No. 05-130

IN THE

Supreme Court of the United States

EBAY INC. 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 AMICUS CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF RESPONDENT

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March 10, 2006

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. Member companies are in the business of developing new drugs – a complex process involving huge expenditures of time and money. In 2005 alone, PhRMA members invested an estimated $39.4 billion toward the discovery and development of new medicines. Collectively, PhRMA members are responsible for a huge portion of the innovative medicines approved for use in the United States in the past several decades.

Pharmaceutical companies spend many years working to develop each new drug that appears on the market, as well as many that will never earn approval. The process typically begins with creating a new compound or screening hundreds of thousands of existing compounds. The most promising compounds are then modified to optimize their properties, thus producing a candidate drug. At that point, both compounds and their potential uses are often separately patented. Selected compounds are then tested in the lab and in animals to determine whether they might effectively and safely treat a disease. This is followed by clinical trials in normal human volunteers and a series of studies in a relatively small number of patients. The next stage of development is a series of large clinical trials testing the effectiveness as well as the safety of a drug in patients. These clinical trials, which typically take six to eight years,

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[1] Counsel for both parties have consented to the filing of this brief, and the parties' letters of consent have been filed with the Clerk of Court. No counsel for any party authored this brief in whole or in part, and no person or entity, other than the *amicus curiae* and its counsel, contributed monetarily to the preparation or submission of this brief. A complete listing of PhRMA's members is available online at http://www.phrma.org/member_company_list/.

precede the process of seeking approval from the Food and Drug Administration ("FDA"). Altogether, the entire drug development process might last upwards of fifteen years.

Given the time and financial expenditures necessary to develop new drugs, intellectual property principles, especially those involving the protection of patent rights, are of critical importance to PhRMA members and their research and development efforts. PhRMA has a strong interest in seeing the law continue to protect those patent rights essential to ensuring future innovation and the timely development of new medicines. As practitioners in an industry where research and development are expensive and competition is fierce, PhRMA's members need strong patent protection to be able to recoup the costs of their investments.

In this case, the Federal Circuit accurately applied existing, settled law, including the general presumption in favor of granting a permanent injunction after a jury has determined a patent to be both valid and infringed. Failing to affirm that decision would significantly undermine the confidence of innovators like PhRMA members in their ability to enforce patents against infringers. Further, overruling *Continental Bag* would upset over a century of settled law and will make it difficult for innovators to enforce patents on the successful discoveries that were picked from a broader field of potential patented compounds.

SUMMARY OF THE ARGUMENT

Although professing to apply traditional standards, Petitioners in fact seek to weaken the patent system dramatically. Revising settled law to suit Petitioners' convenience will profoundly impact all industries that rely upon strong patent protection, not just theirs. Patent law, as it currently exists, has a long history of successfully promoting innovation. PhRMA members in particular, and the pharmaceutical industry in general, rely heavily upon the

certain and well-defined protections that patent law currently provides. In light of the high cost of research and development and the low probability of finding and marketing a successful product, pharmaceutical companies must have strong assurances that any resulting intellectual property will be protected. Absent such protection, the development of new drugs will slow as the incentive to invent and invest diminishes. Given the ease with which infringers can reverse engineer pharmaceutical products and the profits available to those who steal rather than develop them, injunctive relief offers in many circumstances the only effective protection. Limiting the availability of an injunction after a judge or jury have found a patent to be valid and infringed would severely undermine the patent system and drive up the cost of innovation.

The purpose of patent law is to create an incentive for inventors both to innovate and to share their discoveries and inventions with the rest of society. A functioning patent system enables inventors to profit from the exercise of their creativity and hard work by procuring for them the temporary right to exclude others from the fruits of their labors. The patent system simultaneously creates the incentive to spur innovation, the means to protect it, and the method for its wide public dissemination.

Petitioners incorrectly suggest that a presumption in favor of permanent injunctions – once a patent has been found to be valid and infringed – is inconsistent with the district courts' equitable discretion. But as this Court has just recently reiterated, a law calling for an exercise of judicial discretion does not preclude recognition of standards or presumptions to guide that discretion. Where a jury has determined a valid patent is violated, the patent holder should be presumptively entitled to a permanent injunction. This is not an unjust or unreasonable bias in favor of patent holders;

it merely reflects the fact that after conducting a trial and winning a jury verdict, a patent holder is generally entitled to have society vindicate the right Congress gave her to exclude others from her intellectual property. At that point, a number of legitimate interests favor the grant of injunctive relief.

