**No. 05-130**

IN THE

# Supreme Court of the United States

---

EBAY AND HALF.COM, INC.,
*Petitioners,*

v.

MERCEXCHANGE, L.L.C.
*Respondent.*

---

**On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

---

## BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

---


BRIAN P. BARRETT
Chair,
BIOTECHNOLOGY INDUSTRY ORGANIZATION
Amicus Committee
ELI LILLY AND COMPANY
Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-7243

NANCY J. LINCK
*Counsel of Record*
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1225 Eye Street, NW
Washington, DC 20005
(202) 962-6668



WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

TABLE OF CONTENTS—Continued

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

TABLE OF AUTHORITIES—Continued

## STATEMENT OF INTEREST

The Biotechnology Industry Organization ("BIO") is a trade association representing more than eleven hundred member-companies, academic institutions and biotechnology centers.[1] Its members range from the largest Fortune 500 companies to the smallest start-ups. BIO members expand the boundaries of science on a daily basis. They are involved in the research and development of healthcare, agricultural and environmental products. In fiscal year 2003 alone, the biotech sector filed over 40,000 new U.S. patent applications. The promise of exclusionary rights in validly patented subject matter provides the investment incentive for the research and development of innovative products used to improve the quality of millions of lives worldwide. BIO members, therefore, have great interest in this case. Increased uncertainty about the availability of exclusive rights in validly patented subject matter will negatively impact the amount of research and development resources available to member-companies and, most importantly, negatively impact public health and welfare.

## SUMMARY OF ARGUMENT

The last century has seen unprecedented improvements in public health, much of which has resulted from technological advances in the field of medicine. The continued improvement of public health, however, depends on the ongoing development of new and more effective treatments. The United States Congress has repeatedly recognized the critical need for robust medical research. Accordingly, and con-

[1] Pursuant to Supreme Court Rule 37.3(a), all parties have filed with the Court general written consents. Pursuant to Rule 37.6, *amicus curiae* states that no person or entity other than BIO or its members has made any monetary contribution to the preparation or submission of this brief. Further, no counsel for Petitioner or Respondent authored this brief in whole or in part.

sistent with the Patent Clause of the United States Constitution, art. I, § 8, cl. 8, Congress has enacted and refined a national policy that creates incentives for investment in this area—specifically, an intellectual property regime to reward innovators by granting a general right to exclude in exchange for disclosure of new and useful ideas.

New inventions and discoveries drive the biotechnology industry. Millions of people worldwide benefit daily from biotechnology-derived medicines and products. The right to *exclude* others from practicing a validly patented invention provides the investment incentive that is essential for high-risk, high-cost biotechnology research and development. Increased unpredictability with respect to the availability of exclusive rights will greatly diminish the value of patent rights, weaken the hand of patent owners in negotiations to determine the value of a patent, shift such value determinations to the courts, reduce inventors' desire to promptly disclose inventions to the public, and discourage the investment required to research and discover innovative technologies.

This Court in its prior opinions and the Federal Circuit in the case at bar have correctly determined that Congress guaranteed patent owners an exclusive right to their patented inventions. This consistent statutory interpretation has promoted the progress of the useful arts, including the biotechnology arts, far better than any other system in the world by providing a strong incentive to invent, disseminate information, and discover alternatives and improvements to patented inventions. It has also provided the necessary certainty for parties to determine the value of exclusive property rights without prolonged litigation that simply is not affordable by most biotechnology companies. The success of the U.S. patent system and the biotechnology industry derives from the careful balance Congress has established in the patent laws. Congress has not disturbed the patentee's exclusive right in more than two centuries. This Court should not do so now.

## ARGUMENT

### I. THE RIGHT TO INJUNCTIVE RELIEF IS VITAL IN ENSURING INNOVATION IN THE BIOTECHNOLOGY INDUSTRY

#### A. The Risks of the Biotechnology Industry Require a Patent System that Adequately Protects the Investment Necessary to Bring a Product to Market

1. Advances in medicine do not happen by themselves. They require the ingenuity of scientists, the perseverance of companies working in the medical field, and huge investment by the private sector and others. Members of BIO and others working in the biotech sector have made significant contributions to previously unimaginable research discoveries and medical advances, including medicines to treat diseases such as heart disease, cancer, AIDS, stroke, septic shock, diabetes, anemia, cystic fibrosis, multiple sclerosis, lupus, kidney disease and liver disease. Although millions of lives already have been saved and improved, the biotechnology revolution is in its infancy. Literally every day, biotechnology companies invent and discover new tests, new drugs, new cures, or new products.

