No. 2008-1300

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMGEN INC.,

Plaintiff-Appellee,

v.

F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GMBH,
and HOFFMANN-LA ROCHE INC.,

Defendants-Appellants.

Appeal From The United States District Court For The District Of Massachusetts
In Case No. 05-CV-12237, Judge William G. Young

BRIEF OF BIOTECHNOLOGY INDUSTRY ORGANIZATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLEE AND AFFIRMANCE

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Dated: July 7, 2008

CERTIFICATE OF INTEREST

Counsel for *amicus curiae,* Biotechnology Industry Organization, certifies the following:

1. The full name of every party or *amicus* represented by me is:

   Biotechnology Industry Organization

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) is:

   Biotechnology Industry Organization.

3. The parent companies, subsidiaries (except wholly-owned subsidiaries), and affiliates that have issued shares to the public, of the party or *amicus* curiae represented by me are:

   None.

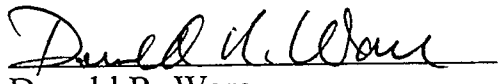
4. The names of all law firms and companies and the attorneys that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

   Biotechnology Industry Organization: Hans Sauer.

   Foley Hoag LLP: Donald R. Ware, Barbara A. Fiacco, Jeremy A. Younkin.

FOLEY HOAG LLP

Dated: July 7, 2008



Donald R. Ware

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Industry Organization ("BIO") is a trade association representing more than 1,200 member-companies, academic institutions, and biotechnology centers. Its members range from the largest Fortune 500 companies to the smallest start-ups that have yet to bring a product to market and attain profitability. BIO members expand the boundaries of science on a daily basis. They are involved in the research and development of biotechnological healthcare, agricultural, environmental and industrial products. In the healthcare sector, the biotechnology industry has more than 400 drug products and vaccines currently in clinical trials being studied to treat more than 200 diseases.

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. 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.

Plaintiff-Appellee Amgen Inc. is a member of BIO; Defendants-Appellants are not. No party to this appeal has contributed to the filing of this brief. In

accordance with Federal Rule of Appellate Procedure 29(b), BIO files herewith a Motion for Leave to File A Brief of *Amicus Curiae*.

STATEMENT OF THE CASE

BIO's focus as *amicus curiae* concerns the proper application of the public interest prong of the traditional four-factor injunction test. With regard to the public interest factor, Roche argues that the district court should have entered an ongoing-royalty remedy rather than a preliminary injunction because the launch of its MIRCERA product in the United States will (1) satisfy unmet medical needs based upon the allegedly superior dosing profile of its product; and (2) "spur price competition that is anticipated to save the public billions of dollars."[1]

This brief does not address the issue of whether MIRCERA satisfies an unmet medical need, and BIO takes no position on it.[2] Rather, this brief addresses the issue of whether district courts should weigh, as a public interest factor sufficient to override the grant of an exclusive patent right, the possibility of price competition resulting from an infringer's entry into the market for a patented drug. This Court should not expand the public interest prong as urged by Roche. Doing

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[1] Roche's Blue Brief ("BB") at 60-61 ("BB60-61").

[2] The district court made no findings with respect to Roche's unmet medical need argument at the time it granted the preliminary injunction, and with respect to a permanent injunction indicated it would not consider the issue until after it received findings from a court-appointed special master. A00180; A21178. Accordingly, BIO submits, the question of unmet medical need is not ripe for review by the Court at this time.

so here would misapply the Supreme Court's decision in *eBay*, wreak havoc on investment and innovation in the field of biotechnology, and contradict national health policy and the intent of Congress.

ARGUMENT

I. THE GRANT OF PATENT EXCLUSIVITY IS CRITICAL TO THE RESEARCH AND DEVELOPMENT OF NEW BIOLOGICS TO TREAT UNMET MEDICAL NEEDS.

BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental products and services based upon applications of biotechnology. Recombinant EPO is an example of a pioneering biologic that has served a critical and unmet medical need for treatment of anemia. Strong intellectual property protection has been essential to the more than 1,400 biotechnology companies in the United States today. For these companies, the patent system provides the economic incentives for private sector investment in new biologics.[3] Scientists, entrepreneurs, and venture capital investors, encouraged by the prospect of market exclusivity afforded by U.S. patent protection, expend enormous resources to develop and produce innovative

[3] This Court has recognized that "the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006), *quoting Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985); *see Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372-73 (Fed. Cir. 2007).

new biotechnology products. Today, it takes on average $1.2 billion in research and development costs to bring a biologic to market.[4]

The U.S. biotechnology companies undertaking these costly development efforts are primarily small, private start-ups that rely heavily on venture capital financing and are years away from product commercialization. In fact, small biotechnology companies (all but the top ten) account for two-thirds of the industry's future clinical pipeline.[5] They face significant economic challenges. Biologics research and development is high-risk, with greater capital costs, higher material costs, greater manufacturing costs and uncertainties, longer development times, and lower late-stage success rates than small molecule pharmaceutical drugs.

Strong patents are critical to attract the capital needed to continue this massive R&D investment. One study shows that the breakeven point for recouping the R&D cost of a biologic does not occur until it has been on the market between

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[4] Joseph A. DiMasi and Henry G. Grabowski, "The cost of biopharmaceutical R&D: is biotech different?" 28 *Managerial and Decision Economics* 469, 469-79 (2007).

[5] The Boston Consulting Group, *Rising to the Productivity Challenge: A Strategic Framework for Biopharma* (July 2004), *available at* http://www.bcg.com/impact_expertise/publications/publication_list.jsp?practice=13&pubtype=pubs&expert=&start=10&type=.

12.9 and 16.2 years.[6] This figure highlights the importance of patent protection that lasts the full term of the innovator's patent. In other words, it is the last few years of the product's patent exclusivity period when the innovator finally earns a return on its investment. If infringers are allowed to enter the market during this period in order to compete on price, the innovator's incentives to make the necessary R&D expenditures would be greatly diminished.

II. EXPANDING THE "PUBLIC INTEREST" PRONG AS A BASIS FOR DENYING PRELIMINARY INJUNCTIVE RELIEF WOULD DEPRIVE A PATENT HOLDER OF EXCLUSIVITY *PENDENTE LITE* AND CREATE GREAT UNCERTAINTY AND MARKET DISRUPTION.

In the biomedical and drug context, the decision whether to enter a preliminary injunction has profound implications. A decision to allow a potentially infringing product on the market under an ongoing-royalty preliminary injunction such as Roche seeks here would, as a practical matter, amount to a decision denying permanent injunctive relief. This is because the introduction of a medicine into the marketplace, especially one priced and dosed differently from the competing patented product, would be virtually impossible to undo, as patients, providers and payors will begin to rely on it quickly. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (affirming district court grant of

[6] Henry G. Grabowski, "Data Exclusivity for New Biological Entities," Duke University Department of Economics Working Paper, June 2007, *available at* http://www.econ.duke.edu/Papers/PDF/DataExclusivityWorkingPaper.pdf.

preliminary injunction based, in part, on irreparable harm caused by irreversible price erosion in light of the complex pricing scheme for drugs); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 28 U.S.P.Q.2d 1362 (D. Del. 1993) (granting preliminary injunction after finding that there is a public interest in minimizing disruption in hospital reliance on allegedly infringing products). By the time the district court considers whether to grant permanent injunctive relief, there may well have developed a "public reliance" interest on the infringing product that could "tip the balance" of equities in favor of a permanent injunction on terms.

Because of the practical implications of authorizing entry of an infringing product into the market for therapeutic drugs, the preliminary injunctive relief decision is therefore an important one, potentially with permanent consequences. Such an important decision should not be made based upon nothing more than an infringer's abstract argument that the public's interest in price competition outweighs the public's interest in providing patent exclusivity to encourage long-term biomedical investment and innovation.

III. REDUCING PATENT TERM EXCLUSIVITY FOR MEDICINES TO FURTHER A PUBLIC INTEREST IN DRUG PRICE COMPETITION IS UNSUPPORTED BY SUPREME COURT AND FEDERAL CIRCUIT PRECEDENT AND CONTRAVENES CONGRESSIONAL INTENT.

Roche argues that the district court abused its discretion by not considering and then finding that an alleged public interest in price competition outweighed the

irreparable harm to Amgen caused by continued patent infringement. Roche's argument lacks support in the Supreme Court's and this Court's precedents and invites a misuse of the equitable powers of the district courts that would contradict the intent of Congress in the field of medicine.