This Court should reject Petitioners' request to ignore the traditional factors favoring the grant of a permanent injunction for patent infringement. The right to exclude constitutes a central and well-settled aspect of both traditional and intellectual property rights. The right to invoke the state's power to enforce that right merely represents the patent holder's return on her bargain with society. Alternatives are inadequate, imprecise and ultimately inhibit the development of voluntary institutions that would otherwise reduce transaction costs by allowing the parties to set prices. In addition, consideration of an infringer's hardship is only required where that hardship is not an inseparable part of the patent holder's right. Similarly, the public interest exception to the presumption in favor of injunctive relief applies only in extremely rare instances. Courts have consistently concluded that the public interest almost always receives greater benefit from a functioning and reliable patent system than short-term increases in competition. Finally, whether or not a patent holder practices an invention is not a relevant consideration in the quid pro quo patent structure implemented by Congress, which requires only disclosure of the invention in exchange for a limited monopoly. Imposing a use requirement will result in fewer inventors seeking patent protection and thus less innovation reaching the public.

ARGUMENT

I. INJUNCTIONS ARE ESSENTIAL TO PATENT HOLDERS, ESPECIALLY IN THE PHARMACEUTICAL INDUSTRY.

The pharmaceutical industry depends for its very existence upon strong, reliable patent protection including the general rule that injunctive relief will be granted against patent infringers absent exceptional circumstances. The expectation that patent infringement will be enjoined after a full hearing in the courts and a finding of infringement and validity has been a fixture in the law during a period of tremendous growth of research and development ("R&D") spending in the drug industry.[2]

More so than most, the pharmaceutical industry has extremely high R&D costs. By some estimates, the average fully capitalized cost for developing new drugs is roughly $800 million per drug, and is predicted to climb to $1.9 billion by 2013. *See* Joseph A. DiMasi, *et al.*, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 166, 181 (2003); Christopher P. Adams and Van V. Brantner, *Estimating the Cost of New Drug Development: Is It Really $802 Million?*, 25 Health Affairs 420, 427 (March/April 2006) ("Our estimate of $868 million suggests, if anything, that $802 million is an underestimate."); *see also Good Chemistry*, The Economist,

[2] The issues in this case do not relate to enforcement of patents under the Hatch-Waxman Act against generic drug companies that file Abbreviated New Drug Applications (ANDAs). These enforcement actions have a separate and automatic remedy that precludes the FDA from approving a generic drug company's infringing product before "the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). As Congress has mandated that when there is infringement "the court shall" provide such an order, *id.*, district courts have no discretion to deny this remedy.

Feb. 4, 2006, at 58 ("The cost of developing a new drug to be marketed worldwide is usually put at about $1 billion.").

Costs are high in large part because there are so many compounds that initially look promising but, after years of research and millions of dollars, prove ineffective or unsafe. Researchers must investigate anywhere between 5,000 and 10,000 compounds to identify five drugs eligible for clinical trials. This pre-clinical winnowing takes years and costs millions of dollars. In the end, of the five drugs accepted for clinical testing in humans, the FDA will approve one. Pharm. Research & Mfrs. of Am., *Pharmaceutical Industry Profile 2005*, March 2005, at 4, http://www.phrma.org/files/2005IndustryReport.pdf. And of course, FDA approval alone does not guarantee a successful financial return on investment. Roughly seven out of ten drugs approved by the FDA never earn back the average cost of R&D. *Id.* at 12. Some otherwise important drugs fail to be profitable because competitors' products eclipse them in the marketplace. Those few products that do return large profits necessarily subsidize the vast majority of those that do not.

These tremendous R&D outlays are essential to developing innovative new drugs. Not surprisingly, studies have demonstrated a clear link between the amount of money spent on pharmaceutical R&D and the discovery of new medicines. Elizabeth J. Jensen, *Research Expenditures and the Discovery of New Drugs*, 36 J. Indus. Econ. 83, 93 (Sept. 1987). In order to produce new medicines, pharmaceutical companies must invest tremendous capital in R&D, and hope against the odds to see a return on it in ten to twelve years. For this gamble to be even remotely reasonable, pharmaceutical companies depend on intellectual property protection. Patents create the incentive to invest money in R&D, which is essential for the development of new drugs.