Biotechnology companies must rely on investments (both from private investors and from inside the company) to fund development of risky and expensive new products. Biotechnology is still an emerging field, despite remarkable breakthroughs. Its further growth depends entirely on a commitment to invest in research and development. *See NIH: Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the House Comm. on Energy and Commerce*, 108th Cong., 1st Sess. 47 (2003) (testimony of Phylliss Gardner, M.D). ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world."). Most biotechnology

companies are small ventures with little or no operating income to meet these costs. These small, emerging companies must turn to private investors for capital to fund their labor-intensive research. Currently, a full 98% of research and development investment in biotechnology comes from the private sector. *NIH: Moving Research from the Bench to the Bedside*, *supra*, at 49. The continued support of the private sector, however, is far from guaranteed, due to the highly speculative nature of biopharmaceutical product development.

The journey companies take from idea to marketable product is neither simple, safe, nor short. The investment that a company makes to develop even a single therapy is astonishing. The average cost of developing a therapy exceeds $800 million, and development can take up to fourteen years. *Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million*, News Release (Tufts Center for the Study of Drug Development), Nov. 30, 2001, available at http: //csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6. The chances that a biopharmaceutical product will achieve FDA approval are approximately one in 5,000. *See* Tommy G. Thompson, Remarks at the Milken Institute's Global Conference (Apr. 26, 2004), available at www.hhs.gov/news/speech/2004/040426.html. Of the products that are approved as therapies for patients, a mere one-third cover their cost of development, much less turn a significant profit. John V. Duca & Mine K. Yucel, *An Overview of Science and Cents: Exploring the Economics of Biotechnology*, Federal Reserve Bank of Dallas Economic and Financial Policy Review (2002). In 2004, the industry suffered a net loss of more than $5.3 billion. Jim Wasserman, *Cancer Drugs Fuel Biotech Expansion*, Sacramento Bee, June 15, 2005 at D1; *see also* Ross Kerber, *Spread The Wealth Biotech Group Says States Need To Fund All Areas, Not Just Stem Cells*, Boston Globe, Jan. 15, 2005 at F1. ("[B]iotechnology's complicated drugs can take a decade or

longer to reach the market, leading to billions of dollars of annual losses for the industry.").

The majority of biotechnology companies are small, emerging companies with few employees, no therapies on the market, and no operating income. They must find investors willing to risk hundreds of millions of dollars on a very slim chance of the therapy reaching market and turning a profit. The company must not only convince investors that its long-shot invention will pay off, but that investing in the company is a better investment than countless, less risky, alternatives. And larger BIO member companies make their own investment in R&D. In effect, they are "investors" who must be willing to take risks and therefore also need certainty.

2. The primary asset of biotechnology companies is intellectual property, and specifically patents. The *sole* right granted by the patent—the right to *exclude* others from practicing a validly patented invention for a limited time—provides the incentive for BIO members' high-risk, high-cost research and development aimed at high rewards in promoting improved health, longevity, and well-being. Without the ability to enjoin infringers as the general rule, the right to exclude would be meaningless and many, if not most, of BIO's members would be unable to attract the capital necessary to fund research and development of new medicines.

Three examples from BIO members demonstrate the importance of investment in their product candidates to the health and welfare of the public. Robert Chess, Executive Chairman of Nektar Therapeutics, recently testified about his company's reliance on patents to attract investment capital for developing the world's first inhaled insulin for diabetic patients. He explained that his company is not profitable despite being in existence since 1991 and raising $1.2 billion through seventeen rounds of financing. The issuance of a single U.S. patent covering a form of inhaled insulin made it possible to attract the investment required for critical research

and development. In 2006 his company and its partner received FDA approval for their inhaled insulin product, the first insulin not administered to patients by injection. *See Patent Reform Act of 2005: Hearings on an Amendment in the Nature of a Substitute to H.R. 2795 Before the Subcomm. on the Courts, Internet, and Intellectual Property of the House Comm. on Judiciary*, 109th Cong., 1st Sess. (2005) (testimony of Robert Chess).