A. NEITHER SUPREME COURT NOR FEDERAL CIRCUIT PRECEDENT JUSTIFIES AN EXPANSION OF THE PUBLIC INTEREST PRONG IN THE FIELD OF MEDICINE.

Roche's argument relies on *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). However, nothing in the *eBay* decision supports Roche's argument. *eBay* involved a business method patent owned by a company that did not practice the invention. The Supreme Court held that the decision whether to grant injunctive relief "must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id.* at 394. The two concurring opinions emphasized that the Court's decision was not intended to upset the historical application of equitable relief in patent disputes, where such relief has consistently been granted against competitors. *Id*. at 394-96.

The *eBay* decision does not suggest that reducing the period of patent exclusivity in an effort to lower the price of patented products is a sufficient public interest that could be determinative when weighed in the exercise of discretion under 35 U.S.C. § 283. Indeed, permitting compulsory licenses to increase competition in the market for the patented invention – *i.e.*, creating a "non-

exclusive" market – is simply the converse of the grant of exclusive patent rights. By definition, the grant of exclusive patent rights includes the right to foreclose price competition in the market for the patented invention during the term of the patent. A finding that ongoing patent infringement is a public good to be weighed in the balance would effectively override the judgment of the Framers of the Constitution and Congress that the grant of exclusive patent rights ***serves*** the public interest.

This Court has recognized that the goal of the patent law, as enshrined in the Constitution, is promoted by providing inventors "a federally protected 'exclusive right' to exclude others from making, using, or selling embodiments of their invention." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007). Consistent with this view, the Court has held that an abstract public interest in price competition does not trump the public interest in enforcing validly issued patents. In *Payless Shoesource, Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 991 (Fed. Cir. 1993), this Court stated:

> . . . the [district] court, in concluding that the public interest favored keeping Payless' lower priced shoes on the market, failed to take into consideration that selling a lower priced product does not justify infringing a patent. Were that to be a justification for patent infringement, most injunctions would be denied because copiers universally price their products lower than innovators.

See also Eli Lilly & Co. v. Premo Pharm. Labs., Inc. 630 F.2d 120, 138 (3d Cir. 1980) ("Thus, Premo's claim that the public interest would be served by permitting it to enter the cephalexin market and sell at a lower price than currently offered by Eli Lilly is contrary to Congress' purposes in enacting the patent laws. . . . [T]his type of short-term competition does not, at least in the considered opinion of the Congress, serve the public interest.").

The focus of the district court's public interest analysis should be "*whether there exists some critical public interest that would be injured* by the grant" of injunctive relief. *Hybritech Inc. v. Abbott Laboratories*, 849 F.2d 1446, 1458 (Fed. Cir. 1988) (emphasis added).[7] This is consistent with the Supreme Court's decision in *eBay*: "that the public interest *would not be disserved* by a permanent injunction." 547 U.S. at 391 (emphasis added). The public interest factor allows courts to consider whether enforcing the patent laws will affirmatively harm the public, not whether, by restructuring the market and introducing price competition,

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[7] An often-cited example of where this principle was applied is *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577 (7th Cir. 1934). There, the proposed injunction would have forced the City of Milwaukee to shut down a sewage treatment plant. With no other practicable treatment methods available, the Court of Appeals determined that public health interests would be harmed if the plant were ordered closed.

In *Hybritech*, this Court affirmed the district court's grant of a preliminary injunction that enjoined the sale of infringing diagnostic test kits, but carved out of the injunction certain cancer and hepatitis kits manufactured by defendant that would otherwise become unavailable to the public. 849 F.2d at 1458.

they can improve upon the policy balance that Congress struck in defining the scope and duration of U.S. patents.