The promise of the protection afforded by injunctive relief is essential to the patent incentive system. Pharmaceutical patents typically contain a single, easily identifiable compound. The costs of determining whether such a compound was previously patented are relatively low, making it easy for companies to avoid accidental infringement. Infringement, when it does occur, is relatively easy to demonstrate. Once infringement is shown, an injunction is nearly always the right remedy. Any other remedy in those circumstances would not be an effective deterrent for infringers. Lacking the high R&D costs to develop the drugs themselves, infringers can easily copy a successful drug, put it on the market for a fraction of the cost of the patent holder and still generate tremendous profits. An injunction appropriately serves to forestall such exploitation of the patent holder's property before it occurs. Moreover, a presumptive right to an injunction means that the patentee, when negotiating with would-be licensees, will receive the full value for the invention in return.

To undermine and weaken patent protection by sowing doubt on the availability of injunctive relief against confirmed infringers – as in the manner Petitioners advocate – will necessarily increase the costs of developing new medicines. Pharmaceutical companies employ sophisticated models to evaluate the risk and potential return of investment in R&D. Making the availability of injunctive relief less certain drives up the risk and so immediately dries up the pool of investments in R&D. Furthermore, changing the rule now devalues past investments made with the expectation that patent rights would be vindicated. *See* Rebecca S. Eisenberg, *The Shifting Functional Balance of Patents and Drug Regulation*, 20 Health Affairs 119, 120 (Sept./Oct. 2001) ("The long-standing availability of patent protection for drugs . . . has been a fixture in the expectations of firms during a period of tremendous growth in R&D spending.").

This is not just unfair; it would directly impact the number of new drugs brought to market. Pharmaceutical companies would be unable to raise as much money to invest in R&D, and the resulting decrease in R&D funding would translate directly into fewer new drugs. Frank R. Lichtenberg, *Probing the Link Between Gross Profitability and R&D Spending*, 20 Health Affairs 221, 222 (Sept./Oct. 2001) ("The [link between R&D and expected future profits] implies that policies that threaten to diminish future profits will reduce R&D investment today, even if they do not affect current profits."). Companies permitted to produce generic versions of the same drugs would receive a huge windfall. Eisenberg, *supra*, at 120 ("According to the pharmaceutical industry, their R&D costs average hundreds of millions of dollars per new product, while costs of developing generic imitations are lower by orders of magnitude.").

II. A PRESUMPTION IN FAVOR OF A PERMANENT INJUNCTION UPON A FINDING OF PATENT INFRINGEMENT IS CONSISTENT WITH LONGSTANDING PATENT PRINCIPLES.

Patent law has traditionally presumed that a patent holder who prevails on a claim of infringement of a valid patent is entitled to injunctive relief. "A patentee has the exclusive right to manufacture, use, and sell his invention. The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) (internal citations omitted). The general rule used by the Federal Circuit reflects this view of patents. "Although the district court's grant or denial of an injunction is discretionary depending on the facts of the case, . . . injunctive relief against an adjudged infringer is usually granted. . . . [A]n injunction should issue once infringement has been established unless there is a sufficient

reason for denying it." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988); *see* 7 Donald S. Chisum, *Chisum on Patents* § 20.04[2] at 20-761 (2002) ("A patent owner prevailing on the merits of a patent infringement claim will usually be granted a permanent injunction against future infringement unless the public interest otherwise dictates."). This presumption does not reflect an unjust or unreasonable legal preference for patent holders. Rather, it reflects the fact that once a judge or jury has determined that a defendant is infringing a valid patent, strong protection of the patent holder's right to exclude is necessary to prevent the infringement from undermining the patent system.

Petitioners nevertheless argue that to the extent federal case law presumes a patent holder (whose patent a court has determined to be both valid and infringed) is entitled to injunctive relief, that case law contravenes congressional intent as expressed in 35 U.S.C. § 283, in which Congress left to the discretion of the courts the decision whether to grant injunctive relief to patent holders. That contention is mistaken.

