II, on the other side of the scale, was intended to benefit pioneer drug manufacturers by "restor[ing] . . . some of the time lost on patent life while the product is awaiting pre-market approval."

The Hatch-Waxman provisions concerning patent infringement are part of this balance. Under 35 U.S.C. §271(e)(1), it is not infringement to conduct otherwise infringing acts necessary to prepare an ANDA. Under section 271(e)(2), however, a generic drug manufacturer infringes by filing an ANDA to obtain FDA approval for the purpose of marketing a generic drug product claimed in a patent before the patent expires. Despite this provision, not all ANDA applicants can be sued immediately for infringement; moreover, they cannot sue immediately for declaratory judgment with respect to the patent, as further discussed below.

As part of the ANDA process, an applicant seeking to market a generic version of a listed drug must make a certification as to each patent listed in the Orange Book which "claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval." Further, according to regulations enacted by the FDA, an applicant whose ANDA is pending when a pioneer drug manufacturer lists additional patents in the Orange Book must make certifications as to the new patents, unless the additional patents are submitted more than thirty days after they were issued.

In either case, the applicant must certify either that: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted. These are commonly referred to as Paragraph I, II, III, and IV certifications. Further, if one of the listed patents is a method-of-use patent which does not claim a use for which the applicant is seeking approval, the applicant must make a statement to that effect (a "Section viii Statement").

An ANDA containing a Paragraph I or II certification may be approved without additional delay. An ANDA containing a Paragraph III certification indicates that the applicant does not intend to market the drug until after the expiration of the patent, and the approval of the ANDA cannot be made final until the patent expires.

When an ANDA contains a Paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid, unenforceable, or not infringed. The patentee is then given forty-five days to sue the ANDA applicant for infringement. If the patentee does not file suit, the application may be approved. If the patentee files suit within that period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever is earliest. The court in which the suit is pending may order a shorter or longer stay on the approval time if "either party to the action fail[s] to reasonably cooperate in expediting the action." Moreover, the availability of declaratory judgment actions is limited: "Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent." These provisions give the pioneer manufacturer the first opportunity to file suit against the ANDA applicant for infringement, and may substantially delay the ANDA approval during the pendency of the litigation.

The Hatch-Waxman Amendments, however, do not include any explicit provisions either enabling or prohibiting an action to challenge a patentee's listing of a patent in the Orange Book. By regulation, the FDA has provided a limited process for disputing the accuracy or relevance of patent information submitted to the FDA and listed in the Orange Book. One who questions the accuracy of the patent information may write to the FDA, and the FDA will request that the applicant confirm the information. According to the FDA's regulations, however, "[u]nless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list" and an ANDA applicant must still make certifications for each patent despite its disagreement.[31]

Common Law Exemption to Patent Infringement Liability

In contrast, outside the narrow context prescribed under § 271(e)(1), no statutory defense exists to excuse research generally from patent infringement liability. To be sure, the 1952 Patent Act, which established virtually all of the statutory authority in operation today, did not codify such an infringement defense. Nor did the 1952 Patent Act disavow any common law precedent for an exemption in this vein. The notion of a generally applicable common law exemption to patent infringement liability thus arguably has some continuing vitality.

31. *Id.* at 1325-27 (internal citations omitted).

The consideration that the patent laws could not have been intended to reach all activity can be traced to judicial opinions dating back as far as the early 1800s.[32] However, the relatively rare number of reported cases in which an accused infringer invoked a common law experimental use exemption suggests a discord between the theoretical and practical applicability of this defense.[33] In any event, an examination of the common law origins of this concept reveals the rationales for the exception.

The first articulation of a common law exemption to patent infringement liability is often attributed to dictum in the opinion by Justice Story in *Whittemore v. Cutter*.[34] The case involved an infringement claim regarding a patent to a machine for producing playing cards. Justice Story addressed the lower court's distinction based upon the defendant's underlying motive for engaging in the infringing activity. Justice Story noted:

> [I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.[35]

At first blush, Justice Story appeared to support the exclusion of two types of otherwise infringing conduct, the first relating to abstract study, and the second to a more purposeful testing for reproducibility and verification. However, Justice Story did not elaborate a standard for entitlement to immunity from patent infringement liability under either rubric. Nor did Justice Story suggest whether such standards would be applied objectively or subjectively, or as a matter of law or equity.

In any event, Justice Story's continued conviction on this issue was evident in his opinion in *Sawin v. Guild*.[36] In this case, Justice Story revisited the notion of excluding certain otherwise infringing activity from liability. Furthermore, Justice Story expanded his reasoning regarding an exemption for otherwise infringing use into the context of an allegedly infringing sale.

In *Sawin*, the court considered whether a sheriff's seizure and sale of three patented brad nail cutting machines as execution upon a debt, as well as the

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32. *See infra* notes 34-39 and accompanying text (discussing Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) and Sawin v. Guild, 21 F. Cas. 554, 554 (C.C.D. Mass. 1813) (No. 12,391)).

33. *Cf.* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 222 (1987) ("[H]ardly any cases have allowed the defense to excuse otherwise infringing activities that were conducted 'merely for the purpose of philosophical experiments.'").

34. 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

35. *Id.* at 1121.

