# FINDING THE RIGHT TOOL FOR THE JOB: ADEQUATE PROTECTION FOR RESEARCH TOOL PATENTS IN A GLOBAL MARKET?

This comment discusses the remedies available for enforcement of research tool patents used in the biotechnology and pharmaceutical industries. Part I describes the general function of U.S. patent laws and addresses a loophole allowing infringement of process patents. As discussed in Part II, recognition of this loophole prompted Congress to add section 271(g) to the Patent Act. Part III introduces the scientific principles that govern modern drug discovery, describes what is meant by the term "research tool," and presents current business and research trends in the biotech and pharmaceutical industries.

Part IV analyzes recent decisions from the Court of Appeals for the Federal Circuit (CAFC) regarding infringement exceptions. Part V describes a limited, alternative remedy available to U.S. patent holders when the Patent Act provides inadequate protection. Finally, Part VI highlights the challenges encountered by small businesses seeking adequate international protection for research tool patents. In large part, these challenges are due to impracticalities in the application for and enforcement of foreign patents. The author concludes that the decisions collectively promote willful infringement of research tool patents in international forums that will harm primarily small biotech entities and stifle innovation and suggests expanded coverage for research tool patents under the Patent Act.

## I. PATENT LAWS IN THE UNITED STATES

Globalization of the world economy has created an ever-

increasing need for consistent and reliable protection of intellectual property (IP) rights.[1] In the United States, the protection afforded by constitutional[2] and legislative[3] mandate provides a dependable means for securing exclusive rights to the "fruits" of an inventor's creative labor. Patents serve as the main source of domestic protection for new ideas and may issue for one of three types of claimed inventions: products, methods of manufacture, or methods of use (the last two are also called "process" inventions).[4] The scope of protection afforded to U.S. patent holders against acts of domestic infringement is definitive.[5] The exclusionary rights granted by a patent are crucial where commercial ventures rally around a central technology-based product or idea.[6] In developed nations, this security is universally assumed.[7]

While the protections granted by U.S. patents are explicit,[8] the protection has limited effect beyond the U.S. borders.[9] Inventors relying solely on United States patents for protection were once completely powerless to enforce their rights against

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1. *See* John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Rights*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 83 (2002) (arguing for a unified international system of obtaining global patent protection).

2. *See* U.S. CONST. art. I, § 8, cl. 8. (authorizing Congress "[t]o 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").

3. *See* 35 U.S.C. §§ 1–376 (2000); s*ee also* 37 C.F.R. §§ 1.1–1.825 (2004).

4. *See* 35 U.S.C. § 101.

5. *See* 35 U.S.C. § 271(a)–(c) (defining acts of direct infringement).

6. 35 U.S.C. § 154(a) ("Every patent shall . . . grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling . . . or importing the invention into the United States, . . . if the invention is a process, of the right to exclude others from using, offering for sale, . . . selling, or importing into the [U.S.], products made by that process . . . .").

7. *See Universal Declaration of Human Rights*, G.A. Res. 217A (III), U.N. GAOR, 3d Sess., pt. 1, art. 27(2), at 76, U.N. Doc. A/810 (1948). *But see, e.g.,* ROBERT L. OSTERGARD, JR., THE DEVELOPMENT DILEMMA: THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS IN THE INTERNATIONAL SYSTEM 28–31 (Eric Rise ed. 2003) (arguing that protection of intellectual property rights may conflict with protection of more fundamental human rights, including rights to food, medicine, and shelter).

8. 35 U.S.C. § 154.

9. Rotec Indus., Inc. v. Mitsubishi Corp., 215 F.3d 1246, 1251 (Fed. Cir. 2000) (citing Dowagiac Mfg. Co. v. Minn. Moline Plow Co., 235 U.S. 641, 650 (1915)).

infringers who chose to make, use, offer to sell, or sell patented subject matter in foreign countries.[10] This possibility created an obvious loophole around the protection extended to valuable process patents. Infringers could use such processes outside of the United States to manufacture unpatentable products for subsequent import and sale in the United States.[11] Exploitation of this loophole may be borne disproportionately by certain industries due to the nature of the processes claimed. The problem is particularly relevant to biotech process patent holders because "[b]iotechnology companies are often built around a new process for artificial manufacture of a substance that occurs in nature and is therefore itself unpatentable."[12] Congress recognized that foreign manufacturers could easily abuse the loophole for competitive advantage in both the biotech and pharmaceutical sectors.[13]

Addressing the loophole, Congress amended the Patent Act to strengthen existing laws.[14] Prior to amendment, the law allowed only for exclusionary orders under section 337 of the Tariff Act of 1930, which Congress simultaneously amended.[15] Such orders are granted under authority of the International Trade Commission (ITC).[16] To curtail blatant infringement,

10. 35 U.S.C. § 271.

11. United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127–28 (D.C. Cir. 1981) ("Sale of a product made by a patented process does not infringe the patent; it is the unauthorized use of the process that infringes the patent.").

12. S. REP. No. 100–83, at 30 (1988).

13. *Process Patent Legislation: Hearing before the Subcomm. on Patents, Copyrights, and Trademarks of the Comm. on the Judiciary U.S. Senate*, 100th Cong. 3 (1987) (statement of Sen. Orrin Hatch) ("Certainly, all of us here today share the goal of this legislation: protecting American business interests from exploitation by foreign corporations.") [hereinafter Process Patent Legislation].

14. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100–418, §§ 9002–05, 102 Stat. 1107, 1563–66 (1988) (codified at 35 U.S.C. §§ 154, 271, 287, 295) [hereinafter Trade and Competitiveness Act].

15. *See* Trade and Competitiveness Act, *supra* note 14 at §§ 1341–42 (codified at 19 U.S.C. § 1337) (2000).

16. *About Us*, at http://www.usitc.gov/ext_relations/about_itc/index.htm (last visited Jan. 22, 2005) ("The U.S. International Trade Commission [(ITC)] is an independent, nonpartisan, quasi-judicial federal agency that provides trade expertise to both the legislative and executive branches of government, determines the impact of imports on U.S. industries, and directs actions against certain unfair trade practices, such as patent, trademark, and copyright infringement.").

Congress sought to "expand[] the scope of [U.S.] laws to bring them into conformity with the European Patent Convention [(EPC)] and the national laws of many industrialized countries . . . to protect the continued growth of American business."[17]

## II. PROCESS PATENTS AMENDMENT ACT – HISTORICAL PERSPECTIVE[18]

Congress provided a new remedy for injured process patent holders by allowing collection of monetary damages via the Process Patents Amendment Act (PPAA).[19] Congress approved the Act under weighted concerns that the biotech and pharmaceutical industries would lose their competitive edge in the world market, with specific regards to then newly developed technologies.[20] The relevant portion of the Act, codified in 35 U.S.C. § 271(g), states that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product that is made by a process patented in the United States shall be liable as an infringer . . . ."[21] Thus, the amendment effectively extends process patent protection beyond U.S. borders. Importation of goods into the United States made by the patented process triggers the government's authority to impose liability.

This provision is effective due to the economics of the pharmaceutical market. The United States accounts for nearly half of all sales of pharmaceuticals worldwide.[22] Considering the

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17. *See* S. REP. No. 100-83, at 31–35 (1988). (citing equivalent laws from Denmark, France, Great Britain, Italy, Japan, Portugal, Sweden, Switzerland, and West Germany providing the type of desired process patent protection).

18. Process Patents Amendments Act Pub. L. No. 100-418, § 9003, 102 Stat. 1107, 1563–64 (codified in part at 35 U.S.C. § 271(g)(1988)) [hereinafter PPAA].

19. *Id*.

20. *See, e.g.*, Process Patent Legislation, *supra* note 13, at 24–32 (statement of Richard D, Godown, President, Indus. Biotech. Ass'n).

21. 35 U.S.C. § 271(g) (2000).

22. German Association of Research Based Pharmaceutical Companies, *Statistics 2004: the Pharmaceutical Industry in Germany*, 55 (2004) (reporting sales of pharmaceuticals through pharmacies by country), *available at* http://www.vfa.de/download/SHOW/en/vfa_en/publikationen_en/e_statistics/e_statistics_2004.pdf.

high costs of developing a drug,[23] the amendment constructively deters infringement by excluding the United States from the available market for products made abroad by a U.S. patented process, thereby limiting both the possibility of profit and the probablility of infringement. With this in mind, Congress tailored the language of the provision to encompass then-anticipated challenges facing the protection of IP rights in the biotech and pharmaceutical industries.[24] Unfortunately, the focus of the statute may have been overly near-sighted, thereby precluding current technologies in the "post-genomic" era from protection under its narrow language.[25]

## III. BIOPHARMACEUTICALS: THE SCIENCE AND THE INDUSTRY

### *A. Biotech 101 – A Basic Primer on the Relevant Science*

The biotech and pharmaceutical (collectively, biopharmaceutical) industries share an intimate scientific relationship, and the recent changes in the patent laws affect them alike. To understand how, it is important to realize the underlying scientific principles involved.

Modern biotechnology builds on a pioneering theory reported by Francis Crick in 1958, which he called "The Central Dogma."[26] Crick's theory described a process whereby biological material comprised of deoxyribonucleic acid (DNA) transfers genetic information to direct protein biosynthesis.[27] Long,

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23. *See* FRANÇOISE SIMON & PHILLIP KOTLER, BUILDING GLOBAL BIOBRANDS: TAKING BIOTECHNOLOGY TO MARKET 47 (2003) (estimating average R&D expenditures to be $880 million per marketable drug).

24. S. REP. No. 100–83, at 51 (1988) (citing once-revolutionary genetic engineering techniques).

25. Symposium, *Use of Patented Research Tools Abroad: Loophole or Liability*, 8 B.U. J. SCI. & TECH 218, 222 (2001) Prof. Cynthia Ho discussed the inclusion of section 271(g) in the Patent Act due to concerns facing "old-age biotech." *Id.*

26. F. H. C. Crick, *On Protein Synthesis*, 12 SYMP. SOC'Y EXPERIMENTAL BIOLOGY 138 (1958).

27. *Id.* at 138; *see also* Oswalt T. Avery, M.D. et al., *Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types: Induction of Transformation by a Desoxyribonucleic Acid Fraction Isolated from Pnuemococcus Type III*, 79 J. EXPERIMENTAL MED. 137 (1944) (reporting DNA as the carrier of genetic information).

strand-like molecules of DNA are composed of four different types of DNA "bases" called adenine, guanine, cytosine, and thymine (commonly represented by the first letter of each base name).[28] Two strands of DNA combine to form a double-helical structure, much like the rails of a steep, circular staircase.[29] Metaphorically, each step of the staircase would represent an interacting pair of DNA bases, each tethered to its own rail. These pairs usually consist of A-T (or T-A) and G-C (or C-G).[30] Strands of DNA "encode" genetic information through a specifically ordered, linear combination of the base pairs.[31]

Discrete stretches of DNA make up *genes*.[32] From the beginning of each gene, every stretch of three consecutive base pairs (termed "codons") represents a specific instruction for the biological machinery that assembles proteins.[33] Returning to the metaphor, three steps up the DNA staircase would represent one piece of encoded information. Through another intermediary,[34] the information encoded in one gene ultimately acts as the blueprint for the the synthesis of a specific *protein*, comprised of ordered chains of amino acids.[35] Scientists have defined the informational link between 64 possible codons and the 20 individual amino acids that they represent.[36] Accordingly, researchers can determine the amino acid composition of a particular protein from a given DNA sequence through a process

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28. *See* J. D. Watson & F. H. C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953).

