

# A CROSS-ATLANTIC DIALOG ON EXPERIMENTAL USE AND RESEARCH TOOLS

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## I. THE DEBATE OVER EXPERIMENTAL USE AND RESEARCH TOOLS IN THE UNITED STATES AND IN EUROPE

The scope of the experimental use exception to patent infringement is one of the most important and hotly contested issues in patent law.<sup>1</sup> For more than a century, courts in the United States regarded as well settled that the use of a patented invention for the purpose of scientific experimentation, particularly in a university setting without associated commercial activity, did not infringe the

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<sup>1</sup> Although we refer throughout the article to the experimental use exception, it may have different meanings if understood as conduct that simply does not fall within the initial grant of exclusive patent rights, as opposed to an exemption for conduct that qualifies as infringement. See, e.g., THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (4th ed. 2006), available at <http://dictionary.reference.com/browse/except> (last visited Oct. 21, 2007) (defining the conjunctive form of “except” alternately as “1. If it were not for the fact that; only. . . . 2. Otherwise than”); cf. *infra* notes 38, 48 and accompanying text. The experimental use exception also should not be confused with experimental use of an invention that will prevent it from being considered “in public use,” and thus from constituting prior art. 35 U.S.C. § 102(b) (2007); see, e.g., *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126 (1877). Further, the experimental use exception is not merely an application of the equitable doctrine *de minimis non curat lex*. See, e.g., *Douglas v. United States*, 181 U.S.P.Q. 170, (Ct. Cl. 1974), *aff’d per curiam*, 510 F.2d 364 (Ct. Cl. 1975) (citing *Radio Corp. of Am. v. Andrea*, 15 F. Supp. 685, 687 (E.D.N.Y. 1936), *modified* 90 F.2d 612 (2d Cir. 1937)), *aff’d on other grounds*, 510 F.2d 364, 365 (Ct. Cl. 1975)); cf. *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (treating these issues as distinct). But see *Integra LifeSciences I Ltd. v. Merck, KGaA*, 331 F.3d 860, 864 n.2 (Fed. Cir. 2003) (stating that “the judge-made [experimental use] doctrine is rooted in the notions of *de minimis* infringement better addressed by limited damages.”).

rights of a patent holder.<sup>2</sup> As one American commented in 1985, “[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function.”<sup>3</sup> The precise scope of the exception remained uncertain, however, as cases from this period found infringement for product and marketability testing that deprived the patent holder of lawful profits to which it was entitled.<sup>4</sup>

For the last two decades, the U.S. Court of Appeals for the Federal Circuit (which possesses nearly exclusive intermediate appellate jurisdiction over all patent cases) has narrowly construed the scope of the experimental use exception.<sup>5</sup> This narrowing trend culminated in the *Madey v. Duke University*<sup>6</sup> decision, which held a university liable for performing basic research with a patented laser.<sup>7</sup> Nevertheless, these recent interpretations have been seriously criticized by some of the Federal Circuit’s own judges,<sup>8</sup> and are potentially subject to correction by the U.S. Supreme Court or revision by the U.S. Congress.

It was hoped that the Supreme Court would provide further clarification of the scope of the experimental use exception in *Merck KGaA v. Integra LifeSciences I Ltd.*,<sup>9</sup> particularly with respect to patented research tools (broadly understood as products or processes used in research to investigate subjects

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<sup>2</sup> See *Chesterfield v. United States*, 159 F. Supp. 371, 376 (Ct. Cl. 1958); *Kaz Mfg. Co. v. Chesebrough-Ponds, Inc.*, 211 F. Supp. 815, 819 (S.D.N.Y. 1962), *aff’d*, 317 F.2d 679 (2d Cir. 1963); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 230 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2d Cir. 1946); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 332 (N.D.W.V. 1937); *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Col. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936); *Poppenhusen v. Falke*, 19 Fed. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279); *Poppenhusen v. New York Gutta Percha Comp Co.*, 19 Fed. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283). See generally DONALD S. CHISUM, CHISUM ON PATENTS, § 16.03[1] (2007).

<sup>3</sup> Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC’Y 617, 633 (1985).

<sup>4</sup> See, e.g., *Cataphote Corp. v. De Soto Chem. Coatings, Inc.*, 356 F.2d 24, 27 (9th Cir. 1966); *Radio Corp. of Am. v. Andrea*, 90 F.2d 612, 614 (2d Cir. 1937); *Clerk v. Tannage Patent Co.*, 84 F. 643, 644 (3d Cir. 1898); *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976).

<sup>5</sup> See, e.g., *Embrex*, 216 F.3d at 1353 (Rader, J., concurring); *Roche Prod. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984).

<sup>6</sup> 307 F.3d 1351 (Fed. Cir. 2002).

<sup>7</sup> *Id.* at 1363.

<sup>8</sup> See, e.g., *Integra LifeSciences I Ltd. v. Merck, KGaA*, 331 F.3d 860, 872–76 (Fed. Cir. 2003) (Newman, J., dissenting).

<sup>9</sup> 545 U.S. 193 (2005).

other than the tools themselves).<sup>10</sup> In *Merck*, the Court further clarified the scope of the codified regulatory approval exception to infringement<sup>11</sup> for research involved in gaining regulatory approval to market drugs and other medi-

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<sup>10</sup> See *Integra LifeSciences*, 331 F.3d at 872 n.4 (defining research tools as “tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.” (citation omitted)); Principles for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Request for Comments, 64 Fed. Reg. 28,205, 28,205–06 n.1 (May 25, 1999), available at <http://www.ott.nih.gov/pdfs/64FR28205.pdf> (defining “unique research resource” to encompass “the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines,” and using the term interchangeably with the term “research tools”); John Walsh, Ashish Arora & Wesley Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE BASED ECONOMY 287 (Wesley M. Cohen & Stephen A. Merrill eds. 2003) (defining research tools broadly as “any . . . input into the process of discovering” products); Dianne Nicol, *Cooperative Intellectual Property in Biotechnology*, 4 SCRIPT-ED 136, 137 (2007), available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol4-1/nicol.asp> (“Research tools are the technological developments that enable particular lines of research to be pursued.” (citation omitted)). Because almost any invention is potentially capable of being used in scientific research, a narrower definition of “research tool” is an invention for which the patent specification discloses the performance of scientific research as a principal use. See Philippe Ducor, *Research Tool Patents and the Experimental Use Exception – a No-Win Situation?*, 17 NATURE BIOTECH. 1027, 1027–28 (1999); Thomas D. Mays, *Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts: Race Horse or Trojan Horse?*, 2 BIO-SCI. L. REV. 56, 61 (1999/2000). However, it may be hard to determine the principal use of a patented invention (e.g., an optic process of materials testing can be utilized for both quality control by industry and for research into new alloys by academic materials scientists), and the principal use may change over time (e.g., when a DNA sequence initially useful for genome research leads to use as a diagnostic test for a protein having therapeutic applications). Furthermore, distinguishing among inventions based upon the types of principal uses or the state of their development would raise complex doctrinal choices that could result in substantial uncertainty. Another narrower definition is a tool used to produce a product that does not incorporate the tool, and thus does not trigger patent infringement liability by sales of the product. See Janice M. Mueller, *No “Dilettante Affair”*: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 14–15 (2001); Esther Pfaff, “Bolar” Exemptions – A Threat to the Research Tool Industry in the U.S. and the EU?, 38 INT’L REV. OF INTELL. PROP. & COMPETITION L. 258, 262–63 (2007). We employ below a broad definition of “research tools”—as anything that is useful for conducting research but is not itself at the time the object of scientific inquiry—because it is difficult to distinguish research tools based on their intended uses or stage of development, and so as to explore the full scope of the issues presented.

<sup>11</sup> 35 U.S.C. § 271(e)(1) (2007).

cal products. That exception was enacted in 1984 as part of the Hatch-Waxman Act, which addressed patent term extension and competition between pioneering and generic products.<sup>12</sup> But the Court in *Merck* declined the opportunity to address either the experimental use exception or application of the regulatory approval exception to research tools.<sup>13</sup> The Federal Circuit's recent panel decision on remand similarly declined the invitation, and that court as a whole has not yet sought to resolve the scope of either the experimental use or regulatory approval exceptions.<sup>14</sup>

In contrast to the United States, recent multilateral treaties, European Community directives, national legislation, and judicial decisions have helped to reduce uncertainties over the scope and application of experimental use and regulatory approval exceptions in national patent laws.<sup>15</sup> Nevertheless, signifi-

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<sup>12</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271 (e)(1)).

<sup>13</sup> See *Merck*, 545 U.S. at 205 n.7 (noting that neither party argued that research tools were involved). The Court's decision nowhere mentions the experimental use exception. One of the authors filed an amicus brief urging the Supreme Court to address the experimental use exception, arguing that the regulatory approval exception relates to and overlaps with the experimental use exception. See Brief for *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation and Public Knowledge in Support of Petitioner at 2–3, 6–11, 20–30, *Merck KGaA v. Integra LifeSciences I Ltd.*, 545 U.S. 193 (2005) (No. 03-1237), available at [http://patentlaw.typepad.com/patent/files/merck\\_v.%20Integra%20-%20Sarnoff.pdf](http://patentlaw.typepad.com/patent/files/merck_v.%20Integra%20-%20Sarnoff.pdf).

<sup>14</sup> See *Integra LifeSciences I Ltd. v. Merck KGaA*, Nos. 2002-1052, 2002-1065, 2007 U.S. App. LEXIS 17930, at \*37–\*39 (Fed. Cir. July 27, 2007). One of the authors filed an amicus brief urging the Federal Circuit to clarify the scope and nature of the experimental use exception, notwithstanding its prior holding that the exception was not raised by the parties and particularly given its suggestion that the exception is a *de minimis* infringement doctrine. See *Integra LifeSciences I Ltd.*, 331 F.3d at 863 n.2; Brief for *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation and Public Knowledge in Support of Defendant-Appellant at 1–7, *Integra LifeSciences I Ltd. v. Merck KGaA*, 2007 U.S. App. LEXIS 17930 (Fed. Cir. July 27, 2007) (Nos. 02-1052, 02-1065), available at <http://www.wcl.american.edu/ipclinic/documents/Integrav.Merck-Oct2005.pdf?rd=1>.

<sup>15</sup> See Agreement Relating to Community Patents, Dec. 15, 1989, art. 27 [hereinafter CPC]; Council Directive 2004/27, art. 1.8(6), 2004 O.J. (L 136) 34 (EC) (amending Council Directive 2001/83 art. 10 (EC)); Das deutsche Patentgesetz [German Patents Act], § 11, available at <http://www.gesetze-im-internet.de/patg/index.html> (last visited Oct. 21, 2007); Bundesgerichtshof [BGH] [Federal Court of Justice] July 11, 1995, 1996 Neue Juristische Wochenschrift [NJW] 782 (785) (F.R.G.) (*Klinische Versuche I* [Clinical Trials I]), translated in [1997] R.P.C. 623; BGH Apr. 17, 1997, 1997 NJW 3092 (*Klinische Versuche II* [Clinical Trials II]), translated in [1998] R.P.C. 423. For a recent analysis that compares the German experimental use exception principally to the codified regulatory approval exception at 35 U.S.C. § 271(e)(1), see Peter Ruess, *Accepting Exceptions?: A Comparative Approach to*

cant uncertainties remain.<sup>16</sup> Efforts to clarify these exceptions through further regulatory efforts at the transnational level are unlikely in the short term, even if some further clarification may result at the national level.<sup>17</sup>

Determining the scope of the experimental use and regulatory approval exceptions remains a pressing concern in the United States as well as in Europe. Recent decisions in both jurisdictions have called into question the validity of some highly publicized patents on research tools, including the preliminary decisions on the Wisconsin Alumni Research Foundation (WARF) patents for stem cells.<sup>18</sup> These patents were licensed earlier to academics at relatively high

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*Experimental Use in U.S. and German Patent Law*, 10 MARQ. INTEL. PROP. L. REV. 81, 110 (2006).

- <sup>16</sup> See TREVOR COOK, A EUROPEAN PERSPECTIVE AS TO THE EXTENT TO WHICH EXPERIMENTAL USE, AND CERTAIN OTHER, DEFENSES TO PATENT INFRINGEMENT, APPLY TO DIFFERING TYPES OF RESEARCH, A REPORT FOR THE INTELLECTUAL PROPERTY INSTITUTE 85 (2006) (citing to conclusions in ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 81 (2002)); Kathrin Tauber, *European Harmonization Simplifies Clinical Trial Process*, ON THE SUBJECT: UPDATE FROM GERMANY (McDermott, Will & Emery), Dec. 15, 2005, at 4–5 (notwithstanding having implemented Directive 2001/83/EC by national legislation, “details of the scope of the German Bolar-type provision still need to be assessed by the German jurisdiction”), available at <http://www.mwe.com/info/news/gu1205.pdf>.
- <sup>17</sup> See, e.g., COOK, *supra* note 16, at 168 (recommending clarification of uncertainties regarding experimental use exceptions through consensus guidelines in uncontroversial areas and recommending against new provisions for research tools and gene patents but rather compulsory licensing if evidence of problems develops); ANDREW GOWERS, GOWERS REVIEW OF INTELLECTUAL PROPERTY 45–47 (2006) (noting uncertainties and recommending clarification of the U.K. experimental use exception along the lines recently adopted by Switzerland), available at <http://www.official-documents.gov.uk/document/other/0118404830/0118404830.pdf>.
- <sup>18</sup> See BENNETT CELSA, UNITED STATES PATENT AND TRADEMARK OFFICE, *EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM, REEXAMINATION CONTROL NO. 90/008,139 Mar. 30, 2007, available at <http://www.pubpat.org/assets/files/warfstemcell/806rejected.pdf> (initial rejection in reexamination of all claims of issued U.S. Patent No. 6,200,806 for WARF stem cell inventions); GARY L. KUNZ, UNITED STATES PATENT AND TRADEMARK OFFICE, *EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM, REEXAMINATION CONTROL NO. 95/000,154 Mar. 30, 2007, available at <http://www.pubpat.org/assets/files/warfstemcell/913rejected.pdf> (initial rejection in reexamination of all claims of issued U.S. Patent No. 7,029,913 for WARF stem cell inventions); PADMASHRI PONNALURI, UNITED STATES PATENT AND TRADEMARK OFFICE, *EX PARTE* REEXAMINATION COMMUNICATION TRANSMITTAL FORM, REEXAMINATION CONTROL NO. 90/008,102 Mar. 30, 2007, available at <http://www.pubpat.org/assets/files/warfstemcell/780rejected.pdf> (initial rejection in reexamination of all claims of issued U.S. Patent No. 5,843,780 for WARF stem cell inventions); Case T 1374/04 – 3.3.08, *Primate Embryonic Stem Cells* (Nov. 2005) (EPO, Board of Appeals) (referring to the Board of Appeals’ rejection of patent application 96903521.1 for

cost and thus may have impeded scientific research.<sup>19</sup> Similarly, the famous Cohen-Boyer recombinant DNA patent was widely licensed in the United States, but was of questionable validity given unrestricted dissemination of information about the invention more than a year before filing.<sup>20</sup> When invalid patents delay, restrict, or chill scientific research, the social harm is obvious and there is no corresponding social benefit.<sup>21</sup> In contrast, valid patents pose difficult questions regarding the need to exclude competition in the use of inventions in research,<sup>22</sup> and the proper scope of the experimental use exception and its

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WARF stem cell inventions on moral grounds under the European Patent Convention), available at <http://legal.european-patent-office.org/dg3/pdf/t041374ex1.pdf>. See generally Franz-Josef Zimmer & Georg Seisenberger, *Does T0866/01 ("Euthanasia Compositions") of an Appeal Board of the EPO Provide the Answers for the Enlarged Board of Appeal Case G 2/06 ("Primate Embryonic Stem Cells")?*, available at <http://www.grunecker.de/download/publications/primaten.pdf> (last visited Oct. 21, 2007).

- <sup>19</sup> See, e.g., Joyce E. Cutler, *Wisconsin Research Foundation Amends Stem Cell Policies*, 73 PAT. TRADEMARK & COPYRIGHT J. 368 (2007) (discussing changes announced in 2007 to ease licensing requirements for academic and nonprofit researchers); Constance Holden, *U.S. Patent Office Casts Doubt on Wisconsin Stem Cell Patents*, 316 SCIENCE 182 (2007) (discussing reexamination of the WARF patents and noting that licensing costs for "basic stem cell research" in academic or government labs currently are minimal, but involve significant "red tape" that "slow[s] considerably" scientific collaborations); Jeanne F. Loring & Cathryn Campbell, *Intellectual Property and Human Embryonic Stem Cell Research*, 311 SCIENCE 1716, 1717 (2006) (discussing substantial commercial and academic licensing costs of WARF patents, and serious questions regarding their validity raised during initial prosecution).
- <sup>20</sup> See 35 U.S.C. § 102(b) (2007); Harold C. Wegner, *The Right to Experiment with a Patented Invention*, BAR ASSOCIATION OF DISTRICT OF COLUMBIA PTC SECTION, Dec. 10, 2002, at 32–33 n.51 (also noting that no foreign patents were issued for the Cohen-Boyer technology, because of publication before filing).
- <sup>21</sup> Further, the very ability to patent scientific research may divert scientific efforts from more socially useful endeavors. See, e.g., Dirk Czarnitzki, Wolfgang Glänzel & Katrin Hussinger, *Heterogeneity of Patenting Activity and Its Implications for Scientific Research*, (Center for European Economic Research, Discussion Paper No. 07-028, 2007), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=987906](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=987906) (reviewing empirical data and concluding "that the underlying effort to generate such patents distracts scientists from their other more fundamentally orientated research tasks").
- <sup>22</sup> Cf. U.S. DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 3.2.3 (Apr. 6, 1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.htm> (defining and discussing "innovation markets" and the need to protect competition in research and development); *Competition Policy and Intellectual Property Rights*, DAFNE/CLP(98)18, 278 (Sept. 16, 1998) available at <http://www.oecd.org/dataoecd/34/57/1920398.pdf> (noting that a "distinction between upstream research markets and downstream product markets appears justified."). See generally Richard J. Gilbert, *Holding Innovation to an Antitrust Standard 47 passim* (Competition Policy International, Paper No. 17, 2007), available at

application to research tools. Although these concerns may be minimized by enlightened licensing policies,<sup>23</sup> even the costs of licensing patented general purpose technologies (implicit in the purchase price of such technologies<sup>24</sup>) may delay or restrict the progress of scientific research.

Many scholars have long debated the need for the U.S. Congress to codify a broad experimental use exception for a wide range of activities.<sup>25</sup> Some of

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[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=987322](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=987322); Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 826–28, 844–52 (2001) (discussing innovation markets and potential antitrust regulation of biotechnology platform technologies).

<sup>23</sup> See, e.g., Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18413 *passim* (Apr. 11, 2005); ARTHUR BIENENSTOCK ET AL., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (Stanford News Service 2007), available at <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf> (describing licensing policies to be encouraged by a number of major research universities); ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, GUIDELINES FOR THE LICENSING OF GENETIC INVENTIONS *passim* (2006), available at <http://www.oecd.org/dataoecd/39/38/36198812.pdf>. But see Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, in *European Competition Law Annual 2005 – The Interaction Between Competition law and Intellectual Property Law* 3–5 (Law & Econ. Research Paper Series, Working Paper No. 05-13, 2006), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=763688](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763688) (discussing examples and reasons why patent holders refuse to license patents in a socially efficient manner).

<sup>24</sup> See, e.g., Kate Murashige, *Patents and Research – An Uneasy Alliance*, 77 ACAD. MED. 1329, 1331 (2002) (noting the “inhibiting effect” of both explicit licenses for patented research tools and the royalty implicit in the purchase price without explicit licenses).

<sup>25</sup> See HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS 460 (2d ed. 1994); Lauren C. Bruzzone, *The Research Exception: A Proposal*, 21 AIPLA Q.J. 52, 53 (1993); Donald S. Chisum, *The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 1019 (1986); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1019–20 (1989) [hereinafter Eisenberg, *Patents and the Progress of Science*]; Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC’Y 819, 836–37 (1989); Steven J. Grossman, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243, 247 (1990); Hantman, *supra* note 3, at 640, 644; Ned A. Israelsen, *Making, Using, and Selling without Infringing: An Examination of 35 U.S.C. Section 271(e) and the Experimental Use Exception to Patent Infringement*, 16 AIPLA Q.J. 457, 472, 74 (1988–1989); Jordan P. Karp, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169, 2170 (1991); Timothy J. McCoy, *FDA Medical Device Approval: The Noninfringing Experimental Use Defense is Expanded: Eli Lilly & Co. v. Medtronic, Inc.*, 110 S. Ct. 2683 (1990), 14 HAMLIN L. REV. 201, 217, 228 (1990); Mueller, *supra* note 10, at 17; David L. Parker, *Patent Infringement Exceptions for Life Science Research*, 16 HOUS. J. INT’L L. 615, 618–19, 644 (1994); Patricia M. Thayer & Richard A. De Liberty, *The Research Exception to Patent*

the arguments for a broader exception rest upon the rationale of promoting technological progress, a purpose of patent law articulated in the U.S. Constitution<sup>26</sup> as well as in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).<sup>27</sup> However, relatively recent efforts to enact an experimental use exception have not been successful thus far,<sup>28</sup> and such legislation has encountered significant resistance

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*Infringement: The Time Has Come for Legislation*, 4 J. BIOLAW & BUS. 15 *passim* (2000); Eyal H. Barash, Comment, *Experimental Use, Patents, and Scientific Progress*, 91 NW. U. L. REV. 667, 695 (1997); Veronica Lanier, Note, *Medical Device Eligibility for the Statutory Experimental Use Exception to Patent Infringement*, 17 HASTINGS COMM. ENT. L.J. 705, 710 (1995); Suzanne T. Michel, Comment, *The Experimental Use Exception to Infringement Applied to Federally Funded Inventions*, 7 HIGH TECH. L.J. 369, 376, 389 (1992).

<sup>26</sup> U.S. CONST. art. I, § 8, cl. 8 (“The Congress shall have power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”). Arguments have also been made that patenting of DNA sequences restricts, rather than promotes, scientific and technological progress. See, e.g., Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 846, 847 (2005).

<sup>27</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 81 [hereinafter TRIPS].

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

*Id.* art. 7.

<sup>28</sup> See Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. § 2 (2002) (proposed 35 U.S.C. § 271(j)(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.); Patent Competitiveness and Technological Innovation Act, H.R. 5598, 101st Cong. § 402 (1990) (proposed 35 U.S.C. § 271(j): “It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention. This subsection does not apply to patented invention to which subsection (e)(1) applies.”). See generally Parker, *supra* note 25 (discussing the origins of the 1990 legislative proposal).



from groups concerned over the potential application of an experimental use exception to research tools.<sup>29</sup>

Discussions of the potential application of the experimental use exception to research tools have focused primarily on the context of genetic inventions, such as expressed sequence tags (ESTs)<sup>30</sup> and single nucleotide polymorphisms (SNPs),<sup>31</sup> particularly following the Human Genome Project.<sup>32</sup> Reservations against the patentability of DNA arose in part from concerns about the accessibility of these “upstream” genetic inventions to future scientific research. If the experimental use exception applied to downstream scientific research with such genetic inventions, concerns over impediments to research would be diminished.<sup>33</sup> Conversely, application of the experimental use exception to re-

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<sup>29</sup> See, e.g., Harold C. Wegner, *Post-Merck Experimental Use and the “Safe Harbor,”* 15 FED. CIR. BAR J. 1, 36 (2005) (noting the ability of “research-based larger pharmaceutical companies, the smaller research tool companies, or the academic community” to block legislation to codify an experimental use exception “that would deeply cut into their own interests”); Letter from W. Mark Crowell, President, Association of University Technology Managers, to Michael Kirk, Executive Director, American Intellectual Property Law Association (Mar. 8, 2005) (on file with authors) (expressing opposition to AIPLA’s proposal for legislation to codify the experimental use exception based on its application to research tool patents).

<sup>30</sup> ESTs are small pieces of DNA sequence (usually 200 to 500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene. ESTs provide researchers with a quick and inexpensive route for discovering new genes, for obtaining data on gene expression and regulation, and for constructing genome maps.

National Center for Biotechnology Information, *A Science Primer: ESTs: Gene Discovery Made Easier*, <http://www.ncbi.nlm.nih.gov/About/primer/est.html> (last visited Oct. 21, 2007).

<sup>31</sup> SNPs (pronounced “snips”) are small genetic variations that occur within a population’s DNA. An example of a SNP is the alteration of the DNA segment GATACA into GATTCA. Research on SNPs may improve diagnostics for many diseases, enable physicians to screen patients for susceptibility to a disease and help in the creation of “personalized” medicine. National Center for Biotechnology Information, *A Science Primer: SNPs: Variations on a Theme*, <http://www.ncbi.nlm.nih.gov/About/primer/snps.html> (last visited Oct. 21, 2007).

<sup>32</sup> See, e.g., John Barton, *Patents, Genomics, Research, and Diagnostics*, 77 ACAD. MED. 1339, 1341–42, 1344 (2002) (discussing utility guidelines and concerns with SNP and EST patents, and the need for a legislative exception to their patentability); Chin, *supra* note 26, at 847 (noting general concerns raised with DNA patenting, including obstructing downstream pharmacological and other research). For a useful discussion of the experimental use exception in the context of software (particularly for reverse engineering); Robert A. Migliorini, *The Narrowed Experimental Use Exception to Patent Infringement and its Application to Patented Computer Software*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 523 (2006).

<sup>33</sup> See, e.g., John H. Barton, *Patent Scope in Biotechnology*, 26 INT’L REV. INDUS. PROP. & COPYRIGHT L. 605, 609 (1995); Martin Bobrow & Sandy Thomas, *Patents in a Genetic Age*, 409 NATURE 763, 763 (2001); Trevor Cook, *Experimental Use as an Exception to Patent Infringement*, 5 BIO-SCI. L. REV. 167, 174 (1998–1999); Michael A. Heller & Rebecca S.

search tools has been argued to threaten the market for development of diagnostics and therapeutics—which could diminish investment, invention, and disclosure of upstream genetic inventions in the first instance—and that these types of inventions and the companies that produce them are particularly in need of patent protection.<sup>34</sup>

In the second section of this paper, we trace the rationale and scope of the traditional experimental use exception in U.S. patent law, and its relation to the codified statutory regulatory approval exception. We explain how the statutory law and case law have not clearly resolved whether the unauthorized making and use (but not sale) of research tools to develop new inventions deprives patent holders of commercial benefits to which they should be entitled. We then explore briefly the status of concerns regarding the application of the experimental use exception to research tools used in academic and other environments.

The frequent call for reform of the present experimental use exception in U.S. patent law is often combined with the suggestion to align a broadened experimental use defense with European patent laws, whose experimental use exceptions are perceived as more generous than their U.S. counterparts.<sup>35</sup> Therefore, in the third section of this paper, we review the basic principles and scope of Europe's experimental use and regulatory approval exceptions. We also explore the application of these exceptions to research tools in academic and commercial sectors, seeking to distinguish research *on* an invention from research *with* it, and consider national constitutional law protections for property rights and consistency with the TRIPS Agreement.

Finally, in the fourth section, we discuss the implications of our findings and earlier discussions. In doing so, we do not seek to resolve ongoing disputes over the proper scope and role of experimental use and regulatory approval ex-

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Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998); Thomas D. Kiley, *Patents on Random Complementary DNA Fragments?*, 257 SCIENCE 915, 917 (1992); Mueller, *supra* note 10; Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 139 (1999); Timothy A. Worrall, *The 2001 PTO Utility Examination Guidelines And DNA Patents*, 16 BERKELEY TECH. L.J. 123, 134 (2001); *infra* note 277 and accompanying text; cf. David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate* 1679, 1685 (Arizona Legal Studies, Discussion Paper No. 06-10, 2006), available at <http://ssrn.com/abstract=881842> (discussing data on biotech patents that suggest the lack of anticommons problems).

<sup>34</sup> See, e.g., ADVISORY COUNCIL ON INTELLECTUAL PROPERTY, PATENTS AND EXPERIMENTAL USE: ISSUES PAPER 14, (2004) (citing Lee Bendekgey & Diana Hamlet-Cox, *Gene Patents and Innovation*, 77 ACAD. MED. 1373 (2002)).

<sup>35</sup> See, e.g., GOWERS, *supra* note 17.

ceptions. Rather, we pose a number of questions that require consideration when seeking to resolve those disputes, particularly with regard to research tools. These questions include: Should the European concept of the experimental use exception become a role model for an amendment to U.S. patent law? Should an experimental use exception differentiate between basic and applied research? Should an experimental use exception cover the use of research tools in commercial and non-commercial scientific experiments, or would a liability rule regime be preferable to facilitate research tool use? Would experimental use restrictions on patent rights be fair and consistent with constitutional protections for property? In posing and discussing these questions, we hope to provide an additional impetus to resolving these disputes.

## II. THE EXPERIMENTAL USE AND REGULATORY APPROVAL EXCEPTIONS IN U.S. PATENT LAW, AND RESEARCH TOOL USE IN ACADEMIC AND OTHER SETTINGS

### A. *How Did the Exceptions Emerge and What Is Their Current Scope?*

The United States' experimental use exception to patent infringement was first articulated by Supreme Court Justice Story in two 1813 cases. In *Whittemore v. Cutter*,<sup>36</sup> Justice Story indicated that a proper construction of the statutory rights enacted by Congress did not extend to the broadest literal interpretation of the then-existing statutory right to the exclusive "making, constructing, using, and vending to others to be used, the said invention or discovery."<sup>37</sup> As Justice Story noted, "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."<sup>38</sup> Justice Story thus excluded from the inter-

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<sup>36</sup> 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

<sup>37</sup> Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318, 321 (1793) (current version at 35 U.S.C. § 271(a) (2007)).

<sup>38</sup> *Whittemore*, 29 F. Cas. at 1121. Justice Story was interpreting Section 3 of the 1800 Patent Act ("make, devise, use, or sell"), which changed the language of the damages provision of Section 5 of the 1793 Act ("make, devise, and use or sell") and thereby eliminated any ambiguity as to whether there could be an infringement by "making" without "using" (or vice-versa). *Id.* (citing Act of April 17, 1800, ch. 25, § 1, 2 Stat. 37, 38); see *Evans v. Weiss*, 8 F. Cas. 888, 889–90 (C.C.D. Pa. 1809) (No. 4,572) (noting that the 1800 Act made clear that use without making was an act of infringement, and questioning whether "devise" could encompass mental invention or intent). Thus, Justice Story rejected the defendant's argument that no offense could result from making without any actual damages to the plaintiff. *Whit-*

preted meaning of the statutorily granted exclusive right both philosophical experiments with, and evaluations of, described inventions.<sup>39</sup> As was commonly understood at the time, philosophical experiments meant scientific research in general, and research on physical principles in particular.<sup>40</sup>

This historic exclusion of patent rights from applying to scientific research is fully understandable, given the special status of science in contemporary beliefs. Discoverers of scientific principles were the “favoured mortals” through whom God’s divine providence was revealed; “they must not . . . hoard up for themselves the common stock.”<sup>41</sup> Patents applicable to scientific research

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*temore*, 29 F. Cas. at 1121. In doing so, Justice Story clearly distinguished experimental use as beyond the scope of exclusive patent rights from de minimis damages for which infringement would lie. See N. Scott Pierce, *A New Day Yesterday: Benefit as the Foundation and Limit of Exclusive Rights in Patent Law*, 6 J. MARSHALL REV. INTELL. PROP. L. 373, 381 (2007) (noting that Story’s approach requires that the excluded activities, even if performed “with the prospect of monetary gain as a consequence, is not activity within the Patent Act”); cf. *supra* note 1.

<sup>39</sup> See, e.g., Ted Hagelin, *The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold*, 58 FLA. L. REV. 483, 490 (2006) (describing the two contemplated exemptions as “to perform scientific experiments” and “to test [patented subject matter’s] claimed utility.”).

<sup>40</sup> See Brief for *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation and Public Knowledge in Support of Petitioner, *supra* note 13, at 13 n.10 (“defining ‘[p]hilosophical’ as ‘[p]ertaining to, or used in the study of, natural philosophy, or some branch of physical science’”) (quoting II THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY 2154 (Oxford Univ. Press 1971)); WILLIAM SHAKESPEARE, *HAMLET* act 1, v. 166–67, n.167 (Houghton Mifflin 1974) (defining “philosophy” as “natural philosophy, science” in regard to Hamlet’s famous line to Horatio at I.v.166–67); *A Visit to Henkel’s Ware-rooms* in 41 GODEY’S LADY’S BOOK 123 (1850) (discussing “philosophical experiments . . . of great value in the construction of furniture”); *Education of Farmers* in THE COLORED AMERICAN, July 27, 1839 (treating nature as “a laboratory where chemical and philosophical experiments are going on upon a larger scale”); PENNSYLVANIA GAZETTE, Jan. 13, 1790 (discussing receipt of “a Philosophical Apparatus” for exhibiting “a whole course of experiments in natural philosophy and astronomy”); PENNSYLVANIA GAZETTE, Apr. 6, 1785 (advertising to “make and repair Thermometers and Barometers, likewise all kinds of Glasses for philosophical experiments”).