Another small biotechnology company, AlphaVax, has patented a technology that has the potential to deliver millions of doses of seasonal flu vaccine, as well as a pandemic flu vaccine. This company does not anticipate any of its vaccines will be approved for use by patients until 2011, and, therefore, must attract investors willing to forego other investment alternatives and risk millions of dollars on the chance this therapy will ultimately reach the market and make a profit. AlphaVax and its investors must have confidence that their patents will provide a predictable right to exclude others who did not make these discoveries or undertake comparable risk.

A third BIO member, Guilford Pharmaceuticals (now MGI Pharma), licensed patent rights to enable critical private investment that ultimately led to regulatory approval of a product to treat malignant brain tumors that extends the expected average life span of treated patients by almost 20%. Nevertheless, prior to its purchase, Guilford had not become profitable, even though its product had been on the market for several years.

These stories are commonplace among BIO members. Biotechnology companies and their investors rely on patent protection to provide the company its value. And without a general right to injunctive relief to enforce the right to exclude, these and other companies might never have been able to receive the investment needed to fund their ideas.

### B. The Patent System Represents a Careful Balance Between Providing Incentives for Investment and Protecting the Public Interest

1. The Patent Act is clear: A patent grants the patentee "the right to exclude others from making, using, offering for sale, or selling the invention . . ." 35 U.S.C. § 154; and provides that the patentee "may . . . grant and convey an exclusive right" under the patent. 35 U.S.C. § 261. Furthermore, under the Act "no patent owner . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent . . ." 35 U.S.C. § 271(d)(4). The statutory right to exclude, the sole right granted by a patent, cannot exist without the right to injunctive relief.

Yet in order to obtain this right and receive a patent, the prospective inventor must pass a gauntlet of hurdles. The *exclusive right* to injunctive relief arises only after a court has found a patent is valid. Both the Patent and Trademark Office ("PTO") and then a court upon review, must find that the patent is limited to subject matter found to be entirely (1) novel, (2) useful, and (3) non-obvious under stringent criteria Congress has placed into the patent laws. 35 U.S.C. §§ 101-103 (2002). A patent is subject to challenge for any of these reasons. Defendants accused of patent infringement often introduce reams of evidence at trial trying to invalidate a patent on these grounds. Thus, as was the case here, a patentee must withstand extensive challenges to his or her patent prior to seeking a *permanent* injunction.

In addition to the requirements above, Congress has imposed an additional barrier before a patent is issued. The patented subject matter must be sufficiently definite and have a completeness and exactness such that the patented invention can be put into practice. 35 U.S.C. § 112. *See also, e.g., In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). The bargain between the inventor and the government requires definite-

ness because the driving force of the patent system is *disclosure*. *See, e.g., Kewanee Oil Co*. v. *Bicron Corp*., 416 U.S. 470, 480-81 (1974). In exchange for disclosing to others a new invention, the government grants the right to exclude others from practicing the invention for a limited time period, *i.e.*, typically 20 years from the patent application's filing date.

2. Therefore, only when the inventor has adequately disclosed to the public something entirely novel, useful, and non-obvious—and set out with definiteness the "metes and bounds" of such an invention—does a court address the issue of whether an ongoing infringement of such a patented invention should be halted via an injunction.

For validly patented subject matter, an injunction allows the patent holder to prevent a person from using the invention — an invention that did not exist before the inventor created it. Stopping such infringement of valid patents serves as the economic incentive to create the new and non-obvious subject matter that, in turn, promotes technological advances through public disclosure via the patent. Changing the availability of exclusionary rights would diminish this strong economic incentive. The inability to enjoin the infringement of a valid patent would produce an unavoidable diminishment of the economic power—and economic value—of rights in valid patents.

Further, for validly patented subject matter, an injunction takes nothing from the public that existed before the invention was made and nothing that was merely an obvious alteration of known technology. A general rule enjoining infringement of valid patents promotes the public interest. Stopping such infringement of valid patents serves as the economic incentive to create the new and non-obvious subject matter that, once publicly disclosed via the patent, permits that advance in technology to be further refined, extended and improved. *Cf. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 736 (2002) ("[E]xclusive patent

rights are given in exchange for *disclosing* the invention to the public.") (emphasis added).

Diluting the general right to injunctive relief, in contrast, would diminish a patent's value. In negotiations among private parties, any increased uncertainty that infringement of a valid patent would be stopped by the courts would demonstrably weaken the hand of the patent owner. Investors in BIO member-companies would be less willing to invest in high-risk research and development and less investment could result in creating less new technology.