When a statute calls for courts to exercise discretion based on particular factors, there is nothing improper about courts enunciating a presumption or other legal principle to guide the exercise of discretion. As this Court recently affirmed in *Martin v. Franklin Capital Corp.*, 126 S. Ct. 704 (2005), even where an issue is left to a court's discretion, exercise of that discretion must be guided by legal principles. "We have it on good authority that a motion to [a court's] discretion is a motion, not to its inclination, but to its judgment; and its judgment is to be guided by sound legal principles. . . . Discretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike." *Id.* at 710

(internal quotation marks omitted, alteration in original). The Court in *Martin* enunciated a legal test governing discretionary awards of attorney's fees. It then recognized that "courts retain discretion to consider whether unusual circumstances warrant a departure from the rule in a given case." *Id.* at 711. But the Court cautioned that "[w]hen a court exercises its discretion in this manner, . . . its reasons for departing from the general rule should be" faithful to the purposes of the statute authorizing fee awards. *Id.*

In *Martin*, this Court expressly determined that Congress neither "meant to tilt the exercise of discretion in *favor* of fee awards," nor was there any "basis here for a strong bias *against* fee awards." 126 S. Ct at 710 (emphasis in original). Yet the Court went on to establish a general rule, placing limits on the district courts' discretion, based on "the large objectives of the relevant Act which embrace certain equitable considerations." *Id*. (citations and internal quotations omitted). Like the general rule at issue here, the general rule in *Martin* provided for a specific result "[a]bsent unusual circumstances." *Id.* at 711.

A. The Right to Exclude Is at the Heart of Patent Rights.

It has long been clear that a court exercising equitable discretion should not deny equitable relief where that remedy is essential to protecting core rights. *See Tennessee Valley Authority v. Hill*, 437 U.S. 153 (1978) (granting injunction forbidding completion of dam to protect core interest of federal statute). "In practical effect [such an action] would not be merely denial of an equitable remedy, but denial of a substantive right created by Congress." 1 Dan B. Dobbs, *Law of Remedies* § 2.4(7), at 120 (2d ed. 1993). "[T]he decision against discretion is completely in accord with the view that equity must not use discretion and balancing to deny substantive rights." *Id.* at 120.

Here, the decision about whether to grant an injunction must begin with the fact that a patent is a form of property. That means that its owner has a right to exclude others from using it. Professor Felix Cohen memorably described the nature of property as that "to which the following label can be attached: To the world: Keep off X unless you have my permission, which I may grant or withhold. Signed: Private citizen. Endorsed: The state." Felix S. Cohen, *Dialogue on Private Property*, 9 Rutgers L. Rev. 357, 374 (1954). This Court has consistently recognized that the right to exclude others is "universally held to be a fundamental element of the property right" and in fact constitutes one of "the most essential sticks in the bundle of rights that are commonly characterized as property." *Kaiser Aetna v. United States*, 444 U.S. 164, 176, 179 (1979); *see also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982) ("The power to exclude has traditionally been considered one of the most treasured strands in an owner's bundle of property rights."); *International News Service v. Associated Press*, 248 U.S. 215, 250 (1918) (Brandeis, J., dissenting) ("An essential element of individual property is the legal right to exclude others from enjoying it.").

The Court has not limited the right to exclude to tangible property, but has long and consistently affirmed the right to exclude in the context of intellectual property as well. *Special Equip. Co. v. Coe*, 324 U.S. 370, 378 (1945) ("The patent grant is not of a right to the patentee to use the invention, for that he already possesses. It is a grant of the right to exclude others from using it."); *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405, 430 (1908) ("From the character of the right of the patentee we may judge his remedies. It hardly needs to be pointed out that the right can only retain its attribute of exclusiveness by a prevention of its violation. Anything but prevention takes away the privilege which the law confers upon the

patentee."); *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1852) ("The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee. This is all that he obtains by the patent.").