<sup>41</sup> Lord Camden (Feb. 22, 1774), in 17 THE PARLIAMENTARY HISTORY OF ENGLAND FROM THE EARLIEST PERIOD TO THE YEAR 1803 col. 999 (London, T.C. Hansard 1806–20). See generally Joshua D. Sarnoff, *Shaking the Foundations of Patentable Subject Matter* 6–12, 135–47 (Apr. 2, 2008) (unpublished draft), available at <http://www.wcl.american.edu/pijip/go/research-and-advocacy/ip-policy-and-law-reform> (tracing historic exclusions for patentable subject matter and requirements to treat science and nature as part of the public domain to religious conceptions). The idea of the inventor-scientist as a human genius developed over the course of the late 18<sup>th</sup> and 19<sup>th</sup> Centuries. See Oren Bracha, *Geniuses and Owners: The Construction of Inventors and the Emergence of American Intellectual Property* (2007) (unpublished manuscript, on file with authors).

could interfere with the divine plan, as scientists were “[e]ntrusted by Providence with the delegated power of imparting to their fellow-creatures that instruction which heaven meant for universal benefit.”<sup>42</sup>

As Justice Story next elaborated in *Sawin v. Guild*,<sup>43</sup> infringement could only occur when an invention was used without authority for commercial profit,<sup>44</sup> and in a manner that deprived the patent holder of income to which it was reasonably entitled:

[T]he 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.<sup>45</sup>

As Justice Curtis later explained, the premise of *Whittemore* and *Sawin* was that scientific research and competitive evaluation do not cause injury to the exclusive patent right and are not performed “with [an] intent to deprive the patentees of some lawful profit.”<sup>46</sup>

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<sup>42</sup> Camden, *supra* note 41, at col. 999; see EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE 39 (2002) (“It was the perception which arose during the Middle Ages that genius was a gift of God that largely precluded an earlier development of the concept of intellectual property. For how could one properly seek to obtain commercial value from that which was perceived to have been granted by the grace of God?”).

<sup>43</sup> 29 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

<sup>44</sup> See Hantman, *supra* note 3, at 625 (distinguishing “use for profit” from cases in which “the experimenter neither made money nor tried to make money while infringing the patented invention.”); Ronald D. Hantman, Letter to the Editor, *Re: The Experimental Use Defense*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 348, 348–49 (2005) (noting that the historic case law for the exception required both experimentation and the absence of an intent to use for profit, i.e., where “the infringer makes or attempts to make a monetary profit while infringing the patent”); cf. Andrew S. Baluch, *Relating the Two Experimental Uses in Patent Law: Inventor’s Negation and Infringer’s Defense*, 87 B.U. L. REV. 213, 250–53 (2007) (discussing factors to distinguish experimental from commercial use derived from the public use bar cases); Pierce, *supra* note 38, at 384–412 (discussing cases finding infringement focusing on the benefit of the invention gained by use, rather than profit, and later cases focusing on commercial intent).

<sup>45</sup> *Sawin*, 29 F. Cas. at 555 (citing *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600)).

<sup>46</sup> *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262); see *Poppenhusen v. New York Gutta Percha Comp Co.*, 19 Fed. Cas. 1059, 1063 (C.C.S.D.N.Y. 1858) (No. 11,283) (“when there has been no profit and no sale, it will not make a party liable, because the patent holder would not be injured by it”).

The experimental use doctrine articulated by Justice Story thus may reflect statutory interpretive limits on the scope of the patent exclusive right conveyed by the legislature, rather than a “common law” exemption that restricts the application of those statutory rights.<sup>47</sup> Accordingly, the experimental use doctrine may not be an exception to or an exemption from infringement, but merely the absence of infringing conduct. This distinction may be significant for numerous reasons, not only with respect to burdens of pleading and proving the relevant conduct, but also with respect to whether the exception acts to restrict property rights that have initially vested by the grant of a patent.<sup>48</sup> Since Justice Story’s time, the U.S. patent system has struggled to come to grips with the nature and scope of the experimental use exception. In particular, the legislature and the courts have not yet resolved which types of research involving patented inventions are *merely for philosophical experiments*, and which unauthorized *for profit* uses of inventions (including those intended for research) deprive patent holders of their *lawful rewards*.

By the end of the Nineteenth Century, it was clear that making and using an invention for experimentation, without subsequent sale of the invention, was not an infringement of patent rights.<sup>49</sup> In the few cases in the Twentieth Century where courts addressed research by scientists and evaluations by competitors to develop improvements, these activities did not qualify as infringement. For example, in *Chesterfield v. United States*<sup>50</sup> the court held that governmental use of a purchased new alloy (that met the patented range of claimed alloy compositions) solely “for testing and for experimental purposes” was not

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<sup>47</sup> Nevertheless, because it was articulated by judges, the experimental use exception is commonly referred to as a “common law” development. *See, e.g.,* *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 863 n.2 (Fed. Cir. 2003); *id.* at 872 (Newman, J., dissenting); Hagelin, *supra* note 39, at 486–87.

<sup>48</sup> Under U.S. patent law, noninfringement must be pled but may not necessarily be an affirmative defense to infringement, as the plaintiff has the burden of proving facts that establish an infringement. *See* 35 U.S.C. § 282(1) (2007); *see, e.g.,* *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 (Fed. Cir. 2006); *Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004).

<sup>49</sup> *See* 3 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (Boston, Little, Brown, & Co. 1890) (“where [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character . . . . But if the products of the experiment are sold . . . the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”).

<sup>50</sup> 159 F. Supp. 371 (Ct. Cl. 1958).

infringing, and stated categorically that “[e]xperimental use does not infringe.”<sup>51</sup> Similarly, in *Ruth v. Stearns-Roger Manufacturing Co.*,<sup>52</sup> the district court reduced a damage award by excluding from the calculation commercial sales of replacement parts to a mining school for which such parts were used only experimentally in patented machines “in the laboratory . . . [that] were cut up and changed . . . .”<sup>53</sup> The defendant was not contributorily liable for these sales, because the experimental uses did not constitute an infringement.<sup>54</sup> “The making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement.”<sup>55</sup>

Evaluation of patented inventions by commercial competitors to develop improvements also did not constitute infringement, although such making and using would not confer a right to subsequently sell or commercially use the same or other patented inventions in the normal course of business.<sup>56</sup> Where the asserted experimental use was found illegitimate, however, the experimental use exception did not apply. Thus, a large number of cases found infringement from either commercial sale of patented inventions during the patent term, or commercial uses that were not fairly characterized as research or evaluation to assess patent validity or to design improvements.<sup>57</sup> Competing commercial sales

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<sup>51</sup> *Id.* at 375–76. See Steven P. Caltrider and Paula Davis, *The Experimental Use Defense: Post-Madey v. Duke and Integra LifeSciences I, Ltd. v. Merck KGaA*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 1011, 1015 (2004) (discussing testing of a patented alloy for use in “turbo-supercharger buckets” for jet engines).

<sup>52</sup> 13 F. Supp. 697 (D. Colo. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936).

<sup>53</sup> *Id.* at 703.

<sup>54</sup> *Id.* at 713.

<sup>55</sup> *Id.*; see also *Ordinance Eng. Corp. v. United States*, 84 Ct. Cl. 1, 2 (Ct. Cl. 1936) (excluding from an infringement accounting experimental shells “built for experimental purposes”).

<sup>56</sup> See *Kaz Mfg. Co. v. Chesebrough-Ponds, Inc.*, 317 F.2d 679, 680-81 (2d Cir. 1963) (holding that use of the patented invention in comparative advertising did not infringe); *Levin v. Ripple Twist Mills, Inc.*, 416 F. Supp. 876, 881 n.9 (E.D. Pa. 1976) (noting that “[t]he manufacture and experimental use of a machine which is covered by a patent is not an infringement unless and until the machine is put to a commercially valuable use”); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 224, 229 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2d Cir. 1946) (finding no infringement from a competitor’s experimental making of a direction-finding system); *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W.V. 1937) (finding no infringement from a competitor’s experimental use before commercial production of a non-infringing substitute).

<sup>57</sup> See *Cataphote Corp. v. De Soto Chem. Coatings, Inc.*, 356 F.2d 24, 27 (9th Cir. 1966) (finding infringement from testing for “ascertainment of the product’s marketability” and distinguishing “an inventor’s, experiment”); *Radio Corp. of Am. v. Andrea*, 90 F.2d 612, 614–15 (2d Cir. 1937) (finding infringement from product marketability testing of vacuum tubes in

of patented inventions for experimental making and using infringed the exclusive right of sale.<sup>58</sup>

In 1950, the House of Representatives Committee on the Judiciary drafted proposed legislation to codify and amend the existing patent laws.<sup>59</sup> The draft would have codified a very broad infringement exception for experimental uses, with only commercial sales for such uses considered infringing conduct.<sup>60</sup> Proposed section 73 would have provided that:

The making or using of a patented invention solely for the purpose of research or experiment, or for instruction, in connection with the patented invention, and not for sale or for the making of anything for sale, shall not constitute infringement, without prejudice to the rights of the patentee against anyone who makes for sale or sells the patented invention which may be subsequently used for such non-infringing use.<sup>61</sup>

Significantly, the House Report characterized the proposed section as intended “to codify the holding of a number of courts that experimental use of a patented invention is not infringement of the patent,”<sup>62</sup> which strongly suggests that this provision described the then-existing state of the law. A specific experimental use provision, however, was not ultimately adopted when the Act was revised in 1952.<sup>63</sup>

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receivers, prior to shipment for overseas sales); *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976) (finding infringement from government testing of specially procured helicopters to assure they conformed to product specifications, as “intended uses . . . and are in keeping with the legitimate business of the using agency.”); *Douglas v. United States*, 181 U.S.P.Q. 170, 177 (Ct. Cl. 1974); *Nat’l Meter Co. v. Thomson Meter Co.*, 106 F. 531, 541–42 (C.C.S.D.N.Y. 1900) (finding threatened infringement from the manufacture and stockpiling of six water meters and additional castings and parts, warranting an injunction and an accounting).

<sup>58</sup> See *Ruth*, 13 F. Supp. at 700, 701, 708, tbls. B, C & M (including sales of completed machines to the Colorado School of Mines in the damage accounting); cf. *Giese v. Pierce Chem. Co.*, 29 F. Supp. 2d 33, 36–38 (D. Mass. 1998) (suggesting that there could be no contributory liability from selling unpatented products to academic researchers for experimental use in patented methods, because the research itself was excepted from infringement, but that such sales could have directly infringed a hypothetical product patent even if the research was excepted).

<sup>59</sup> STAFF OF H. COMM. ON THE JUDICIARY, 81ST CONG., PROPOSED REVISION AND AMENDMENT OF THE PATENT LAWS, PRELIMINARY DRAFT WITH NOTES (Comm. Print 1950).

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 59.

<sup>62</sup> *Id.*

<sup>63</sup> See S. REP. NO. 82-1979 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2402 (noting that proposed § 271(a) was merely declaratory of what constitutes infringement and was not necessary given the granting clause, without discussing experimental use).



The scope of the experimental use exception has been affected by legislation only once since the 1952 revision, and then only indirectly. In 1984, the Federal Circuit adopted a very narrow view of the scope of the exception in *Roche Products Inc. v. Bolar Pharmaceuticals Co.*,<sup>64</sup> finding the exception inapplicable to scientific tests using a patented pharmaceutical compound for the purpose of obtaining generic product marketing approval from the Food and Drug Administration (FDA)<sup>65</sup>:

Bolar's intended "experimental" use is solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry . . . . Bolar may intend to perform "experiments," but unlicensed experiments conducted with a view to the adaption 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.<sup>66</sup>

Congress promptly responded to the *Bolar* decision by codifying a regulatory approval exception to patent infringement, as part of broader legislation balancing the rights of pioneering and generic pharmaceutical manufacturers.<sup>67</sup> The principal concerns expressed by Congress when adopting this exception were that the *Bolar* decision had been decided wrongly and that the ability of patent holders to dominate research into and development of competitive alternatives during the patent term would effectively result (particularly given the need for regulatory approval) in the improper extension of the right to exclude beyond the patent term.<sup>68</sup> To prevent such overextension of patent rights, Congress codified a statutory exception to infringement that applied to otherwise-infringing activities (originally "make, use, or sell"<sup>69</sup>) with "a patented invention

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<sup>64</sup> 733 F.2d 858 (Fed. Cir. 1984).

<sup>65</sup> *See id.* at 862–63.

<sup>66</sup> *Id.* at 863.

<sup>67</sup> *See* 35 U.S.C. §§ 155, 155A, 156, 271(e) (2007).

<sup>68</sup> *See, e.g.*, H.R. REP. NO. 98-857, pt. 2, at 61 (1984) ("*Roche* was wrongly decided . . . Congress did not intend the word 'uses' in § 271 (a) to extend so broadly." (citation omitted)); H.R. REP. NO. 98-857, pt. 1, at 46 (1984) ("[t]here should be no other direct or indirect method of extending patent term" than the express provisions for term extension).

<sup>69</sup> Congress later amended 35 U.S.C. § 271(e) to extend these protections to offers for sale and imports (when those rights were added to 35 U.S.C. § 271(a)) and to uses for approval of veterinary biological products (when pre-marketing approval was required). *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, § 201, 102 Stat. 3971, 3988 (1988); Uruguay Round Agreements Act, Pub. L. No. 103-465, § 533, 108 Stat. 4809, 4988 (1994).

. . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs.”<sup>70</sup>

The Supreme Court subsequently held in *Eli Lilly & Co. v. Medtronic, Inc.*<sup>71</sup> that this regulatory approval exception was not limited to use of patented inventions for human drug development, but rather applied to use in all products requiring pre-market approval by the FDA and subject to the patent term extension provisions that had been simultaneously adopted.<sup>72</sup> Significantly, the Federal Circuit earlier held in the same case that “the *Roche* interpretation of the language of [the statute’s infringement provision] is necessarily repealed (that is, by implication) by the addition of” the regulatory approval exception.<sup>73</sup> Congress thus disapproved of the Federal Circuit’s narrow construction of the experimental use exception in *Bolar*, but explicitly removed such profit-motivated research from the *lawful rewards* of patent holders only in the context of regulatory approval uses.<sup>74</sup> Congress thereby left the scope of the experimental use exception uncertain as applied to other research activities using patented inventions.

The regulatory approval exception, moreover, is broader in scope than the experimental use exception (with respect to the activities to which they both might apply). In the codified provision Congress excepted commercial acts—sales of the patented invention for such research—that would have been considered an infringing use for profit not entitled to the experimental use exception.<sup>75</sup> Congress thus made clear its desire to assure unimpeded regulatory approval of generic products, notwithstanding the loss of traditional exclusivity for patent holders and potentially significant lost revenues. Further, although the exception did not clearly apply retrospectively to existing patents,<sup>76</sup> Congress apparently was not concerned about potential diminution of incentives for investment, invention, and disclosure.

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<sup>70</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1)).

<sup>71</sup> 496 U.S. 661 (1990).

<sup>72</sup> See *id.* at 669–78; 35 U.S.C. § 156 (2007).

<sup>73</sup> *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989) (citing 35 U.S.C. § 271(a), (e)(1)).

<sup>74</sup> See *id.*; *Sawin v. Guild* 29 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

<sup>75</sup> See 35 U.S.C. § 271(e)(1) (2007).

<sup>76</sup> See, e.g., *Landgraf v. USI Film Prods.*, 511 U.S. 244, 265–73 (1994) (requiring a clear legislative statement for civil legislation to have retrospective effect). What constitutes a retrospective effect, however, may be a complex question. See generally Jill E. Fisch, *Retroactivity and Legal Change: An Equilibrium Approach*, 110 HARV. L. REV. 1055 *passim* (1997).

The language of the regulatory approval exception also is categorical, applying to “a patented invention” made, used, or sold “solely for” regulatory approval uses, and thus does not distinguish among types of inventions that are used in seeking such approval, or how they are used in the approval process.<sup>77</sup> On its face, the statutory provision would except from infringement any and all research tools made, used, or sold solely for such uses, even though they were not themselves the subjects of regulatory approval.<sup>78</sup> One district court has held that research tools should be included within the scope of § 271(e)(1) based on “the language of *Merck* and a plain reading of the statute.”<sup>79</sup> However, various commentators have argued that the language of § 271(e)(1) is limited to patented inventions that themselves are potentially subject to regulatory approval (and thus delays), given the term-extension purposes of the act adopting the provision.<sup>80</sup>

More recently, the Federal Circuit has further narrowed the experimental use exception from its earlier holding in *Bolar*. In *Madey v. Duke University*,<sup>81</sup> the Federal Circuit expansively interpreted the “use for profit” of a patented invention in research that will deprive an inventor of lawful rewards. Specifically, the Federal Circuit held that use of a patented laser for basic research by scientists in a research university constitutes an actionable infringement, because such research projects “unmistakably further the institution’s

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<sup>77</sup> Congress likely would have used “the patented invention” or otherwise made its intent clear had it intended to limit the exception to patented inventions that were themselves the subject of regulatory approval. Similarly, “solely for” should not be understood as precluding making, use, or sale of the patented invention for different uses at different times, but rather to focus on the specific products or processes actually used for approval. Such a narrow interpretation not only would exclude research tools, but also would exclude products and processes themselves the subject of approval but sometimes made, used, or sold for other purposes, including purposes disclosed in the patent itself.

<sup>78</sup> See *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, No. 95 Civ. 8333 (RPP), 2001 WL 1512597 (S.D.N.Y. Nov. 28, 2001) (holding that intermediates to a regulated drug product taxol were patented inventions within the scope of § 271(e)(1)). But see Michael R. Mischnick, Note, *Evaluating the Integrity of Biotechnology Research Tools: Merck v. Integra and the Scope of 35 U.S.C. § 271(e)(1)*, 91 MINN. L. REV. 484, 499–513 (2006) (arguing that Congress did not intend to include unregulated products within the exception).

<sup>79</sup> *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F. Supp. 2d 621, 625 n.2 (D. Md. 2006).

<sup>80</sup> See, e.g., Pfaff, *supra* note 10, at 266 (citing Michael Vella, Beth Brinkmann & Janet Xiao, *Behind the Footnote in Merck v. Integra*, PHARM. L. INSIGHT 13–14 (Oct. 2005)). See also *id.* at 268–69 (discussing arguments against application of the regulatory approval exception to innovative—rather than generic—drug and other regulated product development and to downstream research).

<sup>81</sup> 307 F.3d 1351 (Fed. Cir. 2002).

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.<sup>82</sup> The Supreme Court declined to hear the case on review.<sup>83</sup> The *Madey* decision came as a surprise to both legal scholars and natural scientists, most of whom had believed that the experimental use defense would completely shield basic research activities carried out by academic institutions from patent infringement liability.<sup>84</sup>

Finally, in *Merck, KGaA v. Integra LifeSciences I Ltd.*,<sup>85</sup> the Supreme Court reversed a narrow Federal Circuit interpretation of the regulatory approval exception of § 271(e)(1) with respect to early-stage in vitro and animal experiments on a species of peptide having potential application to cancer treatment.<sup>86</sup>

At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is “reasonably related” to the “development and submission of information under . . . Federal law.”<sup>87</sup>

The Supreme Court did not address the potential application of the experimental use exception to such research, and expressly refused to address whether the regulatory approval exception “exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”<sup>88</sup> Earlier in the same case, the Federal Circuit refused to consider the application of the experimental use exception, which likely had not been argued on appeal in light of the *Madey* decision.<sup>89</sup> In dissent, Judge Newman argued that the experimental use exception applied to the conduct at issue and that the regulatory approval exception picked up where the experimental use exception left

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<sup>82</sup> *Id.* at 1362.

<sup>83</sup> *See* 539 U.S. 958 (2003).

<sup>84</sup> *See, e.g.*, Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 *YALE L.J.* 177, 221–31 (1987) [hereinafter Eisenberg, *Proprietary Rights in Biotechnology Research*]; Parker, *supra* note 25, at 635. *But see* Michel, *supra* note 25, at 385–86; Mueller, *supra* note 10, at 36.

<sup>85</sup> 545 U.S. 193 (2005).

<sup>86</sup> *Id.* at 207.

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 205 n.7.

<sup>89</sup> *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 864 n.2 (Fed. Cir. 2003).

off, so that there would be no “intervening kind of limbo” in the ability of researchers to develop FDA regulated products using patented inventions.<sup>90</sup>

At oral argument on remand from the Supreme Court, Judge Rader (the author of the earlier Federal Circuit majority opinion) stated that the application of the regulatory approval exception to research tools was “the central issue we’re going to be dealing with here” and that “[t]here’s no research tool exemption, you and I know that. There never has been.”<sup>91</sup> However, a different majority of the panel reached a decision that explicitly refused to decide whether the regulatory approval exception applies to research tool patents.<sup>92</sup> The majority opinion applied the regulatory approval exception to experiments with patented compounds that were not ultimately the subject of a regulatory approval applications, but that develop information “after the biological mechanism and physiological effect of a candidate drug have been recognized, such that if the research is successful it would appropriately be included in a submission to the FDA.”<sup>93</sup> Judge Rader, in dissent, argued that the majority’s decision also extended the Supreme Court’s holding to “eliminate protection for research tool inventions.”<sup>94</sup> Judge Rader focused on language in the Supreme Court’s opinion discussing application of the regulatory approval exception to “patented compounds” and “patented drugs,”<sup>95</sup> and argued that some of the asserted patents claimed methods that could not be potential pharmaceutical regulatory approval candidates.<sup>96</sup> Thus, the majority opinion treated these patented “research tools”

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<sup>90</sup> *Id.* at 877; *see id.* at 873–78.

<sup>91</sup> Audio file: *Integra LifeSciences v. Merck*, available at <http://www.cafc.uscourts.gov/oralarguments/mp3/2002-1052.mp3> (last visited Oct. 22, 2007).

<sup>92</sup> *See Integra LifeSciences I Ltd. v. Merck KGaA*, 496 F.3d 1334, 1349–50 (Fed. Cir. 2007).

<sup>93</sup> *See id.* at 1340 (“Of particular significance to the issues requiring resolution is the [Supreme] Court’s ruling that the FDA Exemption includes experimentation on products that are not ultimately the subject of an FDA submission, provided that the particular biological process and physiological effect had been identified and the work was reasonably related to that appropriate for inclusion in an IND application.”).

<sup>94</sup> *Id.* at 1348–49 (Rader, J., dissenting).

<sup>95</sup> *Id.* (quoting *Merck, KGaA v. Integra LifeSciences I Ltd.*, 545 U.S. 193, 207–08 (2005)); *cf.* Pfaff, *supra* note 10, at 265–67 (discussing arguments that only products that are experimented on with the expectation of gaining regulatory approval should be excepted, which would exclude application to most patented research tool inventions) (citing the same Supreme Court language and Judge Newman’s earlier dissent, *Integra LifeSciences I, Ltd.*, 331 F.3d at 878).

<sup>96</sup> *See Integra LifeSciences I Ltd.*, 496 F.3d at 1350–51 (Rader, J., dissenting). One of the patents cited by Judge Rader actually addressed a method of detaching cells from a substrate, which constituted a method of treatment that might have been the subject of a regulatory approval (and that might have been infringed by a person taking an approved pharmaceutical).

as within the scope of the regulatory approval exception, at least to the extent used for “research with” compounds that are *potential* drug candidates.

**B. Current Concerns Regarding the Experimental Use Exception and Regulatory Approval Exceptions in Academic and Other Settings**

The *Madey* decision raised substantial concerns regarding whether the narrow construction of the experimental use exception would lead to increased costs of and impediments to scientific research, based on the need to license patents or the chilling effect of uncertain potential liability.<sup>97</sup> A number of studies have evaluated the effects of the *Madey* decision. These studies provide inconclusive but troubling evidence regarding delays or impediments to scientific research (with concerns appearing much more pronounced with respect to patented diagnostics) that result from patent licensing costs, licensing failures, or the chilling effects of uncertain potential liability.<sup>98</sup> These studies are frequently

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<sup>97</sup> See, e.g., Walsh, Arora & Cohen, *supra* note 10, at 335 (noting concerns that the *Madey* decision might adversely affect “continued reliance on current ad hoc practices of de facto infringement under the informal rubric of the research exemption,” which had precluded significant licensing breakdowns and restrictions on access to patented research tools); Brief of Amici Curiae Consumer Project on Technology and Public Knowledge in Support of Petition for Writ of Certiorari at 4, 13, Duke Univ. v. *Madey*, 539 U.S. 958 (2003) (No. 02-1007), available at <http://www.wcl.american.edu/ipclinic/documents/DukevMadey-2002.pdf?rd=1> (discussing how the *Madey* decision would lead to foregone and delayed research due to refusals to license, increased costs, diversion of efforts from research to licensing, and discouragement of licensing from restrictive offers, and noting existing adverse effects of licensing practices on basic scientific research) (citing Eliot Marshall, *A Deluge of Patents Creates Legal Hassles for Research*, 287 SCIENCE 255, 255–56 (2000)).

<sup>98</sup> See, e.g., AMERICAN ASS'N FOR THE ADVANCEMENT OF SCIENCE, THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 21–23 (2d ed. 2006), available at [http://sippi.aaas.org/survey/AAAS\\_IP\\_Survey\\_Report.pdf](http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf) (40% of survey respondents reported that their research was affected by difficulties in obtaining patented technology, and 35% of university-based bioscience researchers who had acquired patented technologies reported difficulties affecting their research, principally by delay but with significant percentages changing or abandoning research); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 7 (2003) (discussing significant, adverse effects of patent licensing practices on use of diagnostic tests); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577–79 (2002) (same); cf. Rebecca S. Eisenberg & Arti K. Rai, *Harnessing and Sharing the Benefits of State-Sponsored Research: Intellectual Property Rights and Data Sharing in California's Stem Cell Initiative*, 21 BERKELEY TECH. L.J. 1187, 1200 (2006) (discussing similar concerns over restrictions on data and materials transfers) (citing Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473, 477 (2002)); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309

cited to suggest that there is no immediate cause for concern,<sup>99</sup> particularly as there have been no reported cases filed against basic researchers and only a minor impact on commercial researchers given the low rate of litigation of genetic patents.<sup>100</sup> Notwithstanding the fact that patents are rarely asserted against researchers, even in commercial contexts, the biotechnology industry strongly believes that protection against experimentation is needed to assure private sector investment in research tools.<sup>101</sup> However, any reduced incentives for investment in research tools, due to an exception from infringement for such tools, may be counterbalanced by a concomitant reduction in royalty-stacking problems that otherwise might preclude the development of new products.<sup>102</sup>

As noted by a highly influential study, “‘law on the books’ need not be the same as ‘law in action’ if the law on the books contravenes a community’s norms and interests.”<sup>103</sup> These types of studies highlight the potential for serious and rapid problems as patent holders more vigorously assert their rights and as scientists and their institutions start taking more seriously the potential for

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SCIENCE 2002 (2005) (discussing results of a survey of scientists that none abandoned their research due to patents and only about 1% encountered delays as a result of patents).

<sup>99</sup> See, e.g., Walsh et al., *supra* note 98.

<sup>100</sup> See, e.g., Jorge A. Goldstein & Elena Golod, *Human Gene Patents*, 77 ACAD. MED. 1315, 1321–22 (2002) (noting “very few” cases against universities and none on gene patents); Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. (forthcoming 2008) (finding a low rate of human gene patent litigation, and none against universities that are not engaged in substantial commercial activity, although there is significant litigation relating to genetics and biotechnology, including research tools).

<sup>101</sup> See Christopher M. Holman, *Biotechnology’s Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. 318, 324–27 (2006) (also noting differences from university-based biotechnology patent holders, “[who] have little need to worry about being sued”). *But cf.* Rebecca S. Eisenberg, *Why the Gene Patenting Controversy Persists*, 77 ACAD. MED. 1381, 1383–84 (2002) (noting that patent protection for research tools “has undoubtedly motivated valuable private sector investments” in platform technologies, but also noting the “highly questionable” assumption that research tool patents are for technology that would not otherwise be made freely available); Bendekgey & Hamlet-Cox, *supra* note 34, at 1377–78 (focusing on the need for patent protection for investment in genomic-based diagnostic companies); Frederic M. Sherer, *The Economics of Human Gene Patents*, 77 ACAD. MED. 1348, 1353–54 (2002) (noting uncertainties with respect to the importance of patent rights to attracting investment in new high-technology—including biotechnology—ventures; speculating that patents may play a larger role by addressing “perceived vulnerability . . . [to] larger rivals”; and concluding that patent protection “is in most cases quite important”); *id.* at 1363 (noting uncertainties of private-sector investment effects if genome patents were prohibited).

<sup>102</sup> See Mueller, *supra* note 10, at 41.

<sup>103</sup> Walsh et al., *supra* note 98.

their experiments to infringe patents and result in liability.<sup>104</sup> The evidence also demonstrates serious current problems with the sharing of research materials and increasing concerns over the negotiation and terms of material transfer agreements.<sup>105</sup> Practices involving such material transfer agreements also have the potential to affect behavior with patented inventions. Further, concerns exist with respect to concentrating patent rights in upstream research-tool inventions, as patent holders may not be well situated to direct sequential research and innovation.<sup>106</sup> Science “depends on the view that it is good to have many people doing different types of things because different ones will see . . . different types of things. Trying to make orderly or rationed access to innovations is likely to be socially very costly.”<sup>107</sup> Such changes to upstream research may lead to ad-

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<sup>104</sup> See, e.g., *id.* (discussing slightly increased numbers of notifications sent by patent holders and instructions to respect patents sent by institutions since the *Madey* decision, but continuing failures of scientists to pay attention to or to check for patents); WALSH, ARORA & COHEN, *supra* note 10, at 322–31 (discussing how scientists routinely ignored the potential for patent liability); see also Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 NOTRE DAME L. REV. 1917, 1963 & n.243 (2007) (noting that researchers may gamble on the lack of lawsuits and that such behavior could rapidly change with a single, high-profile litigation).

<sup>105</sup> See, e.g., Walsh et al., *supra* note 98 (discussing a survey in which 19% of the respondents’ most recent request for materials was denied, 8% of requests resulted in negotiating delays of more than one month, and 29% of executed agreements contained conditions imposing reach-through rights); SCIENCE & INTELLECTUAL PROPERTY IN THE PUBLIC INTEREST, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE, EFFECTS OF INTELLECTUAL PROPERTY PROTECTIONS ON THE CONDUCT OF SCIENTIFIC RESEARCH: RESULTS OF A SURVEY OF U.S. AAAS MEMBERS 2–3 (Jan. 16, 2007) (of respondents who acquired intellectual property—accounting for roughly a quarter of the respondents—32% experienced difficulties in accessing technologies, with fewer problems for academics than for industry; academics acquired technology principally by material transfer agreements; 54% of respondents who acquired technology stated that their last acquisition was a research tool; and most research tools were acquired in less than one month); Loring & Campbell, *supra* note 19, at 1717 (discussing high costs and difficulties of access in the U.S. to patented human embryonic stem cells). See generally Sean O’Connor, *The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics*, 21 BERKELEY TECH. L.J. 1017, 1052 (2006) (discussing use of material transfer agreements to control both physical and intellectual property and noting that physical property rights controlled through MTAs “are often the most difficult to overcome” to enable research).

<sup>106</sup> See, e.g., Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 *passim* (2003) (discussing changes to federal law that permitted patenting of upstream technologies developed with federal funding and to the economic structure of academic research).

<sup>107</sup> Richard D. Nelson & Roberto Mazzoleni, *Economic Theories About the Costs and Benefits of Patents*, in INTELLECTUAL PROPERTY RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 24 (1997).



verse normative changes in scientific practices, diminishing the ethical standards of open research and increasing the costs or impediments to innovation.<sup>108</sup>

Licensing concerns also exist with respect to patents for which the regulatory approval exception will apply. No license is required once the patented inventions are used in research solely for regulatory approval. In contrast, inventions that are potential candidates for pharmaceutical research (if not subject to the experimental use exception) require licenses, at a time when their potential future value is much more uncertain. Valuing these inventions for licensing at such an early stage may be difficult, and may lead to licensing breakdowns when high up-front costs are demanded.<sup>109</sup>

Conversely, efforts to conclude licenses based on later uses and subsequent revenues may also be problematic, raising potential patent misuse issues.<sup>110</sup> If licensing revenue is based on a period of non-infringement (due to the regulatory approval exception) the license may improperly extend the patent's scope.<sup>111</sup> And if licensing revenue is based on expected sales after the product emerges from regulatory approval, particularly if the patented invention was used only as a tool to invent the product (rather than being incorporated into the product), it may improperly impose unreasonable reach-through licensing conditions.<sup>112</sup> Finally, the ability to prevent development of such new products

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<sup>108</sup> See generally Rai, *supra* note 33.