To be sure, there may be times when a critical public health interest favors denial of relief to the patentee, at least for a transition period. In particular, courts have sometimes been faced with a situation where the grant of injunctive relief would harm the public health by withdrawing from patients an important and otherwise irreplaceable therapy. For example, in *Johns Hopkins University v. CellPro*, a jury found that CellPro willfully infringed valid patents covering suspensions of isolated human stem cells for use in bone marrow transplantation. Prior to trial, CellPro had obtained FDA approval to market an infringing stem cell separation device for therapeutic purposes, whereas Hopkins' licensee had applied for but not yet obtained FDA approval for its comparable licensed product. The district court (McKelvie, J.) entered an injunction but, consistent with the plaintiffs' proposed terms, stayed it until three months after Hopkins' licensee obtained FDA approval. *Johns Hopkins Univ. v. CellPro*, No. 94-105-RRM, 1997 U.S. Dist. LEXIS 24162, at *20-22, 50 (D. Del. July 24, 1997), *aff'd in part, vacated in part*, 152 F.3d 1342 (Fed. Cir. 1998).[8] *See also Schneider (Europe) AG*

[8] In a subsequent "march-in" proceeding under 35 U.S.C. §§ 200-212, the National Institutes of Health denied CellPro's request for a government-imposed license under § 203, finding that the district court's order adequately protected the public health, and that the public health factor was relevant only during the period prior to the availability for sale of an FDA-approved comparable product. *Determination*

v. SciMed Life Systems, 852 F. Supp. 813, 861 (D. Minn. 1994) (enjoining, after a one-year phase out period, the production of a balloon dilation catheter for treating coronary heart disease), *aff'd*, 60 F.3d 839 (Fed. Cir. 1995); *Shiley, Inc. v. Bentley Labs*, 601 F. Supp. 964, 970 (C.D. Cal. 1985) (enjoining, after a six-month transition period, the manufacture of a bubble blood oxygenator for use in open heart surgery), *aff'd*, 794 F.2d 1561 (Fed. Cir. 1986).

In the context of this appeal, however, the question is not whether the grant of injunctive relief would withdraw from the public an important and otherwise irreplaceable therapy. The question is whether price competition in the market for a patented medicine should outweigh the uncontested irreparable harm to the patent holder resulting from continued infringement. BIO believes that vacating the preliminary injunction based on the premise that a second market entrant will create price competition would improperly expand the traditional four-part test for injunctive relief and jeopardize innovation in new and potentially life-saving medical technology.

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in the Case of Petition of CellPro, Inc. (National Institutes of Health, Office of the Director, August 1, 1997), *available at* www.nih.gov/news/pr/aug97/nihb-01.htm.

B. IN THE FIELD OF MEDICINE, CONGRESS HAS STRUCK A BALANCE BETWEEN INCENTIVES FOR INNOVATION AND ACCESS TO LOWER PRICED DRUGS THAT DISTRICT COURTS ARE NOT FREE TO SECOND GUESS.

This Court has properly recognized that "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Biotechnology Indus. Org.*, 496 F.3d at 1374 (holding that a District of Columbia law governing pricing of patented drugs was preempted by federal law). Roche's proposal that the "public interest" inquiry be expanded to include price competition in therapeutic drugs would usurp the legislative authority of Congress, which has developed a complicated web of statutory provisions to balance the competing interests at stake. Several examples of Congress' careful attention to this subject include:

The Bayh-Dole Act. Often credited with spurring the biotechnology revolution, the University and Small Business Patent Procedures Act of 1980 (commonly referred to as the "Bayh-Dole Act"), Pub. L. No. 96-517, 94 Stat. 3015 (1980), demonstrates Congress' recognition of the critical importance of patent exclusivity to medical innovation. Prior to the Bayh-Dole Act in 1980, universities could not own their patented inventions if the federal government funded any part of the underlying research. As a result, universities could not offer exclusive patent licenses to the private sector, and companies refused to invest in academic research. *See* S. Rep. No 96-480 (1979) at 18-19 (citing finding of Advisory

Committee on Patent and Information Policy that the "major reason that over 90 percent of all Government patents are not used" was that companies were reluctant to take non-exclusive licenses to inventions that were costly to develop because such licenses offered "no protection from competition"); 35 U.S.C. § 200 (a principal goal of the Act was "to use the patent system to promote the utilization of inventions arising from federally supported research and development").

The passage of Bayh-Dole had a dramatic effect on technology transfer from academia to the private sector. By 2006, more than 3,000 U.S. patents were issued to universities and hospitals, and nearly 5,000 new patent license agreements were executed.[9] Because of the ability of universities to grant exclusive licenses to federally-funded inventions, promising new medical technologies no longer sit on the shelf in academic laboratories.