29. *Id.*

30. *Id.*; *see also* Boris Magasanik & Erwin Chargaff, *Studies on the Structure of Ribonucleic Acids*, 7 BIOCHEMICA ET BIOPHYSICA ACTA 396, 400 (1989).

31. Crick, *supra* note 26, at 144–45, 152–53, 159–60.

32. *See* Watson & Crick, *supra* note 28, at 737.

33. *See* Crick, *supra* note 26, at 158.

34. The intermediary is Messenger Ribonucleic Acid (mRNA). *Id*.

35. G. W. Beadle & E. L. Tatum, *Genetic Control of Biochemical Reactions in Neurospora*, 27 PROC. NAT'L ACAD. SCI. 499 (1941) (describing their famous "one gene, one protein" hypothesis).

36. *See* J. Heinrich Matthaei & Marshall W. Nirenberg, *Characteristics and Stabilization of DNAase-Sensitive Protein Synthesis in E. coli Extracts*, 47 PROC. NAT'L ACAD. SCI. 1580 (1961); *see also* J. Heinrich Matthaei & Marshall W. Nirenberg, *The Dependence of Cell-Free Protein Synthesis in E. coli Upon Naturally Occurring or Synthetic Polyribonucleotides*, 47 PROC. NAT'L ACAD. SCI. 1588 (1961) (reporting seminal work in "cracking the genetic code").

called "sequencing".[37]

Researchers may designate proteins into two classes, structural proteins and functional proteins (enzymes and binding proteins). Functional proteins catalyze (expedite) and regulate the chemical processes that occur in all living organisms.[38] For purposes of this discussion, it is sufficient to understand that practically all pharmaceuticals (including everything from antibiotics, to anti-inflammatories, to anti-depressants) work by either chemically interacting with a functional protein, or is itself comprised of a functional protein or a segment thereof.[39] Accordingly, understanding how the genetic information encoded by DNA ultimately relates to the structure, function, and chemical mechanism of an encoded protein (human or otherwise) is central to new drug development.

### *B. The Focus of Biotechnology in the "Post-Genomic" Era*

Sequencing of the human *genome*, "the whole of the genetic information of an organism,"[40] has ushered in the "post-genomic" era.[41] The mass of data generated by this milestone provides the foundation for the current phase in biotech and pharmaceuticals

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37. F. Sanger et al., *Nucleotide Sequence of Bacteriophage X174 DNA*, 35 NATURE 687 (1977) (reporting the most common method of DNA sequencing).

38. The discussion of the relatively limited number of known non-protein catalysts is well beyond the scope of this paper. The discovery of catalytic ribonucleic acids (ribozymes) in the early 1980s earned researchers Sidney Altman and Thomas Cech the 1989 Nobel Prize in Chemistry. For further information, see Cecilia Guerrier-Takada et al., *The RNA Moiety of Ribonuclease P is the Catalytic Subunit of the Enzyme*, 35 CELL 849 (1983); and K. Kruger et al., *Self-splicing RNA: Autoexcision and Autocyclization of the Ribosomal RNA Intervening Sequence of Tetrahymena* 31 CELL 147 (1982).

39. See U.S. Dept. of Health and Human Servs., NIH Pub. No. 01-2778, *The Structures of Life* (rev. Nov. 2000) (providing a thorough description of how drugs interact with protein targets), *available at* http://www.nigms.nih.gov/news/science_ed/structlife.pdf.

40. OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY 260 (rev. ed. 2001).

41. *See* J. Craig Venter et al., *The Sequence of the Human Genome,* 291 SCIENCE 1304 (2001)(reporting the complete sequence of the human genome for private corporation Celera Genomics); *see also* The Genome International Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001) (report of competing, publicly-funded group).

research, understanding how this data relates to the molecular basis of disease.[42] The phase has launched or transformed entire disciplines in the fields of biotechnology and pharmacology, including: bioinformatics, proteomics, functional genomics, microarray technology, high performance computing technologies, data mining, pharmacogenetics, and others.[43] What is important to understand for purposes of this discussion is that the scientific techniques employed in each of these "new biology" disciplines focus on inter-related aspects of obtaining *information* about raw DNA sequence data or its encoded protein products. Commercially, researchers use this data for devising new drugs and other human health and animal related therapies.[44]

### *C. What is a "Research Tool"?*

Despite its low cost relative to other phases of drug development, finding a potentially suitable drug or drug target is often the barrier to bringing a new drug to market.[45] Accordingly, any inventive process that employs a method or process to more efficiently or effectively acquire the information sought is invaluable to an entity in the competitive biopharmaceutical industry. Scientific and legal practitioners designate resources that facilitate such laboratory discoveries as "research tools."[46]

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42. *See* David Eisenberg et al., *Protein Function in the Post-Genomic Era*, 405 NATURE 823 (2000) (describing the complexity of the challenges facing interpretation of raw DNA sequence data).

43. For a non-comprehensive, but informative explanation of some of these disciplines, see Bioinformatics.Org, *Bioinformatics Frequently Asked Questions*, *at* http://bioinformatics.org/faq/ (last visited Jan. 22, 2005) (providing basic definitions and descriptions of "post-genomic" disciplines with other informative resources and web links).

44. *See* U.S. Dept. of Health and Human Servs., NIH Pub. No. 03-474, *Medicines by Design* (rev. June 2003), *available at* http://www.nigms.nih.gov/medbydesign/booklet.pdf; *see also* Dan L. Burk, *Introduction: A Biotechnology Primer*, 55 U. PITT. L. REV. 611 (1994) (describing other biotechnology applications).

45. *See* SIMON & KOTLER, *supra* note 23, at 48 (reporting that identification and screening of potential drugs and drug targets consumes approximately 19 percent of the estimated cost of developing a drug).

46. NATIONAL INSTITUTES OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS background (June 4, 1998) ("We

There is no particular legal significance in defining a method as a research tool, but doing so helps identify its nature and value, to facilitate discovery. Theorists often refer to research tools as "upstream" inventions because researchers use them to discover other creations "downstream" (for example, pharmaceuticals).[47] Critics of extending patent rights to research tool inventors argue that the monopoly granted to such upstream inventions slows progress by limiting the resources freely available to the scientific community.[48] However, experience shows that this may not be the case.[49]

Arguably, the most significant contribution to the advancement of the biopharmaceutical industry is the invention of a Nobel Prize winning research tool, the Polymerase Chain Reaction (PCR).[50] Without this tool, which allows for *in vitro*

use the term 'research tool' in its broadest sense to embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as 'end products.' For our purposes, the term may thus include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as [Polymerase Chain Reaction]), methods, laboratory equipment and machines, databases and computer software."), *available at* http://www.nih.gov/news/researchtools.htm.

47. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (describing the potentially harmful result of allowing patent rights on biological materials and research tools).

48. *See, e.g.*, Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et al. eds., 2001) (describing the "hold-up" problem in licensing biomedical technologies); *see also* Heller & Eisenberg, *supra* note 47; Robert P. Merges & Richard Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 904–08 (arguing that broad patents on nascent technology limits progression).

49. John P. Walsh, *Effects of Research Tool Patenting and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285–86 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (reporting data that patents on research tools do not actually foster the problems heralded by critics).

50. PCR is a nucleic acid amplification technology that allows minute amounts of genetic material to be amplified into billions of copies within hours. *See* K. Mullis et al., *Specific Enzymatic Amplification of DNA in Vitro: the Polymerase Chain Reaction*, LI Cold Spring Harbor Symposia on Quantitative Biology (1986). In 1993, American biochemist, Kary Mullis, received the Nobel Prize in Chemistry "for his invention of the polymerase chain reaction (PCR) method." Press Release, The Royal Swedish Academy of Sciences, The 1993 Nobel Prize in Chemistry (Oct. 13, 1993), *available at* http://nobelprize.org/chemistry/laureates/1993/press.html.

amplification of genetic material, the biopharmaceutical industry would not be where it is today.[51] Patent assignees, Hoffmann-La Roche have successfully asserted their IP rights in the research tool.[52] Nonetheless, researchers freely use the patented tool as licensees in biochemistry and molecular biology laboratories worldwide. PCR's widespread use demonstrates that patenting research tools does not create unduly burdensome requirements on licensees.

### *D. The Marriage of the Biotech and Pharmaceutical Sectors*

The biological processes and associated technologies described above may sound overwhelmingly complex, and they are. They are also big business. In 2001, U.S. pharmaceutical companies spent approximately $30.3 billion on research and development (R&D), utilized 157,000 employees, and collected domestic revenues totaling approximately $130 billion.[53] In the same year, biotech[54] companies spent an additional $16.4 billion on R&D, hired approximately 66,000 scientific employees, and earned roughly $33.5 billion ($8 billion from sales to international markets).[55] In comparison to the existing number of biotech patents (23,992), the number of method and process patent claims reported pending in the fourth quarter of 2002 is

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51. Dan L. Burk & Mark A. Lemly, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1583 [hereinafter Burk& Lemly, *Policy Levers*] ("[P]owerful bioinformatics databases and the development of mass-production techniques like polymerase chain reaction ("PCR") have revolutionized the biotechnology industry, making the identification of gene sequences and the development of related therapies much cheaper and quicker than they were in preceding decades.").

52. *See, e.g.*, Hoffmann-La Roche, Inc. v. Promega, Corp., 323 F.3d 1354 (Fed. Cir. 2003) (defending against challenges of patent enforceability); Carnegie Mellon Univ. v. Hoffmann-La Roche, 55 F. Supp. 2d 1024 (N.D. Cal. 1999); *see also* U.S. Patent No. 4,683,195 (issued July 28, 1987); U.S. Patent No. 4,683,202 (issued July 28, 1987).

53. 2002 Pharmaceutical Research and Manufactures of America Annual Membership (PhRMA) Survey, *reprinted in* PLUNKETT'S BIOTECH & GENETICS INDUSTRY ALMANAC 2003–2004 (Jack W. Plunkett ed., 2003).