<sup>109</sup> Concerns about licensing breakdowns have also been raised by a recent U.S. Supreme Court decision, which may have reduced the certainty of patent licenses by finding that licensees have standing to sue for patent invalidity without first breaching the license. See *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007); Brief of Respondent at 46, *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007) (No. 05-608) (arguing that the new rule would result in “greatly increased litigation expenses, decreased licensing, and decreased use of the patent system”) (citing John W. Schlicher, *Judicial Regulation of Patent Licensing, Litigation and Settlement Under Judicial Policies Created in Lear v. Adkins*, in AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, 3 SELECTED LEGAL PAPERS, No. 1, I-8-13 (1985); Joyce E. Cutler, *MedImmune Seen as Chilling Innovation in Survey by Licensing Executives Society*, 73 PAT. TRADEMARK & COPYRIGHT J. 556 (2007) (discussing likely responses to the decision, including higher upfront fees).

<sup>110</sup> See Kate Murashige, *Patents and Research—An Uneasy Alliance*, 77 ACAD. MED. 1329, 1331 & n.9 (discussing high costs of licenses that priced research tools out of the market, and potential patent misuse based on requirements to continue to pay licensing fees after expiration of the patent term); see also John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 458–59 (1997) (discussing antitrust concerns under § 2 of the Sherman Act).

<sup>111</sup> See *Brulotte v. Thys Co.*, 379 U.S. 29, 33–34 (1965) (royalty payments that extend patent rights beyond patent term constitute per se misuse of the patent, rendering it unenforceable).

<sup>112</sup> Cf. *Bayer AG v. Housey Pharm., Inc.*, 228 F. Supp. 2d 467, 470–71 (D. Del. 2002) (finding no misuse absent evidence that the patent holder had impermissibly “‘conditioned’ its li-

by refusing to license before the regulatory approval exception would apply (and by obtaining injunctions or threatening reach-through royalty damages) raises anti-competitive concerns with effective extension of patent term similar to those that led to codification of the regulatory approval exception.<sup>113</sup> However, such unilateral refusals to license are unlikely to result in antitrust scrutiny in the United States, although conditions imposed on such licenses may do so.<sup>114</sup>

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censes” on royalty payments for unpatented compounds, which had been developed with patented methods); WEGNER, *supra* note 20, at 31–45 (discussing misuse concerns with reach through royalties); Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK 163, 172 (1994) [hereinafter Eisenberg, *Technology Transfer and the Genome Project*] (describing how reach-through royalties provide disincentives for product development as a tax on sales); Stephen G. Kunin et al., *Reach-Through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609, 618 & nn.57, 58 (2002) (discussing the increasing prevalence of reach-through license terms for research tool patents). *But cf.* Mueller, *supra* note 10, at 58–62 (proposing compulsory licensing of research tools using reach through royalties). Reach-through patent claims pose related but distinctive concerns. *Cf.* Andrew F. Christie & Amanda Lim, *Reach-through Patent Claims in Biotechnology: An Analysis of Examination Practices of the United States, European, and Japanese Patent Offices* 5 (Univ. of Melbourne Legal Studies Research Paper No. 176, 2005), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=934951](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=934951) (discussing reach-through claims “to subsequent and future things that have some relationship to the current invention” and that—if valid—would apply directly to subsequent products, processes, or agents created using the invention for purposes of exclusion and royalties); Sharon Farnley, Pamela Morey-Nase & Diana Sternfeld, *Biotechnology—A Challenge to the Patent System*, 15 CURRENT OPINION IN BIOTECHNOLOGY 254 (2004) (noting that reach-through claims address “something beyond what has been disclosed”).

<sup>113</sup> See Hagelin, *supra* note 39, at 517–18 (discussing antitrust licensing concerns and their application to the experimental use exception context, specifically limiting competition in research and development, exclusive dealing, and requiring grantbacks of developed technologies).

<sup>114</sup> See U.S. Dept. of Justice and Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* 5–6, 15–32 (2007), available at <http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf>; *cf.* *Verizon Comm’n, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (refusing to recognize or repudiate an “essential facilities” doctrine in U.S. antitrust law). In contrast, European unilateral refusals to license intellectual property rights to competitors may be found to constitute an abuse of dominant position in “exceptional circumstances,” such as when the refusal relates to indispensable uses on a “neighbouring market,” excludes any effective competition in that market, and prevents the appearance of a new product for which there is a market demand. *Case T-201/04, Microsoft Corp. v. Comm’n of the European Communities*, 2007 *Report of Cases Before the Court of Justice of the European Communities and the Court of First Instance* (E.C.R.), ¶¶ 331, 332 (2007).

### III. THE EXPERIMENTAL USE AND REGULATORY APPROVAL EXCEPTIONS IN EUROPEAN PATENT LAWS, AND RESEARCH TOOL USE IN ACADEMIC AND OTHER SETTINGS

In order to contrast the experimental use and regulatory approval exceptions in U.S. patent law to their counterparts in European patent law, we will avoid a detailed look at European laws on experimental use and regulatory approval exceptions on a country-by-country and case-by-case basis, as others have done this recently.<sup>115</sup> Rather, we focus on the basic principles of Europe's experimental use and regulatory approval exceptions. We do so by explaining the history of the national provisions and the various means for interpreting them, based on (a) literal language, (b) legislative history, (c) the structure and (d) the purposes of the provisions, and (e) consistency with other relevant international legal instruments. In doing so, we refer to corresponding issues under U.S. law. We conclude this section with a discussion of the more complex issues raised by experiments using patented inventions as research tools under European laws in academic, regulatory approval, and other settings.

#### A. *How Did They Emerge?*

In Europe, questions of infringement and exceptions to infringement by use of patented inventions have always been governed by national patent laws.<sup>116</sup> Article 64(1) of the European Patent Convention (EPC) provides that the rights conferred by a European patent in all designated countries to which the European patent extends shall be the same as those conferred by a national patent granted in that state.<sup>117</sup> Furthermore, Article 64(3) of the EPC states that

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<sup>115</sup> See, e.g., William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 INT'L REV. INDUS. PROP. & COPYRIGHT L. 735 (1998); Christopher Heath, *The Patent Exemption for "Experimental Use" in Clinical Trials*, 22 AIPPI J. 267 (1997); Joseph Straus, *On the Admissibility of "Biological Equivalence Tests" During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties*, 23 AIPPI J. 211 (1998); Paul Tauchner, *Experimental Use Exemption in Germany*, PAT. WORLD, Dec. 1997–Jan. 1998, at 23; Corinna Vossius, *Comments on the German Federal Supreme Court 'Clinical Trials' and 'Clinical Trials II' Decisions*, 3 BIO-SCI. L. REV. 106 (1997).

<sup>116</sup> See, e.g., Bernhard Jestaedt, in GEORG BENKARD ET AL., EUROPÄISCHES PATENTÜBEREINKOMMEN arts. 64.5, 64.16 (2002); Uwe Scharen, in GEORG BENKARD ET AL., PATENTGESETZ GEBRAUCHSMUSTERGESETZ § 9.8 (10th ed. 2006). See generally Eike Ullmann, in GEORG BENKARD ET AL., PATENTGESETZ GEBRAUCHSMUSTERGESETZ, Internationaler Teil ¶ 1 (10th ed. 2006) (providing an overview of patent agreements between various European countries).

<sup>117</sup> RIGHTS CONFERRED BY A EUROPEAN PATENT.

“[a]ny infringement of a European patent shall be dealt with by national law.”<sup>118</sup> Thus the scope of rights conveyed, and the limitations of the rights of patent holders in regard to private and experimental uses, are not stipulated by the EPC, but rather by national patent laws.<sup>119</sup>

Like in the U.S., the experimental use exception was initially introduced to European patent law by judicial interpretation of the statutory exclusive right.<sup>120</sup> Unlike in the U.S., those judicial interpretations have been wholly superseded by European national legislation. In 1975, the then-members of the European Economic Community concluded the Community Patent Convention (CPC) as a multilateral treaty.<sup>121</sup> The CPC was subsequently revised and re-numbered in 1989.<sup>122</sup> Article 27 of the CPC of 1989 (Article 31 of the CPC of 1975), addressed the “[I]mitation of the effects of the Community patent.”<sup>123</sup> It provided that “[t]he rights conferred by a Community patent shall not extend to: (a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes relating to the subject-matter of the patented invention.”<sup>124</sup> This two part structure reflects prior experience under European national patent laws that avoided treating as infringement uses that did not have significant economic effects (private and non-commercial uses) as well as scientific experiments (even if done commercially).<sup>125</sup> It thus coincides with Justice Story’s

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(1) A European patent shall, subject to the provisions of paragraph 2, confer on its proprietor from the date of publication of the mention of its grant, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State.

(2) If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

Convention on the Grant of European Patents, art. 64, ¶¶ 1–2, Oct. 5, 1973, 1065 U.N.T.S. 255, 274, 13 I.L.M. 270, 287, available at <http://www.european-patent-office.org/legal/epc/e/ma1.html> [hereinafter EPC].

<sup>118</sup> *Id.* ¶ 3.

<sup>119</sup> *Id.*

<sup>120</sup> For cases in the U.K., see, e.g., *United Tel. Co. v. Sharples*, (1885) 29 Ch.D. 164, 1885 WL 17659; *Frearson v. Loe*, (1878) 9 Ch.D. 48, 1878 WL 17375. For a case from Germany, see, e.g., *Reichsgericht [RG] [Supreme Court of the German Reich]* May 29, 1907, 66 *Entscheidungen des Reichsgerichts in Zivilsachen [RGZ]* 164, 165–66.

<sup>121</sup> CPC, *supra* note 15.

<sup>122</sup> *Id.*

<sup>123</sup> *Id.* art. 27.

<sup>124</sup> *Id.*

initial formulation excluding both scientific experimentation and uses that did not deprive patent holders of commercial rewards to which patent holders were legally entitled.<sup>126</sup> However, the European exceptions are more generous to experimenters, given the broad construction of “use for profit” under U.S. patent law, and neither early European case law nor the CPC explicitly drew from U.S. patent law when adopting these judicial exclusions.<sup>127</sup>

Due to a lack of ratification by the necessary number of contracting states, the CPC itself never came into force.<sup>128</sup> However, its indirect effects

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<sup>125</sup> See examples from early German case law: RG Oct. 19, 1935, 149 RGZ 102 (108); RG Jan. 28, 1933, 1933 GRUR 292 (294–95); AG Düsseldorf (Schöffengericht) June 4, 1930, 1931 MuW 583 (583); RG June 26, 1929, 1929 GRUR 1199 (1200); RG May 29, 1907, 66 RGZ 164 (166); RG Mar. 31, 1897, 39 RGZ 32 (33); RG Mar. 8, 1895, 27 Entscheidungen des Reichsgerichts in Strafsachen [RGSt] 88 (91).

<sup>126</sup> See Pierce, *supra* note 38, at 381. By authorizing private and non-commercial uses separately from experimental uses, the CPC formulation creates exceptions that are closer to the “fair use” exception to copyright infringement in U.S. law. See 17 U.S.C. § 107 (2007) (providing factors to be considered for “fair use” of a copyrighted work). See generally Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (arguing that patent law should adopt a fair use defense, modeled on copyright law, to address problems of market failure).

<sup>127</sup> See *supra* note 44 and accompanying text. For examples from early European case law, see *supra* note 125.

<sup>128</sup> However, to promote further harmonization of European patent law the Commission of the European Communities proposed draft changes to comply with the CPC. See *Commission of the European Communities, Proposal for a Council Regulation on the Community Patent*, COM (2000) 412 final (Aug. 1, 2000), available at [http://eurlex.europa.eu/LexUriServ/site/en/com/2000/com2000\\_0412en01.pdf](http://eurlex.europa.eu/LexUriServ/site/en/com/2000/com2000_0412en01.pdf) [hereinafter EC Council Regulation]. This draft contains in Article 9(b) a provision complying with Article 27(b) of the CPC of 1989. *Id.* at 41. However, the proposal has not been adopted so far. In 1992, the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI) addressed the scope of the experimental use exception in a report and recommendation. Executive Committee of Tokyo, *Experimental Use as a Defence to a Claim of Patent Infringement*, in AIPPI, 3 YEARBOOK 282–83 (1992), available at [http://www.aippi.org/reports/resolutions/Q105\\_E.pdf](http://www.aippi.org/reports/resolutions/Q105_E.pdf). In their concluding resolution, AIPPI posted the following guidelines:

2. AIPPI is in favor of the authorization of experimental use of a patented invention by the third parties because of the potential importance of such use for technical progress.

....

3.1 Experimental use includes any use of the patented invention performed for academic purposes and having no commercial nature.

3.2 Experimental use includes testing to evaluate the teaching of the patent and validity of the patent.

must not be underestimated, as the contracting states amended their national patent laws to match the provisions of the CPC. In particular, European countries (except for Austria) incorporated provisions into their national patents acts that match either literally or, in the case of the Netherlands, with minor deviations,<sup>129</sup> the experimental use exception provided in Article 27(b) of the CPC. Recently, however, Belgium adopted an experimental use exception that extends very broadly to research “on and/or with” patented inventions.<sup>130</sup>

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3.3 Experimental use includes any use of the patented invention to an extent appropriate to experimentation (as opposed to commercial use) which is for the purpose of improving the invention or making an advance over the invention or finding an alternative to the invention, but not the commercial exploitation of the subject of any improvement or advance.

3.4 Experimental use should be subject to the overriding principle that the use must involve work on the subject of the patent; use merely to obtain the advantage of the invention disclosed by the patent is not experimental use.

*Id.* In contrast to the AIPPI guidelines, the recent recommendation for a codified experimental use exception in the U.S. by the American Intellectual Property Law Association (AIPLA) seeks to minimize the commercial and non-commercial distinction, including within the proposed exemption specific uses that may have commercial motivations (e.g., designing improvements). See THE NATIONAL ACADEMIES’ BOARD ON SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AND THE FEDERAL TRADE COMMISSION, TOWN MEETING ON PATENT REFORM (Feb. 18, 2005) at 114–15,

[http://www.aipla.org/Content/ContentGroups/Meetings\\_and\\_Events1/Roadshows/20058/TownMeeting\\_SanJose\\_Transcript.pdf](http://www.aipla.org/Content/ContentGroups/Meetings_and_Events1/Roadshows/20058/TownMeeting_SanJose_Transcript.pdf) (comments of Janice Mueller, Professor of Law, University of Pittsburgh Law School, discussing an approved AIPLA Board Resolution and an AIPLA draft of proposed legislation).

<sup>129</sup> Rijksoctrooiwet [Dutch Patents Act] 1995, art. 53(3), *translated in* <http://www.ivir.nl/legislation/nl/patentact1995.html> (adding the word “solely” to the exception). Whether this change reflects an intent to alter the scope and nature of the experimental use exception is an uncertain and controversial issue. See Pharbita und Medicopharma/ICI, Hoge Raad der Nederlanden [HR] [Supreme Court of the Netherlands], 18 Dec. 1992, 1993 GRUR INT’L 887 (Neth.); Reinhardt Schuster, *Experimental Use and Clinical Tests in the Patent Case Law of Germany, the Netherlands, and the United Kingdom*, PAT. WORLD, Aug. 1996, at 33, 36.

<sup>130</sup> Belgian Patent Act, art. 28, § 1(b) (enacted Apr. 25, 2005), *available at* <http://www.ejustice.just.fgov.be/cgi/summary.pl>. See Geertrui Van Overwalle, *The Implementation of the Biotechnology Directive in Belgium and its After-Effects. The Introduction of a New Research Exemption and a Compulsory Licence for Public Health*, 37 INT’L REV. OF INTELL. PROP. & COMPETITION L. 889, 906–08 (2006) (noting the broad interpretation of scientific purposes, to include such purposes pursued with commercial intent). The research exception excludes experiments with purely commercial purposes, although it applies in cases of mixed scientific and commercial purposes. *Id.* at 907 (citing STATEMENT OF THE MINISTER FOR ECONOMIC AFFAIRS, VERWILGHEN, ON THE SCOPE OF THE RESEARCH EXEMPTION,

To further promote the desired harmonization of patent laws, European national governments have generally abstained from supplying an independent justification for amendments to national patent laws in view of the CPC, and instead have referred to the preparatory work of the CPC.<sup>131</sup> Because of the unequivocal motivation of national parliaments to leave their historical exceptions from patent infringement behind and to adopt legislation seeking to harmonize their laws collectively under CPC formulation and its premises, the prior national cases are less material. Subsequent decisions of national courts have focused on the language, intent, structure, and purposes of the CPC provision.<sup>132</sup>

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Parl. Doc., Chamber, 2004–2005, Doc. 51 1348/006, at 58, and Parl. Doc., Senate, 2004–2005, 3-1088/3, at 2).

<sup>131</sup> E.g., Patents Act, 1977, c. 37, § 130(7) (U.K.), available at <http://www.jenkins-ip.com/patlaw/index.htm> provides:

Whereas by a resolution made on the signature of the Community Patent Convention the governments of the member states of the European Economic Community resolved to adjust their laws relating to patents so as (among other things) to bring those laws into conformity with the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty, it is hereby declared that the following provisions of this Act, that is to say, sections [60 among others] are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Co-operation Treaty have in the territories to which those Conventions apply.

See also PETER MES, PATENTGESETZ, GEBRAUCHSMUSTERGESETZ §§ 11.5, 11.9 (2d ed. 2005); Thomas Hieber, *Die Zulässigkeit von Versuchen an patentierten Erfindungen nach § 11 Nr. 2 PatG 1981*, 1996 GRUR 439, 443; Alfons Schäfers, *Aspekte des neuen Patentrechts*, 1981 MITT. 6, 7.

<sup>132</sup> See, e.g., *Monsanto Co. v. Stauffer Chem. Co.*, [1985] R.P.C. 515 (537–38) (High Court of Justice – Patents Court), 1985 WL 311100; BGH Apr. 17, 1997, 1997 NJW 3092 (3094–96) (*Clinical Trials II*), translated in [1998] R.P.C. 423 (433); BGH July 11, 1995, 1996 NJW 782 (785–86) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (639–41); Alfred Keukenschrijver, *Das Patent*, in RUDOLF BUSSE ET AL., PATENTGESETZ § 11.17 (6th ed. 2003); see also SIMON THORLEY ET AL., TERRELL ON THE LAW OF PATENTS § 8.69 (15th ed. 2000) (summarizing European case law on the experimental use exception); ALAN W. WHITE, CHARTERED INST. OF PATENT AGENTS, C.I.P.A. GUIDE TO THE PATENTS ACT § 60.12 (5th ed. 2001) [hereinafter GUIDE TO THE PATENTS ACT] (interpreting CPC art. 27); Hieber, *supra* note 131, at 445–46 (commenting on the *Clinical Trials I* decision); Rolf Pietzcker, *Patentrechtliche Fragen bei klinischen Untersuchungen – eine Erwiderung*, 1994 GRUR 319, 319–20 (commenting on the admissibility of clinical trials under the German experimental use exception); Corinna Vossius, *supra* note 115, at 107 (commenting on the *Clinical Trials I* and *Clinical Trials II* decisions).

## B. How Are the Experimental Use Exceptions Construed?

### 1. Literal Interpretation

#### i. “Experimental Purpose”

Great Britain’s Court of Appeal was the first senior European court to define the meaning of “experimental purposes” in Article 31(b) of the CPC of 1975 (Article 27(b) of the CPC of 1989) and section 60(5)(b) of the U.K. Patents Act of 1977.<sup>133</sup> In *Monsanto v. Stauffer Chemical Co.*, Lord Justice Dillon held that the words “experimental purposes” have an ordinary meaning, and that therefore acts:

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 . . . will work in different conditions can fairly . . . 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, whether a customer or a [regulatory] body . . . that the product works as its maker claims are not . . . to be regarded as acts done “for experimental purposes.”<sup>134</sup>

Given what was already known about the allegedly infringing glyphosate herbicide, the Court of Appeal upheld an injunction prohibiting planned uses of the glyphosate herbicide on third-party farms as they would have been used solely to demonstrate marketability (but modified the injunction to permit uses on the experimenter’s own farm).<sup>135</sup> The court argued that such uses would not have resulted in the experimenter (as opposed to the marketing approval body) learning anything new about the patented invention.<sup>136</sup> Lord Justice Dillon also recognized the possibility of mixed purpose cases, indicating (by suggesting that a different outcome would result) that the experimental purpose would govern.<sup>137</sup>

These distinctions reflect the language of the codified CPC provision. Article 27(b) of the CPC of 1989 clearly contemplates application to experi-

<sup>133</sup> *Monsanto*, [1985] R.P.C. at 537–38; Patents Act, 1977, c. 37, § 60(5)(b) (U.K.), available at <http://www.jenkins-ip.com/patlaw/index.htm>.

<sup>134</sup> *Monsanto*, [1985] RPC at 542. See THORLEY, *supra* note 132, § 8.69.

<sup>135</sup> *Monsanto*, [1985] RPC at 537, 542.

<sup>136</sup> *Id.* at 542.

<sup>137</sup> *Id.* (“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.”).



ments performed with commercial motivation, given that Article 27(a) provides a separate exception from infringement for private and non-commercial uses.<sup>138</sup> Where the acts are performed solely to gather commercial information and not to discover information about or applications of the invented subject matter, there is no experimentation—as the term is commonly understood—involved.<sup>139</sup> *Monsanto* did not, however, address use of the patented invention as a research tool to invent or discover new things about or with the patented subject matter.

Other national courts have followed *Monsanto's* interpretive approach. Specifically, the definition of “experimental purposes” adopted in *Monsanto* is generally agreed upon throughout Europe.<sup>140</sup> For example, in Germany, the Bundesgerichtshof (Federal Court of Justice) employed a similar definition in its *Clinical Trials I* decision,<sup>141</sup> i.e., any systematic procedure aimed at obtaining new information is considered an experiment within the meaning of Article 27(b) of the CPC of 1989, and thus of section 11(2) of the Patentgesetz (German Patents Act).<sup>142</sup>

ii. “Relating to the Subject Matter”

The phrase “relating to the subject-matter of the patented invention” is obviously intended to qualify the preceding expression “acts done for experimental purposes.”<sup>143</sup> By narrowing the category of experimental purposes to

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<sup>138</sup> CPC, *supra* note 15.

<sup>139</sup> BGH Apr. 17, 1997, 1997 NJW 3092 (3094), [1998] R.P.C. 423 (424) (*Clinical Trials II*); Scharen, *supra* note 116, § 11.6.

<sup>140</sup> See Keukenschrijver, *supra* note 132, § 11.17; Thomas Kühnen, in RAINER SCHULTE ET AL., PATENTGESETZ MIT EUROPÄISCHEM PATENTÜBEREINKOMMEN § 11.12 (7th ed. 2005); MES, *supra* note 131, § 11.6; CHRISTIAN OSTERRIETH, PATENTRECHT 156 (2000); Gottfried Freier, *Patentverletzung und Versuchsprivileg*, 1987 GRUR 664, 666–67; Hieber, *supra* note 131, at 441; Andries van der Merwe, *Experimental Use and Submission of Data for Regulatory Approval*, 31 INT'L REV. INDUS. PROP. & COPYRIGHT L. 380, 384 (2000); Wolfgang von Meibom & Johann Pitz, *Experimental Use, Patent Infringement: A Transatlantic Review from the German Perspective in Regard to the Decision of the German Supreme Court in Ortho v. Merckle*, “*Clinical Trial II*”, 1 J. WORLD INTELL. PROP. 633, 638–39 (1998); Pietzcker, *supra* note 132, at 320.

<sup>141</sup> BGH July 11, 1995, 1996 NJW 782 (785) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (642). This decision was affirmed in Bundesverfassungsgericht [BVerfG] [Federal Constitutional Court] May 10, 2000, 2001NJW 1783 (F.R.G.) (*Klinische Versuche* [*Clinical Trials*]).

<sup>142</sup> Das deutsche Patentgesetz [German Patents Act] § 11(2), available at <http://www.gesetze-im-internet.de/patg/index.html> (“The effects of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.”) (translated).

<sup>143</sup> CPC, *supra* note 15.

those that relate to the subject matter of the patented invention, the CPC reflects an intent that the experiments must be intended to develop information on the used invention itself.<sup>144</sup> This would exclude experiments where the patented inventions are used *solely* as a research tool to investigate other things (such as use of a microscope to investigate bacteria), or are used *solely* to obtain a regulatory marketing approval. The legislative history of the CPC, in particular the memorandum on the Convention, makes this clear, creating a distinction between experiments “on” a patented invention from experiments “with” the invention.<sup>145</sup> The Hoge Raad der Nederlanden (Supreme Court of the Netherlands) expressly held to this effect in *Organon International BV v. Applied Research Systems (ARS) Holding BV*.<sup>146</sup>

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<sup>144</sup> See ALEXANDER KREFFT, PATENTE AUF HUMAN-GENOMISCHE ERFINDUNGEN 318 (2003); MES, *supra* note 131, § 11.5; Cornish, *supra* note 115, at 738; Friedrich Feuerlein, *Patentrechtliche Probleme der Biotechnologie*, 2001 GRUR 561, 565; Freier, *supra* note 140, at 667; Hieber, *supra* note 131, at 441; Keukenschrijver, *supra* note 132, § 11.18; Kühnen, *supra* note 140, § 11.12; Meibom & Pitz, *supra* note 140, at 637; Scharen, *supra* note 116, § 11.7; Schuster, *supra* note 129, at 38; Ingve Björn Stjerna, *Die Voraussetzungen und Grenzen des patentrechtlichen Versuchsprivilegs*, 2004 Mitt. 343, 348; Joseph Straus, *Zur Zulässigkeit klinischer Untersuchungen am Gegenstand abhängiger Verbesserungserfindungen*, 1993 GRUR 308, 311; Tauchner, *supra* note 115, at 25; Corinna Vossius, *supra* note 115, at 107; Volker Vossius, *Klinische Versuche*, 1997 MITT. 116, 116; Alan W. White, *Problems of Patents for Research Tools*, 4 BIO-SCI. L. REV. 138, 138–39 (1998); see also Bernhard Fischer, *Reach-Through and Experimental Use*, MANAGING INTELLECTUAL PROPERTY, IP STRATEGY YEARBOOK, Oct. 23, 2001, at 9, 10 (commenting on the difficult “line between verifying [a research tool’s] functioning and taking it’s claimed function as granted”); Merwe, *supra* note 140, at 385 (suggesting that, for the experimental use defense to apply, “the experimentation or testing must relate to an exploration of the unknown . . . while involving the protected subject matter as primary object”).

<sup>145</sup> A German version of the memorandum of understanding regarding the CPC of 1975 is published in 1979 Blatt für Patent-, Muster- und Zeichenwesen [Bl.f.PMZ] 325–49 [hereinafter Memorandum]. The memorandum comments on Article 31(b) of the CPC of 1975 (Article 27(b) of the CPC of 1989) that all of the exceptions of Article 31 of the CPC of 1975 should be applied restrictively, and:

As is likely the case with most national patent laws, Article 31(b) permits use of the invention protected by a community patent for experimental purposes, e.g. in order to test usability and possibilities for enhancements. The chosen wording is intended to make it clear that the experiment itself must relate to the protected invention; i.e. use of the protected invention within the scope of an experiment that relates to a different subject-matter shall not be permitted.

*Id.* at 333.

<sup>146</sup> *Organon Int’l BV/Applied Research Sys. ARS Holding BV*, HR, 23 June 1995, 1997 GRUR INT’L. 838.

The *Organon* case, however, did not discuss the outcome of mixed purpose experiments, nor how to distinguish “research on” from “research with” when the subject matter of the patented invention is broad and experimentation to evaluate it can readily lead to the identification of new applications and new inventions.<sup>147</sup> In particular, the case did not distinguish whether research “relat[es] to the subject matter of the invention” within the meaning of Article 27(b) of the CPC of 1989 when the purpose is to develop applications of the patented invention that were not contemplated by the disclosure, or when the purpose is to develop improvements or alternatives that can act as substitutes for, or can interact with, the patented subject matter.

As a further refinement, in *Smith Kline & French Laboratories Ltd. v. Evans Medical Ltd.*,<sup>148</sup> Justice Aldous of the U.K. Patents Court construed the phrase “relating to the subject-matter of the patented invention” as “relat[ing] to the claimed subject-matter of the patent in suit in the sense of having a real and direct connection with that subject-matter.”<sup>149</sup> However, this “real and direct connection” test does not provide a conceptual basis for distinguishing between the permissible use of a patented invention as an object of study and the impermissible use as a device for studying something else. Nor does it provide an easily administered standard to distinguish permissible from prohibited experiments.

The wording of Article 27(b) of the CPC of 1989 contains no quantitative or qualitative restriction on the type of information that must be sought to qualify the experiments that are excepted from infringement by relating to the subject matter of the used invention.<sup>150</sup> Experiments thus may be conducted without infringing the patent, without regard to the ultimate commercial application to which the discovered information may be put and without regard to whether they are conducted in an academic or commercial setting. Accordingly, the German Federal Court of Justice held in its *Clinical Trials I* decision that the admissibility of experiments, understood as the gathering of information, was to

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<sup>147</sup> Cf. Mueller, *supra* note 10, at 40 (“When research tool transaction costs are severe enough to impede or stop the development of new biomedical products, line-drawing between ‘experimenting on’ and ‘experimenting with’ is no longer justified.”). See generally Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 146–52 (proposing a hybrid experimental exception: exception from infringement for “experimentation on,” and providing for eventual compulsory licensing for “experimentation with,” patented inventions).

<sup>148</sup> *Smith Kline & French Labs. Ltd. v. Evans Med. Ltd.*, (1989) 1 F.S.R. 513 (U.K.), 1988 WL 623784.

<sup>149</sup> *Id.* at 523–24.

<sup>150</sup> CPC, *supra* note 15.

be assessed independent of the purposes to which the information was intended to be put.<sup>151</sup>

Similarly, as the German Federal Court of Justice held in its *Clinical Trials II* decision, generation of test data legitimately required to obtain a regulatory marketing approval for a generic drug can qualify for the experimental use exception, as long as the respective experiments are not performed *solely* to demonstrate bioequivalency, but can be considered as aimed at discovering something unknown about the used drug invention.<sup>152</sup> Experiments performed *solely* to demonstrate bioequivalency normally do not aim to experiment on the subject matter of the drug agent used.<sup>153</sup> Rather, they seek to demonstrate the capability of a generic drug manufacturer to produce a generic drug that is manufactured to essentially the same chemical composition and formulation, and thus should have the same effects as the pioneering drug.<sup>154</sup> Nevertheless, through bioequivalency tests, the generic manufacturer will learn if manufacturing variations or changes to a drug's formulation (e.g., use of different excipients) will alter the composition, function, or effects of the pharmaceutical com-

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<sup>151</sup> BGH July 11, 1995, 1996 NJW 782 (785) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (642).

<sup>152</sup> BGH Apr. 17, 1997, 1997 NJW 3092 (*Clinical Trials II*), translated in [1998] R.P.C. 423. But see Ruess, *supra* note 15, at 100 (suggesting that *Clinical Trials II* held “that the trials conducted solely for obtaining regulatory approval do qualify for the experimental use exemption.”).

<sup>153</sup> *Monsanto Co. v. Stauffer Chem. Co.*, [1985] R.P.C. 515 (High Court of Justice – Patents Court), 1985 WL 311100 (holding that “trials carried out in order to demonstrate to a third party that a product works . . . are not . . . to be regarded as acts done ‘for experimental purposes.’”); *Auchincloss v. Agric. & Veterinary Supplies Ltd.*, [1997] R.P.C. 649, 682 (U.K. Patents Court), 1997 WL 1104133 (“Making (and indeed experimenting) merely for the purposes of getting an official [regulatory] approval is not a defence”); *Organon Int'l BV/Applied Research Sys. ARS Holding BV*, HR, 23 June 1995, 1997 GRUR INT'L 838; *Boehringer Mannheim GmbH/Kirin Amgen Inc.*, HR, 21 Apr. 1995, 1997 GRUR INT'L 836, 837; *Pharbita und Medicopharma/ICI*, HR, 18 Dec. 1992, 1993 GRUR INT'L 887; Cour d'appel [CA] [regional court of appeal] Paris, 1985, PIBD 1985, III-118 (Fr.); GUIDE TO THE PATENTS ACT, *supra* note 132, § 60.14; see also *Wellcome Found. v. Flamel*, CA Paris, Jan. 27, 1999 (unpublished decision); Pierre Véron, *Contrefaçon de brevet d'invention – Usage expérimental et essais cliniques*, 107 *Revue du Droit de la Propriété Intellectuelle* [RDPI] 17, 22–23 (2000) (reporting that *Wellcome Foundation* exempted trials comparing alternative galenic formulations of a patented drug).