Notably, in enacting Bayh-Dole, Congress did not authorize compulsory licensing of federally-funded inventions, except in the narrowest of circumstances, such as proof of a public health need that could not be satisfied by the funding recipient or its licensees. 35 U.S.C. § 203(a)(2). No authority was provided to order compulsory licensing merely to promote price competition and the

[9] Association of University Technology Managers, *FY2006 Licensing Activity Survey: FY2006 Survey Summary* 5 (2007), *available* at http://www.autm.net/about/dsp.pubDetail2.cfm?pid=41.

possibility of lower drug prices. As the NIH cautioned in the *CellPro* "march-in" proceeding:

> We are wary . . . of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far reaching repercussions on many companies' and investors future willingness to invest in federally funded medical technologies. The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the development and dissemination of new and useful technologies. It has proven to be an effective means for the development of health care technologies. In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.

Determination in the Case of Petition of CellPro, Inc. (National Institutes of Health, Office of the Director, August 1, 1997), *available at* www.nih.gov/news/pr/aug97/nihb-01.htm.

The Hatch-Waxman Act. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress again recognized the critical role of patents in fostering innovation:

> Patents are designed to promote innovation by providing the right to exclude others from making, using or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct

> competition existed. These profits act as incentives for innovative activities.

H.R. Rep. No. 98-857, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650. *See Biotechnology Indus. Org.*, 496 F.3d at 1373.

While the Hatch-Waxman Act created a regulatory pathway allowing entry of lower-priced "generic" drugs, it did not authorize courts to shorten the terms of patents covering the innovators' products. On the contrary, Congress ***extended*** patent terms to compensate innovators for the delay to market created by the regulatory approval process. In addition, Congress provided that if the innovator sues the generic for patent infringement, FDA approval of the generic product is stayed for 30 months, or until the patent expires. 21 U.S.C. § 355(j)(5)(B)(iii) (30-month stay of FDA approval triggered by filing patent infringement action). This allows time for the resolution of any patent disputes before the innovator's market exclusivity can be destroyed by the generic's launch of a competing product. In balancing the competing interests in innovation and consumer access to lower priced drugs, Congress thus chose to create a statutory mechanism designed to ensure that innovative drugs are allowed to enjoy their full patent term.

Notably, the Hatch-Waxman Act does not contain any provision authorizing district courts to suspend enforcement of valid patents in order to promote price competition prior to patent term expiration. Indeed, it includes no price control provisions whatsoever. The Hatch-Waxman Act reflects Congress' judgment that

lower prices will result from unfettered competition commencing *after* expiration of the patents covering the innovator's product. *See Biotechnology Indus.*, 496 F.3d at 1373.

The Medicare Act. Roche's argument that lower drug prices will benefit the public by reducing Medicare expenditures oversimplifies Congress' intent with respect to Medicare reimbursement. In fact, Congress has been careful not to cut Medicare reimbursement rates when doing so might have adverse long-term consequences for the provision of health care.

For example, in 2000, Congress forbade a proposed reduction in Medicare reimbursement until a study could be conducted to determine whether the reduced reimbursements would be "adequate to compensate physicians, providers or services, or other suppliers of drugs and biologicals." Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act, Pub. L. No. 106-554 §429(a)(1)(iii), 114 Stat. 2763A-463 (2000); *id*. §429(c) (imposing a moratorium on decreases in Medicare drug reimbursement rates pending study). Congress directed that the study consider not only the pricing of the drugs at issue, but also "the potential for patients to receive inpatient or outpatient hospital services in lieu

of services in a physician's office" and the impact of any proposed revision on "the delivery of drug therapies by hospital outpatient departments." *Id.* §429(a)(3)(C).[10]

Congress' action in 2000 with respect to Medicare reimbursement rates reflects the multifaceted nature of drug pricing issues, and underscores the delicate balance of competing economic and health care policies that is best left to the legislative branch.