In fact, this Court has historically understood a patent grant in terms of the right to exclude. "[T]he [patent] grant is nothing more than a means of preventing others, except under license from the patentee, from appropriating his invention." *Special Equipment Co.*, 324 U.S. at 378. This is not surprising, given that the Constitution itself uses the language of exclusion with regard to patent rights: "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the *exclusive* Right to their . . . Discoveries." U.S. Const. art. I., § 8 (emphasis added); *see also Continental Paper Bag Co.*, 210 U.S. at 423 ("The patent law is the execution of a policy having its first expression in the Constitution. . . . It is worthy of note that all that has been deemed necessary for that purpose, through the experience of years, has been to provide for an exclusive right to inventors to make, use, and vend their inventions.").

Central to the right to exclude is the availability of injunctive relief to prevent infringers from using a patentee's property without consent. "A patentee has the exclusive right to manufacture, use, and sell his invention. . . . The heart of his legal monopoly is the right to invoke the State's power to prevent others from utilizing his discovery without his consent." *Zenith Radio Corp.*, 395 U.S. at 135 (internal citations omitted). "Without the right to obtain an injunction, the right to exclude granted to the patentee would have only a fraction of the value it was intended to have, and would no longer be as great an incentive to engage in the toils of scientific and technological research." *Smith Int'l, Inc. v.*

Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983). The right to exclude, along with the right to invoke the state's power to enforce that right, represent the patentee's quid pro quo with the public at large. For her part, an inventor offers up a precise description of her discovery or invention. In return, the public agrees to protect the inventor's temporary right to exclude all others from non-consenting use of her discovery or invention. "The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery, after its enjoyment by the discoverer for fourteen years, is preserved; *and for his exclusive enjoyment of it during that time the public faith is pledged*." *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 242 (1832) (emphasis added). Injunctive relief against infringers is an essential aspect of the patentee's right to exclude others from her intellectual property.

B. Inadequacy of Legal Remedies.

No patent remedy other than an injunction offers adequate protection of the core right to exclude. As one early decision put the matter:

> Upon the pleadings now before the court *it cannot be said that a money judgment for damages alone will indemnify the complainant*, or that ultimately an injunction should not issue for his protection. If the contention of the defendant should become established law, inventors, in all similar cases, will receive a staggering blow. The 'exclusive right' granted by the patent will exclude no one. The door will be thrown wide open to wrong-doers. *The courts will be powerless to protect*, and the only remedy remaining to the patentee, if fortunate enough to discover the injury done him, will be a *suit at law for*

> *actual damages, which, in most cases, is no remedy at all*.

Brick v. Staten Island Ry. Co., 25 F. 553, 554-55 (C.C.S.D.N.Y. 1885) (emphasis added).

Compensation as an alternative to injunctive relief is inadequate as a response to continued infringement for several reasons. Primarily, a "forced sale" of patent rights does not, by its very nature, fully protect the patentee's right to decide whether and when to allow others to use a patented invention. In any event, leaving the determination of the appropriate amount of compensation to the courts is extremely problematic. As one court has explained:

> The injunction creates a property right and leads to negotiations between the parties. A private outcome of these negotiations – whether they end in a license or a particular royalty or in the exclusion of an infringer from the market – is much preferable to a judicial guesstimate about what a royalty should be. The actual market beats judicial attempts to mimic the market every time, making injunctions the normal and preferred remedy.

In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litigation, 831 F. Supp. 1354, 1397 (N.D. Ill. 1993), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995).

That is why this Court has recognized that compulsory licenses are disfavored for patent infringement.

> If petitioners' argument were accepted, it would force patentees either to grant licenses or to forfeit their statutory protection against

> contributory infringement. Compulsory licensing is a rarity in our patent system. . . . Compulsory licensing of patents often has been proposed, but it has never been enacted on a broad scale.

Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 & n.21 (1980); *accord Ortho Pharm. Corp. v. Smith*, 15 U.S.P.Q.2d 1856, 1863 (E.D. Pa. 1990) ("A compulsory license, which may arise from a refusal to enjoin, is fundamentally at odds with the right of exclusion built into our patent system."); *see also* Robert P. Merges, *Of Property Rules, Coase and Intellectual Property*, 94 Colum. L. Rev. 2655, 2668 (1994) ("In general, [compulsory licenses] are available for patents only as a remedy for violation of the antitrust laws.")