<sup>154</sup> See Gesetz über den Verkehr mit Arzneimitteln [Pharmaceuticals Act] §24b(2) (F.R.G.) (authorizing approval of generic drugs in Germany if they have the same composition and dosage form as the reference drug); *Clinical Trials II*, 1997 NJW at 3094–96, [1998] R.P.C. at 429; Scharen, *supra* note 116, §§ 11.6, 11.8.

pound.<sup>155</sup> If the nature and scope of the use are appropriate to the purpose of obtaining new information on the drug agent—that is, if the tests performed do not have the *sole* purpose of obtaining a regulatory marketing approval—even generic bioequivalency tests can be within the scope of the experimental use exception.<sup>156</sup>

After the German Federal Court of Justice rendered its *Clinical Trials II* decision, Germany and other European countries adopted statutory regulatory approval exceptions similar to that in the United States, which complement the existing experimental use exceptions.<sup>157</sup> For example, in the German Patents Act the experimental use exception of section 11(2) was complemented by the regulatory approval exception of section 11(2b):

The rights conferred by a patent shall not extend to . . . studies and trials and the consequential practical requirements necessary for obtaining an authorization to market a drug in the European Union or for obtaining an authorization to market a drug in the Member States of the European Union or in other countries.<sup>158</sup>

Such regulatory approval exceptions will render superfluous many of the intricate questions that have occupied European courts in the past when seeking to determine whether the experimental use exception applies to experiments performed in the course of seeking regulatory marketing approval. Of course, like its corollary in the United States, its scope remains uncertain and will likely breed litigation in regard to what experiments are considered necessary for obtaining authorization, and how far back in the research chain the exception will extend. The breadth of such regulatory approval exceptions and their applicability to research tool use are addressed separately in a section below.

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<sup>155</sup> *Clinical Trials II*, 1997 NJW at 3094–96, [1998] R.P.C. at 432–38; Scharen, *supra* note 116, §§ 11.6, 11.8.

<sup>156</sup> *Clinical Trials II*, 1997 NJW at 3094–96, [1998] R.P.C. at 432–38; Scharen, *supra* note 116, §§ 11.6, 11.8.

<sup>157</sup> See Council Directive 2004/27, *supra* note 15, art. 1.8(6). This directive required member states of the European Union to adopt regulatory approval exceptions:

Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 [i.e., the abbreviated procedure for obtaining an authorization to market a generic drug] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

*Id.*

<sup>158</sup> Das deutsche Patentgesetz [German Patents Act] § 11(2), (2b), available at <http://www.gesetze-im-internet.de/patg/index.html>.

## 2. Legislative History

Interpretation of national European defenses from patent infringement should take into account the legislative history of the CPC.<sup>159</sup> The memorandum of understanding that supports the CPC provisions vaguely noted that the experimental use exception should be applied restrictively.<sup>160</sup> Furthermore, it provided by way of illustration the example that tests aimed at proving usability of and discovering possible improvements to a patented invention are legitimate, while the use of a patented invention to acquire information on something different from the patented invention shall constitute patent infringement.<sup>161</sup> The implications of this distinction are discussed below in the purposive interpretation section.

## 3. Systematic Interpretation

As previously noted, Article 27(b) of the CPC of 1989 applies to experiments performed with partial or complete commercial motivations or by commercial entities, as acts done solely privately or for non-commercial purposes are already excepted from infringement by Article 27(a).<sup>162</sup> As Article 27(b) of the CPC of 1989 must not be rendered superfluous, it must apply to at least some experiments that are not already covered by Article 27(a).<sup>163</sup> Accordingly, the U.K. Patents Court held in *Smith Kline & French Laboratories*

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<sup>159</sup> Several authors have followed this approach. See Freier, *supra* note 140, at 667; Hieber, *supra* note 131, at 443; Corinna Vossius, *supra* note 115, at 106–07; Volker Vossius, *supra* note 144, at 116.

<sup>160</sup> Memorandum, *supra* note 145, at 333.

<sup>161</sup> *Id.*

<sup>162</sup> CPC, *supra* note 15.

<sup>163</sup> See GUIDE TO THE PATENTS ACT, *supra* note 132, § 60.14 (noting that, unlike subpart (a), subpart(b) makes no reference to “experimental work not having a commercial purpose”); PETER CHROCZIEL, DIE BENUTZUNG PATENTIERTER ERFINDUNGEN ZU VERSUCHS- UND FORSCHUNGSZWECKEN 157, 165, 193 (1986); HEINRICH VON HUBMANN & HORST-PETER GÖTTING, GEWERBLICHER RECHTSSCHUTZ § 21.7 (7th ed. 2002); HIDERO NIOKA, KLINISCHE VERSUCHE IM PATENTRECHT 268 (2003); Freier, *supra* note 140, at 667; Hieber, *supra* note 131, at 442–43; Ulrich Krieger, *Die Benutzungsarten*, 1980 GRUR 687, 688; Kühnen, *supra* note 140, § 11.12; Meibom & Pitz, *supra* note 140, at 249; Schuster, *supra* note 129, at 38; Stjerna, *supra* note 144, at 343, 344–45; Straus, *supra* note 144, at 311; see also Cornish, *supra* note 115, at 752 (noting that the experimental use exception is no longer “confined to the strictly non-commercial, because frequently scientific curiosity operates in conjunction with the desire to turn successful work to account”); Keukenschrijver, *supra* note 132, § 11.17.

*Ltd. v. Evans Medical Ltd.*,<sup>164</sup> and the Supreme Court of Netherlands held in *Pharbita and Medicopharma v. Imperial Chemical Industries PLC (ICI)*<sup>165</sup> that excepted experiments may be designed with a commercial end in view and may be conducted in a business environment. The structural analysis thus supports the linguistic holding of the German Federal Court of Justice in *Clinical Trials I* that uses qualify as excepted experiments independent of their motivation.<sup>166</sup> Like the legislative history analysis, however, the structural analysis sheds no light on where to draw the line between permitted research on and impermissible research with patented inventions.

#### 4. Purposive Interpretation

##### i. General Guidelines

In order to implement the scope of patent laws in general and of the experimental use exception provisions in particular, European courts and scholars often refer to the theories and purposes underlying the patent laws. In Europe, intellectual property legislation is based on the assumption that adverse economic and social effects caused by exclusive property rights are sometimes justified by the economic inducement to individual creativity and the public disclosure resulting from the grant of such rights, with respect to new and sufficiently different technological ideas.<sup>167</sup> Legal protection of intellectual property, and

<sup>164</sup> (1989) 1 F.S.R. 513, 523–24 (U.K.), 1988 WL 623784.

<sup>165</sup> *Pharbita und Medicopharma/ICI*, HR, 18 Dec. 1992, 1993 GRUR INT'L 887.

<sup>166</sup> BGH July 11, 1995, 1996 NJW 782 (785) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (642).

<sup>167</sup> For example, in Europe, see BTDrucks [Legislative Materials of the German Federal Diet] 13/8110, at 9–10, available at <http://dip.bundestag.de> (assuming that intellectual property rights are intended to minimize social welfare loss due to underproduction and accepting a social welfare loss due to underutilization); RUDOLF KRASSER, PATENTRECHT 34–35, 41–49 (5th ed. 2004); Michael Lehmann, *Eigentum, geistiges Eigentum, gewerbliche Schutzrechte – Property Rights als Wettbewerbsbeschränkungen zur Förderung des Wettbewerbs*, 1983 GRUR INT'L 356, 360–61; Gerhard Prosi, *Entspricht der Patentschutz noch den Wettbewerbsanforderungen?*, 1980 Wirtschaft und Wettbewerb [WuW] 641, 641–42. In the United States, see, e.g., *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989) (discussing the “carefully crafted bargain” of patent law between an applicant’s disclosure of a new invention and exclusive rights); *Graham v. John Deere Co.*, 383 U.S. 1, 5–6 (1966) (discussing the power in Article I, Section 8, clause 8 of the U.S. Constitution to “promote the Progress of . . . useful Arts” as inherently relating to “[i]nnovation, advancement, and things which add to the sum of useful knowledge”); *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1883) (issuing patents on insignificant but new inventions results in “indiscriminate creation of exclusive privileges [that] tends rather to obstruct than to stimulate in-

more specifically of patented inventions, is meant to form a system of economic incentives for individuals to invest in innovation and to disclose their achieved inventions by rewarding them with a limited term of exclusion (which may convey monopoly market power<sup>168</sup>) on the invention in return.<sup>169</sup>

The experimental use exception defines the limits to (or imposes an exception to) the scope of the property right granted by a patent. According to the dominant utilitarian conception of European<sup>170</sup> and American<sup>171</sup> patent law, any

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vention.”); Michel, *supra* note 25, at 409–10 (discussing the inherent paradox that the “justification of the patent system is that by slowing down the diffusion of technical progress it ensures that there will be more progress to diffuse”) (quoting JOAN ROBINSON, *THE ACCUMULATION OF CAPITAL* 87 (1956)); *cf.* Letter from Thomas Jefferson to James Madison (July 31, 1788), in 5 *WRITINGS OF THOMAS JEFFERSON* 43, 47 (Ford ed. 1895) (arguing, in views he later rejected, against the creation in the U.S. Constitution of a power to grant patents, because “the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression”); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 *AM. ECON. REV.* 691 (1983) (discussing different mechanisms for incentives to invent); Oren Bar-Gill & Gideon Parchomovsky, *Intellectual Property Law and the Boundaries of the Firm* (Univ. of Penn., Inst. for Law & Econ., Research Paper No. 05-10, Apr. 2005; New York Univ., Law and Econ. Research Paper Series, Research Paper No. 04-06, Apr. 2005), available at <http://ssrn.com/abstract=702464> (discussing Kenneth J. Arrow’s famous information paradox, which requires legal protection for information in order to permit its trading in economic markets).

<sup>168</sup> Not all patents convey monopoly power. See Giles S. Rich, *The Relation Between Patent Practices and the Anti-Monopoly Laws*, 14 *FED. CIR. B.J.* 5 (2004–2005). Whether a patent does so depends on whether there are reasonable substitutes for the patented invention. See, e.g., *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177–78 (1965) (discussing substitutability and monopoly); Edmund W. Kitch, *Property Rights in Inventions, Writings, and Marks*, 13 *HARV. J.L. & PUB. POL’Y* 119, 122–23 (1990) (discussing designing around and the relation of patent rights to market value and power). See generally Barton, *supra* note 110, at 450–51 (discussing the balance of intellectual property rights across generations of inventions and products); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 *J. LEGAL STUD.* 247 (1994) (discussing the economic principles underlying the United States patent system).

<sup>169</sup> BGH Apr. 17, 1997, 1997 NJW 3092 (3094–95) (*Clinical Trials II*), translated in [1998] R.P.C. 423 (435); BVerfG Nov. 29, 1989, 1990 NJW 2053 (2055); BGH Feb. 12, 1987, 100 Entscheidungen des Bundesgerichtshofes in Zivilsachen [BGHZ] 67 (71) (F.R.G.) (*Tollwutvirus*); BGH Feb. 3, 1966, 45 BGHZ 102 (108) (*Appetizügler*); WOLFGANG BERNHARDT & RUDOLF KRASSER, *LEHRBUCH DES PATENTRECHTS* §§23, 30 (4th ed. 1986); OSTERRIETH, *supra* note 140, at 4; Friedrich-Karl Beier, *Die herkömmlichen Patentrechtstheorien und die sozialistische Konzeption des Erfinderrechts*, 1970 GRUR INT’L. 1, 2–4.

<sup>170</sup> BVerfG Oct. 5, 2000, 2001 NJW 1783 (1785) (*Clinical Trials*); *Clinical Trials II*, 1997 NJW at 3094–95, [1998] R.P.C. at 433–35; Keukenschrijver, *supra* note 132, at 55–59; Klaus J. Melullis, in GEORG BENKARD ET AL., *EUROPÄISCHES PATENTÜBEREINKOMMEN* art. 52.16



interpretation of the scope of the experimental use exception should balance the adverse effects of providing less of (or impairing more of) the reward to inventors—limited by consideration of the public’s interests in investment, invention, and disclosure without regard to fairness to, or personality interests of, inventors—against the adverse public effects that would result by excluding third parties from the particular uses at issue. Except where concerns over public order or morality arise, the utilitarian framework should govern interpretation, notwithstanding the stronger tradition in many European civil law jurisdictions of recognizing natural or moral rights of inventors.<sup>172</sup>

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(2002); Rüdiger Rogge, in GEORG BENKARD ET AL., PATENTGESETZ. GEBRAUCHSMUSTERGESETZ 1–2 (10th ed. 2006).

<sup>171</sup> See also *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 158 (1948) (reward to owners is “a secondary consideration”); Letter from Thomas Jefferson to Isaac MacPherson (Aug. 13, 1813), in *THE PORTABLE THOMAS JEFFERSON* 525, 531 (Merrill D. Peterson ed., Penguin Books 1977) (1975) (“the exclusive right to invention [i]s given not of natural right, but for the benefit of society”). In *Wheaton v. Peters*, 33 U.S. 591, 658–61 (1834), the U.S. Supreme Court rejected the argument that federal or state common law protected authors’ rights, and thus rejected protection for natural law copy rights. See also *Donaldson v. Beckett*, 98 Eng. Rep. 257 (H.L. 1774) (rejecting that any common law copyright of authors based on natural rights had survived the Statute of Anne); Craig Joyce, “A Curious Chapter in the History of Judicature”: *Wheaton v. Peters and the Rest of the Story (of Copyright in the New Republic)*, 42 *HOUS. L. REV.* 325, 379–81 (2005) (comparing the opposing philosophies underlying the majority and dissenting opinions in *Wheaton v. Peters*). In that context, even the lawyers arguing for the application of natural law and common law argued that patented inventions were not similarly protected. See *Wheaton*, 33 U.S. at 598, 684 (with the court noting that patent laws do not presume the existence of a natural law right to be secured, but rather “the whole exclusive right is created by the law, and ends with the expiration of the patent”). Conceptions of fairness for and appropriate rewards to inventors may continue to affect doctrinal decisions in patent law, but only because legislators may adopt and judges may interpret the law with such factors in mind. See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). See generally Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future After Festo*, 19 *BERKELEY TECH. L.J.* 1157, 1173–96 (2004) (criticizing fairness rationales articulated by Supreme Court Justices for extending patent protection through a modern doctrine of equivalents).

<sup>172</sup> See, e.g., *Clinical Trials II*, 1997 *NJW* at 3094–95, [1998] *R.P.C.* at 433–35; Loi Relative aux Decouvertes utiles, & aux moyens d’en assurer la propriete’ a ceux qui seront reconnus en etre les Auteurs [Law on useful Discoveries and on means for securing the property therein to the Authors], Jan. 7 1791, reprinted in part and translated in Frank D. Prager, *A History of Intellectual Property From 1545 to 1787*, 26 *J. PAT. OFF. SOC’Y* 711, 756–57 (1944). See generally Cyrill P. Rigamonti, *Deconstructing Moral Rights*, 47 *HARV. INT’L L.J.* 353 (2006) (analyzing the theory of moral rights in copyright); W. W. Kowalski, *A Comparative Law Analysis of The Retained Rights of Artists*, 38 *VAND. J. TRANSNAT’L L.* 1141 (2005) (discussing the conflict of interest between an artist’s moral rights and the rights of a buyer of an object in which the artist’s work is embodied).

Under European constitutional principles, such as Article 14 of the German Grundgesetz (Basic Constitutional Law),<sup>173</sup> legislated restrictions on private property rights must be justified by the advancement of public interests that are adequate to outweigh the burdens on the affected property owners.<sup>174</sup> In *Clinical Trials*, the German Bundesverfassungsgericht (Federal Constitutional Court) upheld the constitutional validity of the Federal Court of Justice's interpretation of the German experimental use exception.<sup>175</sup> The German Federal Constitutional Court reasoned that the progress of science and technology, which is of great importance to the public, depends on unfettered experiments that relate to the newest discoveries and inventions.<sup>176</sup> The Court thus held that

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<sup>173</sup> (1) Property and the right of inheritance shall be guaranteed. Their content and limits shall be defined by the laws.

(2) Property entails obligations. Its use shall also serve the public good.

(3) Expropriation shall only be permissible for the public good. It may only be ordered by or pursuant to a law that determines the nature and extent of compensation. Such compensation shall be determined by establishing an equitable balance between the public interest and the interests of those affected. In case of dispute respecting the amount of compensation, recourse may be had to the ordinary courts.

Grundgesetz für die Bundesrepublik Deutschland [GG] [Basic Law] May 23, 1949, Bundesgesetzblatt [BGBl] (2034), art. 14, as amended Aug. 28, 2006, available at <http://www.gesetze-im-internet.de/gg/index.html>.

<sup>174</sup> BVerfG Nov. 30, 1988, 79 Entscheidungen des Bundesverfassungsgerichts [BVerfGE] 174 (198); BVerfG June 19, 1985, 70 BVerfGE 191 (200); BVerfG Mar. 1, 1979, 50 BVerfGE 290 (341); BVerfG Oct. 25, 1978, 49 BVerfGE 382 (400); BVerfG Apr. 23, 1974, 37 BVerfGE 132 (140); BVerfG Feb. 14, 1967, 21 BVerfGE 150 (155); BVerfG July 10, 1958, 8 BVerfGE 71 (80); FRANK FECHNER, *GEISTIGES EIGENTUM UND VERFASSUNG* 164, 239–248, 480 (1999); HARTMUT MAURER, *ALLGEMEINES VERWALTUNGSRECHT*, §§ 26.38, 26.57–59 (11th ed. 1997); Brun-Otto Bryde, in *INGO VON MÜNCH ET AL., GRUNDGESETZ-KOMMENTAR* §§ 14.11, 14.59, 14.62 (5th ed. 2000); Hans-Jürgen Papier, in *THEODOR MAUNZ ET AL., GRUNDGESETZ* §§ 14.301, 14.307 (2001); Rudolf Wendt, in *MICHAEL SACHS ET AL., GRUNDGESETZ* §§ 14.70, 14.73 (2d ed. 1999). In the U.S., such restrictions are analyzed under the rubric of “regulatory takings.” See, e.g., *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 323, 327 (2002) (reiterating the distinction between acquisition of property for public use and regulations prohibiting private uses, and the need to balance interests in deciding whether a governmental action constitutes a taking); *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104, 124–29 (1978) (noting factual inquiries focusing on the character of the regulatory action and the nature and extent of the interference with the property as a whole).

<sup>175</sup> BVerfG May 10, 2000, 2001 NJW 1783 (1784–86) (*Clinical Trials*); see also Henrik Holzapfel, *Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen*, 2006 GRUR 10, 12.

<sup>176</sup> *Clinical Trials*, 2001 NJW at 1784.

so long as permitted experiments must relate to the subject matter of the patented inventions, and are not experiments “with” the used inventions (i.e., experiments that merely exploit the benefits of the patented inventions) the interests of inventors will not be excessively impaired.<sup>177</sup>

The memorandum of understanding regarding Article 31(b) of the CPC of 1975 (Article 27(b) of the CPC of 1989) suggests that the experimental use exception serves at least two purposes that are relevant in this context.<sup>178</sup> On the one hand, permitting experimental use of patented inventions helps to restore fair competition by permitting experimenters to test the validity of the patents.<sup>179</sup> Such experiments may generate data required for a nullification procedure concerning patents that have been granted by the European Patent Office, or by national patent offices on inventions that do not meet patentability requirements.<sup>180</sup> Any expectations that patent holders are entitled to preclude experiments with invalid patents (particularly experiments designed to demonstrate invalidity) must be considered unreasonable, as there would be no impairment of any validly held property right. If experiments are limited to assessing validity, they are not very likely by themselves to impair commercial returns if the patent is found not invalid. Nevertheless, any such potential impairment must be balanced against the public benefit.

On the other hand, permitting experimental use of patented inventions can more rapidly advance technological progress by enabling investigations during the patent term that may lead to the discovery of improvements to or new applications for existing inventions.<sup>181</sup> Any expectation that patent holders are entitled to prevent the knowledge of the patent from being used to spur further invention during the patent term is unreasonable, and for this reason a public disclosure is required with the grant of the patent.<sup>182</sup> It is only when experimentation requires access to the physical invention beyond the disclosed knowledge that the issue arises.<sup>183</sup> Of course, allowing such experiments may lead to the discovery of entirely new inventions that are not merely improvements. The only way to prevent such unexpected results of experimentation would be to

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<sup>177</sup> *Id.* at 1785.

<sup>178</sup> Memorandum, *supra* note 145, at 333.

<sup>179</sup> CHROCZIEL, *supra* note 163, at 174–76; Scharen, *supra* note 116, § 11.8.

<sup>180</sup> CHROCZIEL, *supra* note 163, at 174–76; Scharen, *supra* note 116, § 11.8.

<sup>181</sup> *See* Memorandum, *supra* note 145, at 333.

<sup>182</sup> *See, e.g.,* Eisenberg, *Patents and the Progress of Science*, *supra* note 25, at 1036; Eisenberg, *Proprietary Rights in Biotechnology Research*, *supra* note 84, at 219–224; Feit, *supra* note 25, at 840–41; Hantman, *supra* note 3, at 643.

<sup>183</sup> *See* Eisenberg, *Patents and the Progress of Science*, *supra* note 25, at 1021–22.

entirely prohibit experiments, which would deprive the public of all such benefits.

The question remains whether these public benefits *should* prevail (in adopting interpretations of otherwise ambiguous national legislation) over the additional economic incentives to investment, invention, and disclosure that would result from granting patent holders the right to exclude such experiments. These economic incentives include license fees for the experimental use that might not otherwise be obtained. Furthermore, if the experiments are successful in generating improvements and alternatives, the patent holder may lose some (or in rare circumstances all) of the commercial rewards that it might otherwise have obtained. Any improvements developed may not necessarily incorporate the patented subject matter and thus may not be “blocked” by the patent from commercial application once the research is concluded. Thus, commercial substitution can result without licensing the patent and the patent holder will lose revenue directly. If the patent applies to the improvement (as dominant and subservient inventions), the patent holder’s economic leverage may be reduced, particularly if the improvement is also patented and must be cross-licensed in order to be supplied to the market.<sup>184</sup>

Alternative means may exist to accomplish the public benefits of rapid technological progress and promoting challenges to invalid patents with less interference with patent holders’ potential incentives. One approach proposed for U.S. patent law would seek to limit the amount of damages an experimenter would pay to a patent holder.<sup>185</sup> But this approach begs the question of whether a greater interference with patent holder incentives may nevertheless be justified, and assumes that the experiments at issue should be treated as infringements of patent rights. In that case, the patent holder might obtain an injunction that would prevent the conducting of experiments and thus defeat the possibility either of obtaining the benefits of the experiments or of requiring only limited damages therefore.<sup>186</sup> Although a statutory or compulsory licensing regime may

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<sup>184</sup> See generally Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 860–70 (1990) (discussing blocking patents, the reverse doctrine of equivalents, and substitutes that significantly improve on patented inventions).

<sup>185</sup> Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC’Y 357, 366–67, 377 (1957).

<sup>186</sup> Although courts might refuse to grant injunctions under traditional equitable principles (see *eBay Inc. v. MercExchange, L.L.C.*, 126 S.Ct. 1837, 1839–40 (2006)), this would simply reframe the policy question (subject to reduced compensation in case the injunction were to issue) as a matter of judicial equitable discretion rather than legal interpretive discretion.

result in damages without injunctions,<sup>187</sup> such a regime necessarily treats the conduct at issue as an infringement and imposes costs of seeking licenses and paying license fees on experimenters.

In any case, current European national laws treat experiments as either infringing or as non-infringing; there is no middle ground. For example, section 61(1) of the U.K. Patents Act of 1977 and section 139(1)–(2) of the German Patents Act allow only for the classification of a use of a patented invention as either infringing or non-infringing.<sup>188</sup> If a use is held non-infringing, the patent holder has no remedies whatsoever against the use, and thus is entitled to neither an injunction nor damages. But if a use is held infringing, the patent holder is entitled to seek an injunction restraining users from any as-yet uncompleted infringements, as well as to obtain damages in respect of any past infringements.<sup>189</sup> Given the problems and social costs of administering any limited damages or compulsory licensing regime, the experimental use exception cannot be considered superfluous, and there remains an interpretive need—informed by utilitarian concerns—to determine in the first instance how far it should extend.

*ii. Experiments Aimed at Assessing the Validity of a Patent*

It is well recognized that some granted patents do not meet patentability requirements and should therefore be subject to invalidation proceedings.<sup>190</sup>

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<sup>187</sup> Statutory licenses are common in U.S. copyright law, given the high transaction costs involved in negotiating voluntary licenses or in processing compulsory licenses. *See, e.g.*, 17 U.S.C. § 114 (2007) (audio transmission sound recordings subject to statutory licensing); 17 U.S.C. § 119 (2007) (secondary transmissions by satellite carriers for private home viewing of certain performances and displays are subject to statutory licenses, with royalty rates calculated based on a statutory formula); *cf.* 17 U.S.C. § 115 (2007) (compulsory licenses to make and distribute phonorecords of nondramatic musical works, subject to notification procedures and royalties established by statute). Although compulsory license provisions exist for U.S. patent laws, they are disfavored and are rarely employed. *See, e.g.*, 35 U.S.C. § 203(a) (2007) (government “march-in” rights to grant non-exclusive, partially exclusive, or exclusive licenses in federally funded inventions when certain conditions are found to exist); 42 U.S.C. § 7608 (2007) (compulsory licenses for air pollution control equipment required for compliance with certain Clean Air Act standards).

<sup>188</sup> U.K. Patents Act, 1977, c. 37, § 61(1), *available at* <http://www.jenkins.eu/statutes/patents.asp>; Das deutsche Patentgesetz [German Patents Act], § 139(1)–(2), *available at* <http://www.gesetze-im-internet.de/patg/index.html>.

<sup>189</sup> U.K. Patents Act, 1977, c. 37, § 61(1); German Patents Act, § 139(1)–(2).

<sup>190</sup> *See, e.g.*, EPC *supra* note 117, art. 99; German Patents Act § 81; FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 4–24 (2003) [hereinafter FTC Innovation Report], *available at*

Competitors of patent holders may have a strong commercial motivation to have such patents invalidated. As competitors may have great expertise in their respective field of technology, they may be in a good position to determine and to demonstrate invalidity or overbreadth of such patents.<sup>191</sup> Competitors that invalidate granted patents through administrative oppositions (or reexaminations<sup>192</sup>) or in litigation act in the public interest by minimizing economic losses that result from potential monopoly pricing, and from discouragement of innovation that may otherwise result.<sup>193</sup> But if procedures to invalidate granted patents impose the burdens of production and persuasion on competitors,<sup>194</sup> they

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<http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (discussing current burdens of effective examination, data on patent quality, the need for more resources, and recommending post-grant oppositions to address the numerous invalid patents that predictably issue). See generally Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System -- Design Choices and Expected Impact*, 19 BERKELEY TECH L.J. 989 (2004); Stuart J. H. Graham & Dietmar Harhoff, *Can Post-Grant Reviews Improve Patent System Design? A Twin Study of US and European Patents* (CEPR Discussion Paper No. 5680, 2006), available at <http://ssrn.com/abstract=921826>; Patstats.org, <http://www.patstats.org> (last visited Nov. 11, 2007) (listing statistics on judicial decisions regarding patent validity in the United States).

<sup>191</sup> See, e.g., Kristen Jakobsen Osenga, *Rethinking Reexamination Reform: Is it Time for Corrective Surgery, or is it Time to Amputate?*, 14 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 217, 246 (2003). See generally John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. REV. 77 (2002); FTC Innovation Report, *supra* note 190. For this reason, patent opposition, reexamination, and litigation opportunities exist to challenge granted patents. See, e.g., Hall & Harhoff, *supra* note 190; Jordan K. Paradise, *Lessons From the European Union: The Need for a Post-Grant Mechanism for Third-Party Challenge to U.S. Patents*, 7 MINN. J. L. SCI. & TECH. 315, 317–18 (2005).

<sup>192</sup> See, e.g., 35 U.S.C. §§ 302, 311 (2007).

<sup>193</sup> For this reason, challenges to patent validity historically have been encouraged and patent licensors have been precluded from enforcing license conditions that would prohibit licensees from breaching their licenses to seek invalidation of patents. See, e.g., *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100–01 (1993); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Licensees in good standing may now bring declaratory challenges to patent validity. See 28 U.S.C. § 2201(a) (2007); *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 767, 777 (2007).

<sup>194</sup> See, e.g., 35 U.S.C. § 282 (2007); HOW TO GET A EUROPEAN PATENT: GUIDE FOR APPLICANTS pt. 1, ch. A. subch. IV, ¶ 15 (10th ed. 2004), available at [http://www.european-patent-office.org/legal/guiapp1/pdf/glen\\_net.pdf](http://www.european-patent-office.org/legal/guiapp1/pdf/glen_net.pdf) (a European patent “offers a high presumption of validity”); Draft Agreement on the Establishment of a European Patent Litigation System, art. 41(4), Feb. 16, 2004, available at [http://www.european-patent-office.org/epo/epla/pdf/agreement\\_draft.pdf](http://www.european-patent-office.org/epo/epla/pdf/agreement_draft.pdf) (“The Court of First Instance shall treat the European patent as valid unless its validity is contested by the defendant.”); Bruno Vandermeulen, *The Next Generation of Cross-Border Litigators*, 4/1/05 MG’G INTELL. PROP. 58, 2005 WLNR 8028901 (2005), available at [http://www.twobirds.com/English/publications/articles/Crossborder\\_patent\\_litigation\\_in\\_Belgium.cfm](http://www.twobirds.com/English/publications/articles/Crossborder_patent_litigation_in_Belgium.cfm) (discussing the June 12, 1990, *Improver/Remington* decision of the Antwerp court

should be entitled to the means to satisfy those burdens by developing the facts necessary to prove invalidity, including by conducting appropriate experiments with patented inventions.<sup>195</sup>

As already noted, patent holders have no legitimate interest in prohibiting or charging for experiments that would demonstrate invalidity of the granted patent. Nor are such experiments likely to significantly diminish any legitimate interests of patent holders when the results of the experiments do not demonstrate invalidity. Given the nature of such experiments, any additional benefits generated from the experiments may be wasted rather than retained by competitors, e.g., by disposing of a compound created in the course of testing a patented method, without the patent holder suffering any actual damage. Patent holders cannot reasonably seek to prohibit or to charge license fees for such experiments, if conducted in good faith with a reasonable basis to do so, at a time when the patent's validity is questionable. In any case, it would be much too difficult to disentangle the additional benefits to third parties that any such experiments might generate, or to determine whether a reasonable basis for specific experiments is lacking, to warrant granting patent holders the right to prohibit and charge fees for experiments intended to test validity.

Thus, the adverse effects on the patent holder from experiments to test validity will normally be negligible.<sup>196</sup> Such experiments do not aim to obtain the benefits of intended uses of the patented invention in the course of assessing validity, and those intended uses were necessarily sufficient to induce the creation and disclosure of the invention in return for any potential commercial returns that might result. Thus, any diminution of value to the patent holder resulting from experiments designed to test validity should not adversely affect

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of appeal to accept the *prima facie* validity of an issued patent that had been revoked by an EPO opposition, stayed pending appeal).

<sup>195</sup> See CHROCZIEL, *supra* note 163, at 174; BERNHARDT & KRASSER, *supra* note 169, at 574; Scharen, *supra* note 116, §§ 11.6, 11.8; SIMON WELTE, DER SCHUTZ VON PIONIERERFINDUNGEN 176 (1991); Freier, *supra* note 140, at 667; NIOKA, *supra* note 163, at 28; Schuster, *supra* note 129, at 38; Straus, *supra* note 144, at 311; Volker Vossius, *supra* note 144, at 116. See also Cook, *supra* note 33, at 168. In other relevant contexts, reverse engineering is not normally considered to violate intellectual property rights, although such reverse engineering presumes that the relevant object of study is legally acquired in the market. See, e.g., 17 U.S.C. § 1201(f) (2007) (excepting reverse engineering from legal prohibitions on circumventing of technological protection measures); UNIFORM TRADE SECRETS ACT § 1 cmt. (Nat'l Conference of Comm'rs on Uniform State Laws 1985), available at <http://www.law.upenn.edu/bll/ulc/finact99/1980s/utsa85.pdf> ("Proper means include: . . . Discovery by 'reverse engineering'").