54. *See* U.S. Dep't of Commerce Tech. Admin. Bureau of Indus. and Sec., *A Survey of the Use of Biotechnology in the U.S. Industry* 3 (October 2003), *available at* http://www.technology.gov/reports/Biotechnology/CD120a_0310.pdf ("defin[ing] biotechnology as the application of molecular and cellular processes to solve problems, conduct research, and create goods and services") [hereinafter *Survey*].

55. *Id*. at *ix*, *xi–xii*.

astonishing (33,131).[56] While the United States Patent and Trademark Office refuses patents to a significant number of applicants,[57] the sheer number of applications underscores the explosion of new patentable subject matter in the post-genomic era.[58]

The biopharmaceutical industry has become truly borderless, both geographically and in terms of the collaborative effort between industries. With over 4,300 biotech companies distributed worldwide (600 publicly traded), the R&D potential is enormous.[59] Unfortunately, with an overall industry loss of more than $12 billion in 2002, it is unlikely that the market will be able to sustain the extensive number of entities.[60] Many biotech entities have embraced aggressive business strategies in hopes of increasing profitability and assuring their longevity in a constricting economic market.[61]

Companies in the traditional biotech sector have consolidated with either conventional pharmaceutical entities or other biotech companies through joint ventures, mergers, or acquisitions.[62] In some cases, this trend has produced truly monolithic biopharmaceutical conglomerates.[63] Vertical integration of the manufacturing chain, allowing research from "cradle to grave", provides a substantial financial benefit.[64]

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56. *Id*. at *ix*.

57. *See* United States Patent & Trademark Office, *U.S. Patent Statistics Report* (Mar. 2002) (reporting the average grant of utility patents in 1997–2001 was approximately 55 percent of those applications submitted).

58. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (establishing patentable subject matter under 35 U.S.C. § 101 as "anything under the sun that is made by man"); *see also* Teresa M. Summers, Note, *The Scope of Utility in the Twenty-first Century: New Guidance for Gene-Related Patents*, 91 GEO. L.J. 475, 477 ("*Diamond v. Chakrabarty* opened the door to biotech's gilded age").

59. ERNST & YOUNG, *BEYOND BORDERS: THE GLOBAL BIOTECHNOLOGY REPORT 2004*, 5 (2003).

60. *Id*.

61. *See id*.

62. *See* SIMON & KOTLER, *supra* note 23, at 57–93 (describing business strategies employed in the biopharmaceutical sector).

63. The top ten biopharmaceutical companies ranked by sales all sell greater than $10 billion worth of drugs per year. *Id*. at 15.

64. *Id*. at 14. ("The biotech/pharma symbiosis is easily summed up: Pharma needs biotech's innovation, and biotech needs pharma's scale.").

Biopharmaceutical conglomerates that have the ability to perform essentially all research-related functions in-house enjoy significantly reduced R&D costs. Cost reductions result, in part, because the well-equipped companies operate independently of outside scientific licensors as part of their research plan. This assures that the conglomerates do not have to share profits from product sales with other interested licensors.

As it may suggest, a centralized location of operation, "in-house" research is perhaps a bit of a misnomer in regard to larger biopharmaceutical conglomerates. In fact, such multinational companies have offices and labs in truly diverse and remote countries.[65] Industry trends suggest that further expansion will continue.[66] At the same time, genetic research has become easier to perform and less dependant on large, delicate, and expensive equipment. This fact, coupled with the continuing progression of globalization, will ensure that big biopharmaceutical companies can conduct research anywhere in the world.

While there are scientific implications for the ability to research remotely (for instance, studying exotic plants for novel therapeutics), the legal implications are equally salient. To see why, imagine the possible scenario: BigPharmCo, Inc. learns of a newly developed research tool through a publication reporting the results of a two-year study conducted in a university laboratory. The described method would simplify the testing of their lead cancer drug candidates. Using the new technology, BigPharmCo could save six months worth of additional research in their quest for the ideal drug. This is fantastic because they have other competitors in the same market who are competing to be the first release the next billion-dollar per year blockbuster cancer drug.

Unfortunately, the founder of Small B-Tech, Inc., a biotech start-up company spawned from the work of the university researcher's publicly-funded research grant, already patented the research tool. Small B-Tech, Inc. has patents in the United

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65. *See, e.g.*, David B. Braun, PHARMACEUTICAL MANUFACTURES: AN INTERNATIONAL DIRECTORY (1995).

66. *See* ERNST & YOUNG, *supra* note 59, at 6 (citing a search for broader markets for sales and collaboration as one of the primary motivations for globalization).

States as well as other major European countries that he acquired through the European Patent Office. Unfortunately for BigPharmCo, Inc., the use of the research tool requires licensing under the laws of the representative countries, and that costs money. However, BigPharmCo, Inc. need not worry about such trivial IP impediments, because they can just perform the experimental research at their Brazilian branch. Afterwards, the company can use the results to carry on with their clinical trials in their U.S. and European laboratories. Viola, problem solved . . . sorry professor! You may ask, "Is that possible?" You bet.

### *E. Challenges Facing the Industry*

Despite the volume of IP rights claimed by U.S. biotech companies, 59 percent of them cited difficult, antiquated, and expensive regulatory and approval processes as major barriers to further progress and competitiveness.[67] In addition, 53 percent cited equally both high research costs and difficulty in obtaining capital, with others citing unfair foreign laws as impediments to the same.[68] While many factors may contribute to the oft cited obstacles of progress,[69] the current regime of obtaining and enforcing IP protection for biopharmaceutical inventions domestically and abroad will continue to foster these complaints.[70] Congress has addressed some of the specific concerns of the biopharmaceutical industry through numerous amendments to the Patent Act.[71] However, recent judicial

67. *Survey*, *supra* note 54, at *xii*.

68. *Id*.

69. *See, e.g.*, Biotechnology Future Investment and Expansion Act of 2003, S. 1773, 106th Cong. (2003) (addressing tax concerns detrimental to investment in the biotechnology industry).

70. Dan L. Burk & Mark A. Lemley, Biotechnology's *Uncertainty Principle*, BOALT WORKING PAPERS IN PUBLIC LAW, No. 29 (June 1, 2003), *available at* http://repositories.cdlib.org/cgi/ viewcontent.cgi?art=1032&context=boaltwp (arguing the need for industry-specific analysis of patent cases and disapproving of some of the Federal Circuit's current interpretive norms used in biotech and pharmaceutical disputes).

71. *See, e.g.*, Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified in scattered sections of 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282); Omnibus Trade and

interpretation of the legislation by the CAFC may undermine the Congressional offerings, especially for research tool inventors.[72]

The results of the recent decisions effectively strengthen domestic protection of U.S. research tool patents, but weaken the weight of U.S. patents in the international markets. Consequently, investors will be more reluctant to invest in burgeoning technologies without assurance that others may not lawfully steal the good-will and rewards of risk-laden research endeavors.[73] Ultimately, the features of the patent system that have spawned complaints from the biopharmaceutical industry are likely to worsen because of the recent decisions.

Congressional intent in enacting the PPAA was to protect the American biochemical and pharmaceutical industries from foreign competition and intellectual piracy.[74] In reality, the homogenization of the biotech and pharmaceutical sectors now makes sophisticated American-based multinational companies (MNCs), their partners, or their foreign subsidiaries more likely to seek an advantage by such exploitative means rather than their international competitors.

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Competitiveness Act of 1988, Pub. L. No. 100-418, § 9002–05, 102 Stat. 1107, 1563–66 (1988) (codified at 35 U.S.C. §§ 154, 271, 287, 295); Biotechnology Process Patent Protection Act of 1995, Pub. L. No. 104-41, 109 Stat. 351 (codified at 35 U.S.C. §§ 103, 282).

72. *Compare* Bayer AG v. Housey Pharm., Inc., 169 F. Supp. 2d 328 (D. Del. 2001) [hereinafter Housey I], *aff'd in part*, 340 F.3d 1367 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003) (decreasing international protection), *with* Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002) *cert. denied*, 539 U.S. 958 (2003) (increasing domestic protection), *and* Integra Lifesciences I, Ltd v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003) *reh'g* and *reh'g en banc denied*, 2003 U.S. App. LEXIS 26547 (Dec. 2003), *cert. granted*, 160 L.Ed. 2d 609 (2005) (increasing domestic protection).

73. *See* Fritz Machlup, *An Economic Review of the Patent System: Hearing before the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary*, U.S. Senate, 85th Cong., 2d Sess., Study No. 15, 55–56 (GPO 1958) (discussing traditional justifications for a patent system) [hereinafter *Economic Review of the Patent System*]; *see also* Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813 (2001) (discussing additional justifications and their applicability to the modern biopharmaceutical industry).

74. S. REP. No. 100-83, at 2 (1987).

## IV. CONFLICTING ENFORCEMENT POLICIES OF RESEARCH TOOL PATENTS

The following cases collectively impose new requirements for obtaining adequate protection of a research tool inventor's IP rights. Under the new policy, an integral part of securing such rights will increasingly involve applying for patents in numerous foreign countries. As discussed in Part VI, application for and enforcement of international patents is not a simple solution to the problems facing research tool inventors.

### *A. Bayer AG v. Housey Pharmaceuticals, Inc.*[75]

Facts of the case:

Housey Pharmaceuticals holds several process patents for a "Method of Screening for Protein Inhibitors and Activators".[76] Simply stated, the claims teach a method of identifying potential drugs using a cell-based assay. The court presumed that Bayer had used the claimed method to develop a new pharmaceutical product.[77] In response to Bayer's request for a declaratory judgment that the Housey patents were invalid, unenforceable, and not infringed, Housey counterclaimed for infringement.[78] Housey argued that Bayer was liable for infringement under section 271(g) because Bayer used the patented screening process abroad to obtain *information* useful for the subsequent manufacture of a domestic pharmaceutical product.[79]

The trial court dismissed Housey's case, holding that granting the protection sought would allow for "sweeping liability beyond the scope of the statute."[80] On appeal, the CAFC affirmed, holding that Bayer's product was not "a product which

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75. 169 F. Supp. 2d 328 (D. Del. 2001), *aff'd in part*, 340 F.3d 1367 (Fed. Cir. 2003).

76. U.S. Patent No. 4,980,281 (issued Dec. 25, 1990); U.S. Patent No. 5,266,464 (issued Nov. 30, 1993); U.S. Patent No. 5,688,655 (issued Nov. 18, 1997); U.S. Patent No. 5,877,007 (issued Mar. 2, 1999).

77. *See* 35 U.S.C. § 295 (2000) (establishing a rebuttable presumption of use of a process patent where a "substantial likelihood exists that the product was made by the patented process", if "plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine").

78. *Housey I*, 169 F. Supp. 2d at 328.

79. 35 U.S.C. § 271(g).