In addition, if the role of the courts changes from enjoining infringement of validly issued patents, absent exceptional circumstances, to deciding the terms on which courts will sanction the ongoing infringement of valid patents, the established system of patent licensing will change dramatically. Instead of private parties negotiating to determine the value of validly patented inventions, the courts will find themselves in the judicial licensing business—deciding the remuneration paid to the patent owner when the court sanctions ongoing infringement. Indeed, if an infringer can knowingly avoid an injunction, some potential licensees and partners might relish the prospect of—or at least the threat to a patent owner of—having a jury set the terms for a judicial license. Given the increased uncertainty of being able to enforce their exclusive rights, many biotech companies, particularly those which are resource-constrained, would have difficulty pursuing their uncertain rights through costly litigation. Thus, they likely would be forced to settle for much less than necessary to recoup their investment, to continue research and to discover innovative technologies.

Indeed, to reduce the risk of having their inventions copied, the expense of prolonged litigation, and the threat of judicial licenses, some inventors may choose not to participate in the patent system at all. Instead, they could withhold filing of a patent application, thereby maintaining their inventions as

trade secrets. Alternatively, they could delay the filing of patent applications and the public disclosure of their inventions until after negotiating and securing licensing terms under conditions of strict confidentiality. Either of these approaches would deny other scientists timely and valuable scientific information, normally available through published patent applications. Moreover, any withholding of scientific information by inventors would negatively impact the discovery of alternatives and improvements to published inventions. And it would completely defeat the patent system's fundamental purpose of bringing new ideas into the public domain. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (stating that "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure").

Biotechnology innovation depends on and has prospered because of the long-held consensus that the essence of a patent is the right to exclude. This Court should not now change these settled expectations.

## II. THE PATENT HOLDERS HAVE LONG HAD THE GENERAL RIGHT TO OBTAIN AN INJUNCTION FOR PATENT INFRINGEMENT

### A. The Historical Basis for Injunctive Relief Confirms its General Applicability in Patent Cases

35 U.S.C. § 283 provides: "The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." Injunctive relief is clearly equitable and thus will not be granted in *all* cases. However, petitioners' heavy reliance on the language of § 283 is misplaced. The history of this injunctive relief provision confirms the general principle that after a valid patent has been adjudged infringed, continuing or future infringement generally should

result in the grant of injunctive relief. In fact, its enactment was to make certain all federal courts had the power to grant such relief in all patent cases.

When the first predecessor to Section 283 was enacted on February 15, 1819, it stated:

> That the circuit courts of the United States *shall have original cognizance, as well in equity as at law,* of all actions, suits, controversies, and cases, arising under any law of the United States, granting or confirming to authors or inventors the exclusive right to their respective writings, inventions, and discoveries: and upon any bill in equity, filed by any party aggrieved in any such cases, *shall have authority to grant injunctions*, according to the course and principles of courts of equity, to prevent the violation of the rights of any authors or inventors, secured to them by any laws of the United States, on such terms and conditions as the said courts may deem fit and reasonable . . . .

3 Stat. 481, Ch. 19 (1819) (emphasis added). Thus, its enactment was not intended to limit injunctive relief, but rather was intended to authorize the circuit courts to act both in equity and at law.

The statute authorizing the court to act in equity for patent cases was revised in 1836 (5 Stat. 117, Ch. 357, § 17) and again in 1870 (16 Stat. 198, Ch. 230 § 55). Then, on March 3, 1897, the language was amended and simplified to read:

> The several courts vested with jurisdiction of cases arising under the patent laws *shall have power to grant injunctions* according to the course and principle of courts of equity, to prevent the violation of any right secured by patent, on such terms as the court may deem reasonable . . . .

R.S. 4921, 29 Stat. 694, Ch. 391, § 6 (1897) (emphasis added).

The 1897 language was twice-reenacted without change until 1952. See R.S. 4921, 42 Stat. 392, Ch. 58, § 8 (1922); and 60 Stat. 778, Ch. 726, § 1 (1946). The 1952 statute read:

> The several courts having jurisdiction of cases arising under this title *may grant injunctions* in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

66 Stat. 792, Ch. 29, § 283 (1952) (emphasis added).

In the comments to the final bill regarding Section 283, the editors note that "this section is the same as the provision which opens R.S. § 4921 with minor changes in language." H.R. Rep. No. 1923, 82d Cong., 2d Sess. 29 (1952).