<sup>196</sup> Again, the experimental use exception is not a de minimis exception. See *supra* note 1. But the lack of damages may affect interpretation of when the exception should apply.

the incentive scheme created by the patent system. Such experiments simply have little to do with the information disclosure and free riding problems that the patent system seeks to solve.<sup>197</sup>

iii. *Experiments Aimed at Improving Upon or Designing Around an Invention*

Experiments aimed at improving upon or designing around an existing invention promote technological progress and thus may support the utilitarian premises of the patent system by creating new solutions to known or newly identified problems.<sup>198</sup> Such experiments do not generate information that was known to and disclosed by the inventor. Rather, such experiments seek to generate new information, whether or not it leads to additional patentable inventions. If the new information would be separately patentable, the patent holder may wish to invest more in making the discovery itself. Although it is debatable whether it is more efficient to permit innovative efforts by all or to grant only the patent holder the right to conduct within-firm (or permit extra-firm) research, to avoid waste by duplicative inventive efforts, it is widely accepted that the patent system does not prohibit such third-party inventive efforts.<sup>199</sup>

The public interest in advancing technological progress through such experiments is likely to outweigh the conflicting interests in precluding them, such as any legitimate interests of patent holders in obtaining commercial rewards from licensing the experiments and any additional improvement inventions based on them, and the public interest in the incremental initial investment, invention, and disclosure that might be thereby generated by patent holders. Patent holders' legitimate interests should likely cover only the commercial

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<sup>197</sup> See generally Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005).

<sup>198</sup> See CHROCZIEL, *supra* note 163, at 174; KRASSER, *supra* note 167, at 813; NIIOKA, *supra* note 163, at 282; WELTE, *supra* note 195, at 176; Freier, *supra* note 140, at 667; Scharen, *supra* note 116, § 11.6; Straus, *supra* note 144, at 311; Volker Vossius, *supra* note 144, at 116; see also Cook, *supra* note 33, at 168.

<sup>199</sup> See, e.g., John F. Duffy, *Rethinking the Prospect Theory of Patents*, 71 U. CHI. L. REV. 439, 442–46, 501–03 (2004) (noting inconsistency of a prospect theory that the initial patent holder should control sequential research with the ability to develop improvements and with blocking patents, arguing that by limiting the ability to prevent competitive research to develop blocking patents the patent system provides incentives for further races to innovate within the scope of the initial patent grant, and discussing that “the patent laws of most nations affirmatively encourage improvers to continue prospecting within existing patent claims” through experimental use exceptions and compulsory licensing provisions). See generally Dan L. Burk, *Intellectual Property and the Firm*, 71 U. CHI. L. REV. 3 (2004).



exploitation of their inventions as disclosed and claimed.<sup>200</sup> The static incentives for investment, invention, and disclosure by the inventor are limited to the intended uses that inventors actually predict for their inventions (although a windfall or a shortfall may in fact result).<sup>201</sup> In theory, there may be dynamic incentives for greater investment, invention, and disclosure that result from the existence of legal protection for commercial rewards beyond what inventors predict for their claimed inventions. This is because the claims may apply to unexpected uses or may prevent experiments that would design around or otherwise improve the claimed invention. But it is unlikely that inventors rely on such “insurance” when investing, inventing, and disclosing inventions.<sup>202</sup> In any event, the existing patent system is premised on the ability to competitively improve the disclosed invention, as reflected in requirements for public disclosure of inventions and the ability to grant subservient patents to parties other than the holder of the dominant patent.<sup>203</sup>

Permitting experiments on disclosed patented inventions would least affect patent holders’ interests when the experiments generate subpatentable or patentable improvements that would not design around the claims, but would be subservient to them. If the improvement is subservient to the original claims, the patent holder may continue to derive commercial rents from non-experimental uses of the improvement.<sup>204</sup> If the improvement is also subpatentable, the patent holder will unilaterally control authorization (and thus commercial benefits) of any uses of the improvement; if patentable, the dominant patent holder will jointly control authorization and share in any resulting revenues.<sup>205</sup>

But even when improvements successfully design around patents, experiments on disclosed inventions should not lead to significant decreases in *legitimate* incentives of patent holders. As the U.S. Congress has recognized,

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<sup>200</sup> See, e.g., Sarnoff, *supra* note 171, at 1157 (discussing purported fairness-based protection under the doctrine of equivalents—originating in concerns over piracy or copying—for inventions that extend beyond what patent holders have claimed).

<sup>201</sup> See *id.* at 1206–07 (discussing static and dynamic incentives for disclosure in regard to the doctrine of equivalents).

<sup>202</sup> See *id.* at 1208–09 (discussing similar issues in regard to the doctrine of equivalents).

<sup>203</sup> Bruzzone, *supra* note 25, at 54–55; Eisenberg, *Proprietary Rights in Biotechnology Research*, *supra* note 84, at 219; Gottfried Freier, *Patentverletzung und Versuchsprivileg*, 1987 GRUR 664, 667; Steven J. Grossmann, *Experimental Use or Fair Use as a Defense to Patent Infringement*, 30 IDEA 243, 247 (1990).

<sup>204</sup> BGH July 11, 1995, 1996 NJW 782 (787) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (635–37).

<sup>205</sup> Scharen, *supra* note 116, §§ 9.75–9.81.

patent holders are not legally entitled to protect the commercial *value* of their patents from such competitive innovation (any more than any other business investment is provided with insurance against a decrease in its value).<sup>206</sup> Patent holders have no legitimate interest in preventing use of the information contained in the written disclosure for competitive innovation. Modern patent laws thus have required public disclosure of inventions no later than the date of issuance of the patent (and typically shortly after application), so that others may use the disclosure to innovate during (or even before) the patent term.<sup>207</sup> It is only legal doctrines regulating the sufficiency of the required disclosures<sup>208</sup> that force improvers to resort to physical use of the invention to discover the additional information about the patented invention needed to develop such improvements. If thought alone were required to improve on the disclosure, the patent holder could not prevent or license the experimentation, and the experimental use exception would be unnecessary.

Even if the effects on patent holders' legitimate interests from improvements and design-arounds were significant, however, there are good reasons to impose such effects for public benefit.<sup>209</sup> It is socially desirable to enable parties in addition to the inventor (or assignee) to engage in the time-consuming and intricate process of turning a patentable innovation into a product ripe for sale to consumers.<sup>210</sup> And, as already noted, where the eventual commercialization of any improvement depends on a license from the original

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<sup>206</sup> See H.R. REP. NO. 98-857, pt. 1, at 46 (1984) ("It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent."); H.R. REP. NO. 98-857, pt. 2, at 8 (1984) (noting that the use authorized during the patent term "retains [to the patent holder only] the right to exclude others from the major commercial marketplace during the life of the patent").

<sup>207</sup> See, e.g., Eisenberg, *Patents and the Progress of Science*, *supra* note 25, at 1022; cf. H.R. REP. NO. 101-960, pt. 1, at 41–43 (1990) (discussing the "research exception" and noting that "[t]he framers of the Constitution clearly could not have envisioned shutting the door to further research for the long period of the patent grant." (citation omitted)).

<sup>208</sup> These doctrines include definiteness, written description, enablement, and best mode disclosure doctrines. See 35 U.S.C. § 112(1) (2007); Mark J. Stewart, Note, *The Written Description Requirement of 35 U.S.C. § 112(1): The Standard After Regents of the University of California v. Eli Lilly & Co.*, 32 IND. L. REV. 537, 562 (1999) (prophetic claiming may allow the "inventor to claim more than he has actually invented" and may block subsequent research).

<sup>209</sup> F. M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 446–47 (2d ed. 1980) (discussing the relative advantages of rivalrous competition in research, rejecting prospect theories); Merges & Nelson, *supra* note 184, at 872 (same).

<sup>210</sup> See, e.g., Barton, *supra* note 110, at 454–56; Michel, *supra* note 25, at 391.

inventor, the improvement will add to the value of the original patent, as the German Federal Court of Justice concluded in *Clinical Trials I*.<sup>211</sup>

In Europe, follow-on research is permissible without regard to whether the subject matter of a patent is a product or a process. For example, trials conducted to seek new possible medical indications of a patented pharmaceutical compound or to further investigate the behavior of that compound for the known and disclosed indication are excepted from infringement.<sup>212</sup> This is true even though patents on products generally provide disputed “absolute protection”<sup>213</sup> against uses that are wholly unrelated to the disclosed and intended uses (e.g., making and using a patented paper coffee holder as a doorstop).<sup>214</sup> The German

<sup>211</sup> BGH July 11, 1995, 1996 NJW 782 (787) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (643–45); BVerfG Oct. 5, 2000, 2001 NJW 1783 (1786) (*Clinical Trials*).

<sup>212</sup> BGH Apr. 17, 1997, 1997 NJW 3092 (3094–96) (*Clinical Trials II*), translated in [1998] R.P.C. 423 (431–38); Scharen, *supra* note 116, §§ 11.6, 11.8.

<sup>213</sup> See H. Ulrich Dörries, *Patentansprüche auf DNA-Sequenzen: ein Hindernis für die Forschung? Anmerkungen zum Regierungsentwurf für ein Gesetz zur Umsetzung der Richtlinie 98/44/EG*, 2001 MITT. 15, 16; Bernd Hansen, *Hände weg vom absoluten Stoffschutz – auch bei DNA-Sequenzen*, 2001 MITT. 477, 479–93; Henrik Holzapfel & Michael Schneider, *Wem gehört das menschliche Genom?*, 2001 GRUR INT'L. 860, 862; Uta Köster, *Absoluter oder auf die Funktion eingeschränkter Stoffschutz im Rahmen von "Biotech"-Erfindungen, insbesondere bei Gen-Patenten*, 2002 GRUR 833, 834–44; Jan Krauß, *Die richtlinienkonforme Auslegung der Begriffe "Verwendung" und [zu] "Funktion" bei Sequenzpatenten und deren Effekte auf die Praxis*, 2001 MITT. 396, 397–400; Niclas Kunczik, *Die Legitimation des Patentsystems im Lichte biotechnologischer Erfindungen*, 2003 GRUR 845, 849; Michael Nieder, *Die gewerbliche Anwendbarkeit der Sequenz oder Teilsequenz eines Gens – Teil der Beschreibung oder notwendiges Anspruchsmerkmal von EST-Patenten?*, 2001 MITT. 97, 98; Michael Nieder, *Gensequenz und Funktion – Bemerkungen zur Begründung des Regierungsentwurfs für ein Gesetz zur Umsetzung der Richtlinie 98/44/EG*, 2001 MITT. 238, 238–39; Lutz van Raden & Dorothea von Renesse, *"Überbelohnung" – Anmerkungen zum Stoffschutz für biotechnologische Erfindungen*, 2002 GRUR 393, 393–403; Margot von Renesse et al., *Das Biopatent – eine Herausforderung an die rechtsethische Reflexion*, 2001 MITT. 1, 3–4; Joseph Straus, *Produktpatente auf DNA-Sequenzen – Eine aktuelle Herausforderung des Patentrechts*, 2001 GRUR 1016, 1018–21; Alan W. White, *Gene and Compound Per Se Claims: An Appropriate Reward?*, 6 BIO-SCI. L. REV. 239, 240 (2000–2001).

<sup>214</sup> The exclusion for all uses of products, and not just for disclosed uses, has a long history in the United States. It originated at a time when patent disclosure requirements were minimal, patents for disembodied processes were suspect (as invalid subject matter as well as for overbreadth), and patents were not permitted for new uses of patented products (as the “principle” of an invention was inherent in that invention and thus the application of a machine to a new use was not considered to be the discovery of a new patentable principle). See, e.g., Act of February 21, 1793, ch. XI, § 2, 1 Stat. 318, 321 (“simply changing the form or the proportions . . . in any degree, shall not be deemed a discovery”); *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112–13 (1853); *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356, 431 (1822); *Howe v. Abbott*, 12 F. Cas. 656, 657–58 (C.C.D. Mass. 1842); *Wyeth v. Stone*, 30 F. Cas. 723, 727

Federal Court of Justice based its decision in the *Clinical Trials* cases to except from infringement experiments addressing new uses of products on a literal distinction between the “subject-matter of a patent”—which in the case of a product patent did not encompass the usability of the product—and the “subject-matter of the patented invention” (as addressed in Article 27(b) of the CPC of 1989)—which in the case of a product patent did include the uses of the product.<sup>215</sup> It is possible that other European courts would have taken a stricter line, namely that, to be excepted, the experiment had to be on the product rather than on its use. This is now unlikely since the two *Clinical Trials* rulings represent the most detailed considerations by senior European courts of the scope of the experimental use exception and will be of considerable persuasive authority in any future European cases.

We support this result, but not the reasoning of the German Federal Court of Justice.<sup>216</sup> The decision creates a too subtle distinction between the subject matter of a “patent” and the subject matter of a “patented invention” that was not suggested by the language of the CPC. It also places undue emphasis on the extent of the disclosure and conflicts with the developed understanding in patent law that the invention is precisely what the patent claims.<sup>217</sup> As a historical matter, however, the *Clinical Trials* decisions correctly reflect that the CPC’s exception for experimental purposes was aimed at tests carried out to verify the usability of and possible advancements to inventions (as reflected in the examples provided in the Memorandum on the Convention<sup>218</sup>). The Memorandum does not hint at restricting the safe harbor of the experimental use exception only to process patents.<sup>219</sup>

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(C.C.D. Mass. 1840); *Evans v. Eaton*, 8 F. Cas. 846, 852 (C.C.D. Pa. 1816), *rev'd on other grounds*, 16 U.S. (3 Wheat.) 454 (1818). Although the prohibition on patenting new uses was ultimately eliminated, no similar change was made to the exclusive right so as to prohibit only disclosed uses.

<sup>215</sup> CPC, *supra* note 15, art. 27(b); *Clinical Trials I*, 1996 NJW at 787, [1997] R.P.C. at 644; *Clinical Trials II*, 1997 NJW at 3095–96, [1998] R.P.C. at 431–32 (clarification of effects within known indication). See generally HEINZ GODDAR, THE EXPERIMENTAL USE EXCEPTION: A EUROPEAN PERSPECTIVE 12 (2001), available at <http://www.law.washington.edu/casrip/Symposium/Number7/1-Goddar.pdf>.

<sup>216</sup> The authors also question the wisdom of continuing to grant exclusive rights over uses that are not disclosed, but that issue is beyond the scope of this paper.

<sup>217</sup> EPC, *supra* note 117, art. 69; Das deutsche Patentgesetz [German Patents Act] § 14, available at <http://www.gesetze-im-internet.de/patg/index.html>; Scharen, *supra* note 116, § 14.5.

<sup>218</sup> Memorandum, *supra* note 145, at 333.

<sup>219</sup> *Id.*

The purposive interpretation discussed above supports an exception to infringement for experiments aimed at discovering new indications of known products, including but not limited to drug agents. Such experiments advance the public interest by facilitating the discovery of new diagnostic or therapeutic applications<sup>220</sup> while preserving largely intact the legitimate interests of patent holders. Possible new indications may not be commercialized by third parties without a license granted by the respective product patent holder (when the patent is for the active compound), as the court accurately observed.<sup>221</sup> The discovery of new applications thus ultimately will increase the value of a dominant product patent.

### 5. Interpretation in View of TRIPS Agreement

All EC member states, as well as the EC itself, are contracting parties of the TRIPS Agreement. According to Article XVI (4) of the Agreement establishing the WTO and Article 1(1) of the TRIPS Agreement,<sup>222</sup> each member state must conform its laws to the requirements of the TRIPS Agreement, but is neither obliged nor forbidden to adopt more extensive protections than are required by the Agreement. Assuming that the exclusive rights under Article 28(1)<sup>223</sup> apply to acts of scientific experimentation, experimental use exceptions in national European patent laws and in a forthcoming European Council Regulation on the Community Patent must comply with the scope of exceptions to patent rights authorized by Article 30 of the TRIPS Agreement. We analyze below the application of Article 30, although arguments exist for treating experimental use exceptions as not conflicting with the Article 28(1) requirements, so that experimental use exceptions do not require justification under Article 30.<sup>224</sup>

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<sup>220</sup> EPC, *supra* note 117, art. 52(4), excludes from patentability methods of surgery and therapy, and diagnostic methods “practised on the human or animal body,” by treating them as not susceptible of industrial application. See Case G 0001/04, Opinion of the Enlarged Board of Appeal of the European Patent Office, (Dec. 16, 2005), available at <http://legal.european-patent-office.org/dg3/biblio/g040001ex1.htm> (discussing the proper construction of such practice).

<sup>221</sup> BGH Apr. 17, 1997, 1997 NJW 3092 (3096) (*Clinical Trials II*), translated in [1998] R.P.C. 423 (438); BGH July 11, 1995, 1996 NJW 782 (787) (*Clinical Trials I*), translated in [1997] R.P.C. 623 (644).

<sup>222</sup> TRIPS, *supra* note 27, art. 1(1).

<sup>223</sup> TRIPS Article 28(1) provides that a patent “shall confer on its owner the following exclusive rights,” including making and using without expressing any reservation or limitation.

<sup>224</sup> Given that experimental use exceptions were common in 1994, it is uncertain whether the drafters of the TRIPS Agreement would have thought it necessary to justify them under Arti-

In *Canada—Patent Protection of Pharmaceutical Products*, Article 30 was interpreted to permit a codified Canadian regulatory approval exception for pharmaceuticals similar to that in the United States as discussed above.<sup>225</sup> The ruling strongly suggests that the European experimental use exceptions would comply with TRIPS Article 30 requirements.<sup>226</sup> Article 30 states that “[m]embers may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”<sup>227</sup>

The WTO panel ruled that former § 55.2 of the Canadian Patent Act met the terms of Article 30 of TRIPS.<sup>228</sup> Section 55.2 provided, inter alia, that:

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cle 30. *See* Vienna Convention on the Law of Treaties art. 32, May 23, 1969, 1157 U.N.T.S. 331 (“Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion . . . to determine the meaning when the interpretation according to article 31: (a) [l]eaves the meaning ambiguous or obscure.”). An earlier draft of the TRIPS Agreement contained more expansive authority to adopt exclusions, placing in brackets similar language regarding the balancing of patent holder and third-party interests and listing exemplary categories of permissible exceptions, including “Acts done for experimental purposes” and “Acts done privately and for non-commercial purposes.” *See* DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 241 (2d ed. 2003) (quoting the Draft of July 23, 1990). Including experimental uses in the list of exceptions could be understood either to clarify the scope of required rights or to create agreed exemptions thereto. *Cf. supra* text accompanying notes 1, 38, 47 (discussing whether experimental use defines the limits of prohibited conduct or creates an exemption thereto). The final Agreement adopted a more general exception authority and the balancing language of Article 30. Nevertheless, it is uncertain whether parties would have thought acts done “for experimental purposes” were to be included within the required “uses” under Article 28(1), and thus would require justification through balancing analysis under Article 30.

<sup>225</sup> *See* 35 U.S.C. § 271(e) (2007); Patent Act, R.S.C., ch. P-4, § 55.2(1) (1985) (Can.) available at <http://laws.justice.gc.ca/en/P-4/index.html>; Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) (adopted Apr. 7, 2000) [hereinafter WTO Panel Report], available at [http://www.wto.org/english/tratop\\_e/dispu\\_e/7428d.pdf](http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf).

<sup>226</sup> Notwithstanding the historic existence of regulatory approval exceptions, the Panel Report analyzed Article 30 and suggested that the Article 28(1) exclusive rights facially extend to this kind of experimentation. *See* WTO Panel Report *supra* note 225, ¶ 7.39 (noting arguments of the parties to the dispute that meeting the conditions of Article 30 would mean the Canadian exception “would not be in violation of Article 28.1”). The reasoning of the decision, discussed below, suggests that most experimental use exceptions would be consistent with Article 30, although the decision itself expressly drew “no conclusion about the correctness of any such national exceptions.” *Id.* ¶ 7.69.

<sup>227</sup> TRIPS, *supra* note 27, art. 30.

<sup>228</sup> WTO Panel Report, *supra* note 225.

(1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

...

(6) For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.<sup>229</sup>

According to the WTO panel, Article 30 of TRIPS requires exceptions to patent rights to meet requirements similar to the “three step test” that applies under Article 9 (2) of the Berne Convention<sup>230</sup> in relation to exceptions to copyright law. These exceptions are: 1) to be limited; 2) not to provide unreasonable conflict with normal exploitation of the patent; and 3) not to unreasonably prejudice “the legitimate interests of third parties.”<sup>231</sup> Although these criteria are not precise, the WTO panel provided significant interpretations of the three Article 30 factors.<sup>232</sup> The panel also placed the interpretation in a historical context that made clear that the parties to the TRIPS Agreement did not intend to prohibit regulatory approval exceptions that already existed under national laws.<sup>233</sup>

The § 55.2(1) exception was found limited, because “[a]s long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded.”<sup>234</sup> “Normal exploitation” was interpreted to have both an empirical and a normative conno-

<sup>229</sup> Patent Act, R.S.C., ch. P-4, § 55.2 (1985) (Can.). The dispute settlement procedure did not address the private, non-commercial or subject matter experimentation exceptions of Section 55.2(6) of Canadian Patent Act. See generally 35 U.S.C. § 271(e) (2007); WTO Panel Report *supra* note 225.

<sup>230</sup> Berne Convention for the Protection of Literary and Artistic Works, art. 9, Sept. 9, 1886, revised July 24, 1971, 25 U.S.T. 1341, 1161 U.N.T.S. 3 available at [http://www.wipo.int/treaties/en/ip/berne/trtdocs\\_wo001.html](http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html).

<sup>231</sup> See WTO Panel Report, *supra* note 225, ¶¶ 7.71–7.72.

<sup>232</sup> *Id.* ¶ 7.41.

<sup>233</sup> See *id.* ¶ 7.41. Although this historical context would have foreclosed a broad interpretation of Article 28(1) in regard to such experiments without resort to Article 30, the Panel Report nevertheless further justified these exceptions under Article 30.

<sup>234</sup> *Id.* ¶ 7.45.

tation that excluded “all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.”<sup>235</sup> However, it did not include such returns that are not “a natural or normal consequence of enforcing patent rights.”<sup>236</sup> “Unreasonably prejudice” and “legitimate interests” involved distinct requirements. Legitimate interests were interpreted as distinct from a “legal interest” and instead as “a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.”<sup>237</sup> The panel also held that the desire for equal treatment regarding an effective patent term was not a “legitimate interest,” as many countries (including Canada) did not recognize such a requirement to adopt term extension provisions.<sup>238</sup> The ruling that § 55.2 was consistent with Article 30 was substantiated by the consideration that normal exploitation of the patent was not impaired by a regulatory approval exception; only competition after expiration of the patent was spurred by enabling immediate market access for competitors.<sup>239</sup>

Given the holding of the WTO panel ruling, the experimental use exception in European patent law appears to be fully consistent with Article 30 of TRIPS. Article 27(b) of the CPC of 1989 is limited in the sense that it covers only a small quantity of possible uses of the patented invention, for which the patent holder is unlikely to obtain significant commercial reward, for example, experiments that are for private or non-commercial uses or that relate to the subject matter of the used invention. Similarly, there should be no unreasonable conflict with normal exploitation of the patent. It is at least arguable that the right to exclude does not include as a natural or normal consequence the ability to exclude such experiments. The purposive interpretation discussed above supports this normative analysis.

Finally, the exceptions should not prejudice any *legitimate* interest of patent holders on the normative grounds discussed above that the patent system seeks to permit further experimentation beyond the patent’s disclosure during its term. Although the negotiating parties to the TRIPS Agreement failed to agree on limits to exceptions to patent rights,<sup>240</sup> they would not have intended to pre-

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<sup>235</sup> *Id.* ¶¶ 7.54, 7.55, 7.57.

<sup>236</sup> *Id.* ¶¶ 7.54, 7.55, 7.57.

<sup>237</sup> *Id.* ¶ 7.69.

<sup>238</sup> *Id.* ¶ 7.82.

<sup>239</sup> The Panel Report did not treat potential lost licensing revenue during the patent term as impairing normal exploitation, likely because few pioneering pharmaceutical patent holders willingly license to generic competitors.

<sup>240</sup> *See, e.g.,* GERVAIS, *supra* note 224, at 241 (noting interpretive ambiguity and potential differences from Berne Article 9(2)).



clude well-established exceptions (as the Panel held in *Canada—Patent Protection of Pharmaceutical Products*). Consequently, neither regulatory approval exceptions nor experimental use exceptions like Article 27(b) of the CPC of 1989 should violate TRIPS.

### ***C. Access to Research Tools Under the European Experimental Use Exceptions***

As noted above, the status of research tools under U.S. patent law's experimental use and regulatory approval exceptions are highly uncertain, although the language of the regulatory approval exception is categorical and would appear to apply to all patented inventions used in the course of excepted experiments.<sup>241</sup> Unlike in the U.S., the analysis of the history and purpose of the European experimental use exceptions suggests that use of patented inventions as research tools is not generally excepted from infringement (except, e.g., under the new Belgian experimental use exception, which explicitly applies to research with patented inventions).

#### **1. The Experimental Use Exceptions in European Patent Laws Likely Do Not Cover Research Tool Uses**

The wording of Article 31(b) of the CPC of 1975 (Article 27(b) of the CPC of 1989) requires excepted experiments to relate to the subject matter of the invention used,<sup>242</sup> which as discussed above should (for the most part) be limited to experiments to assess validity or to design improvements.<sup>243</sup> Also as discussed above, the memorandum of understanding of the parties to the CPC suggests that the use of a patented invention to acquire information on something different from the patented invention shall not be excepted from patent

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<sup>241</sup> See *supra* text accompanying notes 9–14, 77–80.

<sup>242</sup> CPC, *supra* note 15.

<sup>243</sup> Drawing lines between these categories and use as a research tool may be problematic. For one example, experiments to assess the validity of generic claims (by evaluating claim breadth, adequacy of description, and enablement) may result in identifying new species within and outside the scope of the claims. *Cf. supra* notes 144–58. For another example, experiments to determine new uses (including medical indications) are likely considered research on the invention, even though the patented invention is used in research to develop wholly new applications. *Cf. supra* notes 213–15 and accompanying text.

infringement.<sup>244</sup> Similarly, the memorandum provides that the exception be interpreted “restrictively,” whereas applying the exception to research tool use would interpret the “subject-matter of the invention” expansively.<sup>245</sup> To effectuate the parties’ intent, any use of a patented invention solely as a research tool should be treated as an actionable infringement that is not covered by the CPC experimental use exception (and related domestic exceptions), whether the patented invention is a biochemical compound (such as PCR polymerase) or a mechanical device (such as a DNA sequencer). In principle, the use of a research tool is an experiment “with” this invention, not “on” the subject matter of the invention.<sup>246</sup>

From a purposive standpoint, it is more questionable whether the CPC experimental use exception should apply to at least some research tool uses, regardless of how research tools are defined. As noted above, patent holders’ interests should likely cover only the commercial exploitation of their inventions as disclosed and claimed.<sup>247</sup> Use of a patented invention as a research tool that was neither expected nor disclosed should not materially detract from the patent holder’s ex ante incentives for invention and disclosure,<sup>248</sup> and such use is less likely to be commercially significant.

In contrast, and unlike the case of experiments to improve on the patented invention, the commercial rewards from research markets for patented inventions intended as research tools are not incidental to patent holder expectations, and are more likely to be significant. Although substantial public benefits may result from unauthorized uses of patented inventions as research tools (particularly when the patent holder is unwilling to make the invention available or to supply it on reasonable terms), an exception to infringement may significantly reduce expected returns for such inventions. In part, this will depend on whether research tool use is excepted from *all* exclusive patent rights (permit-

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<sup>244</sup> Memorandum, *supra* note 145, at 333. Context is important to this interpretation. Unlike for experimental uses designed to test validity or to design improvements, there was no contemporaneous history of prior decisions in the member countries excluding research tool uses from exclusive patent rights (or finding them to be within those rights).

<sup>245</sup> See *supra* Parts III.B.1.ii & III.B.2.

<sup>246</sup> See Cornish, *supra* note 115, at 738; Scharen, *supra* note 116, § 11.7; Joseph Straus, *Patenting Genes and Gene Therapy: Legal and Ethical Aspects*, in FROM GENOME TO THERAPY: INTEGRATING NEW TECHNOLOGIES WITH DRUG DEVELOPMENT 119 (Gregory R. Bock et al. eds., 2000); White, *supra* note 144, at 138. Unintentional or incidental research with a patented invention during experiments reasonably objectively calculated to assess validity or to develop substitutes should not be considered use as a research tool.

<sup>247</sup> See *supra* note 200 and accompanying text.

<sup>248</sup> See *supra* notes 181–83 and accompanying text.

ting commercial competition in supplying the invention for research tool use) or only from making and using rights (permitting researchers to make and use the invention). Many commentators have suggested that excepting research tool use from patent rights will lead to significant decreases in incentives for initial invention or disclosure of research tools.<sup>249</sup> However, these analyses do not evaluate non-market incentives for producing research tools or whether researchers would preferentially purchase research tools rather than make them themselves (to avoid the time and costs of production or to obtain benefits of standardized production).<sup>250</sup> Thus, whether such revenue losses will be significant may vary dramatically with the nature of the invention and with commercial and scientific practices.<sup>251</sup> Additional empirical analysis is needed to determine whether such revenue losses would be significant, how they would affect incentives for inventing and disclosing research tools, and whether these effects would outweigh the public benefits of unauthorized uses.

Assuming that substantial revenue losses would occur, there may be no other intended markets in which a patent holder would expect to obtain commercial rewards from inventions intended to function as research tools. Further, one person's research tool may be another person's end product, and the use of the research tool (such as a genetic sequencing device) for its intended purpose

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<sup>249</sup> Cf. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 875–76 (Fed. Cir. 2003) (Newman, J., dissenting) (noting the need to provide “primary consideration” to initial inventors and distinguishing excepted research from infringing commercial development).

<sup>250</sup> See, e.g., Brief for *Amici Curiae* Consumer Project on Technology, Electronic Frontier Foundation and Public Knowledge in Support of Petitioner, *supra* note 13, at 29 n.21; Katherine Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 78 COLO. L. REV. (forthcoming 2008) (discussing “user innovators” of research tools, including commercial firms, that do not need patent incentives to invent and who freely reveal their inventions, and reviewing empirical literature to conclude that “while researchers are usually not professional sellers of research tools, they are effectively professional inventors of research tools and methods for their own use and fit naturally into the user innovator paradigm”).

<sup>251</sup> See Strandburg, *supra* note 250, at 4–5 & n.9 (noting that “empirical studies show that a large fraction of research tool inventions are made by researchers for their own use”) (citing William Riggs & Eric von Hippel, *Incentives to Innovate and the Sources of Innovation: The Case of Scientific Instruments*, 23 RES. POL'Y 459 (1994)); see also Strandburg, *supra* note 250 at 11–14 (noting that user innovations are motivated to invent where the use value exceeds development costs without regard to copying by others, that such innovations are much less likely to need patent rights for dissemination given the relatively low costs of commercial development, and that user innovators form communities that exchange ideas with lower transaction costs than by licensing); cf. *id.* at 4 & n.7 (discussing university and open source contexts where sales are not needed to motivate innovation and thus patents impose avoidable social costs).

would exploit the disclosed benefits of the invention.<sup>252</sup> In such cases, patent holders may view the ability to exclude research tool uses as a requirement of basic fairness, and excepting research tool uses may have significant effects on their ex ante invention and disclosure incentives.

As a normative matter, it is uncertain whether the countries drafting the CPC or implementing the CPC provisions in national experimental use exceptions would have viewed the benefits of excepting research tool uses under the experimental use exception as outweighing these public incentive and private fairness interests. As a matter of legislative intent, however, we believe it is unlikely that the drafters of the CPC in 1975 or in 1989 would have intended to codify an exception applying to research tool use without saying something about the issue. This is particularly true given the restrictive language of the exception. Nevertheless, others have reached the opposite conclusion.<sup>253</sup>

Further, assuming that the grant of exclusive patent rights extended to research tool uses, adopting a *retrospective* exception from infringement liability under the CPC's experimental use exception could (at the time) have raised constitutional concerns. Given that research is likely to be the primary market for inventions intended to be used as research tools, excepting research tool uses entirely from patent infringement might, in rare cases, result in deprivation of the entire value of the property (through commercial competition) and would effectively require patent holders to subsidize third parties' research programs for public benefit.<sup>254</sup> Such an exceptional sacrifice might trigger concerns regarding the guaranty of equality according to Article 3 German Basic Constitutional Law,<sup>255</sup> as well as regarding the guarantee of property according to Arti-

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<sup>252</sup> See ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (ED.), GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES 59 (2002); Ducor, *supra* note 10, at 1027.