36. 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

buyer's purchase, constituted patent infringement.[37] Indeed, the allegedly infringing conduct did not involve any manufacture or use of the machines, but rested upon their unauthorized sale.[38] Justice Story reaffirmed his statements from *Whittemore*, remarking:

> This court has already had occasion to consider the clause in question, and upon mature deliberation, it has held that the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.
>
> In the present case, we think that a sale of a patented machine, within the prohibitions of the same clause, must be a sale not of the materials of a machine, either separate or combined, but of a complete machine, with the right, express or implied, of using the same in the manner secured by the patent. It must be a tortious sale, not for the purpose merely of depriving the owner of the materials, but of the use and benefit of his patent. There is no pretence, in the case before us, that the officer had either sold or guaranteed a right to use the machine in the manner pointed out in the patent-right. He sold the materials as such, to be applied by the purchaser as he should by law have a right to apply them. The purchaser must therefore act on his own peril, but in no respect can the officer be responsible for his conduct.[39]

In so holding, Justice Story extended the common law exemption to patent infringement liability to conduct beyond the use of a patent invention, such as a sale or other commercial transaction. Furthermore, in distinguishing between tortious and non-tortious acts, Justice Story appeared to draw from common law principles of intentional tort. The touchstone of the common law exemption to patent infringement liability thus seemed less about the actual nature of the infringing activity than about the infringer's intent or underlying motivation. In this sense, the contention that the common law exemption to patent infringement liability survived the 1952 Patent Act appears to have suffered a fatal infirmity.

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37. *See id.* at 554. ("[T]he defendant is a deputy sheriff of the county of Norfolk, and having an execution in his hands against the plaintiffs for the sum of $567.27 debt and costs, by virtue of his office, seized and sold, on said execution, the materials of three of said patented machines, which were at the time complete and fit for operation, and belonged to the plaintiffs.") *Id.*

38. *See id.* ("The purchaser, at the sheriff's sale, has not, at any time since, put either of the said machines in operation; and the whole infringement of the patent consists in the seizure and sale by the defendant as aforesaid.").

39. *See id.* at 555 (internal citation omitted).

The patent law does not require any intent to infringe to establish infringement liability under 35 U.S.C. § 271(a).[40] Indeed, even the defendant's knowledge of existing patent rights is not a prerequisite to finding a violation of § 271(a).[41] Accidental or innocent infringement gives rise to liability no different than willful infringement or infringement by reckless disregard. The defendant's culpability thus has no place in a determination of liability under § 271(a), although it remains a factor in the consideration of infringement under the doctrine of equivalents as well as in the assessment of appropriate infringement remedies.[42] As such, patent infringement under § 271(a) can be construed as a strict liability offense.[43]

Therefore, the common law exemption to patent infringement liability, at least as originally articulated, would seem at odds with the codified patent law. To the extent this conflict exists, the common law exemption to patent infringement liability arguably was superseded by statute, if not earlier. Nevertheless, the courts have not abandoned the common law exemption to patent infringement liability.

The dichotomy between the common law exemption and the strict liability nature of patent infringement seemed apparent. However, the courts did not address any tension between these principles. In *Hogg v. Emerson*,[44] the U.S. Supreme Court treated the issues in concert offhandedly. The patented invention in *Hogg* was an improved steam engine. In considering the award of enhanced damages for the patent infringement, the Court noted:

> [A] fair ground existed for a mitigation below that amount, if the maker of the machine appeared in truth to be ignorant of the existence of the patent right, and did not intend any infringement. That would not, however, furnish a reason, as was insisted by the plaintiffs in error, for allowing no damages when making the machine *to be used*, and not, as in some cases, merely for a model, or for fancy, or philosophical illustration. The intent not to injure, also, never exonerates, as is

40. *See* 35 U.S.C. § 271(a) (1994) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

41. *See* Robert Ryan Morishita, *Patent Infringement after GATT: What is an Offer to Sell?*, 1997 UTAH L. REV. 905, 926 ("Patent infringement is a strict liability offense; that is, no intent or knowledge is required to infringe.").

42. *See* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 35 (1997) ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.").

43. Notably, independent development of the patented technology is irrelevant to infringement liability under § 271(a). By contrast, the independent development of a technology protected by trade secret is a legitimate defense against a claim of trade secret misappropriation, just as the independent creation of a copyrighted work is a valid defense against a claim of copyright infringement.

44. 52 U.S. 587 (1850).

> contended, in these cases, from all damages for the actual injury or encroachment, though it may mitigate them.[45]

Despite concerns about the common law exemption to patent infringement liability, the courts remained faithful to its consideration. In *Byam v. Bullard*,[46] Justice Curtis challenged the common law exemption to patent infringement liability to the extent it rests upon the reasoning that certain activitiesshould be exempt from liability because they create no harm. Justice Curtis stated:

> Nor can I find any solid foundation on which to rest the right of a patentee to support an action on the case for the violation of his exclusive right, except that settled and reasonable common-law basis of all such actions, injury and damage; injury by a violation of the incorporeal right, and damage, at least nominal, presumed by the law to arise from such violation. Such I understand to have been the principle proceeded upon by Mr. Justice Story, in *Whittemore v. Cutter*, where he held that making a machine for a philosophical experiment, or to test the sufficiency of the specification, would not be an infringement; and in *Sawin v. Guild*, where he says the act must be with intent to deprive the patentees of some lawful profit; and also by Mr. Justice Patteson, in *Jones v. Pearce*, where he excepts the making of a patented article for mere amusement, and not for profit. In these cases, inasmuch as there was supposed to be no damage, there was thought to be no action. And though I am rather disposed, with Mr. Justice Washington, in *Watson v. Bladen*, to doubt whether the assumption is correct, that in such cases there is no damage; yet if the assumption be correct, I think the inference is sound that no action lies.[47]

In so holding, Justice Curtis appeared to depart from the intent of the infringer as the touchstone of the common law exemption to patent infringement liability in favor of the *de minimis* nature of the harm to the patentee caused by the infringement. This shift in rationale, however, did not lessen the tension between the common law exemption to patent infringement liability and other patent law tenets. Rather, under Justice Curtis' reasoning, the common law exemption to patent infringement liability would still run afoul of the patent law principle that a patentee would be entitled to at least a reasonable royalty for the infringement even if a patentee cannot prove actual economic harm.[48] In other words, the *de minimis* nature of the harm to the

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45. *Id.* at 607-08 (citations omitted).

46. 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262).

47. *Id.* at 935 (citations omitted).

48. *See* 35 U.S.C. § 284 (1998) ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."); *see also* King Instruments Corp. v. Perego, 65 F.3d 941, 947 (Fed. Cir. 1995) ("Section 284 imposes no

patentee caused by the infringement should not vitiate the liability for such infringement, even though the available remedy might be nominal.

In *Poppenhusen v. Falke*,[49] Justice Curtis' conception of the common law exemption to patent infringement liability achieved its modern day articulation in the specific context of alleged experimentation. In *Poppenhusen*, the court held that the defendants infringed two patents for improved modes of treating caoutchouc and other vulcanizable gums. With respect to one of the patents, Judge Shipman wrote:

> It is said, indeed, that the acts of the respondents are not in violation of either patent, because they are mere experiments. I do not think the facts disclosed warrant the conclusion that these were within that class of experiments protected by law. It has been held, and no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee. I do not think, however, that the acts of the respondents come under that head. They are rivals of the complainant in the very business to which his patents relate. They, or most of them, are perfectly familiar with his patents and processes, having formerly been in his employ in manufacturing articles under his patents. The answer alleges that all the defendants have thus far done since the organization of said company, has been done by way of experiment, for the purpose of hereafter working under certain patents, grants, and licenses of their own; of course, these patents, under which they claim to work, are wholly different from those of the complainant; and it can hardly be necessary for the respondents to experiment with the complainant's inventions in order to perfect their own, especially when they are already perfectly familiar with the former.[50]

The consideration of the common law exemption to patent infringement liability in *Poppenhusen* retrenched the focus on the exclusion of two types of otherwise infringing conduct set forth in *Whittemore*, namely, activity relating to abstract study and activity involving testing for reproducibility and verification. The rejection in *Poppenhusen* of the defendant's reliance upon the common law exemption to patent infringement liability, however, suggested the court's discomfort with a broad application of the exemption, whether based upon the intent standard of *Whittemore* or the *de minimis* standard of *Byam*.

Following these early considerations, the common law exemption to patent infringement liability did not experience a noticeable resurgence until a half century later in the Court of Claims. Unfortunately, its revival was not

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limitation on the types of harm resulting from infringement that the statute will redress. The section's broad language awards damages for any injury as long as it resulted from the infringement.").

49. 19 F. Cas. 1048 (C.C.S.D.N.Y. 1861) (No. 11,279).

50. *Id.* at 1049.

accompanied by a resolution of the inherent tensions with the patent law. In any event, the forum in which the common law exemption to patent infringement liability was reborn has great significance. As a predecessor to the Federal Circuit, the Court of Claims provided precedent adopted by the Federal Circuit as controlling authority.[51] This chain of events more easily facilitated the continued vitality of the common law exemption to patent infringement liability in patent law jurisprudence.

In *Ordnance Engineering Corp. v. United States*,[52] the court applied *de facto* the common law exemption from patent infringement liability in the context of assessing reasonable compensation for the federal government's use of a patented invention.[53] The Court of Claims awarded Ordnance damages for the unauthorized use by the U.S. Navy of its patented illuminating munitions, or star shells. In assessing the proper amount of damages, the court divided the shells into three

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51. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended at 28 U.S.C. § 1295 (1988)) (establishing the Federal Circuit). The Federal Circuit is an Article III court at the same level as the existing United States courts of appeals. S. REP. NO. 97-275, at 2-3 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 12. The Federal Circuit represents the merger of the United States Court of Claims and the United States Court of Customs and Patent Appeals (CCPA). Federal Courts Improvement Act of 1982, Pub.L. No. 97-164, § 101, 96 Stat. 25, 25 (codified as amended at 28 U.S.C. § 1295 (1988)). The Federal Circuit adopted the decisions of the Court of Claims and CCPA as precedent. *See* South Corp. v. U.S., 690 F.2d 1368, 1370 (Fed. Cir. 1982) *en banc* (recognizing holdings of predecessors, Court of Claims and CCPA). The legislative history on the Federal Courts Improvement Act explains the Federal Circuit's purpose as follows:

The United States Congress created the Federal Circuit to fill a void in the judicial system by creating an appellate forum capable of exercising nationwide jurisdiction over appeals in areas of the law where Congress determines there is a special need for nationwide uniformity [and] to improve the administration of the patent law by centralizing appeals in patent cases. S. REP. NO. 97-275, at 2 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 12.