Proposals to Provide for "Compulsory Licensing of Patented Inventions." On several occasions in the past decade, bills have been introduced to require compulsory licensing of U.S. patents on medical technology. These bills would have amended the patent statute by adding a new section 158, "Compulsory Licensing of Patented Inventions." Under the proposed legislation, the Secretary of Health and Human Services would be empowered to authorize the use of a patented invention, without the patent holder's permission, under specified circumstances. One such bill proposed that the Secretary could authorize compulsory licenses if such a license were necessary to alleviate unmet health or safety needs, or if "the patented material is priced higher than may be reasonably

[10] Three years later, Congress did revise the Medicare drug reimbursement framework, but at the same time provided increased compensation for accompanying physician services. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 §303(a)(4) & (5), 117 Stat. 2066, 2238-39 (2003) (codified at 42 U.S.C. §1395w). Similar issues concerning Medicare reimbursement are being debated in Congress today. Robert Pear, "Doctors Press Senate to Undo Medicare Cuts," N.Y. Times, July 7, 2008, at A1.

expected based upon criteria developed by the Secretary of Commerce." Affordable Prescription Drugs Act, H.R. 2927, 106th Cong. (1st Sess. 1999). *See also* Affordable Prescription Drugs and Medical Inventions Act, H.R. 1708, 107th Cong. (1st Sess. 2001); Public Health Emergency Medicines Act, H.R. 3235, 107th Cong. (1st Sess. 2001); Public Health Emergency Medicines Act, H.R. 4131, 109th Cong (1st Sess. 2005). None of these bills was enacted.

As these proposals demonstrate, when Congress intends that a district court or government agency have the power to reduce the grant of patent exclusivity by imposing a compulsory license on a patent holder in an area in which Congress has made a deliberate policy choice, it does so expressly, by amending the patent statute.[11] Indeed, if Congress intended that § 283 be interpreted so broadly as to confer on district courts the discretionary power to order compulsory licensing whenever the "public interest" might be served, there would have been no reason

[11] Apart from Bayh-Dole's march-in provisions, there are only a few examples in the patent statute of express statutory authority to impose compulsory licensing of patents. *See* 35 U.S.C. § 154(c)(2) (limiting patentee's remedy for infringement to "equitable remuneration" for infringement occurring during added term of patent extended by Uruguay Round Agreements Act); 35 U.S.C. §§ 252, 307(b) (authorizing court to impose equitable terms on patentee where infringer establishes intervening rights after patent claim is reissued or reexamined); 35 U.S.C. § 41(c)(2) (providing for the grant of intervening rights, on terms the court deems equitable, when a patent expires for failure to pay a maintenance fee and is later reinstated).

for Congress to grant express statutory authority for compulsory licensing in the limited circumstances set out in the patent statute.[12]

In *Biotechnology Industry*, this Court aptly summed up Congress' decision to rely on the existing patent system as the best way to balance innovation in medical technology and consumer access to drugs:

> The present patent system reflects the result of Congress' deliberations. Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use.

496 F.3d at 1373. In applying the public interest prong of the four-part injunction test, courts must respect Congress' policy judgment. *See United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483, 497 (2001) (In evaluating the public

[12] As this case shows, opening the door to public interest arguments based upon price competition in cases between direct competitors would profoundly reshape patent litigation into an even more expensive and burdensome process, with the federal judiciary bearing the burden. Given the complexity of the inquiry into pharmaceutical market economics, Medicare reimbursement rates and pricing parity, a judicial readiness to enter an "injunction on terms" in lieu of enjoining infringement would result in more motion practice, mini-trials on remedies, multiple appeals from a single action, and potentially more litigation to address the patent holder's likely complaint that it will not have received damages adequate to compensate for the infringement during the entire life of the patent under 35 U.S.C. § 284, *i.e.*, lost profits, price erosion and accelerated market entry damages. In effect, the district court would have to manage the terms of the injunction and supervise the relevant market until expiration of the patent(s) in suit, with the possibility of an interlocutory appeal under 28 U.S.C. § 1292(a)(1) every time the terms of the injunction are modified.

interest prong of the injunction inquiry, "[a] district court cannot . . . override Congress' policy choice, articulated in a statute, as to what behavior should be prohibited. . . . Courts of equity cannot, in their discretion, reject the balance that Congress has struck in a statute."). This is the correct outcome. District court judges sitting in adversary proceedings – unlike Congress – are confined to entering orders on the basis of the limited evidentiary record before them, and cannot commission independent studies, hire economists and health policy specialists, conduct public hearings, balance the interests of stakeholders, and make policy judgments on the basis of legislative facts.