<sup>253</sup> E.g., GUIDE TO THE PATENTS ACT, *supra* note 132, § 60.13, suggests that research tool use is excepted under Article 27(a) of the CPC of 1989.

<sup>254</sup> See DAVID GILAT, EXPERIMENTAL USE AND PATENTS 18, 40, 80 (1995).

<sup>255</sup> (1) All persons shall be equal before the law.

(2) Men and women shall have equal rights. The state shall promote the actual implementation of equal rights for women and men and take steps to eliminate disadvantages that now exist.

(3) No person shall be favored or disfavored because of sex, parentage, race, language, homeland and origin, faith, or religious or political opinions. No person shall be disfavored because of disability.

GG art. 3, *translated at* [http://www.bundestag.de/htdocs\\_e/parliament/function/legal/germanbasiclaw.pdf](http://www.bundestag.de/htdocs_e/parliament/function/legal/germanbasiclaw.pdf). According to the principle of equality of burden, laws must not impose the burden of public duties that have to be fulfilled by society as a whole (like facilitation of

cle 14 German Basic Constitutional Law.<sup>256</sup> As the CPC does not distinguish prospective from retrospective application, the constitutional concerns add some additional force to the argument that the CPC's experimental use exception was not intended to apply to research tool uses.<sup>257</sup>

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future progress) only on a fraction of society (like research tool patent holders). This could constitute an inadmissible exceptional sacrifice. Cf. FECHNER, *supra* note 174, at 218–29; MAURER, *supra* note 174, § 26.38; Bryde, *supra* note 174, § 14.64a; Papier, *supra* note 174, § 14.342. To the extent that patent rights are not constitutionally required to be granted, however, these constitutional concerns may have little current force. For most issued patents, such burden-sharing is a prospective, legislative condition of the initial grant of patent rights. Cf. *Lingle v. Chevron U.S.A., Inc.*, 544 U.S. 528, 547 (2005) (discussing the “unconstitutional conditions” doctrine that sometimes prohibits conditioning receipt of discretionary government benefits on foregoing constitutional rights).

<sup>256</sup> See GG art. 14. According to the guaranty of property, laws regulating property rights must not restrict freedom of property unduly relative to the public interests that are addressed by the respective restriction. In particular, restrictions need special justification if they do not provide compensation for the owner, and restrictions are inadmissible that altogether remove the owner's right of disposal of his property. It has been held unconstitutional to allow third parties to publish works enjoying copyright protection in school books without compensating the respective author, BVerfG July 7, 1971, 31 BVerfGE 229 (240), or to play music under copyright protection at church events without compensation of the respective composer. BVerfG Oct. 25, 1978, 49 BVerfGE 382 (392). See FECHNER, *supra* note 174, at 165–74; PHILIPP MÖHRING ET AL., URHEBERRECHTSGESETZ 16, 53 (2d ed. 2000); MANFRED REHBINDER, URHEBERRECHT 85, 110 (11th ed. 2001); HAIMO SCHACK, URHEBER- UND URHEBERVERTRAGSRECHT 84 (2d ed. 2001); Bryde, *supra* note 174, § 14.59; Ferdinand Melichar, in GERHARD SCHRICKER ET AL., URHEBERRECHT §§ 45 n.1, 8 (2d ed. 1999); Wendt, *supra* note 174, § 14.54.

<sup>257</sup> A discussion of the nature of the legislative grant of exclusive patent rights and the potential for unconstitutional regulatory taking of property under European or United States law is beyond the scope of this article. However, treating patents as property does not necessarily require constitutional protection by compensation for modification or termination of that property. See, e.g., *Bowen v. Gilliard*, 483 U.S. 587, 604, 608 (1987) (“Congress is not, by virtue of having instituted a social welfare program, bound to continue it at all, much less at the same benefit level. . . . This is by no means an enactment that forces ‘some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole.’” (citation omitted)); *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 413 (1922) (“Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law.”). See generally Davida H. Isaacs, *Not All Property Is Created Equal: Why Modern Courts Resist Applying the Takings Clause to Patents, and Why They Are Right to Do So*, 15 GEO. MASON L. REV. 1 (2007) (noting difficulties of determining whether takings exist—including application of the “entire market value” rule—and arguing that patents are federal entitlements protected under the Due Process Clause but not the Takings Clause of the U.S. Constitution). But cf. Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689 (2007) (discussing historic treatment of patents as property protected from government infringement under the Takings Clause).

It is also unlikely that the national governments implementing the CPC provisions would have chosen to impose experimental use restrictions on patented research tools as a matter of patent policy. The patent system has always been characterized by imposing some short-term costs on the public, in exchange for temporary exclusive rewards to patent holders that provide the incentive for initial investment, invention, and disclosure that benefits the public. Again, assuming that research tool use was within the initial grant of rights to patent holders, shifting this presumptive balance would have generated significant discussions. Given the language of the CPC's experimental use provisions and the direction to interpret it restrictively, it is unlikely that any such decision was made.

## 2. How to Deal with Borderline Cases Between Research On and Research With Under Article 27(b) of the CPC of 1989

Experimental use exceptions modeled on Article 27(b) of the CPC of 1989 encounter difficulties of application with regard to certain kinds of biotechnological research tools. Intriguing borderline scenarios are posed,<sup>258</sup> making the task of policing these borders difficult under the rubric of whether they “relat[e] to the subject-matter of the patented invention.”<sup>259</sup>

### *i. Specific Compounds and Intended Purposes*

Consider the case of the use of a receptor that is patented for the purposes of screening small molecules as potential ligands. Such experiments will relate to the subject matter of the invention in the sense of Article 27(b) of the CPC of 1989, as the experiments are intended to generate knowledge about the receptor and its molecular interactions with small molecules. If the focus is on binding properties of the small molecules, however, the experiments can also be characterized as research with the patented receptor that uses the disclosed features of the invention to investigate the interactive properties of various small molecules. Because the information resulting from the experiments relates to the mutual interaction of both of the molecules studied, it cannot be disaggre-

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<sup>258</sup> Some of the scenarios discussed below were first discussed by U.K. Barrister Michael Tappin in a speech given in 2002. Another approach to distinguishing research *on* from research *with* relates to whether additional information on the patented invention would avoid the need to use the invention in the experiment. See Strandburg, *supra* note 147, at 151–52.

<sup>259</sup> CPC, *supra* note 15, art. 27(b).

gated into research on or research with—any more than unlocking a door can occur with only the lock or only the key. It is the combination that matters. In such combination situations, the experiments could be considered excepted from patent infringement, notwithstanding that the exception under Article 27(b) of the CPC of 1989 is to be interpreted restrictively.<sup>260</sup>

Similarly, mutagenesis experiments using a patented protein having a disclosed therapeutic use to identify analogues with higher activity (where no such derivatives or analogues with higher activity were disclosed, even if they were claimed generically) could qualify for the experimental use exception. Such experiments aim at learning which areas of amino acids in the protein are responsible for the therapeutic activity, even though new and better proteins may be the ultimate (and commercially profitable) goal. Such experiments do generate new information about the patented protein, and thus would qualify under Article 27(b) of the CPC of 1989. The same would be true for subsequent comparative studies between the original protein and any analogues discovered from such mutagenesis experiments,<sup>261</sup> as the comparative function of the original protein would be assessed.<sup>262</sup> Any such experiments would not affect the ability of the patent holder to obtain commercial rewards of exploiting the protein patent, even though the experiments might lead to improvements that were not subservient to the protein patent and that might compete for such rewards during the patent term.

Of course, it is possible to adopt alternative approaches that would require distinguishing combination experiments based on the primary purpose of conducting the experiments or on the manner in which the inventive teachings of the disclosure are employed. The primary purpose approach would permit a patent holder to be rewarded for the invention and disclosure of the research tool

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<sup>260</sup> Compare Bernhard Fischer, *Reach-Through and Experimental Use*, in *MANAGING INTELLECTUAL PROPERTY, IP STRATEGY YEARBOOK 2001*, at 9, 11 (2001) (commenting on Great Britain's Court of Appeal *Monsanto v. Stauffer Chemical Co.* decision and on the German Federal Supreme Court *Clinical Trials I* decision), with White, *supra* note 144, at 139 (commenting on the applicability of the experimental use exception to research tools).

<sup>261</sup> If the analogues had been claimed, there could be no question that the comparative studies would relate to the subject matter of the invention. But the ability of third parties to experiment to identify the comparative properties of the broad original invention should not depend on how far the original inventor had developed the subject matter, or whether the further developments had been disclosed and claimed.

<sup>262</sup> See Véron, *supra* note 153 (reporting an unpublished decision, CA Paris, Jan. 27, 1999, that exempted trials comparing alternative galenic formulations of a patented drug).

in a greater number of experiments.<sup>263</sup> This approach can be problematic, however, as such characterizations can be highly subjective.<sup>264</sup>

Similarly, the inventive teaching approach is problematic, given that patents grant the right to exclude from all uses, including those that are not disclosed. Product patents will apply to all experiments employing the product, regardless of the teaching, but for the experimental use exception. Distinguishing whether the experiment exploits the teaching of the invention may be complicated, and may require revisiting complex doctrinal decisions regarding the permissible scope of patent claims, enablement, and the degree of development of disclosed utility. For example, a patent for a new protein sequence that is disclosed as intended to be used to screen for viral attachment might not teach screening for bacterial attachment, even though broad generic claims were drafted (for microorganisms) that would apply to experimental use of the receptor in screening for bacterial attachment. Conversely, excessively narrow claims should not unduly restrict the teaching of the patent so as to bring the experiments outside the scope of the exception, such as when a protein is claimed for its therapeutic effects and research is performed to discover the receptor involved in the protein's mechanism of action.<sup>265</sup> Thus, further refinement of the experimental use exception as applied to such multi-purpose experiments may not be justified.

In any event, the experimental use exception should continue to apply when the patent claims research intermediates<sup>266</sup> or includes subsidiary technologies that have no separate inventive teaching from the primary claims. For example, a patent may claim a protein and the DNA sequence for producing the protein, and the experimenter may need to use the claimed DNA sequence in the manner intended in the patent (without learning anything) to produce the protein so as to experiment with the protein. Without any independent teaching or dis-

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<sup>263</sup> See Feuerlein, *supra* note 144, at 565; Holzapfel, *supra* note 175, at 14.

<sup>264</sup> Some subjectivity will inevitably attach to characterizing the nature of the experiments so as to distinguish research *with* from research *on* the patented invention. But this is not a case where one should make a virtue out of a necessity by making intent the primary focus of the inquiry.

<sup>265</sup> It is a commonplace that any unclaimed teaching in the disclosure is dedicated to the public. See, e.g., Johnson & Johnston Assocs. v. R.E. Serv. Co., 285 F.3d 1046, 1054–55 (Fed. Cir. 2002) (en banc). It would be perverse to argue that disclosing without claiming a particular use somehow would restrict the public from performing that use under an exception to the rights obtained by claiming it.

<sup>266</sup> See STEPHEN BENT ET AL., INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 344–45 (1987); Eisenberg, *Patents and the Progress of Science*, *supra* note 25, at 1022; see also *supra* text accompanying notes 182–83. This is not to say that disclosure only of use as a research intermediary constitutes a sufficient utility that warrants the grant of patent rights.



closed utility to the DNA sequence, the claim to the DNA sequence should not be able to prevent research into the protein. Even with an independent teaching and disclosed utility for the DNA sequence (whether contained in the same or a different patent<sup>267</sup>), precluding legitimate experiments on the claimed protein—when no effective substitutes exist to licensing the intermediates or subsidiary technologies—raises serious concerns.<sup>268</sup>

Under European patent laws, however, such intermediate or subsidiary claims in a patent need not preclude experiments from relating to the subject matter of the claimed invention. Article 82 of the EPC on the unity of inventions stipulates that “[t]he European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.”<sup>269</sup> This language is adopted in § 34(5) of the German Patents Act<sup>270</sup> and § 14(5)(d) of the U.K. Patents Act 1977, and § 14(6) of the U.K. Patents Act 1977 adds that “[w]ithout prejudice to the generality of subsection (5)(d) above, rules may provide for treating two or more inventions as being so

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<sup>267</sup> Consider also that according to European patent law, inventors of products have to disclose at least one possible application of their products, even if their product is disclosed (only) by a product-by-process claim. See BGH Dec. 14, 1978, 1979 GRUR 461 (462–63) (*Farbbildröhre*); BGH Apr. 25, 1972, 1972 GRUR 642 (644) (*Lactame*); BGH Mar. 13, 1972, 58 BGHZ 280 (285) (*Imidazoline*); BGH July 6, 1971, 1972 GRUR 80 (82–88) (*Trioxan*); BGH Feb. 27, 1969, 51 BGHZ 378 (381) (*Disiloxan*); EPO, Opp. Div., Case T 939/92 (*Triazoles/AGREVO*), 1996 O.J. 309 (322); EPO, Boards of Appeal, Case T 281/86 - 3.3.2 (*Präprothautamin/UNILEVER*), 1990 GRUR INT'L. 69 (70–71); EPO, Opp. Div., Case T 22/82 (*Bis-epoxyäther/BASF*), 1982 O.J. 341 (345); GUIDE TO THE PATENTS ACT, *supra* note 132, §§ 14.23, 14.27; FRITJOFF HIRSCH & BERND HANSEN, DER SCHUTZ VON CHEMIEERFINDUNGEN 74, 304.(1995); Keukenschrijver, *supra* note 132, §§ 1.124–42, 9.51–61, 34.100–09; Melullis, *supra* note 170, at art. 52.119; Karl-Hermann Meyer-Dulheuer, *Möglichkeiten und Grenzen des product-by-process-Anspruches*, 1985 GRUR INT'L. 435, 435–40; Rainer Moufang, in RAINER SCHULTE ET AL., PATENTGESETZ MIT EUROPÄISCHEM PATENTÜBEREINKOMMEN §§ 1.329–59 (7th ed. 2005); Alfons Schäfers, in GEORG BENKARD ET AL., PATENTGESETZ, GEBRAUCHSMUSTERGESETZ §§ 34.31–34 (10th ed. 2006); van Raden & von Renesse, *supra* note 213, at 394.

<sup>268</sup> Similar concerns have been noted in the context of material transfer arrangements, where practicing the patent depends on obtaining access to the patented technology. See, e.g., Walsh et al., *supra* note 98. These concerns are particularly problematic when the restriction on the research arises from separate patents (or claims) held by the same person or entity. That patent holder may have no incentive to license or to make available the intermediate or subsidiary claimed inventions, if seeking to suppress the development of a research market for the intermediate or subsidiary.

<sup>269</sup> EPC, *supra* note 117, art. 82.

<sup>270</sup> Das deutsche Patentgesetz [German Patents Act] § 34(5), available at <http://www.gesetze-im-internet.de/patg/index.html>.

linked as to form a single inventive concept for the purposes of this Act.”<sup>271</sup> Thus, in *Auchinloss v. Agricultural & Veterinary Supplies Ltd.*<sup>272</sup> the U.K. Court of Appeals emphasized that the subject matter of an invention for the purpose of the experimental use exception must be ascertained from the patent as a whole.<sup>273</sup> If experiments are conducted “on” the inventive concept for the patented invention as a whole they are excluded from patent infringement. Then it does not matter if the experiments are conducted “with” subject matter of certain intermediate or subsidiary claims in the same patent.

ii. *Diagnostic Tests and Intended Uses*

In contrast to such multi-purpose experiments, many diagnostic uses of biotechnological inventions should not be considered experiments relating to the subject matter of the invention. Typically, mass-produced diagnostic kits are designed to detect the presence of *previously identified* genetic or protein markers, in order to determine potential disease conditions in patients. Such uses cannot reasonably be characterized as experiments on the subject matter of the invention, designed to learn more about it, even if new scientific information about different markers may ultimately result. Determining whether particular humans exhibit the relevant markers does not by itself provide additional information about the invention (except perhaps about its prevalence in the population), given that the receptor and the interaction are already known, and notwithstanding that such “experiments” address the combined effect of the kit and the person.

Conversely, use of diagnostic kits to identify new genetic or protein sequences relating to the same (or different) disease conditions is a more complicated case. Such experiments do seek to discover additional knowledge about the marker and its interactions, even if the primary purpose of any diagnostic test is to diagnose for the indicated condition. Distinguishing under Article 27(b) of the CPC of 1989 whether the additional research purposes would be the primary purpose, however, would be excessively complex (even though such research uses might be excepted under Article 27(a) of the CPC of 1989 when performed for non-commercial purposes<sup>274</sup>). Thus, such research should be considered to fall within the scope of Article 27(b) of the CPC of 1989.

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<sup>271</sup> U.K. Patents Act, 1977, c. 37, § 14(5)(d), (6), available at <http://www.jenkins.eu/statutes/patents.asp>; THORLEY ET AL., *supra* note 132, § 3.19.

<sup>272</sup> *Auchinloss v. Agricultural & Veterinary Supplies Ltd.*, [1999] R.P.C. 397, 404 (Eng.).

<sup>273</sup> *Id.* at 406–07.

<sup>274</sup> CPC, *supra* note 15, art. 27(a).

#### D. No Discrimination Between Academic and Applied Research

Some European scholars discriminate between “ordinary” and “academic” in regard to the experimental use exception. This approach is inspired by the belief that the scope of the exception was (or should be) influenced by constitutional guarantees of freedom of research, such as Article 5(3) of German Basic Constitutional Law.<sup>275</sup> None of these scholars, however, ultimately advocate applying the experimental use exception differently in regard to basic research and academic environments,<sup>276</sup> as compared to applied research<sup>277</sup> and business environments.<sup>278</sup> It is the nature of the research that counts.<sup>279</sup>

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<sup>275</sup> GG May 23, 1949, art. 5(3) (as amended Aug. 28, 2006) (“Art and scholarship, research, and teaching shall be free. The freedom of teaching shall not release any person from allegiance to the constitution.”).

<sup>276</sup> Many different efforts have been made to distinguish basic from applied research. See, e.g., 20 U.S.C. § 9501(3)(A) (2007) (stating that basic research is performed “to gain fundamental knowledge or understanding of phenomena and observable facts, without specific application toward processes or products”); Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 192 n.13 (2002) (“The objective of basic research is to gain more comprehensive knowledge or understanding of the subject under study, without specific applications in mind.”). For our purposes, basic research has as its primary objective the advancement of knowledge and theoretical understanding. It is exploratory and not driven by a practical end immediately in mind, although achieving practical ends may be the ultimate goal of the research.

<sup>277</sup> Applied research is done to solve specific, practical questions; its primary aim is not to gain knowledge for its own sake. It can be exploratory but often it is not. Applied research should be distinguished from commercialization of inventions, which is the focus of the Bayh-Dole Act, although applied research often is conducted for commercialization. See 35 U.S.C. § 200 (2007) (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor . . .”).

<sup>278</sup> See, e.g., CHROCZIEL, *supra* note 163, at 148, 195, 212, 231; KRASSER, *supra* note 167, at 813–14; Peter Chrocziel, *Benutzung zu Versuchszwecken als Einwand gegenüber einem Anspruch wegen Patentverletzung* 1992 GRUR INT’L. 203, 204–06; Scharen, *supra* note 116, §§ 11.6–11.7; see also GILAT, *supra* note 254, at 46; Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018, 1018 (2003); Rudolf Teschemacher, *Buchbesprechung*, 1987 GRUR INT’L. 62.

<sup>279</sup> Cf. Fiona Bor, *Exemptions to Patent Infringement Applied to Biotechnology Research Tools*, 28 EUR. INTELL. PROP. REV. 5, 12 (2006) (discussing difficulties of applying an experimental use exception for research tools; also rejecting an alternative approach based on the stage of commercial progress of research, citing Tanuja V. Garde, *The Effect of Disparate Treatment of the Experimental Use Exemption on the Balancing Act of 35 U.S.C. § 104*, 35 INT’L REV. INTELL. PROP. & COMPETITION L. 241, 267 (2004)); Rebecca S. Eisenberg & Richard R. Nel-

The importance of the distinction between basic and applied research is appreciated,<sup>280</sup> but its validity under European law is doubtful. First, the wording of Article 27(b) of the CPC of 1989 does not point toward it—the language does not differentiate among the types of “research” or “experiments” on the subject matter of an invention.<sup>281</sup> The terms “research”<sup>282</sup> and “experiment”<sup>283</sup> have broad application to methods of discovering both basic and applied scientific facts. The legislative history of the CPC also fails to discriminate between experimental uses in basic and applied research. The intended purpose of providing for separate regulations in Article 31(a), (b) of the CPC of 1975 in respect of uses with non-commercial and experimental purposes was to abolish the need to make distinctions between academic and other research that had been adopted in some national jurisdictions<sup>284</sup> prior to the harmonization by the Convention.<sup>285</sup>

Second, “research” as addressed in Article 5(3) of German Basic Constitutional Law is interpreted in the same way as the CPC, i.e., based on the act rather than the actor or the character of her employment or her institutional setting. Anyone who aspires to discover something unknown about a particular subject is protected by the constitutional freedom of research, whether the investigations occur inside or outside universities or other academic research institutions.<sup>286</sup> Hence, any “experiment” in the sense of Article 27(b) of the CPC of 1989 is covered by Article 5(3) of German Basic Constitutional Law.

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son, *Public vs. Proprietary Science: A Fruitful Tension?*, 77 ACAD. MED. 1392, 1398 (2002) (same for distinguishing an exception between “commercial and research spheres”).

<sup>280</sup> One of the authors focused on the effects on basic research when encouraging the U.S. Supreme Court to address the scope of the experimental use exception in *Madey v. Duke University*. See Brief of Amici Curiae Consumer Project on Technology and Public Knowledge in Support of Petition for Writ of Certiorari, *supra* note 97, at 5–13.

<sup>281</sup> CPC, *supra* note 15, art. 27(b).

<sup>282</sup> Compare Encyclopædia Britannica, <http://www.britannica.com> (last visited Sept. 11, 2007) (for ‘research’), with BROCKHAUS-ENZYKLOPÄDIE (19th ed. 1994) (for ‘Forschung’), and <http://www.xipolis.net> (last visited Oct. 23, 2007) (for ‘Forschung’).

<sup>283</sup> An “experiment” is any systematic procedure aimed at discovering something unknown or testing a hypothesis, see *supra* notes 276, 277 and accompanying text.

<sup>284</sup> Cf. *supra* notes 125–30 and accompanying text.

<sup>285</sup> Cf. AMIRAM BENYAMINI, PATENT INFRINGEMENT IN THE EUROPEAN COMMUNITY 271–76 (1993); Cornish, *supra* note 115, at 736.

<sup>286</sup> BVerfG Feb. 26, 1997, 95 BVerfGE 193 (209); BVerfG Jan. 11, 1994, 90 BVerfGE 1 (11); BVerfG Mar. 1, 1978, 47 BVerfGE 327 (367); BVerfG May 29, 1973, 35 BVerfGE 79 (112); BVerfG Jan. 15, 1963, 15 BVerfGE 256 (263); BVerfG, Aug. 17, 1956, 5 BVerfGE 85 (146); Bundesarbeitsgericht [BAG] [Supreme Labour Court] June 21, 1989, 62 Entscheidungen des Bundesarbeitsgerichts [BAGE] 156 (165); Herbert Bethge, in MICHAEL

Also, since Article 27(b) of the CPC of 1989 and national provisions for its implementation respectively already have shaped the law in favor of research, recourse to the constitutional guarantee of freedom of research is largely superfluous. Article 27(b) of the CPC of 1989 already provides a wide range of excepted research in academic settings. Additional research may be permitted in such settings under Article 27(a) of the CPC of 1989. Further, the German constitutional guarantee of property in patents according to Article 14 of German Basic Constitutional Law would have to be considered.<sup>287</sup> As no hierarchy of interpretation can be deduced in the event of a conflict between these guarantees<sup>288</sup> the balance of constitutional principles remains uncertain.

***E. Do the Regulatory Approval Exceptions in European Patent Law Cover Research Tool Use?***

Legal scholars have considered whether the regulatory approval exceptions in European patent law apply to research tools used for the development of a new drug.<sup>289</sup> These considerations focus on whether use of research tools is “necessary” for obtaining regulatory authorization. This is because Article 1 no. 8 of European Directive 2004/27/EC requires an exception from patent infringement only for uses which are “necessary” for obtaining authorization to market a generic drug.<sup>290</sup>

Use of a research tool is not thought of as “necessary” simply because it occurs during an investigation to develop information for submission to regulatory authorities. Early stage research, such as to create a chemical for which biochemical functions may then be assessed, is a “but for” cause of any regulatory approval of a pharmaceutical invention. However, such early stage experiments may be too remote from an actual authorization to market a drug to

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SACHS ET AL., GRUNDGESETZ §§ 5.206, 5.210 (2d ed. 1999); Rudolf Wendt, in INGO VON MÜNCH ET AL., GRUNDGESETZ-KOMMENTAR § 5.100 (5th ed. 2000).

<sup>287</sup> GG May 23, 1949, art. 14 (as amended Aug. 28, 2006).

<sup>288</sup> FECHNER, *supra* note 174, at 338; KONRAD HESSE, GRUNDZÜGE DES VERFASSUNGSRECHTS DER BUNDESREPUBLIK DEUTSCHLAND 401 (20th ed. 1995); Bethge, *supra* note 286, § 5.198c; Wendt, *supra* note 286, § 5.93.

<sup>289</sup> Christof Augenstein, *The Admissibility of Clinical Trials with Respect to the Utilization of Patented Research Tools*, 21 WORLD INTELL. PROP. REP. 8 (2007); Pfaff, *supra* note 10, at 270–74; Wolfgang von Meibom & Ina vom Feld, in MANFRED HAESMANN ET AL., FESTSCHRIFT FÜR BARTENBACH 398–99 (2005).

<sup>290</sup> Scharen, *supra* note 116, § 11.10. The Council Directive thus differs dramatically from 35 U.S.C. § 271(e)(1) (2007), which is not limited to uses that are “necessary” for marketing approval, but rather uses that are “reasonably related” to developing information for marketing approval. See Council Directive 2004/27, *supra* note 15.

qualify for the regulatory approval exception. It does not seem that the directive was intended to address early stage research to invent or to identify the product for regulatory approval, even if the patented invention was necessary for this purpose.<sup>291</sup> Regulatory approval exceptions must conform to the European Directive 2004/27/EC,<sup>292</sup> and the memorandum supporting the European Directive<sup>293</sup> clearly suggests that the purposes of the exception (to facilitate early market entry and competition by generics) differ from those of experimental use exceptions.<sup>294</sup> Nothing in the memorandum suggests that regulatory approval exceptions were meant to influence the balance of interests between research tool patent holders and research tool users, which in theory should be regulated by experimental use exceptions. It will probably be extremely rare for regulatory marketing approval to require use of any particular research tool to develop the required information on *different* subject matter. But if it were truly “necessary” to do so, the regulatory approval exception likely would apply.

<sup>291</sup> In some cases, there will be alternatives for such invention and identification. In others, the patented invention will be commercially available for purchase or license on reasonable terms, and thus an exception from infringement is not “necessary” in the sense of a requirement for the research to occur. In contrast, protection for research tools may often be unnecessary, given non-patent incentives for their creation. See, e.g., David W. Opderbeck, *A Virtue-Centered Approach to the Biotechnology Commons (or, the Virtuous Penguin)*, 59 ME. L. REV. 316, 326–29 (2007) (discussing moral incentives for individual and communal production within commons such as communications networks and biotechnology); Strandburg, *supra* note 250 (discussing incentives to invent, disseminate, and disclose research tools for both non-profit and commercial researchers and commercial research tool suppliers and patent licensors).

<sup>292</sup> Council Directive 2004/27, *supra* note 15.

<sup>293</sup> *Proposal for a Regulation of the European Parliament and of the Council Laying down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Agency for the Evaluation of Medicinal Products*, COM (2001) 404 final (Aug. 1, 2000), available at [http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001\\_0404en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0404en01.pdf).

<sup>294</sup> Significantly, Council Directive 2004/27/EC is part of the Community code relating to medicinal products, rather than to patents, which could suggest an intent to limit its scope to products that are the subject of regulatory approval. See Pfaff, *supra* note 10, at 270–71. The different purposes of Europe’s regulatory approval exceptions vis-à-vis Europe’s experimental use exceptions make it hard to consider them a special case of the latter exceptions. In contrast, 35 U.S.C. § 271(e) is placed within the patent act, and is often treated as a special case of the experimental use exception. See, e.g., BENYAMINI, *supra* note 285, at 269 n.21 (1993); HAROLD C. WEGNER, PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS 468–70 (2d ed. 1994); Dan L. Burk, *Patenting Speech*, 79 TEX. L. REV. 99, 157 (2000); Israelsen, *supra* note 25, at 475; McCoy, *supra* note 25, at 228; David L. Parker, *Patent Infringement Exemptions for Life Science Research*, 16 HOUS. J. INT’L L. 615, 618–19, 644 (1994); Todd A. Rathe, *Patent Law—Medical Device Experimental Use Exception in Patent Infringement: Eli Lilly v. Medtronic*, 16 J. CORP. L. 625, 639, 641 (1991).

Similarly, at least some of the domestic regulatory approval exceptions, such as § 11(2b) of the German Patents Act, do not suggest that research tool uses are excepted from infringement.<sup>295</sup> Section 11(2b) also distinguishes between unexcepted research that is not necessary to obtain an authorization (arguably including research during identification or development of the drug) and research in clinical studies, trials, and other practical activities that generate necessary data.<sup>296</sup> The key again is whether the research tool use would be necessary for developing information to obtain an authorization, and in most circumstances relating to regulatory approval it should not be necessary.

A systematic interpretation of § 11(2b) also would exclude an exception for research tool use.<sup>297</sup> An interpretation of the regulatory approval exception that would be broad enough to except research tool use would ignore the context of its enactment, given that the experimental use exception of § 11(2) of the German Patents Act in principle does not except research tool use. The regulatory approval exception was certainly drafted with the limits of the experimental use exception in mind, but not with a suggestion that the *Clinical Trials II* decision was wrong.<sup>298</sup> National legislation has been careful to not have the experimental use exception cover research tool uses, given concerns raised regarding Articles 3 and 14 of German Basic Constitutional Law, and Article 27(1) of the CPC of 1989 and Articles 28(1) and 30 of TRIPS.<sup>299</sup> It is unlikely that the drafters would have intended to extend the regulatory approval exception to exploitation of research tools without providing for some compensation or at least significant discussion.

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<sup>295</sup> Pfaff, *supra* note 10, at 270–73. Again, the Belgian experimental use exception may provide a counter-example, given that it applies to research tools, while excluding purely commercial purposes to which the regulatory approval exception will apply. See Overwalle, *supra* note 130, at 907 & n.81 (citing Legislative Proposal amending the Act of 25 March 1964 on pharmaceuticals (Official Gazette, Apr. 17, 1964)).

<sup>296</sup> Cf. *supra* note 87 and accompanying text. However, the wording of 35 U.S.C. § 271(e)(1) (“reasonably related to”) may support a more generous interpretation than the wording of German Patents Act § 11(2b) (“necessary for”).

<sup>297</sup> Unlike for the Directive, it is possible that the drafters may have contemplated or courts might fashion an alternative response—such as compulsory licensing—to extending the regulatory approval exception in any such cases that might arise.

<sup>298</sup> See generally BGH Apr. 17, 1997, 1997 NJW 3092 (*Clinical Trials II*), translated in [1998] R.P.C. 423; *supra* text accompanying note 152. In contrast, the United States Congress adopted its regulatory approval exception in response to an excessively narrow interpretation of the experimental use exception. See *supra* notes 67–76 and accompanying text. The U.S. regulatory approval exception should not, therefore, be interpreted as consistent with that interpretation (or earlier interpretations) of the experimental use exception.

<sup>299</sup> Holzapfel, *supra* note 175, at 16.

### F. Supply to Experimenters

Often those conducting experiments need to obtain from other persons materials to conduct their experiments, to avoid the time and costs of production or to benefit from standardized production. Article 26(1), (3) of the CPC of 1989 (Article 30(1), (3) of the CPC of 1975),<sup>300</sup> which imposes a prohibition on indirect use of inventions, regulates the participation of third parties in the run-up to experimental uses, specifically:

(1) A Community patent shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply within the territories of the Contracting States a person, other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances, that these means are suitable and intended for putting that invention into effect.

....

(3) Persons performing the acts referred to in Article 27 (a) to (c) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1.<sup>301</sup>

Section 60(2), (6) of the U.K. Patents Act 1977<sup>302</sup> and § 10(1), (3) of the German Patents Act<sup>303</sup> comply with these prohibitions on indirect use.<sup>304</sup> Article 26(3) of the CPC of 1989 in effect limits the benefit of the experimental use exception to the experimenter himself; third parties are not entitled to supply the experimenter with means essential for conducting the experiments.<sup>305</sup> The supply prohibition applies even if the third party does not obtain a commercial

<sup>300</sup> CPC, *supra* note 15, art. 26(1), (3); *see also* EC Council Regulation, *supra* note 128, art. 8.