Since well before the Constitution, the general rule was that injunctions issued once the patent was adjudged valid and infringed. *See, e.g.*, *Livingston v. Van Ingen*, 9 Johns. Cas. 507, 585 (1812). ("Injunctions are always granted [sic] to secure the enjoyment of statute privileges . . . . This is the uniform course of the precedents. I believe there is no case to the contrary; and the decisions in the English Chancery, on this point, were the same before as since the American Revolution.").

This general injunctive right did not change with the enactment of the 1819 Patent Act. As Professor Robinson explained in his classic 1890 treatise, *The Law of Patents*: "A perpetual injunction issues, as a matter of course, at the conclusion of a suit in equity, whenever the plaintiff has sustained the allegations of his bill, provided the patent has not then expired." 3 William C. Robinson, *Treatise on the Law of Patents for Inventions*, § 1220, at 657 (1890).[2] *See*

[2] Permanent injunctions granted after a patent had been determined to be valid and infringed are distinct from preliminary injunctions: "A preliminary injunction is not, like a perpetual injunction, a matter of course, nor can its issue be governed by any formulated and established rules." 3

*also id.* § 1088, at 400 (citation omitted). ("An adequate remedy at law does not exist in any case where future infringements are to be prevented . . . . Future infringements can be prevented only by an injunction issuing out of chancery, and to this relief the plaintiff is entitled whenever he has reason to apprehend a violation of his rights by the defendant.").

Professor Robinson identified five different areas where an injunction was not appropriate: Whenever (1) the sole relief being sought is compensation for past infringement; (2) the patentee is seeking a license fee from the infringer and the infringing acts raise an implied acceptance of the patentee's offer; (3) the infringement has ceased; (4) the patent has expired; or (5) the infringement is a breach of contract, by whose provisions the compensation of the plaintiff for the injury is determined. *See id.* § 1087, at 398-99. None of these apply here, although they explain why an injunction should not be automatic.

Exceptional circumstances also have properly led courts to deny or temporarily stay a permanent injunction when an important public need for the invention exists. *See Johns Hopkins Univ. v. CellPro*, 978 F. Supp. 184, 189 (D. Del. 1997); *Schneider (Europe) AG v. SciMed Life Sys. Inc.*, 852 F. Supp. 813, 850-51, 861-62 (D. Minn. 1994), *aff'd*, 60 F.3d 839 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 990 (1995) (granting permanent injunction with a one-year transition "to allow an efficient and non-disruptive changeover for those institutions and physicians who now employ the [infringer's product] exclusively"); *Ethicon Endo-Surgery v. U.S. Surgical Corp.*, 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (noting that to suddenly withdraw the infringing devices with which a large number of surgeons are "unquestionably" familiar and have been trained to use "could have a serious

---

William C. Robinson, *Treatise on the Law of Patent for Inventions*, § 1170, at 557 (1890).

disruptive effect on surgical practice"); *Shiley, Inc. v. Bentley Labs., Inc.*, 601 F. Supp. 964, 971 (C.D. Cal. 1985), *aff'd*, 794 F.2d 1561 (Fed. Cir. 1986) (granting an injunction against the sale of an infringing blood oxygenator, but delaying the injunction for six months to minimize negative impacts on hospitals and surgery candidates).

### B. This Court and the Federal Circuit Have Correctly and Consistently Protected a Patentee's Exclusive Rights Through Injunctive Relief, Absent Exceptional Circumstances

This Court and the Federal Circuit have correctly and consistently protected a patentee's exclusive rights through injunctive relief, absent exceptional circumstances. This Court repeatedly has determined that Congress acted within its authority when it chose to promote the progress of science and the useful arts by expressly granting patentees an exclusive property right in their inventions. More than a century ago, this Court stated:

> The securing to inventors of an *exclusive* right to their inventions, was deemed of so much importance, as a means of promoting the progress of science and the useful arts, that the constitution has expressly delegated to Congress the power to secure such rights to them for a limited period. The inventor has, during this period, a *property* in his inventions; a property which is often of very great value, *and of which the law intended to give him the absolute enjoyment and possession*.