52. 84 Ct. Cl. 1 (1936), *cert. denied*, 302 U.S. 708 (1937).

53. In contrast to patent infringement lawsuits before the U.S. district courts pursuant to 28 U.S.C. § 1338, a lawsuit before the Court of Federal Claims pursuant to 28 U.S.C. § 1498 is more correctly characterized as an action in eminent domain, rather than for patent infringement. *See* Hughes Aircraft Co. v. U.S., 86 F.3d 1566, 1571 (Fed. Cir. 1996) *vacated on other grounds*, 520 U.S. 1183 (1997) ("The government's unlicensed use of a patented invention is properly viewed as a taking of property under the Fifth Amendment through the government's exercise of its power of eminent domain and the patent holder's remedy for such use is prescribed by 28 U.S.C. § 1498(a)."); *see also* Pitcairn v. U.S., 547 F.2d 1106, 1114 (Ct. Cl. 1977); Leesona Corp. v. U.S., 599 F.2d 958, 966-67 (Ct. Cl. 1979) (discussing the various ways patent infringement by the government was characterized prior to the enactment of 28 U.S.C. § 1498); Decca Ltd. v. U.S., 640 F.2d 1156, 1166 (Ct. Cl. 1980). The policy rationale underlying this waiver of sovereign immunity is the protection of contractors against patent infringement liability for their manufacture or supply of goods and services to the U.S. government. In view of this, 28 U.S.C. § 1498 limits a patent owner to recourse only from the U.S. government and restricts the patent infringement remedy to the recovery of reasonable and entire compensation for the unauthorized conduct. Accordingly, in this context, the U.S. government is not in the position of an ordinary infringer, but rather a compulsory, nonexclusive licensee. *See* Crozier v. Fried Krupp Aktiengesellschaft, 224 U.S. 290, 308 (1912) (characterizing the otherwise infringing conduct as "the acquiring by the Government under the right of eminent domain . . . of a license to use the patented inventions in question . . . .").

categories: regular or service shell, ballistic shell, and experimental shell.[54] The court deducted the costs of the shells deemed as ballistic or experimental from the final damages amount.[55] The Court of Claims did not discuss the common law exemption to patent infringement liability, nor did it give any reasons for excluding the costs attributable to ballistic or experimental shell. However the court's definition and exclusion of these categories suggests the application of the exemption: Ballistic shell are not intended for battle or practice use, but are samples fired for test purposes from each lot manufactured before the lot is issued or sent to store. Experimental shells are shell built for experimental purposes.[56]

In so holding, the Court of Claims discounted from the damages award roughly 3.7% of the total number of infringing shells, which was arguably not *de minimis*.[57] Accordingly, the intent behind the otherwise infringing acts seemed controlling in this case, rather than the impact of the infringement.

The Court of Claims again addressed the common law exemption to patent infringement liability in dictum in *Chesterfield v. United States*.[58] Chesterfield sued the federal government for the unauthorized use of its patented technology.[59] The Court of Claims held that the Chesterfield patents were invalid as obvious in view of the prior art.[60]

The court, however, noted further that even if the patents were valid, the defendants did not engage in infringing activity:

> The 422—19 alloy comes within the broad ranges recited in the two patent claims in suit, and actual use by the defendant would constitute infringement of said claims if the claims are valid. However, the evidence shows that a portion of the 422—19 alloy procured by the defendant was used only for testing and for experimental purposes, and there is no evidence that the remainder was used other than experimentally. Experimental use does not infringe. In a patent infringement case, District Judge Rifkind said:
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> > 'The accused devices * * * can be eliminated from consideration for it affirmatively appeared, without

54. Ordnance Eng'g Corp., 84 Ct. Cl. at 2.

55. *Id.* at 4.

56. *Id.* at 2.

57. *See id.* at 4 ("Deducting from this latter figure 7,425 ballistic and experimental shell leaves a net total of 192,427 infringing regular service shell made or used during the accounting period . . . .").

58. 159 F. Supp. 371 (Ct. Cl. 1958).

59. *Chesterfield*, 159 F. Supp. at 372 (reporting the patents-in-suit as U.S. Patents No. 1,698,934 and No. 1,698,935, both of which related to metal alloys containing cobalt and nickel with other metals and nonmetals, designed for use in the production of high-speed cutting tools).

60. *Id.* at 374 ("The two claims in suit are so broad as to cover alloy compositions which fall within the ranges taught by the prior art patent. [I]t is clear that many alloys within the ranges claimed by Chesterfield would have been obvious, at the time the Chesterfield applications were filed, to a person having ordinary skill in the metal alloy art.").