80. *Housey I*, 169 F. Supp. 2d at 330.

is *made* by a process patented in the United States."[81] The court found that the statute's legislative history referred solely to physical goods manufactured directly from the patented process.[82] Consequently, while the information obtained from the use of a claimed process was no doubt useful, it does not constitute direct manufacture.[83] Thus, the court held that the Housey patents were unenforceable under section 271(g).[84] Japan and the United Kingdom have both offered similar interpretations of their equivalent code sections.[85]

The CAFC strictly interprets section 271(g) by examining the accompanying legislative history, and bases its decisions on the constraints imposed by the literal meaning of the text.[86] The *Housey* decision, while perhaps correct under the literal text of the committee reports, takes a major step in extracting the provision's teeth.[87] *Housey* is the first case in the sparse jurisprudence regarding section 271(g) where the facts and technologies involved are not directly comparable to those contemplated in the legislative history.[88] The committee reports

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81. Bayer AG v. Housey Pharma, Inc., 340 F.3d 1367, 1377 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003) [hereinafter Housey II] (emphasis added).

82. For examples framing possible permutations of the "made by" requirement, see Glenn Law, Note, *Liability under the Process Patents Amendment Act of 1988 for the Use of a Patented Process Outside the United States*, 60 GEO. WASH. L. REV. 245 (1991).

83. *Housey II,* 340 F.3d at 1377.

84. *Id*. at 1378.

85. *See* Pioneer Elecs. Capital, Inc. v. Warner Music Mfg. Europe GmbH, [1997] R.P.C. 757 (interpreting the scope of process patents under section 60(1)(c) of the U.K. Patents Act of 1977); *see also* Fujimoto v. Nihon Zoki, 53 MINSHU 957, 1686 Hanrei Jiho 104, 1010 Hanrei Taimuzu 245 (Sup. Ct., July 16, 1999), *as cited in* Toshiko Takenaka, *"Process" in § 271(g) is Limited to Manufacturing Process*, CASRIP NEWSLETTER, Autumn 2001, at 12 (interpreting the corresponding Japanese Patent code).

86. *See* Nancy J. Flint, Note, *Eli Lilly & Co. v. American Cyanimid Co.: A Patent Case of "Dangerous Dicta" in the Federal Circuit?*, 52 U. MIAMI L. REV. 389, 402–11 (1997) (discussing statutory interpretive norms and the effects of applying the varied approaches in achieving the congressional aims of the PPAA).

87. *See* M. Patricia Thayer & Michelle M. Umberger, *Enforcing U.S. Method Patents: How Much Protection Does 35 U.S.C. Section 271(g) Really Provide*?, 4 SEDONA CONF. J. 85 (2003) (describing a series of cases that weaken protection under all provisions of section 271(g)).

88. As of January, 2005, within Westlaw/CTAF, a search for "271(g)" produced fourteen cases since section 271(g)'s enactment in 1988.

accompanying section 271(g) clearly envision intellectual piracy using emergent techniques in biotechnology.[89] However, subsequent technological advancements in the post-genomic era have led to unforeseen applications, modifications, and challenges using "new biology" techniques. The changes are due, in large part, to contemporaneous rapid advancements in the computer science industry beginning in the early 1990s.[90] These modern biotech concerns would not have been ripe for meaningful discussion prior to enactment of section 271(g).[91]

The court's traditional mechanism of a section 271(g) analysis, as applied in *Housey*, may not have been the best means to adapt the provision to the rapid advancements in "new biology" disciplines. The court was particularly concerned that extending protection to research tools under section 271(g) could lead to anomalous results.[92] For instance, "a person possessing the allegedly infringing information could, under *Housey*'s interpretation, possibly infringe by merely entering the country."[93] Unfortunately, the exploitation of patented research tools internationally now promises to be anything but an anomalous occurrence.[94] Adopting a more flexible approach to the provision would avoid alienating an entire class of inventors from protection under the statute.[95]

Regardless of whether the *Housey* decision adopts the most prudent policy, its result raises a significant problem for the

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89. *See* H.R. CONF. REP. NO. 100–576, at 1086–87 (1988), *reprinted in* 1988 U.S.C.C.A.N. 1547, 2119–20; *see also* S. REP. No. 100-83, at 30, 51 (1987).

90. Computing remains a dominant force in the advancing biopharmaceutical industry. For discussion on current trends in the biotech and computing sectors, see, for example, SIMON & KOTLER, *supra* note 23, at 29–38.

91. See for example, the emergence of DNA-chip technology, which has the sole purpose of being used as an information gathering research tool. *See* Thayer & Umberger, *supra* note 87, at 86 (describing uses of Affymetrix's GeneChip® technology).

92. Housey II, 340 F.3d 1367, 1376 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003).

93. *Id*.

94. *See* Walsh, *supra* note 49 (reporting that some researchers state that going offshore is one of the "working solutions" around research tool licenses).

95. *See* Burk & Lemly, *Policy Levers, supra* note 51, at 1641 ("The great flexibility in the patent statute presents an opportunity for courts to take account of the needs and characteristics of different industries. Courts can, and should, apply the general rules of patent law with sensitivity to the characteristics of particular industries").

biotech and pharmaceutical industries. The stated primary near-term focus of 53 percent of all biotech companies is to develop technology intended for licensing.[96] Moreover, 47 percent of companies hope to procure licenses as part of their business strategy, with another 23 percent hoping to enter into a joint-venture.[97] Whereas a number of the products in development are certainly research tools, *Housey* diminishes their value by allowing an infringer to simply use the patented research tool offshore.

Undoubtedly, the processes described in the Housey patents would be protected from direct infringement if they were used in the United States[98] In fact, domestic protection to research tool patents, like those in *Housey*, was previously bolstered by the recent CAFC decisions, *Madey v. Duke University*[99] and *Integra Lifesciences I, Ltd. v. Merck KGaA* (*Integra v. Merck*).[100] Both cases confine the unauthorized use of research tool patents by limiting the circumstances where infringing acts fall within a judicial or statutory safe harbor, respectively. In addition, *Madey* establishes that a permissive attitude to infringement exemptions once enjoyed by university researchers is now a thing of the past.

### *B. Madey v. Duke University*

Facts of the case:

Madey was a prominent researcher in the Department of Physics at Duke University.[101] Madey became sole owner of several patents relating to performance of free electron laser (FEL) technology researched in his lab.[102] Following differences

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96. *Survey*, *supra* note 54 at *xiii*.

97. *Id*.

98. 35 U.S.C. § 271(a) (2000) (". . . whoever without authority makes, *uses*, offers to sell, or sells any patented invention . . . infringes the patent") (emphasis added).

99. 307 F.3d 1351 (Fed. Cir. 2002)*cert. denied*, 539 U.S. 958 (2003).

100. 331 F.3d 860 (Fed. Cir. 2003), *reh'g* and *reh'g en banc denied*, 2003 U.S. App. LEXIS 26547 (2003), *cert. granted*, 125 S.Ct. 823 (2005).

101. *Madey*, 307 F.3d 1352.

102. *See* U.S. Patent No. 4,641,103 (issued Feb. 3, 1987) (claiming a "Microwave Electron Gun"); U.S. Patent No. 5,130,994 (issued July 14, 1992) (claiming a "Free-Electron Laser Oscillator for Simultaneous Narrow Spectral Resolution and Fast Time

between the named litigants, Madey was relieved of his position at the university.[103] Members of the Duke faculty, staff, and affiliated research collaborators subsequently used the FEL equipment that remained at Duke after his departure.[104] Madey sued for infringement.[105] Following partial dismissal of the case on other grounds, the trial court granted Duke's motion for summary judgment on the claim of infringement.[106] The court held that the common law "experimental use" exemption precluded Madey's claim. Madey appealed on both procedural and substantive grounds.[107]

On appeal, the CAFC confirmed the viability of the longstanding "experimental use" exemption[108] in certain circumstances.[109] The court held in favor of Madey, citing several points of error in the trial court's allowance of the exemption.[110] First, that the district court wrongfully assigned the burden of proof to Madey to show Duke's use of the patented process was *non*-experimental in the initial determination of infringement.[111] Second, that the trial court overestimated the scope of the experimental use exception by applying an overly broad standard.[112] Third, that the university's status as a non-profit institution did not implicitly protect the use of the patented process under the experimental use exception.[113] Each of the court's assertions strengthens the domestic protection of

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Resolution Spectroscopy").

103. *Madey*, 307 F.3d at 1352–53.

104. *Id.* at 1353.

105. *Id*. at 1352.

106. *Id.*

107. *Id.* at 1355.

108. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.) (explaining in dicta, "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."); *see also* Integra Lifesciences I, Ltd. v. Merck KGaA*,* 331 F.3d 860, 874–78 (Fed. Cir. 2003) (Newman, J. dissenting in part) (citing subsequent authority).

109. *Madey*, 307 F.3d at 1361–62.

110. *Id.* at 1352.

111. *Id*. at 1361 (emphasis added).

112. *Id*. at 1361–62.

113. *Id*. at 1362–63.

research tool patents.

*1. Wrongful Assignment of the Burden of Proof*

The decision whether to assert a claim, and its likelihood of success, is frequently contingent on the allocation of the burden of proof.[114] In *Madey*, the CAFC held that the trial court wrongfully required the patent holder to show a "non-experimental" use of the patented process in determining whether infringement had occurred at all.[115] The CAFC announced the correct standard. First, the patent holder must sufficiently allege an unlicensed, infringing use of his IP.[116] Second, the alleged infringer may then assert the experimental use exception as a defense, but ultimately bears the burden of proof to show that his use falls within the experimental use exception.[117] Finally, the patentee may offer evidence to rebut.[118] The court reversed the summary judgment and remanded the case for further consideration of the issue.[119]

Thus, to prove infringement of a research tool, the patent holder must specifically allege a "use" as required under section 271, but is not required to qualify the purpose of such use. This allocation of the burden eliminates the necessity to allege additional facts sufficient to establish a non-permissible purpose.[120] Thus, the decision increases the likelihood that a patent holder would be able to overcome an initial motion for summary judgment under the relevant standard.[121]

*2. Reinforcement of the "Experimental Use" Standard*

The CAFC rejected the trial court's formulation of the

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114. *See* Bruce L. Hay, *Allocating the Burden of Proof*, 72 IND. L.J. 651 (1997) (examining the considerations in assigning the burden and the effects of the assignment on litigation strategy).

115. *Madey*, 307 F.3d at 1360.

116. *Id.* at 1361.

117. *Id.*

118. *Id.*

119. *Id.* at 1364.