*Ex parte Wood*, 22 U.S. (9 Wheat.) 603, 608 (1824) (Story, J.) (emphasis added). The "exclusive right" would not provide "absolute enjoyment" if it were forfeitable based on any number of unpredictable circumstances. *See also Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 36 (1923) ("It is the fact that the patentee has invented or discovered something useful and thus has the common law right to make, use and vend it himself which induces the

Government to clothe him with power to exclude everyone else from making, using, or vending it.").

More recent decisions from this Court confirm this long-standing principle of a patentee's right to exclude: "By the very terms of the statute the grant is nothing more than a means of preventing others, except under license from the patentee, from appropriating his invention." *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) (interpreting the predecessor of 35 U.S.C. § 154, U.S. Rev. Stat. § 4884). *See also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without consent."); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("Petitioners' argument runs contrary to the long-settled view that the essence of a patent grant is the right to exclude others from profiting by the patented invention.").

### C. Exclusive Patent Rights Are Enforceable Via the General Right to Injunctive Relief Even When A Valid Patent Covers A Single Component of A Multi-Component Product

Exclusive patent rights are enforceable via injunction even when a valid patent covers a single component of a multi-component product. Although the biotechnology industry typically relies on one or only a few patents to adequately protect an entire marketed product, BIO's members regularly make inventions that are incorporated into and used in conjunction with more complex products. There is no need to alter the longstanding general right to injunctive relief because sometimes one valid and infringed patent protects only a single component of a multi-component product. Testimony during a recent patent reform hearing referred to this situation as "a case of someone wanting to enjoin the sale of pick-up trucks because they contain a built in beer cooler that

is claimed to be infringing." *Patent Reform Act of 2005: Hearing on an Amendment in the Nature of a Substitute to H. R. 2795 Before the Subcomm. on the Courts, Internet, and Intellectual Property of the House Comm. on the Judiciary*, 109th Cong., 1st Sess. (2005) (testimony of David Simon).

Such a situation does not justify a change in this Court's precedent. *First*, the issuance of a permanent injunction is based on a final determination that a presumptively valid patent—meeting all statutory requirements—is infringed. *Second*, seldom is the issuance of the patent a surprise. As a result of the American Inventors Protection Act of 1999, Public Law 106-113, 113 Stat. 1501, substantially all patent applications publish 18 months after filing. 35 U.S.C. § 122 (b)(1)(A); 37 C.F.R. § 1.211 (2005). Prudent companies regularly monitor and analyze the patent literature in areas where they research and develop products, and continue to assess their risk during the several years usually required to complete patent litigation. *Third*, an injunction can and should be tailored to prevent the infringement of the "claimed invention," for example, the cooler in the case of Mr. Simon's hypothetical. *Fourth*, the infringer has choices—remove the cooler from the truck, design a cooler that doesn't infringe the valid patent, wait for the patent to expire, or seek a license from the patent owner.

In the vast majority of cases in which a party is found guilty of infringement, permanent injunctions are not issued because the parties negotiate a settlement or the accused infringer redesigns its product to avoid infringement. If a product cannot be redesigned to avoid a patent, it is likely that the patent is protecting an important invention and an injunction is warranted, absent exceptional circumstances.

## III. BIOTECH INNOVATION WOULD BE FRUSTRATED IF THIS COURT CREATED AN EXCEPTION TO THE RIGHT TO INJUNCTIVE RELIEF WHEN THE PATENT HOLDER DOES NOT USE THE INVENTION

BIO members, particularly small companies and universities, make valuable, patentable discoveries but frequently do not practice or develop ("use") them for a variety of reasons. They may lack scientific expertise, financing, or development and manufacturing capacity. Likewise, they simply may be unable to currently license other essential know-how. And licensing immediately may not make economic sense, or they may try and be unable to do so. In some cases, it may take years before commercialization is feasible, or even possible. These patent owners should not be deprived of their exclusive rights, as they would be if this Court created a new basis to avoid an injunction whenever a patent owner does not use its patented invention.

Such a change in the law would run counter to this Court's jurisprudence and to Congress's command.[3] Moreover, it begs the question of what "use" means. Licensing the patent so that others might use it benefits the public, and is a "use." *Continental Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405 (1908).