> contradiction by the plaintiff, that defendant built that device only experimentally and that it has neither manufactured it for sale nor sold any.'
>
> This principle was applied earlier by District Judge Seymour, who said:
>
> 'It is true that, if an infringing machine is made or used as an experiment merely, it does not infringe former patents.'
>
> The claims in suit, if valid, are not infringed by defendant's experimental use of the accused 422—19 alloy. The 6059 alloy was likewise a cobalt-nickel alloy with chromium, molybdenum, carbon, and other metals and non-metals. . . . Plaintiff's metallurgical expert testified that 6059 alloy was used experimentally. As point[ed] out above, experimental use is not an infringing use. It is noted that plaintiff has stated that 6059 alloy does not make full use of the plaintiff's patented invention.[61]

The Court of Claims thus acknowledged the common law exemption to patent infringement liability in the specific context of experimental use. The court appeared to focus on the absence of any sale of the patented inventions. In so stating, the court seemingly approved of the unauthorized manufacture or use of a patented invention as an experimental use so long as such activities did not result in a sale. The dictum in *Chesterfield*, however, was to become the high water mark for the common law exemption to patent infringement liability in the post-1952 Patent Act era.

The reversal of fortune for the common law exemption to patent infringement liability came to the fore in *Pitcairn v. United States*.[62] The Court of Claims rejected the federal government's reliance upon the common law exemption to patent infringement liability. In particular, the federal government sought to exclude from infringement its testing, evaluation, demonstration and experimentation of certain helicopters for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors.[63] The Court of Claims emphasized that:

> Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.[64]

In so holding, the Court of Claims rejected any implication that *Ordnance* and *Chesterfield* were controlling authority on the applicability of the common law

61. *Id.* at 375-76 (citations omitted).

62. 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied*, 434 U.S. 1051 (1978).

63. *Pitcairn*, 547 F.2d at 1124-25.

64. *Id.* at 1125-26.

exemption to patent infringement liability, finding the relevant portions of the court's opinions in those cases to be inapposite or dictum.[65] As a foreshadowing of the Federal Circuit's reasoning some 20 years later, the Court of Claims appeared to depart from the standards of intent to infringe in *Whittemore* and *de minimis* harm in *Byam*, in favor of the touchstone inquiry of whether the otherwise infringing activity was consistent with the legitimate business of the accused infringer. Aside from foreclosing the considerations of intent or impact, the adoption of such a threshold seemingly rendered the common law exemption to patent infringement liability inapplicable except perhaps to hobbyist undertakings.

The Federal Circuit has not departed from the strict construction of the common law exemption to patent infringement liability observed by the Court of Claims in *Pitcairn*. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,[66] the Federal Circuit rejected the application of the common law exemption to patent infringement liability to the specific context of the clinical testing of the generic version of a patented pharmaceutical for FDA approval purposes. The Federal Circuit's holding in *Roche* precipitated the legislative response of enacting the statutory experimental use exemption as 35 U.S.C. § 271(e)(1).[67]

In refusing to apply the common law exemption to patent infringement liability to Bolar's activities, the Federal Circuit declined to abolish the exemption *per se*, but held that it did not apply in this particular case. According to the Federal Circuit, the clear pre-commercial nature of Bolar's experimentation rendered inapposite the application of the common law exemption to patent infringement liability. The Federal Circuit stated:

The so-called experimental use defense to liability for infringement generally is recognized as originating in an opinion written by Supreme Court Justice Story while on circuit in Massachusetts [in which] Justice Story sought to justify a trial judge's instruction to a jury that an infringer must have an intent to use a patented invention for profit, stating:

> [I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.
>
> Despite skepticism, Justice Story's seminal statement evolved until, by 1861, the law 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 not an infringement of the rights of

65. *Id.* at 1125.

66. 733 F.2d 858 (Fed. Cir. 1984), *cert denied*, 469 U.S. 856 (1984), *superseded on other grounds by* 35 U.S.C. § 271(e) (1984).

67. *See supra* notes 21-31 and accompanying text (discussing Hatch-Waxman Amendments and ANDA infringement).

> the patentee.' Professor Robinson firmly entrenched the experimental use exception into the patent law when he wrote his famous treatise . . . .
>
> The Court of Claims, whose precedents bind us, on several occasions has considered the defense of experimental use. Bolar concedes, as it must, that its intended use of flurazepam HCl does not fall within the 'traditional limits' of the experimental use exception as established in these cases or those of other circuits. Its concession here is fatal. Despite Bolar's argument that its tests are 'true scientific inquiries'' to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar's argument that the experimental use rule deserves a broad construction is not justified.
>
> Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. Bolar's intended use of flurazepam HCl to derive FDA required test data is thus an infringement of the '053 patent. Bolar may intend to perform 'experiments,' but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimentor's business is a violation of the rights of the patentee to exclude others from using his patented invention. It is obvious here that it is a misnomer to call the intended use *de minimis*. It is no trifle in its economic effect on the parties even if the quantity used is small. It is no dilettante affair such as Justice Story envisioned. 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.[68]

Following *Pitcairn* and *Roche*, seemingly few, if any, unauthorized activities involving a patented invention would not violate § 271(a) under the broad definition of an infringing use, given the narrow, and arguably waning, view of a common law exemption to patent infringement liability, whether applied to research or experimental use or otherwise.