120. FED. R. CIV. P. 8(a).

121. FED. R. CIV. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317 (1986) (providing the standard for grant of summary judgment).

experimental use standard.[122] That standard would protect any uses that "were solely for research, academic, or experimental purposes," or that were "made for experimental, non-profit purposes only."[123] The court reiterated that the exception is very narrow and strictly limited to instances where the use is "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[124] Furthermore, the court distinguished such permitted use from any act that is "in keeping with the legitimate business of the alleged infringer."[125]

Under the correct standard, the court rejected the argument that Duke's non-profit and educational status was adequate proof that its use was experimental.[126] The court held that the infringing use was to further the university's legitimate business objectives of (1) educating and enlightening both students and faculty; (2) increasing the status of the institution; and (3) attracting additional research grants, talented students, and faculty.[127] The court explicitly refuted any notion that an alleged infringing act must be of commercial nature to disqualify it from the exemption.[128]

*Madey* increases the strength of protection to U.S. process patent holders by plainly defining the restricted scope of the experimental use exemption. Furthermore, the court's

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122. *Madey*, 307 F.3d at 1361–62.

123. *Id.* at 1361–62..

124. *Id.* at 1362 (citing Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000) and Roche Prods., Inc. v. Bolar Pharm. Co. 733 F.2d 858, 863 (Fed. Cir. 1984), *overruled by* 35 U.S.C § 271(e)(1)).

125. *Madey,* 307 F.3d at 1362 (adopting language from Pitcairn v. United States, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

126. *Id*. *But see* Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 874–78 (Fed. Cir. 2003) (Newman, J. dissenting in part). Judge Newman asserts that the *Madey* court defined the use of a research tool too broadly, therefore tainting the analysis. *Id.* Judge Newman makes the important distinction that the court failed to distinguish that experimentation on the tool itself should be exempt from infringement. *Id.* Thus, if experimentation was performed using a research tool in efforts to make improvements to the tool (that is, finding a new and better way to screen for drug targets than allowed by the tool in-hand), such use would not constitute infringement. Despite this crucial distinction, the holding remains clear for the discussion of the research tools discussed in this comment.

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

128. *Id.*

unwillingness to create a *per se* exemption for the academic community limits the exemption's availability strictly to uses in conducting basic research. Some commentators predict that this policy will hamper research efforts in the academic community.[129] However, the accompanying increase in patent protection may ultimately serve to attract new sources of private funding for university researchers, rather than predominantly from traditional public sources such as the National Institutes of Health and National Science Foundation.[130]

Adoption of a similar rationale led to the promulgation of the Bayh-Dole Act of 1980.[131] The Act allows university researchers to patent inventions developed using public funding. Congress passed the Act to increase private investment in academic research institutions, in hopes of promoting the commercialization by U.S. companies of fundamental technologies discovered through public funding.[132] While the Act has its critics, it has resoundingly achieved what Congress had intended by its enactment.[133] Despite this criticism,

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129. *See* Tom Saunders, Case Comment, *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine*, 113 YALE L.J. 261, 262–63, 268 (2003); *see also* Jennifer Miller, *Sealing the Coffin in the Experimental Use Exception*, 2003 DUKE L. & TECH. REV. 12, ¶ 21 (2003).

130. Robert Kneller, *University-Industry Cooperation and Technology Transfer in Japan Compared with the United States: Another Reason for Japan's Economic Malaise*?, 24 U. PA. J. INT'L ECON. L. 329, 333 (2003) ("Exclusive IP rights are one way to prevent copying by competitors . . . [and] can also be important for university startup companies to obtain private funding to develop early-stage, commercially risky academic discoveries.").

131. Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019–28 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2000)).

132. 35 U.S.C. § 200 (2000) ("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."); 35 U.S.C. § 204 (requiring, with limited exception, that "products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States . . . .").

133. *Compare* David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 118 (2001) ("The theory behind Bayh-Dole . . . flies in the face of the position that patents tend to restrict use of scientific and technological information, and that open publication facilitates wider use and application of such inventions and knowledge."), *with* Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003) ("The explicit U.S.

"biotechnology research tools have been licensed widely, and the transaction costs involved in taking out a license appear to be relatively low."[134] After *Housey*, the fact that infringers may now use research tool patents overseas without a license strongly undermines their overall value. That the CAFC recognizes the value of research tool patents is evident from its decision in the following case.

### *C. Integra Lifesciences I, Ltd. v. Merck KGaA*[135]

Facts of the case:

Dr. David Cherish, a researcher at the Scripts research institute, made a significant biochemical discovery[136] that showed promise for development of a new class of anti-angiogenic drug therapies.[137] Merck agreed to fund Dr. Cherish and the Scripts Institute for "the necessary experiments to satisfy the biological bases and regulatory (FDA) requirements for the implementation of clinical trials with [a potential drug candidate] or a derivative thereof."[138] In testing the efficacy of primary drug candidates, Dr. Cherish used a method described in a series of Integra's patents.[139] Hearing of the possible commercial use of their patents, Integra offered to license the technology to Merck.[140] Following failed negotiations, Merck declined to enter into any agreement.[141] Integra sued Dr.

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policy of allowing grantees to seek patent rights in government-sponsored research results . . . has turned universities into major players in the biopharmaceutical patenting arena").

134 *Mowery*, *supra* note 133, at 118.

135. 331 F.3d 860, 874–78 (Fed. Cir. 2003), *reh'g* and *reh'g en banc denied* 2003 U.S. App. LEXIS 26547 (2003), *cert. granted*, 160 L. Ed. 2d 609 (2005).

136. Angiogenesis is the formation of blood vessels which, in addition to the normal formation, occurs rapidly during invasive growth of tumors. *See* OXFORD DICTIONARY OF BIOCHEMISTRY AND MOLECULAR BIOLOGY 39 (rev. ed. 2001).

137. *Integra*, 331 F.3d at 863.

138. *Id*. (internal quotes omitted).

139. U.S. Patent No. 4,789,734 (issued Dec. 6 1988); U.S. Patent No. 4,792,525 (issued Dec. 20, 1988); U.S. Patent No. 4,879,237 (issued Nov. 7, 1989); U.S. Patent No. 4,988,621 (issued Jan. 29, 1991); U.S. Patent No. 5,695,997 (issued Dec. 9, 1997).

140. *Integra*, 331 F.3d at 863.

141. *Id.*

Cherish, Scripps, and Merck (Merck) for patent infringement.[142] Merck argued that the safe harbor exemption, included under the Hatch-Waxman Act of 1984, protected their use of the patented research tool.[143] The trial court held Merck liable for infringement, declaring that their use of the patented methods did not fall within the stated exemption.[144] Adopting a new legal test to determine applicability of the exception, the CAFC affirmed on the issue of infringement.[145]

The *Integra* decision increases protection of research method process patents by retracting the scope of the "safe harbor" exemption codified by section 271(e)(1) of the Patent Act.[146] The provision exempts from liability an infringing user if the process (or manufactured good) is "solely for uses reasonably related to the development and submission of *information* under a Federal law".[147] Prior to *Integra*, the exception was invoked regularly and without impunity if the use

> would [] have been reasonable, objectively, for a party in [the] defendant's situation to believe that there was a decent prospect that the 'use' in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the process[] by which the FDA would decide whether to approve the product . . . .[148]

The *Integra* decision revoked such license to infringe domestically. The court held that the provision "does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process," and limited to the exception to acts *actually related* to FDA

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142. *Id.*

143. *Id.*; *see also* 35 U.S.C § 271(e)(1)(2000).

144. *Integra*, 331 F.3d at 863.

145. *Id.* at 862, 865–66.

146. *Id.* at 866–67; 35 U.S.C. 271(e)(1) (2000) (overruling Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984) by statute).

147. 35 U.S.C. 271(e)(1) (2000) (emphasis added).

148. *See* Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) (describing the test for "reasonably related uses" under the section 271(e)(1) exception); *see also* Bristol-Myers Squibb Co. v. Rhône-Poulenc Rorer, Inc., No. 95 CIV. 8833(RPP), 2001 WL 1512597, at *4 (S.D.N.Y. Nov. 28, 2001) (applying the *Intermedics* test).

approval.[149]

Holding that Merck infringed the Integra patents, the court remanded the case for determination of a reasonable royalty for damages.[150] While the court refrained from opining on pertinent factors in determining what constitutes a reasonable royalty for research tool infringement, the majority suggested that reach-through licensing agreements (RTLAs) might be implied in certain instances.[151] RTLAs "allow the provider to either own, or license exclusively, or obtain payments upon the sale of, developments that the recipient makes with the provider's materials."[152] Some commentators have argued that RTLAs may be undesirable because of their proprietary effect on valuable research tool patents;[153] similarly, others contend that reach-through patent claims are unenforceable.[154] Although certainly not appropriate in all circumstances, routinely permitting such assumptions would increase the deterrence of research tool infringement due to the potential weight of the penalties assessed.

The most compelling aspect of the *Integra* decision for purposes of this discussion is the court's rationale for limiting the section 271(e) exemption. The court held:

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149. *Integra*, 331 F.3d at 867 (citing bioequivelency testing of generic drugs as the primary aim of the statutory safe harbor) (emphasis added).

150. *Id.* at 862; *see also* 35 U.S.C. § 284 ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer . . . .").

151. *Integra*, 331 F.3d at 871–72 (citing Donald Ware, *Research Tool Patents: Judicial Remedies*, 30 AM. INTELL. PROP. L. ASS'N Q.J. 267, 282–88, 293–95 (2002) (describing methods of fashioning a "reasonable royalty" for infringement and objective considerations for defining terms of a reach through royalty)).

152. NATIONAL INSTITUTE OF HEALTH, REPORT OF THE NATIONAL INSTITUTE OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS, Appendix B (June 4, 1998), *available at* http://www.nih.gov/news/researchtools/appendb.htm (describing reach-through provisions but discouraging their use as limiting future invention and innovation).

153. *See* Heller & Eisenberg, *supra* note 47, at 699 (describing the underlying basis for obtaining a financial stake in downstream inventions); *see also* Michael J. Stimpson, *Damages for Infringement of Research Tool Patents: the Reasonableness of Reach through Royalties*, 2003 STAN. TECH. L. REV. 3, ¶ 16 (2003).

154. Stephen G. Kunin et al., *Reach-through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609, 637–38 (2002).

> Extending § 271(e)(1) to embrace all aspects of new drug development activities would ignore its language and context with respect to the 1984 [Hatch-Waxman] Act in an attempt to exonerate infringing uses only potentially related to information for FDA approval. Moreover, such an extension would not confine the scope of § 271(e)(1) to *de minimis* encroachment on the rights of the patentee. For example, expansion of § 271(e)(1) to include the Scripps Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents. After all, patented tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs. Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions. Needless to say, the 1984 [Hatch-Waxman] Act was meant to reverse the effects of *Roche* [*Prod., Inc. v. Bolar Pharma Co.*] under limited circumstances, not to deprive entire categories of inventions of patent protection.[155]

Thus, the court affirms that the value of many biotech tool patents lies in the ability to facilitate the costly and complex research tasks associated with drug discovery and commercial development.[156] Accordingly, the court held it improper to extend the section 271(e)(1) exemption for such use unless research is explicitly for "submission of *information* under Federal Law."[157] Permitting any further use would result in the vitiation of an entire category of process patent inventions or deprivation of an inventor's IP rights.[158]

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155. *Integra*, 331 F.3d at 867.