Regardless of what "use" means, however, "[t]his Court has consistently held that failure of the patentee to make use of a patented invention does not affect the validity of the patent." *Special Equip.* 324 U.S. at 78-79. This Court's

[3] Of course, under present jurisprudence, if lack of use negatively impacts the public interest, as it could in the case of a life-saving drug, sufficiently to outweigh the public interest in a strong patent system, then that interest should be considered in deciding whether to issue an injunction.

decision in *Continental Paper Bag* was not an outlier. Rather, it relied on traditional principles of patent law:

> It is manifest as is said in Walker on Patents, § 106, that Congress has not 'overlooked the subject of non-use of patented inventions' . . . . In some foreign countries the right granted to an inventor is affected by non-use. This policy, we must assume, Congress has not been ignorant of nor of its effects. It has, nevertheless, selected another policy; it has continued that policy through many years. We may assume that experience has demonstrated its wisdom and beneficial effect upon the arts and sciences.

*Id.* at 429-30. As explained by this Court, use of patented inventions is not required:

> A suppression can endure but for the life of the patent, and the disclosure he has made will enable all to enjoy the fruit of his genius. His title is exclusive, and so clearly within the constitutional provisions in respect of private property that he is neither bound to use his discovery himself nor permit others to use it.

*Bement v. National Harrow Co.*, 186 U.S. 70, 90 (1902) (*quoting Heaton-Peninsular Co. v. Eureka Specialty Co.*, 77 F. 288, 294-95 (6th Cir. 1896)).

A rule distinguishing patents by whether the patent holder "uses" the invention is directly contrary to Congress's command. Not only would such a rule diminish the value of the patent, it will inexorably result in court-imposed compulsory licensing—something acknowledged forthrightly by the one case relied upon so heavily by petitioners and their *amici*, *Foster v. Am. Mach. & Foundry Co.*, 492 F.2d 1317 (2d Cir. 1974). Yet Congress consistently has rejected all attempts to create compulsory licensing, except in certain

limited situations necessary to the public welfare.[4] These exceptions show not only that Congress does not want compulsory licensing as a general rule, but that not having an injunctive right is appropriate only where the public interest is involved. Indeed, this Court stated over 60 years ago that "Congress has frequently been asked to change the policy of the statutes as interpreted by this Court by imposing forfeiture or providing for compulsory licensing if the patent is not used within a specified time, but has not done so." *Special Equip.* 324 U.S. at 379 (footnotes omitted). The same is equally true today.[5] Likewise, Congress has consistently re-

[4] Congress has, for example: (1) limited a patentee's remedies against the government to reasonable compensation (28 U.S.C. § 1498); (2) exempted from infringement practicing an invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" (35 U.S.C. § 271(e)(1)); (3) provided the government authority to grant licenses to government-funded inventions, under certain circumstances (35 U.S.C. § 204); (4) mandated a compulsory license if necessary to ensure an adequate supply of food (7 U.S.C. § 2404); (5) required licensing under reasonable terms of technology to prevent and control air pollution (42 U.S.C. §§ 7401-7626); (6) provided licensing of certain patented inventions related to nuclear material and atomic energy (42 U.S.C. § 2183(c)); (7) mandated licensing of patented inventions as necessary to comply with the Clean Air Act (42 U.S.C. § 7608); and (8) limited the enforceability of certain medical procedures patents (35 U.S.C. § 287).

[5] Granting compulsory licenses, unless narrowly and carefully tailored, may well "run afoul" of the United States' TRIPS obligations. *See*, Harold C. Wegner, *Injunctive Relief: A Charming Betsy Boomerang*, 1st Annual Northwestern Journal of Technology and Intellectual Property Symposium: IP Litigation in the 21st Century, Northwestern University (Feb. 2006), available at http://www.foley.com/files/ tbl_s31Publications/ FileUpload137/3231/Injunctive%20Relief%20%20A%20Charming%20Betsy%20Boomerang.pdf. The practice would certainly frustrate the United States' efforts to halt the grant of such licenses in other countries. At the very least, this Court should consider what would be required in order to sufficiently address these and other international issues. *See Wegner*, *supra*.

jected any attempt to distinguish among patent owners based upon whether the claimed invention is being "worked" or "used."[6]

In addition, Congress has amended the patent laws on numerous occasions without altering the right to exclude infringement of valid patents.[7] And Congress will certainly continue to consider proposals to amend the patent laws to promote the progress of the useful arts. In fact, the Federal Trade Commission (FTC) and the National Academy of Sciences (NAS) each recently conducted multi-year studies of the U.S. patent system resulting in detailed reports and extensive recommendations on how to improve the patent system.[8] These two reports spurred the 109th Congress to