Nearly two decades later in *Embrex, Inc. v. Service Engineering Corp.*,[69] the Federal Circuit affirmed the district court's denial of the SEC's motion for judgment as a matter of law. The district court rejected the SEC's contention that certain tests performed did not infringe because they were scientific experiments and did not result in the sale of any machines, and therefore were either merely *de minimis* or exempt under common law defense to patent infringement liability. In his concurring opinion, Judge Rader stated:

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68. *Roche Products, Inc.*, 733 F.2d at 862-63 (citations omitted).

69. 216 F.3d 1343 (Fed. Cir. 2000).

[T]he Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement. Because the Patent Act confers the right to preclude 'use,' not 'substantial use,' no room remains in the law for a *de minimis* excuse. Similarly, because intent is irrelevant to patent infringement, an experimental use excuse cannot survive. When infringement is proven either minimal or wholly non-commercial, the damage computation process provides full flexibility for courts to preclude large (or perhaps any) awards for minimal infringements.

This court affirms the district court's denial of SEC's *de minimis* and experimental use excuses, but I read the Patent Act to preclude these excuses altogether. SEC essentially asserts an affirmative defense, combining a plea based on the amount or quantum of infringing activity (*de minimis*) with a plea based on the character or intent of the infringing activity (experimental use). Although courts have occasionally addressed these separate excuses as if they were one, clarity calls for separate analyses.

Since its inception, this court has not tolerated the notion that a little infringement—*de minimis* infringement—is acceptable infringement or not infringement at all. The statute states directly that any unauthorized use of a patented invention is an infringement. Thus, the statute leaves no leeway to excuse infringement because the infringer only infringed a little. Rather, the statute accommodates concerns about *de minimis* infringement in damages calculations. Although not influencing the finding of infringement itself, the amount, quantum, or economic effect of wrongful conduct is central to the damages assessment. For these reasons, this court might better have declined SEC's invitation to engage in an inherently subjective determination of how little infringement is necessary to escape infringement liability. The Patent Act simply authorizes no such conjecture.

Turning next to the experimental use excuse, neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation or idle curiosity. Rather, the Supreme Court and this court have recently reiterated that intent is irrelevant to infringement. These recent pronouncements should dispose of the intent-based prong of SEC's argument.

Before *Warner-Jenkinson*, this court addressed arguments based on the character or intent of infringement . . . . The Supreme Court's recent reiteration that infringement does not depend on the intent underlying the allegedly infringing conduct, to my eyes, precludes any further experimental use defense, even in the extraordinarily narrow form recognized in *Roche*. Of course, even if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable, as occurs in the court's resolution today. Therefore, I

> concur completely in the court's resolution of this case, although I would lay to rest permanently SEC's infringement excuses which find no support in the Patent Act.[70]

Indeed, this notion was recently reaffirmed in *Madey v. Duke University*,[71] where the Federal Circuit, *inter alia*, reversed and remanded the district court's summary judgment that Duke did not infringe U.S. Patents No. 4,641,103 and No. 5,130,994, which related to free electron lasers, because the experimental use defense applied to Duke's use of patented laser technology owned by Dr. John M. J. Madey.[72]

Duke had recruited Madey and his free electron laser (FEL) research lab from Stanford University in 1989.[73] Duke constructed a building addition to its physics facility to accommodate the FEL lab and its substantial equipment.[74] Madey served for almost a decade as director of the FEL lab at Duke, during which time the lab achieved continued success in both research funding and scientific breakthroughs.[75] Eventually, however, a conflict arose between Madey and Duke.[76] The university charged Madey with the ineffective management of the FEL lab, while Madey asserted that Duke attempted to use the lab's equipment for unauthorized research.[77] Duke removed Madey as director of the lab in 1997, and Madey resigned from Duke in 1998.[78] When Duke continued to operate some of the equipment in the lab, Madey sued Duke for patent infringement.[79]

The district court granted summary judgment to Duke, dismissing Madey's patent infringement claim based upon the common law exemption to patent infringement liability.[80] Specifically, the district court found that Duke's use of the FEL lab equipment was "solely for research, academic or experimental purposes."[81] The Federal Circuit stated:

> Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form. [E]xperimental use is [not] an affirmative defense...
>
> [T]he district court had an overly broad conception of the very narrow and strictly limited experimental use defense. The district court stated

70. *Id.* at. 216 F.3d at 1352-53 (Rader, J., concurring) (citations omitted).
71. 307 F.3d 1351 (Fed. Cir. 2002).
72. *Id.* at 1352-53.
73. *Id.* at 1352.
74. *Id.*
75. *Id.*
76. *Madey*, 307 F.3d at 1352.
77. *Id.*
78. *Id.* at 1353.
79. *Id.*
80. *Id.* at 1355-57.
81. *Madey*, 307 F.3d at 1361.