156. *See id.*

157. *Id.* (emphasis added).

158. *Id.* Despite the acknowledgement of the value in research tool patents, it remains to be seen if the U.S. Supreme Court will find that the importance of patent protection for research tools outweighs their obvious public utility in drug discovery. The Court granted certiorari in *Integra* to determine whether in interpreting the "'reasonably

Alternatively, the *Housey* court refused to extend the scope of section 271(g) to research tool patents because granting protection to the use of such methods for obtaining *information* would allow for "sweeping liability beyond the scope of the statute".[159] Thus, while *Madey* and *Integra* now prohibit the general use of research tools for the sake of obtaining information for new drug development, *Housey* permits such a use for development of drugs intended for manufacture in the United States if the infringer merely performs the acts abroad. Therefore, *Housey* has accomplished exactly what the *Integra* court and Congress have both specifically shunned: depriving biotech research tool inventors of protection. The 271(g) loophole makes patent holders susceptible to "infringement" by both international competition and U.S. companies with foreign divisions.[160]

## V. ALTERNATIVE PROTECTION FOR RESEARCH TOOLS UNDER U.S. LAW

Following *Housey*, it is imperative that research tool patent holders explore alternative remedies to protect their IP from infringement on foreign soil. The following sections discuss the modes of protection available for research tool patents. The most

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related to the development and submission of information' [language of 271(e)(1)]. . . the Federal Circuit err[ed] in concluding that th[e] drug-research safe harbor does not protect animal studies of the sort that are essential to the development of new drugs, where the research will be presented to the FDA, and where barring the research until expiration of the patent could mean years of delay in the availability of life-saving new drugs" Merck KGaA v. Integra Lifesciences I, Ltd., et al., NO. 03-1237 (Docket) (U.S. Mar. 03, 2004) *available at* http://www.supremecourtus.gov/docket/03-1237.htm. Despite his advocacy for increased protection for research tools under section 271(g), this author would favor a more liberal exemption under section 271(e)(1). The section 271(e)(1) exemption, however, should not allow otherwise infringing users to "reach back down the chain of experimentation to embrace development and identification of new drugs that will, in turn, be subject to FDA approval." *Integra*, 331 F.3d at 865-66. This is exactly the type of activity that the author hopes would be abated by a broadening of section 271(g).

159. Housey I, 169 F. Supp. 2d 328, 330 n.2 (D. Del. 2001), *aff'd in part*, 340 F.3d 1367 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003).

160. *See id.* Here, the author uses "infringement" because, after *Housey*, there is no provision prohibiting the foreign use. Therefore, while the result is the same, there is no legal infringement.

obvious protection comes in the form of section 337 claims under the Trade and Tariff Act of 1930, the statutory provision that section 271(g) protection was intended to supplant.[161]

### *A. Patent Protection under Section 337 of the Tariff Act of 1930*

Exercise of the section 337 cause of action[162] has substantial benefits, including: expedited adjudication by experienced patent judges,[163] a court familiar with foreign discovery, and the "foreign perception [of the court] as a protectionist forum."[164] In addition, because section 337 claims encompass protection of U.S. patents, an inventor need not take additional steps to secure protection under section 337 beyond what is required to obtain a U.S. patent. Unfortunately, a section 337 claimant faces impediments not normally associated with the Patent Act.[165]

Just as under the patent code, a section 337 claimant must prove infringement of his patent and defend any challenges to its validity[166] or enforceability.[167] In addition, an inventor

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161. Trade and Competitiveness Act §§ 1341–42, 19 U.S.C. § 1337 (2000).

162. 19 U.S.C. § 1337(a)(1)(B). That subsection states:

> The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that— (i) infringe a valid and enforceable United States patent . . .; or (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

*Id.*

163. 19 U.S.C. § 1337(e)(2) (mandating that determinations be made within 90 days of public notice of investigation, extendable by 60 days for complex cases); *see also* 19 C.F.R. § 210 (2004) (citing regulations for Adjudication by Administrative Law Judge (ALJ) and Enforcement of orders under section 337).

164. Cecilia H. Gonzalez, *Section 337 Actions before the ITC*, 766 PLI/PAT 533, 537 (2003); *see also* Kimberly A. Moore, *Xenophobia in American Courts*, 97 NW. U. L. REV. 1497 (2003) (arguing that U.S. juries are prejudiced against foreign litigants). *But see* Kevin Clermont & Theodore Eisenberg, *Xenophilia in American Courts*, 109 HARV. L. REV. 1120 (1996) (suggesting that all Federal courts are "protectionist forums").

165. *See* S. REP. No. 100-83, at 37 (1987) ("[T]he tests that must be met to win an ITC order excluding the infringing products are more elaborate than in a Federal court action where all that is necessary is to show infringement.").

166. 35 U.S.C. § 282; *see also* John A. Jeffery, Comments, *Preserving the Presumption of Patent Validity: An Alternative to Outsourcing the U.S. Patent Examiner's Prior Art Search*, 52 CATH. U. L. REV. 761, 765–74 (2003) (explaining procedural aspects of challenging patent validity).

claiming illegal importation of an infringing product under section 337 must show that a patent claimed relates to a current or establishing industry in the United States.[168] The code section further defines "industry".[169] If the inventor meets all requirements, the only relief granted for a section 337 violation is the issuance of an exclusionary order prohibiting further importation of infringing goods into the United States.[170] Despite the imposition of civil monetary fines for noncompliance with the order, the inventor obtains no compensation for prior or subsequent infringing uses of a patent.[171]

Even if the inventor meets the previous requirements establishing illegal importation, the Commission may withhold injunctive relief if "after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and the United States consumers, it finds that such articles should not be excluded from entry."[172] Furthermore, the ITC must present each final determination to the President for adoption or disapproval.[173] The President has sixty days to weigh the final determination against the public policy considerations for exclusion listed above.[174] If the President disapproves of the Commission's

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167. *See* Michael G. Cowie & Joseph P. Lavelle, *Patents Covering Industry Standards: The Risks of Enforceability Due to Conduct Before Standard-Setting Organizations*, 30 AM. INTELL. PROP. L. ASS'N Q.J. 95, 103–33 (2002) (discussing legal grounds for a finding of unenforceability).

168. 19 U.S.C. § 1337(a)(2); *see also* Terry Lynn Clark, *The Future of Patent-Based Investigations under Section 337 after the Omnibus Trade and Competitiveness Act of 1988,* 38 Am. U. L. Rev. 1149 (1989) (discussing the benefits of eliminating the prior injury-in-fact requirement for patent enforcement).

169. 19 U.S.C. § 1337(a)(3) (considering industry to exist if there is: "(A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, or licensing").

170. 19 U.S.C. § 1337(b)(3).

171. The ITC assesses civil penalties if the importer does not comply with a cease and desist order. *See* 19 U.S.C. § 1337(f).

172. 19 U.S.C. § 1337(c)–(f).

173. 19 U.S.C. § 1337(j)(1).

174. 19 U.S.C. § 1337(j)(2).

decision, the Commission will dismiss the ITC order.[175] If the President approves of the ITC decision or allows the revocation period to lapse, the inventor may appeal final determinations and orders of the Commission directly to the CAFC.[176]

The inclusion of the "weighing provision" distinguishes a section 337 cause of action from one under the Patent Act. Using a balancing approach to determine whether to issue an injunction puts the inventor's IP rights in a precarious position. For biotech research tool patents, considerations of public health and welfare are particularly relevant. If the imported good is a drug or health-related therapy, it is likely to provide a societal benefit. The provision creates a system where the utility of the patented process becomes inversely proportional to the likelihood of enforcement of the IP rights. For example, if the research tool is wildly successful in helping to develop a new class of drugs,[177] the more likely it is that the exclusion of the resulting imports (the drugs) will detrimentally affect the public health and welfare. Thus, the more inventive and successful the patented process, the less protection an inventor may expect to receive from the ITC.

The U.S. Patent Act does not ask whether to enforce an inventor's patent rights. Treatment of a patented invention as an exclusive property right assures the patent owner that, aside from explicit limitations set forth in the Patent Act, the government will enforce the patent owner's rights upon proof of infringement.[178] However, research tool owners do not enjoy the same protection under section 271(g) as other process patent holders.[179] Fortunately, the ITC has adopted a different policy in

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175. 19 U.S.C. § 1337(j)(3).

176. 19 U.S.C. § 1337(c), (j)(4).

177. *See, e.g.*, Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *reh'g* and *reh'g en banc denied*, 2003 U.S. App. LEXIS 26547 (2003), *cert. granted*, 160 L. Ed. 2d 609 (2005).

178. 35 U.S.C. § 261 ("Subject to the provisions of this title, patents shall have the attributes of personal property."); *see also* Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573 (Fed. Cir. 1983) ("The grant of a patent is the grant of the right to invoke the state's power in order to exclude others from utilizing the patentee's discovery without his consent.").

179. *See infra* Part IV; Housey II, 340 F.3d 1367 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003).

enforcing process patent claims by explicitly refuting the argument that adjudication of section 337 claims must consider the section 271(g) standard in assigning liability.

### *B. Process Patents and the ITC – In re Certain Abrasive Products*

Facts of the case:

Patent licensee, Minnesota Mining & Manufacturing, Co. (3M), and licensor, Ultimate Abrasive Systems (UAS), sued under section 337, alleging unfair trade practices against Kinik Co., a Taiwanese business entity.[180] 3M and UAS alleged unlawful importation of certain abrasives made by a patented process, and identified a related industry as statutorily required.[181] Upon finding that the UAS patent was not invalid, enforceable, and infringed, the Administrative Law Judge (ALJ) issued a final determination in favor of 3M and UAS.[182] Kinik sought review, alleging that it had been precluded under ALJ order No. 40 from asserting infringement defenses under section 271(g) of the Patent Act.[183] The Commission affirmed the ALJ order on grounds that: (1) Kinik proposed the statutory defense too late in the proceedings, and (2) section 271(g) is not pertinent in section 337 investigations.[184]

As is customary for the CAFC, the ITC examined the committee reports of the Trade and Competitiveness Act to determine the congressional intent in permitting section 271(g) and section 337(a) to simultaneously regulate similar acts of infringement.[185] Supporting the contention that section 271(g) is not relevant to analysis of section 337 claims, the ITC quoted the following section of the PPAA committee reports: "Retention of other Remedies – The amendments made by this subtitle [(including the addition of section 271(g))] shall not deprive a

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180. In re Certain Abrasive Products Made Using a Process for Making Powder Preforms, & Products Containing Same, USITC Inv. No. 337-TA-449, 2002 WL 31093607 (U.S.I.T.C. Aug. 2002).