<sup>301</sup> CPC, *supra* note 15, art. 26(1), (3).

<sup>302</sup> U.K. Patents Act, 1977, c. 37, § 60(2), (6), *available at* <http://www.jenkins.eu/statutes/patents.asp>.

<sup>303</sup> Das deutsche Patentgesetz [German Patents Act], § 10(1), (3), *available at* <http://www.gesetze-im-internet.de/patg/index.html>.

<sup>304</sup> *See* [BGH] Oct. 10, 2000, 2001 GRUR 228 (228–32) (*Luftheizgerät*) (regarding the prohibition of indirect use of inventions); BERNHARDT & KRASSER, *supra* note 169, at 588, 596; GUIDE TO THE PATENTS ACT, *supra* note 132, §§ 60.07, 60.17; THORLEY ET AL., *supra* note 132, §§ 8.18, 8.31; Henrik Holzapfel, *Zu § 10 PatG als Rechtszuweisungsnorm*, 2002 GRUR 193, 193–98; Reimar König, *Mittelbare Patentverletzung*, 2000 MITT. 10, 10–25; Albert Preu, *Die unmittelbare und die mittelbare Benutzung*, 1980 GRUR 697, 697–99.

<sup>305</sup> According to German Patents Act § 10(3), not only the benefit of the experimental use exception of German Patents Act § 11(2) is limited to the experimenter himself. Also the benefit of the regulatory approval exception of German Patents Act § 11(2b) is limited to the conductor of studies and trials himself.



benefit, and is more restrictive than the United States counterpart.<sup>306</sup> Further, its scope is excessive and it imposes unjustified restrictions that interfere with legitimate activity.

The excessive scope of this provision may be illustrated by an example. Assume a person “E” wants to conduct experiments to improve a chemical process for which a process patent only has been granted to a person “P.” For economic or other reasons, E cannot produce the chemical agents involved in the patented process by himself, but has to rely on obtaining them from a supplier “S.” In this constellation, E, himself, is entitled to both produce the agents and perform the patented process for experimental purposes. Furthermore, S is entitled to produce the agents, as we assumed P possessed a process patent but not a product patent, so that the agents should be available for use. Nevertheless, because of Article 26 of the CPC of 1989, S is prevented from selling or otherwise supplying his lawfully produced agents to E for the purpose of conducting the lawfully excepted experiments. This is because they are “means, relating to an essential element of that invention, for putting it into effect therein.”<sup>307</sup> This is true even if S may lawfully supply E for purposes other than excepted experimentation.<sup>308</sup>

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<sup>306</sup> Historically in the U.S., the experimental use exception applied to making and using, but not to selling. See, e.g., *supra* Part II(A) and text accompanying notes 56–58. Although no case appears to have addressed the question, one exempt party might legally supply the invention to another for experimentation, so long as the invention was not sold or otherwise used for profit. In contrast, the regulatory approval exception of 35 U.S.C. § 271(e)(1) (2007) expressly permits sale for the specified regulatory approval uses.

<sup>307</sup> CPC, *supra* note 15, art. 26(1).

<sup>308</sup> Cf. 35 U.S.C. § 271(b) (2007) (prohibiting “actively induc[ing] infringement”); 35 U.S.C. § 271(c) (providing for contributory infringement liability for offering to sell, selling, or importing “a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use”). A similar excessive scope to supplying liability has been found recently under U.S. secondary liability laws. In *Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004), the Court of Appeals upheld inducement liability under 35 U.S.C. § 271(b) (and the District Court had found contributory liability under 35 U.S.C. § 271(c)) for a diagnostic company conducting and supplying the results of unpatented assays (the first step of the patented method), which doctors were assumed to have correlated to the results of a disease condition (thereby completing the patented method). See Brief Amicus Curiae of AARP in Support of Petitioner at 7–8, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607), available at <http://www.wcl.american.edu/ipclinic/documents/LabCorpMetabolite-Dec2005.pdf?rd=1>. However, other unpatented assays that accomplished the same measurement had been used for years for similar diagnostic purposes, liability was premised on the assumption that doctors would inevitably perform the correlation when they continued to

If the policy behind the experimental use exception is to encourage the performance of experiments, there appears to be little logic in discouraging experiments by preventing the supply of means essential for their performance. What legitimate interest would a patent holder have in requiring the experimenter to produce such means by himself instead of buying them from a third party, if the production is not prohibited because the patent holder holds only a process patent? Even when the essential means for performing the experiment relate to a product patent, there may still be situations where third-party supply is appropriate (and will not detract from the patent holder's legitimate commercial rewards).<sup>309</sup> After all, if experimenters produce the product themselves (based on the patent holder's disclosure), no compensation is due to the patent holder. Indeed, there is widespread criticism about the personal limitation of Article 26(3) of the CPC of 1989 among European scholars who have suggested abolishing this paragraph altogether.<sup>310</sup>

Rather than wholly eliminate Article 26(3) of the CPC of 1989, however, a more limited revision is preferred, which differentiates among the Article 27(a)–(c) of the CPC of 1989 exceptions. The purpose of Article 26 of the CPC of 1989 is that third parties should not be allowed to make money at the patent holder's expense by supplying the invention during the lifetime of the patent. Private and non-commercial uses are markets that the patent holder would normally supply, and a patent holder may expect to receive exclusive revenues from supplying such markets. The purpose of Article 27(a) of the CPC of 1989, in contrast, is to protect private citizens and non-commercial users

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use prior art assays for traditional diagnostic purposes, and the acts constituting inducement included communicating the newly discovered scientific correlation that the patent itself taught. *See id.* at 13–15.

<sup>309</sup> For example, if the experimenter is unable to produce the patented product and the patent holder is unwilling to supply it on reasonable commercial terms, excepted experimentation can result only by third-party supply. In the absence of commercial sales, the patent holder is not prejudiced any more than if the experimenter himself produced the product for experimentation. Nor should the experimenter be required to create a joint venture or to acquire the third party (or its assets) to obtain the product and avail itself of the experimental use exception.

<sup>310</sup> BENYAMINI, *supra* note 285, at 274; BERNHARDT & KRASSER, *supra* note 169, at 593; CHROCZIEL, *supra* note 163, at 191; GILAT, *supra* note 254, at 86; MES, *supra* note 131, §§ 10.2, 10.35; NIIOKA, *supra* note 163, at 351; Cornish, *supra* note 115, at 751; Martin Fährndrich & Winfried Tilmann, *Patentnutzende Bereitstellungshandlungen bei Versuchen*, 2001 GRUR 901, 903; Keukenschrijver, *supra* note 132, § 10.26; Bernhard Villinger, *Anmerkungen zu den §§ 9, 10 und 11 des neuen deutschen Patentgesetzes*, 1981 GRUR 541, 545.

from liability, not to open up the market to supply such non-infringing uses.<sup>311</sup> As this privilege is based on the particularized interests of private citizens and non-commercial users, there is no compelling reason to expand the scope of the exception to liability to cover business competitors. Nor should it matter in this case whether the competitors supply private citizens or non-commercial uses for free or for profit, so long as the patent holder is being deprived of revenues that it would otherwise obtain (which may not be a simple matter to determine).<sup>312</sup> It would also be wrong to blame Article 26(3) of the CPC of 1989 for stifling those private or non-commercial uses by limiting the supply of the invention.<sup>313</sup> Article 26(3) of the CPC of 1989 appears legitimate with respect to Article 27(a) of the CPC of 1989.

In contrast, Article 26(3) of the CPC of 1989 is overbroad with respect to Article 27(b) of the CPC of 1989. This is because Article 27(b) of the CPC of 1989 differs from Article 27(a) of the CPC of 1989 in two relevant ways. First, unlike the private and non-commercial uses under Article 27(a) of the CPC of 1989, which are intended to prohibit liability and are focused on the user, Article 27(b) of the CPC of 1989 focuses on the acts of experimentation, and affirmatively seeks to promote these acts for social benefit. So long as the experiments relate to the subject matter of the used invention, they should not unduly prejudice the interests of the patent holder. Second, given Article 27(b) of the CPC of 1989, research markets for experiments that evaluate the disclosed invention and assess patent validity (unlike private and commercial use markets that exploit the disclosure) should not be considered markets for which compensation can legitimately be expected. Accordingly, there should be less concern that third parties will benefit at the patent holder's expense when supplying inventions to such markets, and in any event the public interests in such cases should outweigh any such concerns.

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<sup>311</sup> CPC, *supra* note 15, art. 27(a). See also OSTERRIETH, *supra* note 140, at 154; H. Herzfeld, *Die Gewerbsmässigkeit als Tatbestandselement der Patentverletzung*, 1927 GRUR 151, 152; Joseph Straus, *Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzüchtung und Tierproduktion*, 1990 GRUR INT'L 913, 923–24.

<sup>312</sup> Similar concerns limit the ability of patent holders to obtain lost profit damages. See, e.g., *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545–49 (Fed. Cir. 1995); *Panduit Corp. v. Stahl Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).

<sup>313</sup> Cf. *Rite-Hite Corp.*, 56 F.3d at 1547–48 (noting that patent holders need not make, use, or sell their inventions and that courts may refuse injunctions to protect the public interest in accessing inventions). If the patent holder refuses to supply or license for such private or non-commercial uses, government-directed production or compulsory licensing can assure the availability of the invention and the patent holder will be compensated. See, e.g., 28 U.S.C. § 1498 (2007).

To prevent Article 26(3) of the CPC of 1989 from stifling research, scholars have proposed to interpret “experimental purposes” under Article 27(b) of the CPC of 1989 to exclude from infringement acts that are predicates to, but not part of, the scheme of experimentation.<sup>314</sup> Therefore, supplying the invention or the means for performing the experiment would be excepted. However, such a broad interpretation of Article 27(b) of the CPC of 1989 would conflict with both the language and apparent purpose of Article 26(3) of the CPC of 1989. In concurrence with the scholarly interpretation, it is proposed that European law be changed to permit supply of the invention (or the means for performing it) to persons performing the acts referred to in Article 27(b) of the CPC of 1989.

**G. Summary and Scheme for Evaluating the Application of Article 27(b) of the CPC of 1989**

Europe’s experimental use exception as stipulated in Article 27(b) of the CPC of 1989 and corresponding national provisions exclude from patent infringement acts of use that are carried out for “experimental purposes relating to the subject-matter of the [used] invention.”<sup>315</sup> In this context, an experiment is defined as any systematic procedure aimed at discovering something unknown or testing a hypothesis. The motivation for gathering such information is irrelevant, as is whether or not the research has commercial application. Thus, e.g., pharmaceutical business interests may pursue clinical trials to assess effectiveness, and a doctor may seek to identify a new drug indication, as long as the nature and scale of the acts of use reflect the purpose of obtaining new information. Similarly, the exception applies without differentiation between basic and applied research or between academic and commercial researchers. Application of the experimental use exception depends solely on the investigative purpose of the acts of use, to discover something unknown about the used invention itself. Once the activities conducted by the experimenting party have yielded the information sought, the exception for experimentation ceases.

The purposes of Article 27(b) of the CPC of 1989 are to advance scientific and technical progress and to enable third parties to assess the validity of a patent. Justification for the exception is based on the benefits to the public welfare from such experimentation and from restoring competition where the patent is demonstrated to be invalid. In removing such conduct from liability, Article 27(b) of the CPC of 1989 does not usurp legitimate expectations of patent hold-

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<sup>314</sup> BENYAMINI, *supra* note 285, at 274; Fährndrich & Tilmann, *supra* note 310, at 902–05.

<sup>315</sup> CPC, *supra* note 15, art. 27(b).

ers, and even if it did, it would be justified. The experiments clarify the inventive solution itself, rather than exploit its teaching, and the effects on legitimate patent holder incentives will be negligible where the experiments seek to assess validity or to design around the invention.

European experimental use exceptions can be summed up as following a three-step test:

1. Is an act of unauthorized use of a patented invention at issue (i.e., is there a making, using, offering for sale, selling, or importing)?
2. What is the objective purpose of the act of use?
  - (a) Is it intended to obtain genuinely new information?

The act of use must be aimed at discovering something unknown or testing a hypothesis. The ultimate motivation of this quest is irrelevant, i.e., gathering of information may be inspired by academic curiosity as well as by business interests.
  - (b) Does this information relate to the subject matter of the used invention?

A patented invention may only be used for experimentation to address and further clarify the invention itself (experimentation “on” an invention). The inventive solution to a technical problem is not included within the European exceptions when merely exploited, e.g., in use as a research tool (experimentation “with” an invention).
3. Are the nature and scope of the use appropriate to the purpose of obtaining new information by experiment?

#### **IV. POLICY ISSUES: A TRANSATLANTIC DIALOG ON EXPERIMENTAL USE AND RESEARCH TOOLS**

The above sections have described the nature and scope of the present experimental use and regulatory approval exceptions in the United States and in Europe. Given the relatively uncertain state of the experimental use exception law in the U.S., questions have been raised as to whether or not the U.S. Patent Act should be amended. We believe that it should, and that the issue of research tools should be explicitly addressed. If the U.S. were to modify the Patent Act, another question arises, i.e., whether to harmonize U.S. law with that of other countries. Should the European experimental use exception be adopted in whole or in part as a model for the U.S., and should U.S. and European laws further facilitate research tool use?

We do not purport to resolve these questions, as the answers require empirical data and theoretical resolution of issues that currently are lacking.

Nevertheless, we explore these questions below, by posing a hypothetical discussion between two legal scholars that one could imagine taking place on the podium (or at the refreshments bar) of an international conference. The fictional speakers are *Eve* from London and *Tom* from New York.

**A. *Basic Approach of Europe's Exception as a Role Model?***

*Eve:* So, we have seen that Europe's and the United States' experimental use exceptions are quite different from one another, both in approach and scope. But surely we can stipulate that some sort of experimental use exception is needed to prevent the patent system, which is meant to stimulate technical progress and which seeks to enforce certain patentability requirements, from interfering with these goals. Experimental uses for purposes of checking the validity of a patent, and improving upon or designing around an invention should be permissible without a license from the patent holder, as such uses advance public interests that outweigh the legitimate interests of the patent holder.

*Tom:* I agree. But I think it is also beyond dispute that an experimental use exception of any kind must pay careful attention to the intended functioning of the patent system, which is to create an incentive for future innovation and disclosure by promising an exclusive right as reward for successful inventors. Therefore, an experimental use exception must not except from infringement those acts that materially interfere with the legitimate interests of a patent holder in exclusively exploiting the invention as intended by the patent holder. Thus, acts by competitors that would redirect revenue away from the patent holder or otherwise imperil the patent holder's exclusive right to market the invention should not be excepted. In this regard, the U.S. law may do a better job than European law, as U.S. law may better distinguish between experiments having adverse commercial effects on patent holders and those that do not.

*Eve:* Well, I think you are assuming that patent holders have a legitimate interest in obtaining commercial revenues from licensing certain experiments and from exclusive sales to researchers. Your argument is actually circular, since patent holders' interests will not be limited if they are not entitled to find such experiments or sales by others to be infringing. Further, even if patent holders' legitimate interests were materially impaired, the public interest in allowing the experiments might outweigh those private interests. And they might do so without interfering

with any constitutionally protected property rights granted to the patent holder (even assuming that rights to exclude uses in research had been initially granted). In any event, there may be no good reason to restrict the exception to non-commercial motivations and lack of commercial effects, particularly as to do so might interfere with the public interests that the exception is intended to promote. Besides, as a practical matter (as the United States experience has demonstrated in regard to the *Merck-Integra* case) drawing lines between commercially and non-commercially motivated uses is difficult in today's research landscape.<sup>316</sup> On the one hand, it would not make any sense to limit the exception to academic research; universities acquire considerable revenue from patent licensing and university research often is sponsored by business corporations. On the other hand, business corporations are increasingly engaged in performing basic research and funding such research in universities and other academic settings.<sup>317</sup>

*Tom:* I see your point. We have already agreed that certain excepted experimental uses are backed by considerations of public interest. However, I find it less difficult to identify the legitimate interests of a patent holder. Like our learned scholar William C. Robinson said more than a century ago, “[t]he interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others.”<sup>318</sup> Many patent holders supply their inventions for research, and when they do they have legitimate interests in exclusively supplying those inventions. From this point of view, it seems fair to conclude that any research use that is excepted from patent infringement interferes with “legitimate” interests of a patent holder, as suggested by

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<sup>316</sup> See Thayer & De Liberty, *supra* note 25, at 20.

<sup>317</sup> See, e.g., BENYAMINI, *supra* note 285, at 272; Cornish, *supra* note 115, at 736; Wolfgang von Meibom & Johann Pitz, *Experimental Use and Compulsory Licence Under German Patent Law*, PAT. WORLD, June–July 1997, at 27, 30; Rolf Schultz-Stüchtling, *Anmerkung zu BGH, Klinische Versuche I*, 1996 GRUR 116, 120; see also David Addis et al., *AIPPI's Resolution on Experimental Use: An Australian Perspective*, PAT. WORLD, Nov. 1992, at 26, 30; ASS'N OF UNIV. TECH. MANAGERS, AUTM U.S. LICENSING SURVEY: FY 2004 (2005), available at <http://www.autm.org/events/File/04AUTMSurveySum-USpublic.pdf>.

<sup>318</sup> 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (photo. reprint 1972) (1890).

an analyst of the experimental use exception only a half century ago.<sup>319</sup> I agree, however, that in many cases the interference may be small.

*Eve:* Clearly there will be some lost revenue, but is the expectation of such revenue really legitimate? Remember that the patent system provides a reward to individual inventors only as an exchange for their contribution to the useful arts that was made and disclosed to the public. To assure the exchange is fair to both sides, it should only be necessary to protect the patent holder's exclusive rights in intended—that is disclosed—uses of the invention. Experiments to determine validity of the invention or to design around it are not intended uses, and many research uses are not intended uses. Even if the experimental use exception permitted experiments that were disclosed uses—such as when the invention is intended to be a research tool—the public interest in promoting such experiments might still outweigh the restriction on patent holder interests. And it is not at all clear, as modern scholars have shown, that patent incentives are needed to create research tools in many (if not most) contexts, or that it would not be possible to distinguish between making and use by researchers on the one hand and sales to researchers on the other.<sup>320</sup> Thus, what you are calling legitimate interests may reflect only deadweight losses to society.

*Tom:* I understand that it may not be necessary to award exclusive rights that apply to undisclosed uses or to disclosed uses that do not provide a sufficient benefit to society (compared to the scope of the exclusion that would be granted). Similarly, I can comprehend situations where there is an overwhelming public interest in the disclosed uses that conflicts with the interests of a patent holder, which would include the experiments you describe to check validity or to design around inventions. But I think genuine research tools are different, as they are intended to serve as the means for future inquiry. The crucial point is to preserve the intended benefits of an invention to the inventor. I understand that Europe's Article 27(b) of the CPC of 1989<sup>321</sup> achieves this result by ex-

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<sup>319</sup> This argument was initially made by Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. & TRADEMARK OFF. SOC'Y 357, 366, 377 (1957).

<sup>320</sup> See Strandburg, *supra* note 250, at 23–38 (discussing incentives to invent, disseminate, and disclose research tools for both non-profit and commercial researchers and commercial research tool suppliers and patent licensors).

<sup>321</sup> See CPC, *supra* note 15.



cepting from infringement only uses that relate to the subject matter of the used invention. But couldn't it have expressed the goal of preserving the intended benefits in a more straightforward way?

*Eve:* You are right. The phrase “relating to the subject-matter of the invention” in Article 27(b) of the CPC of 1989<sup>322</sup> is not self-evident, and it can only be understood in light of the historical intention of the parties that concluded the convention. However, European courts and scholars have gotten used to it and have acquired experience from the case law interpreting it. Probably any alternative wording will pose some difficult interpretive questions, as it will have to establish an intricate balance between facilitating future scientific and technical progress on the one hand and rewarding inventors on the other. Perhaps the wording does not even matter so much. It is more important that we agree on the basic idea that patent exclusive rights should not extend to acts where the public interests in performing the acts outweigh the interests of the patent holder. Experiments to assess validity and to design around inventions are clear cases where that principle is met. Although it may be difficult to draw lines beyond these clear cases, that may not be a sufficient reason to avoid doing so. And wherever the lines should be drawn, there is no reason to restrict application of this principle based on commercial or non-commercial motivations of the experimenter. By limiting exceptions to this principle, the patent holder also should continue to receive legitimate intended benefits of the disclosed invention.

### ***B. A More Elaborate Solution Following Fair Use?***

*Tom:* So let's see if we can figure out some additional lines to draw by exploring how much farther the principle should extend. As you know, legal scholars have proposed more refined solutions analogous to the fair use defense of copyright law. They are elaborate enough to encompass a wide range of considerations. For example, one scholar recommends a general standard that considers five factors:

- (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the

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<sup>322</sup> *Id.*

impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work.<sup>323</sup>

Another scholar recommends considering: (1) whether the experiments have a commercial purpose; (2) the relationship that exists between the experiments and the patented invention; (3) commercial availability of the patented invention; (4) whether research is the single or dominant purpose, or merely a purpose of the experiments; and (5) whether experimentation is done by a contracted third party.<sup>324</sup>

*Eve:* It is certainly true that each of these factors relates to public interest concerns. However, such an exception would generate substantial uncertainty as to its application. I understand that uncertainty over application of the fair use exception to copyright infringement has posed significant practical problems in the United States, as potential users of copyrighted materials are frequently unwilling to risk being sued even when their uses would likely be permissible. As a result, good cases of fair use may not get litigated, and (as a result) the judicial decisions elaborating rules for application of the exception may tend to overstate copyright owners' interests at the expense of public interests. In any event, a fair use approach to excepted experiments in patent law would result in a very complex legal regime and case law that would be difficult to apply without clear guidance on how to balance the various public interests against the interests of patent holders. As we heard earlier in regard to claiming and the doctrine of equivalents, similar concerns have plagued theoretical resolution of the proper scope of claims.<sup>325</sup> The resulting uncertainty would likely cause excessive transaction costs for both users and patent holders, even if it permitted greater flexibility in balancing such interests. It may be preferable to adopt clear rules to except experiments in contexts where the public interests should normally predominate. Where more complex balancing is needed, either a supplemental fair use exception could apply or compulsory licensing could assure access to the invention. Compulsory licensing regimes already are provided under European patent and antitrust laws, and to a more limited extent under United States laws. Although European authorities and courts historically have been very reserved towards grant-

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<sup>323</sup> O'Rourke, *supra* note 126, at 1205.

<sup>324</sup> Craig Smith, *Experimental Use Exception to Patent Infringement—Where does Australia Stand?*, 53 INTEL. PROP. F. 14, 21 (2003).

<sup>325</sup> See, e.g., Merges & Nelson, *supra* note 184, at 839.

ing compulsory licenses based on intellectual property laws,<sup>326</sup> a few recent antitrust decisions have granted such licenses in response to abuses of dominant market positions by failures to grant intellectual property licenses to competitors on reasonable terms and conditions.<sup>327</sup>

*Tom:* I think the compulsory licensing issues are much more complex and would justify a future conference. Traditionally, the United States has been as skeptical about compulsory license approaches as Europe, and it has no general patent law compulsory licensing authority.<sup>328</sup> And at least for government-sponsored inventions, where the government could issue such licenses, the United States has refused to exercise its authority by taking the position that supply of the invention at any price assures that the patented invention is “practically available.”<sup>329</sup> Although a compulsory license approach could help to resolve disputes over the need for competition, it is not likely to occur any time soon. And unlike excepted experimental use, a compulsory license approach requires the experimenter to compensate the patent holder for socially beneficial uses. So I think we still need to define what experiments should be excepted from the scope of exclusive patent rights.

### C. *Privileging Academic Researchers?*

*Eve:* Given that the justifications for the experimental use exceptions in Europe and the United States were independent of the commercial or non-commercial motivations for conducting the experiments (even if not independent of any commercial benefit from conducting the experiments), there is no basis to distinguish basic academic research from applied research in this context. If the experimental use exception as we

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<sup>326</sup> Meibom & Pitz, *supra* note 317, at 31; Klaus Schwendy, in RUDOLF BUSSE ET AL., PATENTGESETZ § 24.16 (6th ed. 2003); Volkert Vorwerk, *Probleme der Zwangslizenzregelung*, 1976 GRUR 64; Hans Schade, *Zwangslizenz*, 1964 MITT. 101.

<sup>327</sup> Case C-418/01, *IMS Health GmbH & Co. OHG v. NDC Health GmbH & Co. KG*, 2004 E.C.R. I-5039; BGH July 13, 2004, 2004 GRUR 966 (*Standard-Spundfass*).

<sup>328</sup> Cf. 42 U.S.C. § 7608 (2007) (compulsory licensing for environmental technologies).

<sup>329</sup> See 35 U.S.C. § 203(a) (2007) (“march-in” rights); NAT’L INSTS. OF HEALTH, OFFICE OF THE DIR., IN THE CASE OF NORVIR® (July 29, 2004) 4–6, *available at* <http://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf> (although “practical application” is defined in 35 U.S.C. § 201(f) as “available to the public on reasonable terms,” the NIH determined that the “extraordinary remedy of march-in is not an appropriate means of controlling prices” for pharmaceutical inventions, leaving the issue of excessive pricing to Congress to address).

have sketched it so far appropriately allows only certain classes of uses, then there is no need to further privilege academic researchers relative to their commercial counterparts.

*Tom:* Although I agree with you about the history, other policies and the exception for private, non-commercial activities already allow academic experimentation. Thus, I think that the situation of academic researchers differs from that of commercial researchers in ways that should be accommodated by the experimental use exception. I would suggest distinguishing between basic research and commercial application research, as the incentives are very different and the need for unrestricted and unpaid access also is very different. Important basic research will be foregone if licensing transactions and royalty payment costs are imposed. In contrast, much less commercial application research will be foregone, and I would be less concerned about any such foregone research. Hence, an exception could be crafted in such a way as to make it broader for academic researchers than we have discussed so far, in particular by allowing for easier access to and use of patented research tools.

*Eve:* It is hard to say whether academic research warrants a broader exception. Europe's experimental use exception does not discriminate between basic research typically carried out in academic institutions and applied research undertaken mostly by business entities. As a matter of fact, it might have been a wise decision by the concluding parties of the CPC not to differentiate between academic and applied research. First, it is increasingly difficult to distinguish in practice between academic and applied research. There may have been a time when academic science was distinct from technology and when basic researchers were not involved in industry (or vice-versa), but that time has long gone. As was discussed, the distinction between academic and commercial research has increasingly been blurred by the close relations of academic research institutions and business enterprises as well as the increasing practice of university licensing. As the facts of the *Merck-Integra* case show, basic and applied research in biotechnology merge continuously into each other, with combinations of third-party funding and back-licensing agreements.<sup>330</sup> Many individual research projects can no longer be assigned to only one of these categories.

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<sup>330</sup> See *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003).

Second, it is hard to argue that basic research is intrinsically more valuable than applied research. The first aims at advancing human knowledge, the second at fulfilling human needs. Applied research in pharmaceuticals may be dependent on basic research in biology and medicine, but basic research alone will not be useful in the sense of curing a single patient. In any event, we must be careful not to disregard the traditional interpretation of the information dilemma and dynamic incentives for invention. One cannot facilitate access to present inventions that are useful for research in the short run without curtailing incentives to develop future inventions useful for research, thereby affecting technological progress in the long run. Both need to be considered, and without adequate empirical knowledge of incentives and effects, the balance may be adversely affected by privileging basic research.

Finally, favoring basic research over applied research would be at odds with the basic assumption of the patent system that harnessing the business interests of individuals to innovate for commercial rewards will promote the public interest.

#### ***D. Facilitate Access to Research Tools?***

*Tom:* Throughout the world, patents are granted for research tool inventions, in biotechnology as well as in other fields of technology. But I wonder whether the problem of patented research tools may be more acute under U.S. law than under European law, as Articles 52(1) and 57 of the EPC,<sup>331</sup> §§ 1(1)(c) and 4 of the U.K. Patents Act 1977,<sup>332</sup> and §§ 1(1) and 5 of the German Patents Act<sup>333</sup> require that inventions be susceptible to “industrial application.” These statutes may not so easily cover upstream inventions like genetic and protein sequences, diagnostics, and software that can be used as research tools.

*Eve:* Maybe the term “industrial application” is misleading, as the patent law interpretation of this term has evolved from its historic and common meaning. The requirement of being susceptible to industrial application

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<sup>331</sup> EPC, *supra* note 117, arts. 52(1), 57.

<sup>332</sup> U.K. Patents Act, 1977, c.37, §§ 1, 3, *available at* <http://www.jenkins.eu/statutes/patents.asp>.

<sup>333</sup> Das deutsche Patentgesetz [German Patents Act] §§ 1, 5, *available at* <http://www.gesetze-im-internet.de/patg/index.html>.

was historically introduced to distinguish patentable manufacturing inventions both from unpatentable discoveries of science and nature (excluded principally on religious grounds<sup>334</sup>) and from non-manufacturing businesses (such as farming and mining, excluded on different policy grounds<sup>335</sup>). As these historic discriminations have largely been abolished,<sup>336</sup> the requirement of industrial applicability now serves very different purposes (and different moral sensibilities). For example, Article 52(4) of the EPC,<sup>337</sup> § 4(2) of the U.K. Patents Act 1977,<sup>338</sup> and § 5(2) of the German Patents Act<sup>339</sup> preclude methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body from being considered industrial applications.<sup>340</sup> This restriction, however, does not apply to research tools, as most research tools are not methods. Inventions also are not considered industrially applicable if they cannot be manufactured or used in industrial factories (and probably any product invention can be so manufactured or used) or cannot be used other than privately and for non-commercial purposes (and probably all research uses can be commercial).<sup>341</sup> Thus, research tools generally are not excluded from patentability. However, for biotechnological research tools, recitals 22, 24

<sup>334</sup> See *supra* note 41 and accompanying text; see also John R. Thomas, *The Post-Industrial Patent System*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3, 50–53 (1999).

<sup>335</sup> BERNHARDT & KRASSER, *supra* note 169, at 105; RALPH NACK, DIE PATENTIERBARE ERFINDUNG UNTER DEN SICH WANDELNDEN BEDINGUNGEN VON WISSENSCHAFT UND TECHNOLOGIE 153 (2002); Markus Schar, *Zum objektiven Technikbegriff im Lichte des Europäischen Patentübereinkommens*, 1998 MITT. 322, 337–38.

<sup>336</sup> FRIEDRICH-KARL BEIER, STEPHEN CRESPI & JOSEPH STRAUS, BIOTECHNOLOGIE UND PATENTSCHUTZ 10 (1986); BERNHARDT & KRASSER, *supra* note 169, at 105–14.

<sup>337</sup> EPC, *supra* note 117, art. 52(4).

<sup>338</sup> U.K. Patents Act, 1977, c. 37, § 4(2), available at <http://www.jenkins.eu/statutes/patents.asp>.

<sup>339</sup> Das deutsche Patentgesetz [German Patents Act], § 5(2), available at <http://www.gesetze-im-internet.de/patg/index.html>.

<sup>340</sup> EPO, Boards of Appeal, Case T 385/86 - 3.4.1 (*Nicht-invasive Messwertermittlung/BRUKER*), 1988 GRUR Int'l. 938 (939); EPO, Boards of Appeal, Case T 116/85 - 3.3.1 (*Schweine I/WELLCOME*), 1989 GRUR Int'l. 581 (583); BGH Sept. 26, 1967, 1968 GRUR 142 (143–46) (*Glatzenoperation*).

<sup>341</sup> EPO, Opp. Div., Case T 74/93 (*Verfahren zur Empfängnisverhütung/BRITISH TECHNOLOGY GROUP*), 1995 O.J. 712; BGH Sept. 26, 1967, 1968 GRUR 142 (145) (*Glatzenoperation*); BERNHARDT & KRASSER, *supra* note 169, at 105–14; NACK, *supra* note 335, at 153–54, 222; Bernhard Jestaedt, in GEORG BENKARD ET AL., EUROPÄISCHES PATENTÜBEREINKOMMEN arts. 57.1–57.5 (2002); Keukenschrijver, *supra* note 132, §§ 5.4, 5.8, 5.9.

and Article 5 (3) of the European Biopatent Directive<sup>342</sup> clarify that a genetic sequence is to be regarded as capable of industrial application only if the patent application as filed specifies which protein or part of a protein is produced and/or<sup>343</sup> what function the sequences perform.