> that the experimental use defense inoculated uses that 'were solely for research, academic, or experimental purposes,' and that the defense covered use that 'is made for experimental, non-profit purposes only'.... [T]he defense [is] very narrow and limited to actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.' Further, use does not qualify for the experimental use defense when it is undertaken in the 'guise of scientific inquiry' but has 'definite, cognizable, and not insubstantial commercial purposes'. . . . [U]se is disqualified from the defense if it has the 'slightest commercial implication.' Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense. . . .
>
> Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications... [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.
>
> 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.
>
> In the present case, the district court attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives. On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.[82]

The Federal Circuit has yet to abolish the common law exemption to patent infringement liability. However, its decision in *Madey* leaves grave doubt that the common law exemption to patent infringement liability can act as a safe harbor for

82. *Madey*, 307 F.3d at 1361-63 (citations omitted).

any academic research effort. The relevant factors for such a determination arguably discount the nature of the defendant (whether academic, non-profit or not-for-profit in status) as well as the intent behind the conduct (non-pecuniary or non-commercial), as long as the act somehow can be related to a legitimate business purpose. Moreover, even where the experimental work can be shown to occur outside the umbrella of a research institution or other enterprise, the protection of the common law exemption to patent infringement liability likely will not extend to activity other than hobbyist tinkering or testing of a patented invention for verification and reproducibility. As a practical matter, it is difficult to imagine the first type of activity garnering the attention of a patentee's policing program. With respect to the second type of activity, the doctrines of first sale (patent exhaustion) or permissible repair might be implicated to shield such conduct.

II

In the absence of a safe harbor for academic research in the common law exemption to patent infringement liability, the advocacy for a *bona fide* research use exemption has taken on a renewed vigor.[83] The concerns regarding the public policy and procedural complications that an infringement liability loophole such as a *bona fide* research use exemption would create are matched against concerns, which have support at least anecdotally, that apprehension over patent rights chills innovation and inhibits progress in the academic research community. Furthermore, some have criticized the lack of a *bona fide* research use exemption in the United States as contrary to accepted international standards.[84]

At first blush, it would appear that many countries recognize an experimental use exemption to patent infringement liability. However, upon more careful examination, it becomes clear that such provisions pertain only to the same two aspects of experimental use condoned under U.S. law in 35 U.S.C. § 271(e)(1) and what remains of the common law exemption to patent infringement liability after *Madey*.[85] Despite seemingly broad language, the actual operation of the various foreign laws reveals their specific applications to data collection for regulatory approval and the operability of a patented invention.

Various foreign laws expressly provide for a general research use exemption to patent infringement liability:

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83. *See supra* note 3, at 2 (representing the views in favor of a recognized research use exemption of over twenty-five academic institutions and four organizations whose memberships comprise of U.S. universities and colleges).

84. *See* Lauren C. Bruzzone, *The Research Exemption: A Proposal*, 21 AM. INTELL. PROP. ASS'N Q.J. 1, 52 (1993); Stephen B. Maebius and Harold C. Wegner, *Ruling on Research Exemption Roils Universities*, NAT'L L.J., Dec. 16, 2002, at C3.

85. *See supra* text accompanying note 82 (discussing *Madey* in detail).

European Patent Convention

[R]ights conferred by a Community patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.[86]

German Law

The effects of the patent shall not extend to . . . acts done for experimental purposes which are related to the subject matter of the patented invention . . . .[87]

British Law

An act which . . . would constitute an infringement of a patent for an invention shall not do so if – (a) it is done privately and for purposes which are not commercial; (b) it is done for experimental purposes relating to the subject-matter of the invention . . . .[88]

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86. Community Patent Convention Art. 27(b) (1989).

87. German Patent Act § 11, No. 2 (1994). *See also* German Federal Supreme Court (BGH), GRUR (1996), 109 ("Klinische Versuche I"), *available at* 1997 WL 1104814; German Federal Supreme Court (BGH), Mitt. (1997), 253 ("Klinische Versuche II") (clinical tests II), *in* Hans-Rainer Jaenichen and Friederike Stolzenburg, *Patent Infringement by ClinicalTrials in EPC Contracting States?*, *1, § 1.3, *available at* http://www.vossiusandpartner.com/eng/publication/pub-epc.html (last visited Mar. 19, 2003):

Since Sec. 11 No. 2 of the Patent Act restricts the experimental acts neither qualitatively nor quantitatively this means that studies and trials may represent purely scientific experiments or commercially-oriented tests. According to the wording of the provision it is not relevant whether the tests yield scientifically or commercially useful results or whether a protected active ingredient is tested with the aim of obtaining data for an application for approval as a drug, thereby preparing the launching of the drug after expiration of the patent term. The only requirement is that the tests are intended to yield knowledge on the subject matter including its use that are intended to remove an existing uncertainty. This may also be the case, if – like in the present case – a pharmaceutical composition containing the protected active ingredient shall be tested in clinical tests for its effectiveness and tolerability. It is not evident from the wording of the provision that it would exclude an economical orientation or commercial objective of the experimental acts.

88. United Kingdom Patents Act 1977, Art. 60 § 5 (1985). *See also* Monsanto Co. v. Stauffer Chem. Co., 1985 R.P.C. 515, 542 (Eng. C.A.):

Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions, *e.g.*, of soil or weather, will work in different conditions can fairly, in my judgment, be regarded as experiments. But trials carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party . . . that the product works as its maker claims are not, in my judgment, to be regarded as acts done 'for experimental purposes.' The purposes for which tests or trials are carried out may in some cases be mixed and may in some cases be difficult to discern; indeed, in the present case, if fuller evidence is given at the trial, a different result may then be reached.