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.*

patent owner of any remedies available . . . under section 337 of Tariff Act of 1930, or under any other provision of law."[186] Furthermore, the court indicated that the statutory exceptions to section 271(g) liability are limited to Title 35 of the United States Code.[187] Ultimately, the court adopted a more liberal policy to patent protection under section 337, following the committee report's endorsement of section 337 as a wholly independent cause of action.[188] On appeal, the CAFC affirmed the commission's interpretation regarding the distinction between the causes of action, but reversed the finding of infringement after modifying the claim construction.[189]

Discussion of the ALJ order in *Kinik* primarily addresses the exemptions codified under sections 271(g)(1) and 271(g)(2). This discussion, however, is also relevant to the general assignment of liability for illegal importation. Under section 337, an inventor must still prove infringement in order to sustain a claim.[190] *Housey* established that the "made by" language limits section 271(g) to patented processes utilized in the manufacture of imported goods.[191] However, the ITC follows its own infringement standard that states that "[t]he importation . . . the sale for importation, or the sale . . . of articles that . . . are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent."[192] No equivalent section 271(g) exemptions exist for a claim brought under section 337.

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186. *Id*; *see* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418 § 9006(b), 102 Stat. 1107, 1567 (codified as amended at 35 U.S.C. § 271 (2000)).

187. In re Certain Abrasive Products Made Using a Process for Making Powder Preforms & Products Containing Same, USITC Inv. No. 337-TA-449, 2002 WL 31093607 (U.S.I.T.C. Aug. 2002); *see* 35 U.S.C. §§ 271(g)(1)–(2).

188. In re Certain Abrasive Products Made Using a Process for Making Powder Preforms, USITC Inv. No. 337-TA-449, 2002 WL 31093607 (U.S.I.T.C. Aug. 2002) (quoting S. REP. NO. 100-83 (1987): "[I]t was not Congress' 'intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.'").

189. Kinik v. Int'l Trade Comm'n, 362 F.3d 1359 (Fed. Cir. 2004), *reh'g and reh'g en banc denied*, 2004 U.S. App. LEXIS 11036 (2004).

190. *See* 19 U.S.C. § 1337(a).

191. Housey II, 340 F.3d 1367, 1377 (Fed. Cir. 2003), *reh'g and reh'g en banc denied*, 2003 U.S. App. LEXIS 23814 (2003).

192. 19 U.S.C. § 1337(a)(1)(B)(ii) (emphasis added).

Therefore, while the CAFC has further defined "made", the court has not interpreted the remaining four nonsynonymous descriptors. In *Housey*, the CAFC briefly spoke on the discrepancy between the languages under the two acts.[193] However, the result of such inspection was merely the conclusion that section 337 did not add additional scope to "made" as used in section 271(g). The court did not elaborate about the scope of the corresponding section 337 language. The disavowal of section 271(g) as relevant in a section 337 action serves to free such claims from any further limitation when the ITC assesses liability.[194] Following *Housey,* section 337 claims may be the only viable remedy for a large group of existing U.S. patent holders who have sought no addition IP protection.

## VI. THE DIFFICULTIES OF INTERNATIONAL PATENT PROTECTION

Understandably, for many inventors and investors, the remedy for infringement provided under section 337 does not grant adequate protection for their investments of time or capital. Increasingly, inventors who wish to obtain increased international protection obtain patents directly from foreign states.[195] Logistical problems in both the application process and in enforcement of foreign patents may render such increased efforts ineffective. The following sections (1) present a brief history of the relevant international laws, and (2) address some of the potential drawbacks of the international system that are unique to biopharmaceutical research tool inventions.

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193. *Housey II*, 340 F.3d at 1374 n.9. The court stated:

> We recognize that section 1337 covers both articles that were 'made' and articles that were 'produced, processed, or mined.' While this language in section 1337 perhaps suggests a broader scope for section 1337 than for section 271(g), nothing in section 1337 suggests coverage of information, in addition to articles, under section 271(g).

*Id.*

194. *Id.*

195. The World Intellectual Property Organization, *Patent Applications Filed and Patents Granted During 2002, at* http://www.wipo.int/ipstats/en/publications/a/pdf/patents.pdf (last visited Jan. 22, 2005).

### *A. The History of International Patent Laws*

The idea of international patent law protection is hardly new.[196] In 1883, the adoption by fourteen member countries of the Paris Convention for the Protection of Industrial Property signaled the beginning of international protection for patents, trademarks, and industrial designs.[197] The Paris Convention allowed access to the protections of other union member's patent laws by effectively treating citizens of member nations as one of their own for patent application purposes.[198] In 1886, signatories agreed to a similar system for copyrights by independent adoption of the Berne Convention for the Protection of Literary and Artistic Works.[199] The formation of the United International Bureaux for the Protection of Intellectual Property (BIRPI) consolidated the administration of the Paris and Berne Conventions in 1893.[200]

The World Intellectual Property Organization (WIPO) ultimately succeeded BIRPI after its formation in 1970 and still administers each of the conventions today.[201] Signatories of WIPO and of the treaties it administers each benefit from extensive membership.[202] However, developed countries

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196. The World Intellectual Property Organization, *About WIPO: General Information*, *at* http://www.wipo.int/about-wipo/en/gib.htm (last visited Jan. 22, 2005) (citing the International Exhibition of Inventions in Vienna in 1873 as the decisive event motivating talks regarding international IP protection) [hereinafter WIPO].

197. *Id.*; *see* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *last revised at* Stockholm, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

198. WIPO, *supra* note 196; *see* Paris Convention, *supra* note 197, at art. 3.

199. Berne Convention for the Protection of Literary and Artistic Works, Paris Act of July 24, 1971, *as amended on* Sept. 28, 1979, 828 U.N.T.S. 222 [hereinafter Berne Convention].

200WIPO, *supra* note 196 (discussing the formation of the BIRPI).

201. Convention Establishing the World Intellectual Property Organization, July 14, 1967, *as amended on* Sept. 28, 1979, 828 U.N.T.S. 3.

202. WIPO, *supra* note 196 (stating that as of October 28, 2004, the number of member states of WIPO totaled 180); *see also* The World Intellectual Property Organization, *The Paris Convention Contracting Parties, at* http://www.wipo.int/treaties/en/documents/pdf/d-paris.pdf (last visited Jan. 22, 2005) (listing all member states to total 164); *see also* The World Intellectual Property Organization, *The Berne Convention Contracting Parties, at* http://www.wipo.int/treaties/en/documents/pdf/e-berne.pdf (last visited Jan. 22, 2005).

criticized WIPO's administration for being overly accommodating to developing countries, and for lacking any serious means to enforce violations.[203] As a result, the World Trade Organization (WTO) now administers the international patent law agreements.[204]

In 1947, the United States entered into the Generalized Agreement of Tariffs and Trade (GATT) Agreement.[205] Following World War II, the aim of the agreement was to provide "mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international commerce."[206] In response to pressure from developing member states resulting from perceived deficiencies of the WIPO administration, 114 countries voted to create the WTO as an adjudicatory body for trade disputes.[207] Simultaneously the countries voted to adopt the Trade Related Aspects of Intellectual Property (TRIPS) Agreement, which is in force today.[208] U.S. enforcement of the TRIPS Agreement is accomplished through implementation of trade sanctions under section 301 of the Trade Act of 1974.[209] Thus, as the world's economic leader, the United States has a powerful remedy to encourage compliance with the TRIPS Agreement by member countries.

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203. U.S. General Accounting Office, *Int'l Trade: Strengthening Worldwide Protection of Intellectual Property Rights* 22 (1987) ("The government sees greater opportunity for broad substantive progress by addressing this problem as an unfair trade practice within the new 'Uruguay' GATT round of multilateral trade negotiations.") [hereinafter GAO].

204. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations (The Uruguay Round): Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Dec. 15, 1993, 33 I.L.M. 1 [hereinafter TRIPS Agreement].

205. General Agreement on Tariffs and Trade, *came into force* Jan. 1, 1948, *published* July 1969, 61 Stat. A3, T.I.A.S. No. 1700, 55 U.N.T.S. 187 [hereinafter GATT].

206. *Id*. at pmbl.

207. *See* TRIPS Agreement, *supra* note 204.

208. *Id.*

209. Trade Act of 1974 § 301, Pub. L. No. 93-618, 88 Stat. 2041 (1975) (codified as amended at 19 U.S.C. § 2411 (2000)); *see also* Robin J. Effron, Note, *Secrets and Spies: Extraterritorial Application of the Economic Espionage Act and the TRIPS Agreement*, 78 N.Y.U. L. REV. 1475, 1483 n.47 (2003) (describing the United States' strategic use of section 301 sanctions).

### *B. Application and Enforcement of Foreign Patents*

There is no such thing as an "International Patent".[210] Accordingly, each inventor must file for a foreign patent by submitting an application in every country that the inventor desires protection.[211] Enactment of the Patent Cooperation Treaty (PCT)[212] and formation of regional patent treaties such as the European Patent Convention (EPC);[213] the Eurasian Patent Convention (EAPC);[214] the African Organization of Intellectual Property (OAPI);[215] and the African Regional Industrial Property Association (ARIPO)[216] has greatly facilitated the filing of foreign patent applications. In the "international phase", an inventor submits an application to a PCT receiving office in a designated member state and pays a single application fee.[217] In doing so, an inventor may effectively choose file in all 118 of the PCT member countries simply by checking them off on the international application.[218] The patent applicant need only

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210. *See* Mills, *supra* note 1, at 87.

211. *See* Paris Convention, *supra* note 197, at art. 3 (stating that WIPO members have reciprocity in the ability to file patent applications).

212. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645.

213. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 254. (citing the member states that include: Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Republic of Bulgaria, Repubic of Estonia, Republic of Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom).

214. The Eurasian Patent Convention, *at* http://www.katzarov.com/clickable_map/p_ eurasian_patent.html (last visited Jan. 22, 2005) (stating that the following states are members: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, the Federation of Russia, Tajikistan, and Turkmenistan).

215. Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, *as last amended* Feb. 24, 1999. (listing the member states as Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo).

216. Agreement on the Creation of the African Regional Industrial Property Organization (ARIPO), Dec. 9, 1976. (listing the member states as Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Sierre Leone, Somalia, Sudan, Swaziland, Uganda, United Republic of Tanzania, Zambia, and Zimbabwe).

217. 35 U.S.C. § 361 (2000).