In addition to being unwieldy, compulsory licenses for intellectual property rights inhibit the development of voluntary institutions that would more efficiently reduce transaction costs by allowing parties, rather than courts, to set prices. "[C]ompulsory licensing provisions may prevent the creation of technologies and organizational innovations that would efficiently administer the rights-clearance process. To the extent this is correct, one must be hesitant to endorse compulsory licensing." *Id.* at 2669 (footnote omitted). Once introduced, compulsory licensing schemes are difficult to remove after they have outlived their usefulness. Historically, most industries develop voluntary institutions, thereby obviating the need for government imposed compulsory licensing schemes. "[W]hen the legal system makes a reasoned decision to grant certain [intellectual property rights], courts should enforce these rights through injunctions (i.e., a property rule) and thereby encourage private transactions." *Id.* at 2663 & n.30.

Petitioners and supporting *amici* speculate that the right to exclude others by means of injunction allows a patent holder to charge more for use of his invention than the invention is worth. But their arguments ignore reality, as well as the deleterious consequences that would follow the rule they advocate. A patent holder who asks for more in return for use of his invention than it is worth in the marketplace usually will find no buyers. In contrast, Petitioners seek a rule that would place patent holders in a position where they cannot refuse a transaction with a willing buyer. Without the right to enjoin use of his patent, the patent holder is forced to sell use of his invention to whomever wants to buy it at a price set by the buyer (if there is no protection) or a court (if a there is a compulsory license). This almost guarantees that the buyer will be able to purchase use of the invention for less than its true value to that buyer. *Cf.* 2 Paul Goldstein, Goldstein on Copyright § 13.0, at 13:3 (3d ed. 2005) ("[A]lthough coercive relief will sometimes overcompensate the copyright owner, monetary relief alone will often undercompensate it.").

C. Hardship to an Infringer Rarely Warrants Consideration.

Although hardship to the defendant may be weighed in equity cases generally, courts properly give little if any consideration to hardship suffered by a patent infringer in deciding whether to enjoin future infringements. To the extent that the infringer's hardship results from his obligation to stop infringing upon the patent holder's right, the balance of hardships clearly weighs in the patent holder's favor. The Federal Circuit merely stated the obvious when it announced that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so

elected." *Windsurfing Int'l, Inc. v. AMF Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986).

In fact, in this case, the infringer represents that it could design around the claimed invention. That is a factor favoring the grant of an injunction, not pointing the other way. If eBay can design around the injunction, then the injunction will not harm eBay to any appreciable extent. Furthermore, the incentive to design around to avoid the injunctive power of a patent leads to the creation of new technology and is one of the recognized benefits of the patent system. *See State Industries, Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) ("One of the benefits of a patent system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.").

Consideration of an infringer's hardship is required in only exceptional circumstances. "Hardship to the defendant is perhaps best considered in the balance when the hardship to the defendant is not an inseparable part of the plaintiff's right, or when the cost or hardship to the defendant far exceeds the benefit to which the plaintiff is entitled, or when hardship to the defendant suggests that the plaintiff's right was unfairly acquired in the first place." 1 Dobbs Law of Remedies § 2.4(5), at 111. None of these considerations comes into play in the vast majority of situations in which a court is deciding whether to enjoin ongoing patent infringement as part of its final judgment.[3]

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[3] Whether or not there should be a "*de minimis*" exception to patent infringement, as suggested by *amicus curiae* Teva Pharmaceuticals USA, Inc. ("Teva"), is irrelevant to the matter now before the Court. Without question, eBay's infringement is clearly not *de minimis*. In any event, Teva's arguments about a "*de minimis*" exception in the context of inquiries into patent validity and infringement do not alter the

D. The Public Interest Generally Favors Protection of Patent Rights.

Congress designed the patent system to serve the public interest by promoting progress and to navigating "[t]he tension between the desire to freely exploit the full potential of our inventive resources and the need to create an incentive to deploy those resources." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). Allowing alleged but unproven infringement to continue may be justified on the ground that the alleged infringer has not yet had his day in court. But after a jury has returned a verdict against an infringer, continued infringement harms not just the patent holder but actively undermines the entire patent system. The public interest suffers where proven infringers are permitted to violate valid patents and inventors have less incentive to innovate. To the extent an inventor continues to develop new ideas and technologies, she will prefer to maintain control over them by keeping them secret instead of revealing them through the patent system. Allowing a patent infringer to avoid an injunction does nothing more than benefit the infringer personally while imposing unwanted costs on the general public.