---

[6] *See Hartford-Empire Co. v. United States*, 323 U.S. 386, 416 (1943) (citing rejected attempts by Congress). More recent proposals to limit the right to exclude include: *the Hart Bill of 1973*, S. Rep. No. 1321, 93d Cong., 2d Sess. (1973); *The Affordable Prescription Drugs Act*, H.R. 2927, 106th Cong., 1st Sess. (1999); and *The Affordable Prescription Drugs and Medical Inventions Act*, H.R. 1708, 107th Cong., 1st Sess. (2001) (proposal to allow compulsory licensing under certain conditions related to health care costs).

[7] For example, in 1999 Congress amended the patent law such that nearly 95% of all patent applications now publish eighteen months from filing to allow the public to benefit from the early disclosure of the invention and to prevent unfair surprise to competitors from late-issuing patents. A recent change in term from seventeen years from patent issuance to twenty years from the filing of the application has also harmonized U.S. patent practice with the rest of the world and has prevented patentee delay in the patent office from extending patent exclusivity. Congress has also provided a "first-inventor defense" to certain infringement actions in the area of business methods patents. 35 U.S.C. § 273(b)(1).

[8] The FTC conducted a multi-year study of the U.S. patent system and issued a report in October 2003. Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003). While the FTC determined that the patent system works well, ten recommendations were made, in large part, to improve the

actively consider a number of patent reform proposals.[9] Although neither report recommended changing the patentee's right to injunctive relief, Congress nevertheless considered and rejected legislation urged by select industry groups that would have required courts to weigh any and every fact in deciding whether to enjoin an adjudicated infringer—exactly what Petitioners are asking this Court to

---

balance between patent owner's rights to exclusivity in valid patents and the public's right not to be burdened by invalid patents.

The National Academies of Sciences' Committee on Intellectual Property Rights in the Knowledge-Based Economy also commissioned a multi-year study of the patent system. The report from this study was published in April 2004. Nat'l Acad. of Sciences, *A Patent System for the 21st Century* (Stephen A. Merrill et al. eds., 2004). The NAS report found that the U.S. patent system played an important role in stimulating technical innovation by providing legal protection to inventions and by disseminating useful technical information. It concluded with seven principal recommendations to improve the U.S. patent system, several of which overlap with those made by the FTC.

[9] *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet and the Intellectual Property of the House Comm. on the Judiciary*, 108th Cong., 2d Sess. (2004); *Perspectives on Patents: The Patent System Today and Tomorrow: Hearing Before the Subcomm. on Intellectual Property of the Senate Comm. on the Judiciary*, 109th Cong., 2d Sess. (2005); *Patent Act of 2005: Hearing on H. R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 109th Cong., 2d. Sess. 109-24 (2005); *Patent Reform Act of 2005: Hearing on an Amendment in the Nature of a Substitute to H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 109th Cong., 1st Sess. (2005); *Patent Law Reform: Injunctions and Damages: Hearing Before the Senate Subcomm. on Intellectual Property of the Senate Comm. on the Judiciary*, 109th, 2d Sess. (2005); *Perspectives on Patent Harmonization and Other Matters: Hearing Before the Subcomm. on Intellectual Property of the Senate Comm. of the Judiciary*, 109th Cong., 2d Sess. 109-182 (2005).

do without legislation.[10] Congress, not this Court, is the proper branch to address any policy arguments about altering the long-standing right to exclude. This Court should reject petitioners' attempt to limit the injunctive remedy by court decision when Congress repeatedly has rejected these attempts to do so.

## CONCLUSION

For the foregoing reasons, the judgment of the Federal Circuit should be affirmed.

Respectfully submitted,

BRIAN P. BARRETT
Chair,
BIOTECHNOLOGY INDUSTRY ORGANIZATION
Amicus Committee
ELI LILLY AND COMPANY
Lilly Corporate Center
Indianapolis, Indiana 46285
(317) 276-7243

NANCY J. LINCK
*Counsel of Record*
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1225 Eye Street, NW
Washington, DC 20005
(202) 962-6668

March 10, 2006

[10] *Patent Act of 2005: Hearing on H. R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Comm. on the Judiciary*, 109th Cong., 2d Sess. 109-24 (2005) (legislation remains in subcommittee without the injunction provision).