*Tom:* Well, that may be true, but it does not fully answer whether or not research tools should be considered industrially applicable because they reflect basic scientific discoveries. The United States Supreme Court (if not the lower courts and the Patent and Trademark Office) addresses the issue differently, asking whether or not the claimed invention reflects more than “conventional or obvious” “post-solution activity”<sup>344</sup> or whether it merely limits a newly discovered scientific principle “to a particular technological use.”<sup>345</sup> Moreover, in making that determination (and when evaluating obviousness—or in your terminology, inventive step), the newly discovered scientific principle is treated as if it were prior art public knowledge, requiring a “some other inventive concept in its application.”<sup>346</sup> Thus, in many cases, claimed inventions should not be patentable (either as not industrially applicable or as obvious applications of new scientific discoveries), even if the meaning of industry has radically changed.

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<sup>342</sup> Council Directive 98/44/EC, art. 5(3), 1998 O.J. (L 213) (EC); *see also* van Raden & von Renesse, *supra* note 213, at 395; Straus, *supra* note 213, at 1018.

<sup>343</sup> Probably due to a mistake in the official translation, English and German versions of the Directive differ on whether the wording is “or” or “and.” *See* KREFFT, *supra* note 144, at 233–34.

<sup>344</sup> *Parker v. Flook*, 437 U.S. 584, 590 (1978).

<sup>345</sup> *Diamond v. Diehr*, 450 U.S. 175, 192 n.14 (1981); *see In re Comiskey*, 499 F.3d 1365, 1378–79 (Fed. Cir. 2007) (holding unpatentable claims for arbitration business methods and stating that “the present statute does not allow patents to be issued on particular business systems . . . that depend entirely on the use of mental processes.”); *cf. In re Nuijten*, 500 F.3d 1346, 1353–57 (Fed. Cir. 2007) (holding unpatentable claims for electronic signals that were not limited to a specific physical carrier, as they did not fall within the statutory category of “manufactures”). *See generally* Brief of *Amici Curiae* Ten Law Professors in Support of Appellee Director of the United States Patent and Trademark Office, *In re Bilski*, No. 2007-1130 (Fed. Cir. Apr. 7, 2008) (en banc), *available at* <http://www.wcl.american.edu/pijip/go/research-and-advocacy/ip-policy-and-law-reform>.

<sup>346</sup> *Parker*, 437 U.S. at 594 (citing *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 115 (1853) and *Neilson v. Harford*, Web. Pat. Cases 295, 371 (U.K. 1844)). For a discussion of the history of this requirement, *see* Sarnoff, *supra* note 41, at 21–112.

The United States also addresses genetic sequence inventions differently, requiring a sufficient disclosed functional utility to grant the patent. Although that may not necessarily require the specification of the protein, it does require identification of some useful function that the sequence achieves and which goes beyond the mere use as a research tool to investigate proteins.<sup>347</sup> So if a patent for a research tool is granted, this should imply some intended and sufficiently developed utility for general research that should be protected adequately. Of course, given that a U.S. patent grants exclusive rights as to all uses, the disclosed utility may not be the research tool use of concern and that motivated the invention and the patent. In contrast, the European Biopatent Directive at least suggests that patent protection should be limited to the disclosed functional uses, even if the doctrine of absolute protection is currently the rule.<sup>348</sup> Thus, whether to grant or to deny patents on research tools raises more fundamental questions about the goals of the patent system and the rights that should be granted. It would provide no benefit to society to grant such patents and then to except from infringement liability the intended purpose of the invention (and maybe its only known application).

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<sup>347</sup> See, e.g., *In re Fisher*, 421 F.3d 1365, 1373 (Fed. Cir. 2005) (“[T]he claimed ESTs [expressed sequence tags] act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. . . . Accordingly, the claimed ESTs are . . . mere ‘object[s] of use-testing,’ to wit, objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end.”). Cf. *Ex parte Bouton*, No. 2006-1879, 2006 WL 2822238, at \*6 (B.P.A.I. Sept. 28, 2006) (“A method that enhances the efficiency of transfer of nucleic acids to cells *in vivo*, as the present method is said to do, provides a valid research tool that those skilled in the art could use in carrying out experiments involving transferring nucleic acids to cells *in vivo*. . . . [T]he claimed method is broadly useful for transferring nucleic acids into cells. The instant claims are directed to a completed invention, not a ‘research intermediate’ as in *Fisher*, that can be used to carry out research using a variety of nucleic acids, cells, and subjects. Thus, the instantly claimed method is a valid research tool that can be used to carry out research in general rather than research limited to discovering information about the claimed invention itself.”).

<sup>348</sup> See Council Directive 98/44, *supra* note 342, recital 23 (“Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention”); Johanna Gibson, *The Discovery of Invention Gene Patents and the Question of Patentability* 3 (DIME Working Paper No. 30, 2007), available at [http://www.dime-eu.org/files/active/0/IPR-WORKING-PAPER-30\\_Gibson.pdf](http://www.dime-eu.org/files/active/0/IPR-WORKING-PAPER-30_Gibson.pdf) (citing LIONEL BENTLY & BRAD SHERMAN, *INTELLECTUAL PROPERTY LAW* 387 (2d ed. 2004)) (noting that “as the law currently is applied” claims to genetic sequences based on their identified function nevertheless apply to all uses).



*Eve:* You are right that there would be little reason to grant a patent that had no ability to exclude others from practicing the intended uses of the disclosed invention. But that is very different from saying that we need to issue patents for intended uses as research tools, or that providing protection only for commercial competition in supplying the research tools would be inadequate to protect patent holder incentives. As you noted, the United States may allow patents for research tools where the patent holder has identified only a very limited social function for the research tool, and it is not clear that we need to protect incentives for such limited development. The question of the effects on generation and availability of research tools in both the short run and the long run is uncertain. We need more empirical research into why different kinds of research tools are created<sup>349</sup> and what would happen if they were not patentable, or if only some of the bundle of exclusive rights were provided, as in Belgium.

*Tom:* I agree that we would need to distinguish between different types of research tools and the importance of assuring access to them. It may be necessary to assure access for research tools that are “too useful” to be restricted (rather than having too little identified utility). Under current U.S. law (and some other countries’ laws), the patent holder is free to refuse to license the patent. This is particularly important in biotechnology, where restricting access to new cell lines, new probes, or other “platform” technologies would allow a particular scientist (or institution) to direct the scope of research of an entire field. Imagine what would have happened if Boyer and Cohen had decided to keep their patent limited to University of California and Stanford? Whether assuring public access to important research tools is dealt with through antitrust-like requirements for prohibiting restrictions on licensing that create “monopoly market power” in the research field, or is dealt with through exceptions to infringement or compulsory licensing regimes, is an open question. But we clearly need to prevent such important basic patents from being restricted from further use in experimentation.

*Eve:* I agree that it is important to facilitate future research. However, a distinction between more and less important research tools would be hard to make and lead to yet more uncertainty. The importance of an invention could hardly be assessed in the patent examination procedure, as

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<sup>349</sup> See *supra* notes 249–51 and accompanying text.

experience teaches that the real importance of an invention can be quite unforeseen and turn out only years after the granting of a patent. And the distinction would still be hard to make at the moment of a possible licensing agreement. Opinions of licensor and licensee tend to differ on that particular point, and who is to say which view will be accurate? Nor does economic analysis suggest a clear answer, given that the more important the research tool the more it should deserve a greater reward (either *ex ante* as an incentive to its creation or *ex post* as a reward). Thus, I am skeptical about allowing access to research tool inventions based on their importance, rather than on abuse of market power, which I agree would be a valid justification. If we are going to look at the importance of the research tool, and whether or not licensing behaviors are preventing access, wouldn't it be better to address that issue through compulsory or statutory licensing? Particularly if antitrust principles were implicated, one could make the compulsory license available without compensation.

*Tom:* Here, again, we differ. It is precisely because of the unforeseeable nature of the importance of research tools that I would be inclined to provide a complete, uncompensated exception from infringement for all basic research (and not for applied research). Although I am inclined to agree that it will be difficult to distinguish between basic and applied research based on the technologies, it may be possible to make the relevant distinctions based on the uses sought for the patented technologies.

*Eve:* But wouldn't such an exception be in danger of violating national constitutional guarantees of property and equality, as well as international obligations under Articles 27(1) and 28(1) of TRIPS, which stipulate that "patents shall be available for any inventions, whether products or processes, in all fields of technology,"<sup>350</sup> that patent rights shall be enjoyable without discrimination as to the field of technology, and that patents shall grant the exclusive right to make, sell, and use?<sup>351</sup>

*Tom:* I don't think so. As we heard, these restrictions may be structured (at least prospectively) as limitations on the scope of the right provided, rather than any restriction imposed upon it, and thus should avoid constitutional concerns. Further, they would not facially differentiate by

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<sup>350</sup> TRIPS *supra* note 27, art. 27(1).

<sup>351</sup> *Id.* art. 28(1).

field of technology, and even if they did there would be good normative grounds to do so and thus should satisfy Article 27(1). For the same reason, they should not violate Article 28(1) and, if recourse to it were needed, should comport with the TRIPS Article 30 standard for exceptions to patent rights.<sup>352</sup> I don't think the TRIPS Agreement intended to prescribe the range of possible answers to the normative questions posed in this context, particularly given the wide range of experimental use provisions that existed when the Agreement was negotiated.

*Eve:* I do not think that the non-discrimination provision of Article 27(1) of TRIPS is somehow overruled by Article 30 of TRIPS. This is not implied by the WTO panel's precedent. As we heard, in the *Canada—Patent Protection of Pharmaceutical Products*<sup>353</sup> case, the European Union argued that Canada's regulatory approval exception violated Article 27(1) of TRIPS on, especially, a disparate impact theory. The panel treated technological neutrality as a structural requirement, and rejected the EU's specific contention only on Canada's assurance that the exception at issue was indeed facially neutral as to the field of technology. Article 30 provides for exceptions to patent rights, and contains no suggestion that any exception from the Article 27(1) non-discrimination rules for patent rights was intended. An exception justified under Article 30 thus must still comport with the non-discrimination requirement of Article 27(1). Stated differently, an exception must be both non-discriminatory under Article 27(1) and justifiable under Article 30.

*Tom:* But the panel defined discrimination as normatively unjustified differentiation,<sup>354</sup> so a finding of justification under Article 30 should also preclude a finding of discrimination under Article 27(1). In any event, it is hard to see how a generally available research tool exception could be found to discriminate by field of technology (except under the rejected disparate impact theory). Indeed, such an approach appears particularly anomalous in that it would make a broader-than-necessary exception more sustainable under international law. This is inconsistent with the norm contained in Article 30 that any such exceptions be "limited."<sup>355</sup> A targeted exception that differentiated between types of in-

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<sup>352</sup> *Id.* art. 30.

<sup>353</sup> WTO Panel Report, *supra* note 225, ¶ 4.36.

<sup>354</sup> WTO Panel Report, *supra* note 225, ¶ 7.94.

<sup>355</sup> TRIPS, *supra* note 27, art. 30.

vention would limit a patent holder's rights only in areas where one perceives an imbalance between public and private rights. Regardless of whether a panel might be more sympathetic to an exception that is cast in general terms, TRIPS should be more favorably disposed to exceptions "that are either targeted or, though framed broadly, evolve" to favor more particular uses.<sup>356</sup>

*Eve:* Well, then let's discuss the normative justification. In the *Canada—Patent Protection of Pharmaceutical Products* case, the panel held that the normal practice of exploitation was "to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."<sup>357</sup> As I understand the TRIPS Agreement, it neither allows the exclusion of research tools from patentability nor allows a valid patent to be degraded to such a state that it cannot be exploited commercially because all possible users have already obtained free access.

*Tom:* I am not so sure that there would be a violation of TRIPS. I am suggesting only excepting research tool access for academic researchers, and even for them I am not suggesting that commercial competitors could sell research tools to academics without infringing the patent (unless perhaps the patent holder itself refuses to sell the tools or license others to do so, as no market harm to the patent holder would thereby result). Thus, not every possible user would get free access, and no commercial competitor would benefit from the exception. In most cases, users of research tools will happily obtain them and pay the implied license royalties to the patent holder if the invention is provided on reasonable commercial terms. The important point is for many countries to articulate clearly the public policy supporting the need for a broader exception that precludes compensation when academic researchers use research tools for basic research. If the public policy were clearly articulated, then there could not be—in the sense of Article 30 of TRIPS—any "unreasonably prejudice the legitimate interests of the patent holder,

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<sup>356</sup> Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *WTO Dispute Resolution and the Preservation of the Public Domain of Science Under International Law*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER GLOBALIZED INTELLECTUAL PROPERTY REGIME*, at 861, 875 (2005), available at <http://www.kentlaw.edu/depts/ipp/publications/Cambridge0405.pdf>.

<sup>357</sup> WTO Panel Report, *supra* note 225, ¶ 7.55.

taking account of the legitimate interests of third parties.”<sup>358</sup> As I already noted, expectations of what constitutes “normal” exploitation circularly depend on the appropriate international normative judgments, and nothing in the TRIPS Agreement (much less in the Paris Convention<sup>359</sup>) suggests that such judgments were to be limited to understandings or conditions at the time of entry of the Agreement into force, or of ratification by a party.

*Eve:* Indeed, circularity is a serious criticism of the juridical sciences, and of many international treaty obligations. However the criticism does not necessarily apply to Article 30 of TRIPS and its application to a research tool exception. Admittedly, Article 30 of TRIPS is a provision that is quite difficult to apply because of its vagueness. However, I think we can agree on at least the following: during the negotiation of the TRIPS Agreement, the main focus of attention was on codifying agreed-upon norms of protection that then existed. Hence, the concluding parties of the TRIPS Agreement agreed to a system of intellectual property rights that is based on property rules, with some reservation for exceptions from the rights assigned.<sup>360</sup> With the adoption of a research tool exception, at least for inventions disclosed with the sole intention for use as research tools, the exclusivity in favor of a patent holder would be lost. This would seem a great leap away from what traditional exceptions allowed for, and thus could extend too far under Article 30.

*Tom:* But it is not clear that many such exclusive research tools would or should be patentable, as their only identified use would be in research to develop other useful information. Nor is it clear that, at the time the TRIPS Agreement was adopted, research uses were clearly believed to be within the scope of exclusive patent rights. And in any event, you

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<sup>358</sup> TRIPS, *supra* note 27, art. 30.

<sup>359</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *revised* July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

<sup>360</sup> Compare TRIPS, *supra* note 27, art. 13 (“Members shall confine limitations or exceptions to exclusive rights to *certain special cases* which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder” (emphasis added)) with TRIPS, *supra* note 27, art. 30 (“Members may provide *limited* exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties” (emphasis added)).

are making a fairly positivist argument based on the intent of the patent holder that proves too much. Even if it were true that Article 30 of TRIPS was negotiated with protection for research uses in mind, Article 31 of TRIPS nonetheless allows for the adoption of compulsory licensing regimes, and compulsory licenses can surely be granted to permit the practice of the invention for its intended purpose. I think the important point for distinguishing whether or not an abstract research tool exception would comply with the TRIPS Agreement is between patents for which there is a broader commercial market than basic research and patents for which there is not. In the first case, the ability to recoup investment and to recover a return from the patent still exists. Where the only commercial market is the research use, it gets much more difficult to find an exception that would preserve a patent holder's ability to recoup investment. Assuring that alternative forms of supply to academic researchers are prohibited, but permitting the use (and making) by such researchers seems to me to strike a good balance. And if it were too hard to distinguish between academic and commercial researchers, the same approach could apply more generally, as in Belgium where mixed scientific and commercial purposes should fall within the scope of the exception.

### 1. Possible Benefits of a Liability Rules Regime

*Tom:* So, as I just said, I believe it is possible to preserve the interests of research tool patent holders and facilitate basic research at the same time. In theory, research is stifled only by a patent holder's entitlement to sue researchers and to obtain an injunction preventing the research. If researchers were granted a right to use a research tool, but had to pay reasonable royalties to the patent holder, the research could occur and the patent holder would be able to recoup investment costs. This happens all the time with all sorts of patented products used in research, and the patent holder is compensated either through continuing royalties or by the purchase price (which conveys an implied license). Yes, I know that some reduction in research might still result, because some researchers could not afford the costs of royalties or supra-competitive purchases and thus would be deterred from performing the experiments. But such a "liability rule" regime for patents (as distinct from a "prop-

erty rule” that can prohibit access or use)<sup>361</sup> is supposed to accomplish a more economically efficient allocation of the factors of production, particularly when there is market failure, because the costs of negotiating transfers of rights are prohibitive, or other impediments to concluding negotiations exist.<sup>362</sup> Thus, a liability rule regime for research tools seems like a good idea.

A liability rule regime seems especially desirable in the field of biotechnology, where many basic research tools are patented (which also raises royalty-stacking concerns and the potential for the last licensor to demand an excessive royalty given the sunk costs of previously negotiated licenses) and must be used in substantial research programs. Inventors of biotechnology research tools also may be unwilling to share their inventions with research competitors. Even if they were willing, they may be unable to conclude licensing negotiations, given the ex ante uncertainty about the value of the research tools and the outcomes of their uses. Unlike an injunction to prevent commercial competition when the invention is being supplied on the market, an injunction in this context would directly interfere with the public interest in assuring further scientific research.<sup>363</sup> Although the value of research tools for society is difficult to assess, the public interest in scientific progress is likely to be greatest if research tools were used as intensively as possible.<sup>364</sup> A property rule for research tools thus seems inappropriate.

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<sup>361</sup> See generally REINHARD ELLGER, *BEREICHERUNG DURCH EINGRIFF* 294–98 (2002); Ian Ayres & Eric Talley, *Distinguishing Between Consensual and Nonconsensual Advantages of Liability Rules*, 105 *YALE L.J.* 235 *passim* (1995); Ian Ayres & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement To Facilitate Coasean Trade*, 104 *YALE L.J.* 1027 *passim* (1995); Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 *HARV. L. REV.* 1089, 1106–10 (1972); Louis Kaplow & Steven Shavell, *Do Liability Rules Facilitate Bargaining? A Reply to Ayres and Talley*, 105 *YALE L.J.* 221 *passim* (1995); Louis Kaplow & Steven Shavell, *Property Rules Versus Liability Rules: An Economic Analysis*, 109 *HARV. L. REV.* 713 *passim* (1996).

<sup>362</sup> Calabresi & Melamed, *supra* note 361, at 1095–96.

<sup>363</sup> GILAT, *supra* note 254, at 80–83; Barton, *supra* note 33, at 616–17 (1995); Q. Todd Dickinson, *Reconciling Research and the Patent System*, *ISSUES SCI. & TECH.*, Summer 2006 at 70; Eisenberg, *Patents and the Progress of Science*, *supra* note 25, at 1078; Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 171–74; Feit, *supra* note 25, at 840; Kiley, *supra* note 33, at 917–18; Mueller, *supra* note 10, at 43; Rai, *supra* note 33, at 139; J. H. Reichman, *Of Green Tulips And Legal Kudzu: Repackaging Rights In Subpatentable Innovation*, 53 *VAND. L. REV.* 1743, 1768 (2000); see also O’Rourke, *supra* note 126, at 1177.

<sup>364</sup> Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 171. See generally Rebecca Eisenberg, *Patenting Research Tools and the Law*, in *INTELLECTUAL PROPERTY*

By providing ex post compensation rather than an injunction, a liability rule regime establishes the relative value of the research tool and of its use at a time when they are both better understood. A liability rule regime thus overcomes ex ante failures in the licensing market that are based on information gaps. Further, a liability rule regime can permit the sharing of benefits of successful research without imposing the costs of licensing fees on unsuccessful research, and would likely promote greater overall research activity. One way to do so would be to base compensation on reach-through licensing fees of fractional amounts of the market revenues of research outcomes.<sup>365</sup>

*Eve:* But wouldn't it be hard to pin down a percentage with which a research tool patent holder may take part in the user's revenues? And shouldn't the patent holder be entitled to some revenue even when the research was unsuccessful, or successful but not commercially viable?

*Tom:* I admit that it is a complex problem to actually fix a licensing fee.<sup>366</sup> But the courts do it all the time in the case of infringement. To save transaction costs of extensive lawsuits with expert opinions and counter opinions, it might be advisable to just apply some percentage of the profit before taxes that the research user may derive from marketing products downstream from the research tool use as the appropriate license fee, such as ten percent. This figure would have to be divided among multiple patent holders if several research tools had been used in the same research program, and if regarded as oversimplified, any percentage chosen as a presumptive amount could be modified in particular cases.<sup>367</sup> Or if you like, we could adopt a set of more flexible license fees, depending on whether the contribution of the research tool to the successful conclusion of the research was regarded as minor, medium or significant. Empirical studies could clarify what percentages would be appropriate contributions.<sup>368</sup>

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RIGHTS AND RESEARCH TOOLS IN MOLECULAR BIOLOGY 6 *passim* (1997) [hereinafter Eisenberg, *Patenting Research Tools*].

<sup>365</sup> Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 172; Mueller, *supra* note 10, at 42, 58–66.

<sup>366</sup> Mueller, *supra* note 10, at 63; Robert P. Merges, Comment, *Of Property Rules, Coase, And Intellectual Property*, 94 COLUM. L. REV. 2655, 2664 (1994).

<sup>367</sup> Mueller, *supra* note 10, at 64–65.

<sup>368</sup> See Reichman, *supra* note 363, at 1784.



*Eve:* But if the royalties were typically set too high, and people knew that judges would impose such clear liability rules, wouldn't that chill research just as surely as denying access to the research tools by enforcing injunctions? And would eliminating injunctive relief decrease the value of patents on research tools even with a liability rule, and thereby decrease the incentive to develop research tools in the first place?

*Tom:* That could happen. But whatever disincentive to creating research tools might result must be balanced against the degree to which uses would be facilitated. Moreover, inventors of research tools would still be rewarded after any use. And we can justify a liability rule regime without having to argue that inventors of research tools would be better off than with a property rule, so long as the public welfare would be advanced.<sup>369</sup>

## 2. Possible Downsides of a Liability Rules Regime

*Eve:* You have certainly made some good points there. However, I still don't think you have convinced me that we should adopt a liability rule regime. It comes down to whether you think that liability rules are a better means of pricing and allocating scarce resources than property rules, which I think depends on whether or not there is some significant market failure. If the market is functioning reasonably well, then the individual participants should be better able than a central planning authority (such as a judge) to articulate the participants' needs and to evaluate the appropriate prices for goods necessary to satisfy those needs. By decentralizing decision making, prices may vary in either direction, and can rapidly be imitated by others to efficiently allocate output levels.<sup>370</sup> And it is also important to note that some countries adopt economic policies that not only promote economic efficiency but also maximize personal freedom of their citizens. The freedom to negotiate about one's needs according to one's own choice is therefore backed by both

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<sup>369</sup> See *id.* at 1795; Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 174; Mueller, *supra* note 10, at 41–66.

<sup>370</sup> ELLGER, *supra* note 361, at 257–65; ARNOLD HILKEN, INNOVATION UND PATENTSCHUTZ AUF DEM EG-ARZNEIMITTELMARKT 99–107 (1989); Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 850–52 (1988); Wendt, *supra* note 174, § 14.8; see also HESSE, *supra* note 288, at 223–34.

utilitarian and liberal arguments.<sup>371</sup> And liability rule regimes override the freedom to disagree with another person's demands.

*Tom:* So where do you draw the line between free markets and government intervention to best accomplish both efficiency and liberty goals? A libertarian would of course argue that no government intervention is needed or is desirable. And having compulsory licensing in the background often facilitates freely negotiated licensing.

*Eve:* Property rules are needed to protect the property owner's freedom to determine an acceptable price for a free exchange. Take away the property rule and you take away the freedom of the negotiation. The premise of free markets is that one party is initially assigned property in goods, permitting that party to decide whether and on what conditions to dispose of them.<sup>372</sup> Only with a property rule can an initial owner refuse to transfer the goods when the price does not seem fair. In contrast, once another party has acquired the goods, or if the other party can do so knowing that the initial owner cannot unilaterally set the price at what the initial owner thinks is fair, the initial owner's negotiation position is severely impaired.<sup>373</sup>

*Tom:* So far, this is quite general. What is the connection here to a liability rule for research tools?

*Eve:* Incentives for future innovation of research tools will depend on the connection between perceived justice and potential economic rewards. The economic rewards reflect the benefits of licensing provided by the research tools, which avoids costs that the licensees would otherwise in-

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<sup>371</sup> BVerfG Aug. 17, 1956, 5 BVerfGE 85 (204); BVerfG Nov. 12, 1958, 8 BVerfGE 274 (328); BVerfG May 13, 1986, 72 BVerfGE 155 (170); BVerfG Feb. 7, 1990, 81 BVerfGE 242 (254); BVerfG Oct. 19, 1993, 89 BVerfGE 214 (231); Dietrich Murswiek, in MICHAEL SACHS ET AL., GRUNDGESETZ §§ 2.11, 2.54 (2d ed. 1999); Philip Kunig, in INGO V. MÜNCH ET AL., 1 GRUNDGESETZ-KOMMENTAR § 2.16 (5th ed. 2000);

<sup>372</sup> Wendt, *supra* note 174, §§ 14.5, 14.22, 14.41.

<sup>373</sup> BVerfG Dec. 18, 1968, 24 BVerfGE 367 (400); BVerfG July 7, 1971, 31 BVerfGE 229 (243); BVerfG Oct. 11, 1988, 79 BVerfGE 29 (41); ELLGER, *supra* note 361, at 299; FECHNER, *supra* note 174, at 165; Ayres & Talley, *supra* note 361, at 1037; Kenneth W. Dam, *Die ökonomischen Grundlagen des Patentrechts*, in CLAUS OTT ET AL., ÖKONOMISCHE ANALYSE DER RECHTLICHEN ORGANISATION VON INNOVATIONEN 296 (1994); Kaplow & Shavell, *supra* note 361, at 774; Wilhelm Nordemann, *Nutzungsrechte oder Vergütungsanspruch?*, 1979 GRUR 280, 282; Wendt, *supra* note 174, at § 14.41.

cur.<sup>374</sup> The question is simply, who is to decide what those benefits are worth? Any external evaluation of the fairness of licensing terms and conditions under a liability rule regime would sacrifice the private freedom of property holders for paternalism.<sup>375</sup> Such external assessments would be less efficient in the long run, because the centralized decision making of externally established terms and conditions will reduce opportunities for the competitive evolution of different types of licenses that may be more appropriate for different types of inventions.<sup>376</sup> A general compulsory licensing regime would aim to eliminate free negotiation of licenses because the government's determination would dominate.

And how would a liability rule regime assure that the parties will understand and accept the conditions of any imposed solution? A property rule prevents transactions from happening before consent on the relevant terms is reached, and therefore the negotiated contract is less likely to be questioned by the agreeing parties *ex post*. But there is no equivalent mechanism for settling differing opinions on contract conditions for liability rules; therefore extensive lawsuits on licensing terms could result, increasing instead of decreasing transaction costs and postponing emoluments for patent holders.<sup>377</sup>

*Tom:* I will admit that fixing appropriate royalties is difficult without a free market mechanism in the background to which to refer, and that a liability rule regime does not eliminate legal costs. As I have already mentioned, approaches like reach-through royalties can help to overcome these problems, as they remain based on market values revealed after the uses have occurred. But you still have not provided any reason to believe that a research tool patent holder's ability under a property rule regime to refuse to license will be efficient from a social welfare perspective. It is not clear that the patent holder's perception of fairness should always be protected or that incentives to produce will unduly

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<sup>374</sup> Joachim Bussmann, *Patentrecht und Marktwirtschaft*, 1977 GRUR 121, 131–34.

<sup>375</sup> Calabresi & Melamed, *supra* note 361, at 1117 n.57, 1110 n.40; Willi Erdmann, *Urheberrecht im Meinungsstreit*, 2002 GRUR 923, 925; Nordemann, *supra* note 373, at 282.

<sup>376</sup> Calabresi & Melamed, *supra* note 361, at 1108, 1117 n.57; Erdmann, *supra* note 375, at 925; Mueller, *supra* note 10, at 64; Rai, *supra* note 33, at 142.

<sup>377</sup> Mueller, *supra* note 10, at 64; Nordemann, *supra* note 373, at 282.

suffer if they are not. After all, people adapt rapidly to all sorts of constraints on their freedom.

*Eve:* I don't have a theoretical answer to the question, but I do think that your proposed way of solving the problem is inadequate. The relation between use of a research tool and profits from the sales of downstream products is too distant to provide a coherent basis for any externally imposed royalties. Too many questions arise for which there will likely be insufficient answers: Shall basic research tools like the PCR process and particular research tools like individual genetic sequences for high throughput screening be treated the same? How would you determine that the research tool, in fact, caused the commercial results? For example, one might argue that profits result more from marketing than from the scientific benefit derived from the research tool. What royalty rate would be appropriate when there is no marketable downstream product, such as for purely academic research (the situation for which liability rules are primarily proposed)? How would courts fix a particular royalty rate, given the wide range of rates that are negotiated voluntarily?

The uncertain costs and timing of reach-through licensing might further encumber research tool development and use.<sup>378</sup> The delay in receiving royalties until subsequent commercial uses develop would effectively act as a loan from the patent holder to the research tool user, which may be particularly problematic for small biotechnology startup companies that hold patents to research tools but have limited financial reserves. In contrast, incentives to use research tools will suffer if subsequent commercial benefits of the research will be burdened with tax-like royalties.<sup>379</sup>

Further, a liability rule regime would preclude exclusive licensing arrangements. Unless we conclude that exclusive licensing is always contrary to the public interest, this would be a significant drawback for both development and use of at least some research tools. Empirical studies have shown that for some kinds of biotechnological research tools only

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<sup>378</sup> Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 174.

<sup>379</sup> Eisenberg, *Patenting Research Tools*, *supra* note 364, at 15; Eisenberg, *Technology Transfer and the Genome Project*, *supra* note 112, at 172; Heller & Eisenberg, *supra* note 33, at 699; *see also* Ayres & Talley, *supra* note 361, at 1036, 1085–103.

exclusive licensing is employed.<sup>380</sup> This is because an exclusive license guarantees exclusivity of research with the licensed invention, permitting the licensee a better chance to recoup invested capital in the license itself. Exclusive licensing may be particularly important for pharmaceutical research programs that seek to develop commercial uses for genetic inventions such as drug targets, rather than for research tool uses, given the risks and costs associated with such development.

In summary, I agree that adopting a liability rule regime would facilitate access to research tools. But patent law, like other areas of the law, must look to both production and allocation incentives. And under a liability rule regime, both incentives may sometimes be impaired. Few things in life come for free, and I fear that the problems to be addressed by interfering in the market may only be postponed until after the use and then may be worse for public welfare.

#### *E. Reconciliation of the Fictive Speakers*

*Tom:* At least we agree that access to and licensing of research tools can pose difficult problems, and that liability rule regimes are a means to facilitate access. These problems may not be unique to patent law or to biotechnological research tools, even if they are particularly common and acute in these contexts.

*Eve:* We also agree that adopting a general liability rule regime for research tools would create some disincentives for development and use of research tools, and arguably might require amendment to the TRIPS Agreement. Although it may not be found to be discrimination by field of technology under Article 27(1) of TRIPS, it might go beyond a limited exception under Article 30 of TRIPS if it did not follow the requirements of Article 31 of TRIPS.

*Tom:* While a liability rule regime for research tools is a solution to be kept in mind, we need more empirical information before we could conclude that it should or should not be imposed. In particular, we need to know more about existing incentives to develop and use research tools, how exceptions from infringement liability for research tools are affecting or

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<sup>380</sup> JOSEPH STRAUS ET AL., GENETIC INVENTIONS AND PATENT LAW 22 (2004).

would affect those incentives, and how a liability rule regime would change those incentives.

*Eve:* The empirical studies to date have not demonstrated significant problems with development, licensing, and use of research tools, but this may be more a function of ignorance of (or disdain for) the legal rules than of recognition of what they are or should be.<sup>381</sup> There are reasons both to be optimistic and concerned about the future. On the one hand, patent holders typically seek to maximize revenue, and given their inability to exploit all conceivable uses of their inventions they continue to have incentives to license their inventions on terms and conditions that others will pay. Licensing also gives patent holders the possibility to generate revenues with minor risk rather than developing marketable products themselves. On the other hand, patent holders may not be able to perform adequate price discrimination, and both patent holders and users of inventions may be highly sensitive to legal interpretations of the scope of exclusive patent rights that may change over time.

*Tom:* If significant problems develop, we should expect not only the exceptions to patent infringement to change, but also, and perhaps more significantly, patentability requirements, including reconsidering patentable subject matter and inventive step requirements.

## V. CONCLUSION

The experimental use and regulatory approval exceptions in the United States and the European Union differ significantly in their history, scope, and application. These exceptions have been and will become even more essential to patent law and related regulatory policy. Accordingly, we remain certain that the issues discussed above will remain front and center in international patent law developments.

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<sup>381</sup> STRAUS ET AL., *supra* note 380, at 25; John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021, 1021 (2003).