In determining whether or not to grant a permanent injunction, courts will look to the effect of that relief on the public interest. In most cases, this factor points in favor of an injunction. "Generally, it may be said protecting patents from would-be infringers is always acting in the public interest." *Pittway Corp. v. Black & Decker*, 667 F. Supp. 585, 593 (N.D. Ill. 1987). Courts have likewise concluded the public interest is best served by protecting pharmaceutical patent rights and thereby insuring strong incentives for future

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traditional consideration of the appropriate remedies once infringement has been proven.

R&D investment. "It is in the public interest to protect the pharmaceutical industry's investment into the discovery of new drugs." *Ortho Pharm. Corp.*, 15 U.S.P.Q.2d at 1864. This is true even where other companies offer cheaper, but infringing, versions of the same drug. "Although companies such as Premo, which do not engage in significant amounts of research and development, consequently might be able to undercut the prices offered by pharmaceutical manufacturers that devote large sums to invention and product improvement, this type of short-term competition does not, at least in the considered opinion of the Congress, serve the public interest. Instead, Congress has determined that it is better for the nation in the long-run to afford the inventors of novel, useful, and non-obvious products short-term monopolies on such products than it is to permit free competition in such goods." *Eli Lilly & Co. v. Premo Pharm. Labs. Inc.*, 630 F.2d 120, 138 (3d Cir. 1980); *see also Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc.*, 222 U.S.P.Q. 143, 149 (D. Kan. 1983) ("The American public is not served by favoring the short-run effects of competition in the marketplace over the long-run effects of decreased incentives for competition under the patent laws.").

The public interest can, in the appropriate case, override the other factors and warrant denial of an injunction. But these circumstances are rare. *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1547 (Fed. Cir. 1995) ("Accordingly, courts have in rare instances exercised their discretion to deny injunctive relief in order to protect the public interest."); *Hybritech, Inc. v. Abbott Lab.*, 4 U.S.P.Q.2d 1001, 1015 (C.D. Cal. 1987) (granting a preliminary injunction for all but two of the infringed medical devices and denying the injunction only where granting it would cut off the public from *any*, rather than merely cheaper, access to equivalent products.), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988).

E. Whether a Patentee Is Practicing the Invention Is Not a Relevant Consideration.

In determining whether injunctive relief is appropriate to deter future patent infringement, the use a patent holder makes of his patent is irrelevant. "This 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 Equipment Co.*, 324 U.S. at 378-79. There are a number of reasons for this. Most significantly, the creation of a "use it or lose it" rule for patents would radically alter the patent scheme created by Congress. At one point, Congress did choose to condition the grant of a patent to aliens upon their utilization of their invention, but subsequently repealed that condition. *Id.* at 378. Since then, "Congress has frequently been asked to change the policy of the statutes as interpreted by this Court by imposing a forfeiture or providing for compulsory licensing if the patent is not used within a specified time, but it has not done so." *Id.* at 379 (footnotes omitted). When Congress demonstrates it could impose a condition and then elects not to do so, courts should be especially reluctant to impose that same condition themselves. *See also Continental Paper Bag Co.*, 210 U.S. at 429-30 ("In some foreign countries the right granted to an inventor is affected by nonuse. 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.").

The patent scheme adopted by Congress creates a quid pro quo between the inventor and society. In exchange for knowledge of an invention (which an inventor might otherwise keep for himself), the inventor is given the right to

exclude others from use of that invention. As this Court observed over 100 years ago:

> The inventor is one who has discovered something of value. It is his absolute property. He may withhold the knowledge of it from the public, and he may insist upon all the advantages and benefits which the statute promises to him who discloses to the public his invention. He does not make the law. He does not determine the measure of his rights. The legislative body, representing the people, has declared what the public will give for the free use of that invention.

United States v. American Bell Tel. Co., 167 U.S. 224, 250 (1897). The inventor's obligation to the public ends when he makes known his invention and the advances it represents by means of his patent application. He is not "under a sort of moral obligation to see that the public acquires the right to the free use of that invention as soon as is conveniently possible." *Id.* The patent scheme created has achieved its goal and received the benefit of its bargain, namely the public dissemination of a useful innovation, the moment the inventor files for a patent. *See also Motion Picture Patents Co. v. Universal Film Mfs*, 243 U.S. 502, 513 (1917) ("[Exclusive use of his discovery] is all that the statute provides shall be given to [the inventor] and it is all that he should receive, for it is the fair as well as the statutory measure of his reward for his contribution to the public stock of knowledge.").