218. *See* Patent Cooperation Treaty, *supra* note 212.

submit the application in one language, as approved by the receiving office.[219] The filing of the international application establishes the application's priority date under the first-to-file convention.[220]

Upon submission, an International Searching Authority appointed by a committee of the PCT seeks out prior art that may prohibit a patent from issuing. [221] An applicant may also request a preliminary examination of the patent by a designated authority for an additional fee.[222] This optional service provides the applicant with an opinion on the likelihood of obtaining a patent on the submitted claims. This may help an inventor plan his most cost-effective patent strategy. In comparison to a traditional application filed under the Paris Convention, the filing of an international PCT application has a more lenient time schedule.[223] This additional time may allow the inventor to amend his application to include additional countries after submission of the priority application.[224]

The applicant may decide to continue prosecution of his patent in any or all of the previously selected member states.[225] Following payment of the required fees, the application enters the "national" or "regional" phase for prosecution.[226] To proceed, the inventor must pay the application fees for each of the selected countries or the office representing a regional patent treaty and provide a translation of the application when necessary. The designated patent authority evaluates the application for each of the member states.[227] Once an applicant receives his national patent, he may have to pay additional

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219. *See* 35 U.S.C. § 361 (requiring U.S. filed applications to be in English).

220. Sean T. Carnathan, *Patent Priority Disputes – A Proposed Re-Definition of "First-to-Invent"*, 49 ALA. L. REV. 755, 757 (1998).

221. Margaret A. Boulware, et al., *An Overview of Intellectual Property Rights Abroad*, 16 HOUS. J. INT'L L. 441, 477 (1994).

222. Patent Cooperation Treaty, June 19, 1970, art. 31, 28 U.S.T. 7645.

223. *See* Catherine Brown & Christine Manolakas, *Trade in Technology Within the Free Trade Zone: The Impact of the WTO Agreement, NAFTA, and Tax Treaties on the NAFTA Signatories*, 21 NW. J. INT'L L. & BUS. 71, 129 n.12 (2000).

224. *See* 35 U.S.C. § 371 (2000).

225. *See* 35 U.S.C. § 366.

226. *See* 35 U.S.C. § 371.

227. *See* 35 U.S.C. § 372.

money in the form of a yearly annuity to maintain it.[228]

The PCT application greatly simplifies the procedure of obtaining patents in foreign countries. Thus, its implementation is invaluable in ensuring that inventors may obtain international patent protection. A well-advised inventor may effectively protect his IP by strategic filings in key regional offices.[229] Unfortunately, the peculiarities of research tool patents make the benefits described above fruitless for such inventors. Even if an inventor obtained patent protection that most practitioners would consider overkill for traditional product or process claims, the guarantee of protection remains uncertain.

There is no infringement for manufacture or importation of a product identified by the foreign use of a research tool in the United States under section 271(g) or its Japanese or UK equivalents.[230] This situation forces a research tool inventor into circumstances where his IP is nearly indefensible. Returning to the example of BigPharmCo and Small B-Tech may make the result clear. Small B-Tech, ambitious about international patent protection, files applications in each of the regional offices, the United States, and Japan. In total, 69 nations issue patents for the research tool invention. Sadly, there is no patent issued for Brazil. Accordingly, BigPharmCo can conduct operations at its Brazilian branch without penalty. The result is that all of the foreign patents acquired by Small B-Tech are virtually worthless–an untenable result.

## VII. CONCLUSION

Congressional intent in enacting the Process Patent Amendment Act was to expand protection to inventors primarily in the biopharmaceutical industry.[231] Both the CAFC and Congress have agreed on the value of research tool patents;[232]

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228. Boulware, *supra* note 221, at 474.

229. Strategic applications will typically work best for product claims, for reasons described in this comment.

230. *See supra* notes 83–84 and accompanying text.

231. *See supra* note 17 and accompanying text; *see infra* Part II.

232. *See supra* notes 99–100 and accompanying text.

however, the CAFC's *Housey* decision has greatly compromised patent protection for research tools. Thus, it seems likely that the absence of protection is the result of under-inclusive drafting of section 271(g), rather than a deliberate intent to exclude protection to U.S. research tool inventors. As *Housey* exemplifies, this may be the unintended result of enacting a statute specifically aimed at increasing protection for the biopharmaceutical industry at a time when the associated technology was on the verge of rapid and unpredictable advancement.[233]

*Housey* opens new avenues for those looking to minimize R&D expenditures by using patented research tools on the cheap. The effect of domestic strengthening of patent rights coupled with the weakening of international protection will promote the relocation of infringing activity offshore. In fact, evasion of IP enforcement in this manner has already become common practice.[234] This is particularly troublesome for smaller biotech entities, including independent inventors, small businesses, and nonprofit institutions.[235] Small entities are much more dependent on their patent rights because they typically invest in only one or two key technologies. Accordingly, small entities are much more likely to enforce their patents than their larger counterparts.[236] This distinguishes the smaller entities from their larger counterparts that generally utilize an armada of blocking patents for IP protection.[237] Without strict enforcement of their IP rights in these key inventions, infringers would divest the small entity of its livelihood.

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233. *See supra* notes 38–43 and accompanying text.

234. *See* Walsh, *supra* note 49.

235. *See* Gerald J. Mossinghoff, *The U.S. First-to-Invent System Has Provided No Advantage to Small Entities*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 425, 425–27 (2002) (explaining the reasons for the assignment of inventors into different categories).

236. Burk & Lemly, *Policy Levers*, *supra* note 51, at 1591, 1696 n.46 (Quoting as n example, John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. (forthcoming Jan. 2004) " . . . large companies obtain seventy-one percent of all patents but file only thirty-seven percent of patent infringement lawsuits.").

237. *See* Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent,* 55 STAN. L. REV. 303, 419 n.512 (2002) ("Blocking patents are senior patents that preempt the patentability of junior innovations because of overlapping subject matter.").

Small entities are free to obtain patents in foreign countries. However, this may not provide much benefit to those entities because of the high costs associated with obtaining and enforcing a patent globally.[238] In spite of efforts to obtain such protection, potential infringers may easily evade foreign research tool patents simply by performing research in non-solicited countries. While the United States touts its patent system as friendly to small entities and single inventors,[239] only the largest entities could possibly afford to solicit the international protections required to fend off a multinational company from direct infringement of a research tool. Unfortunately, U.S. biopharmaceutical companies are the most financially equipped to engage in a global game of patent "cat and mouse". This is true despite the simplified filing of international patent applications under the PCT.

To unite the protections extended to research tool patents, Congress should amend the Patent Act to close the *Housey* loophole in accord with the CAFC's strengthening of domestic protection. The amendment should ideally provide protection against extraterritorial uses of U.S. patented research tools for the ultimate purpose of manufacturing pharmaceuticals intended for the U.S. market. Allowing that type of proposed protection would unilaterally deter the willful avoidance of protections granted by U.S. patents. Due to the overwhelmingly large market share of pharmaceuticals targeted for the United States, infringers would be less likely to undertake efforts to evade U.S. patent protection. Adoption of this same policy by

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238. *See* John R. Allison & Mark A. Lemley, *Who's Patenting What? An Empirical Exploration of Patent Protection*, 53 VAND. L. REV. 2099, 2136 (2000) ("Small entities presumably have less money to spend on patent prosecution. They may therefore be more likely to prosecute patents in their home country but not abroad than large entities with overseas sales and large prosecution budgets.").

239. This is primarily due to the unique use of the U.S. first-to-invent system in priority disputes rather than the ubiquitous first-to-file system. *See, e.g.,* Campbell Chiang, Comment, *A Putative Inventor's Remedies to Correct Inventorship on a Patent*, 2003 DUKE L. & TECH. REV. 20, ¶ 8 (2003) ("The 'first-to-invent' system is arguably necessary to protect the small inventor who may well be without the resources of a large corporation that would otherwise enable him to fully utilize the patent system."). *But see, e.g.*, Mark A. Lemly and Colleen V. Chien, *Are the U.S. Patent Priority Rules Really Necessary?*, 54 HASTINGS L.J. 1299 (2003) (arguing that the first-to-invent system does not significantly benefit small entities).

Japan and the UK would all but guarantee this result.

Other available methods could be adopted to curb willful avoidance if proven in court, such as imposing an assumption of reach-through licensing agreements.[240] Enacting alternative provisions should not discourage the concurrent availability of section 337 claims. The remedy provides needed supplemental relief for the monetary loss incurred by infringement. The expediency in the adjudication of section 337 claims and ensuing availability of injunctions provides a valuable means to mitigate the economic loss due to importation of infringing goods.

There is some force to the argument that extending the proposed type of protection to biopharmaceutical research tool inventions may stifle, rather than promote, innovation.[241] Rationalization for this argument is more convincing in the abstract, and may be patently incorrect.[242] Offering incomplete and insufficient protection to research tool inventors in a patent-driven economy will only hurt those who hope to engage in legitimate business. *Housey*, undoubtedly decided with the best intentions, serves as an endorsement to infringe for corporations willing to capitalize on intellectual piracy.[243] For the sake of the biopharmaceutical industry, the United States cannot afford to stand by such an endorsement. This is particularly true since research tool infringers may easily skirt U.S. protections. Economist Fritz Machlup, in characterizing the patent system generally, best describes the current situation facing the protection of research tool patents:

> If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of

240. *See supra* notes 151–54 and accompanying text.

241. *See supra* notes 17–25 and accompanying text.

242. *See* Walsh, *supra* note 49.

243. Patent law generally has a disdain for bad-faith infringement. *See* 35 U.S.C. §§ 284–85 (2000) (allowing the award of treble damages and attorney's fees for willful infringement). Corporations willing to exploit defenseless research tool patents in foreign venues may subject themselves to criticism within the industry (not to mention committing a potentially bridge-burning violation of Confucius' Golden Rule). *See, e.g.*, Walsh, *supra* note 49 at 331 ("[M]embers of a research community (which includes both academic and commercial researchers) are somewhat reluctant to assert their IP against one another if that means they will sacrifice the goodwill and information sharing that comes with membership in the community.").

> its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.[244]

Backing off from the protections extended to decidedly valuable research tool patents is equally unwise. The CAFC offered incentive to research tool inventors to invest in such technologies through assurances of (recently increased) protection. It is injudicious and unjust to strip those inventors of their protection by ratifying the use of a readily exploitable loophole.

In the congressional report accompanying the Patent Act amendments discussed here, the Committee declared "there is no clear justification for discriminating against certain types of process inventions."[245] Regrettably, this admonishment has become a reality for research tool inventors. Congress should rectify this problem to ensure that the biopharmaceutical industry maintains its strength and competitiveness for years to come in the post-genomic era.

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244. Machlup, *supra* note 73, at 80.

245. S. REP. No. 100-83, at 45 (1987).

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