Japanese Law

[T]he effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.[89]

Chinese Law

None of the following shall be deemed an infringement of the patent right: . . . where any person uses the patent concerned solely for the purpose of scientific research and experiment.[90]

However, the operation of these laws belies their applicability to instances of otherwise infringing acts other than those involving experimental use akin to the activities exempt in the United States under 35 U.S.C. § 271(e)(1), or those relating to testing a patented invention for verification and reproducibility purposes.[91]

III

A *bona fide* research use exemption to patent infringement liability in the specific context of genetic research has been the subject of recent legislative action. Former U.S. Representative Lynn Rivers (D-Michigan) introduced a bill on March 14, 2002, seeking, *inter alia*, to exempt genetic research from patent infringement liability. The text of H.R. 3967[92] reads in pertinent part:

> SEC. 2. EXEMPTION FROM INFRINGEMENT FOR RESEARCH ON GENETIC SEQUENCE INFORMATION.
>
> Section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsection:
>
> "(j) USE OF GENETIC SEQUENCE INFORMATION.—

89. Japanese Patent Law § 69(1) (1991). *See also* H. Stephen Harris, Jr., *Competition Law and Patent Protection in Japan: A Half-Century of Progress, A New Millennium of Challenges*, 16 COLUM. J. ASIAN L. 71, 118 (2002) ("Until recently, Japanese court decisions diverged from U.S. law that permits experimental use (typically clinical studies) of patented pharmaceuticals by non-licensees aimed at expediting introduction of generic versions of those drugs.") (footnote omitted); John A. Tessensohn, *Reversal of Fortune-Pharmaceutical Experimental Use and Patent Infringement in Japan*, 4 J. INT'L LEGAL STUD. 1, 34 (1998) ("The broader issue of non-regulatory experimental use is not exempted by Article 69(1) and any non-health regulatory commercial-related experimental use will most probably still infringe the patent right since this sort of experimental use will not be in furtherance of the goals of the Pharmaceutical Affairs Law.").

90. Chinese Patent Law ¶ 5, Art. 62 (1984).

91. *See* Parker, *supra* note 7, at 648-57 (reviewing the laws of the United Kingdom, Japan, and Germany regarding experimental or research use); *see generally* Hans-Rainer Jaenichen & Fiederike Stolzenburg, *supra* note 87 (reviewing the relevant laws of Germany, the United Kingdom, France, Switzerland, Sweden, the Netherlands, Italy, Austria, Denmark, Spain, Finland, Greece, Ireland, Luxembourg, Monaco, Portugal, Belgium and Cyprus).

92. H.R. REP. NO. 107-3967 (2002).

> (1) It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.
>
> " (2) For purposes of this subsection—
>
> . . .
>
> "(E) the term 'research' means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.".[93]

No further congressional action has been taken regarding H.R. 3967. In any event, the proposed legislation helps to crystallize the problematic nature of appropriately defining the boundaries of a *bona fide* research use exemption to patent infringement liability. In particular, the limitation to generalizable knowledge purpose would seem an illusive standard to apply reliably and consistently.

The absence of a statutory research use exemption does not necessarily leave the academic science community without recourse. For example, federal and state government scientists, including those at federal or state academic institutions, arguably are shielded from patent infringement liability by virtue of statutory or constitutional provisions of sovereign immunity. The federal government may appropriate patented technology without authorization. The remedy for such use lies with an action under 28 U.S.C. § 1498,[94] which allows a prevailing patentee to recover reasonable compensation for the unauthorized use. Similarly, the state government may rely upon the Eleventh Amendment as a shield against patent infringement liability.[95] The remedy for such state action may lie with individual state laws regarding eminent domain proceedings. Furthermore, although the patent law does not provide for a compulsory license scheme, under in special circumstances, the public interest in access to certain patented subject matter might warrant the district court's denial of a grant of injunctive relief to prevent the use of the technology. The result of such a denial is effectively a compulsory license by which the infringer would owe a reasonable royalty for the infringing use.

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93. *Id.* § 2 (j)(2).

94. 28 U.S.C. § 1498 (1998).

95. *See* U.S. CONST. amend. XI ("The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State."); *see also, e.g.*, Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999) (holding unconstitutional the Patent Remedy Act provision that abrogated state immunity from patent infringement suits).

In each of the situations described above, a balance is struck between the necessity of public access to patented technology for research purposes and the support of beneficial exclusivity in fostering investment in the commercial development of such research. At least the chilling effects on innovation and progress can be alleviated with the knowledge that research use of a patented invention may not be prohibited, and that a reasonable compensation to the patentee for such use will be set in retrospect in a climate where the concepts of culpability and willful infringement supporting enhanced or otherwise punitive damages might have less applicability.

CONCLUSIONS

The importance to innovation of striking an appropriate balance between unfettered access to patented technology and commercial exclusivity cannot be overstated. Whether or not evidenced by empirical data available today, the notion that the chilling effect of patent rights takes some toll on scientific research endeavors appears to have at least anecdotal support. However, an outright exemption to patent infringement liability for research use, without clear definitional guidelines, would undermine the confidence in the legal rights as well as present investment backed expectations.