This same reasoning helps to dispel the allure of the stock argument against allowing patent holders to protect their rights even when they choose not to actively use them. This objection was raised by Justice Douglas in his dissent from the majority opinion in *Special Equipment.* "Take the

case of an invention or discovery which unlocks the doors of science and reveals the secrets of a dread disease. Is it possible that a patentee could be permitted to suppress that invention for seventeen years . . . and withhold from humanity the benefits of the cure?" *Special Equipment Co.*, 324 U.S. at 383 (Douglas, J., dissenting). That scenario is unlikely precisely because the patent system requires that an invention be publicly disclosed, thus allowing the marketplace to work. Moreover, the scenario is essentially nonsensical. If an inventor created a drug to eliminate a disease, and truly wanted to keep humanity from its benefits, he could do so for far longer than seventeen years. He need only destroy his notes and tell no one of his discovery. If his goal is to deny the public the benefit of his finding, he would chose not to apply for patent protection in the first place.

The quid pro quo between inventor and the public remains at the heart of the patent system: in return for a grant of temporary monopoly over her discovery, society receives from an inventor knowledge of her innovation. Not just knowledge that the invention exists, but detailed information sufficient to allow others to re-create it. The knowledge is disseminated widely when the patent application is published (normally within 18 months of its filing). Society is not owed the product that may or may not be derivable from the patent in exchange for 20 years of exclusivity; it is owed – and, through the patent process, has already received – knowledge of the innovation. The only thing temporarily prohibited others is use of the invention absent the inventor's consent. Other benefits, derived from the publication and dissemination of such knowledge, exist independently of any specific product or use of that knowledge. Society benefits when that knowledge is shared, and suffers when it remains hidden. Absent the patent system, and to the extent existing patent protections are weakened or made less certain, less invention would occur and more of what did would remain

hidden. "[I]n a world without patents, such inventive activity as did occur would be heavily biased toward inventions that could be kept secret." Richard A. Posner, *Economic Analysis of Law* § 3.3, at 43 (5th ed. 1998). Justice Douglas had it backwards: his frightening scenario becomes more, not less, likely where the rights of patent holders are weakened.

In *Continental Bag*, this Court reiterated the view that non-use of a patent does not in any way diminish a patent holder's rights. The ability to call upon the state to enforce the right to exclude others from the patent holder's intellectual property (that is, the right to enjoin future infringement) constitutes the very core of those rights. Limiting the availability of injunctive relief against confirmed infringers necessarily and dramatically diminishes them. This Court should not now disturb the principles reaffirmed in *Continental Bag* that have for so long and with such success contributed to the progress of science.

III. PATENT LAW DOES NOT REQUIRE GENERAL REFORMATION.

Patent law has successfully balanced the interest of inventors with the public interest for over 100 years. It should not be modified without careful consideration, especially where such modifications are tailored to benefit a small if vocal class of patent infringers. Petitioners are seeking not a restoration of patent law after an alteration below, but are instead attempting to force a radical change on the long-settled law of permanent injunctive relief in patent cases. While a long history is no guarantee of correctness, this Court should not lightly rework existing law, especially where that law reflects a balance between competing interests struck by Congress. In addition, numerous businesses and even entire industries have developed in reliance upon patent law as it currently stands. Casually altering those

fundamental assumptions will have a far-reaching impact beyond that intended by Petitioners and supporting *amici*.

The existing patent system provides incentives which all agree have effectively stimulated innovation. Yet even assuming *arguendo* that its implementation is not always perfect, any attempt to reform the patent system should protect those aspects that do effectively promote innovation. Petitioners would substantially diminish the essential nature of the patent grant (the right to exclude), by substantially diminishing the likelihood that the courts will enforce that grant. Making the availability of injunctive relief less certain would discourage investment in new innovation, and dilute the effectiveness of the whole system. The rights of all patent holders would be weakened, and the constitutional and congressional purpose of the system would be undermined.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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March 10, 2006