Roche's argument that district courts applying the four-factor test should weigh the public benefits associated with price competition in the market for a patented drug and impose compulsory, royalty-bearing licenses on an *ad hoc* basis would upset the careful balance struck by Congress. This Court should not accept Roche's invitation to second-guess Congress' policy decisions with respect to medical innovation and public health.[13]

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[13] Roche's reliance on this Court's decision in *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293 (Fed. Cir. 2007) to support its proposed "injunction with terms" is misplaced. *Paice* explicitly disapproved the provision of ongoing royalty awards "as a matter of course." *Id.* at 1314-15. Moreover, *Paice* did not involve direct competitors, did not suggest that the public interest factor should be expanded to recognize a public interest in promoting price competition by infringers, and, most importantly, did not arise in the context of biomedical research, where Congress has so clearly determined that the patent system is critical to encouraging innovation.

IV. USING THE PUBLIC INTEREST PRONG TO ORDER "INJUNCTIONS WITH TERMS" IN AN EFFORT TO PROMOTE DRUG PRICE COMPETITION WOULD UNDERMINE THE SYSTEM OF INCENTIVES CREATED BY THE PATENT STATUTE AND RECOGNIZED BY CONGRESS.

At the time the district court granted the preliminary injunction, it also informed the parties that it would consider modifying the injunction if Roche made a proposal, satisfactory to the court, containing five specified elements. These elements would have required, among other things, payment of a 22.5% royalty to Amgen and a covenant to price Roche's MIRCERA product in the Medicare field at an Average Selling Price ("ASP") – the basis for Medicare reimbursement to physicians under the Medicare statute – "at or less than" the ASP for Amgen's patented EPOGEN product. A21173. This apparently is the "injunction with terms" that Roche seeks and that the district court is considering in the context of entering a permanent injunction. In other words, the relief Roche seeks is not merely denial of an injunction for the remaining term of the patents-in-suit, but rather a judicially-sanctioned right to infringe – in substance, the award of an individual compulsory license – on terms ordered by the district court.

Authorizing district courts to order compulsory licenses in order to promote price competition in the market for the patented invention would have a devastating effect on investment and innovation in biotechnology. Such a ruling would create enormous uncertainty among innovators, both large and small, and the investors that fund their development of new biologics. No longer could

investors count on a business model that relies upon the grant of exclusivity for the life of the patent to spur their billion dollar investment in clinical development.

To make matters worse, the grant of patent exclusivity for the term of the patent would be put at risk on an *ad hoc*, case-by-case basis, with the outcome unknown and unpredictable until years after the investment is made. The outcome could depend on factors outside the control of the innovator and investor, including the testimony of competing economists in individual cases, the quality of advocacy in each case, and the varying standards of equity applied by multiple judges in multiple jurisdictions. Potentially inconsistent results at the district court level would be reviewed by this Court only under the deferential abuse of discretion standard, which cannot be expected to assure consistency and predictability of ultimate outcomes. This would greatly discourage the up-front investment necessary to support the development of new, successful biologics as well as the cost of the inevitable failures that occur after hundreds of millions of dollars have already been spent on clinical trials.

The district court's ongoing-royalty proposal also highlights the complexity of drug pricing and demonstrates why Congress, in establishing national health policy, has time and again rejected legislative proposals for either price controls or compulsory licensing of drug patents. Roche argues on appeal that an ongoing royalty remedy would "spur price competition that is anticipated to save the public

billions of dollars." BB60-61. But the district court made no findings to this effect, and given the complexity of drug procurement and reimbursement under multiple federal healthcare programs, denial of an injunction with the objective of promoting price competition in no way guarantees lower drug prices, particularly under Medicare where the reimbursement for drugs is only one of many factors affecting prescribing decisions.

Recognizing the uncertainty as to future pricing decisions, the district court indicated it would condition an ongoing royalty injunction on Roche's agreement to price its product "at or less than" Amgen's. A21173. This term itself is problematic. If an infringing would-be entrant were to price its drug at the same price as the patentee's, the result would be that the district court will have authorized early market entry of an infringing product with ***no*** price advantage to the consumer. The message that district courts are empowered to permit competitors to avoid valid patents and enter the market prior to patent expiration, based not on Congressional authority but rather on their own notions of equity, would set off alarms in the investment community and do immeasurable damage to biotechnology companies throughout the United States.

Alternatively, under terms such as those of the proposed injunction, a would-be entrant might decide to discount its prices below the patentee's. This scenario favors large companies that can afford to absorb the cost of deep discounting,

particularly if the remaining life of the patent is short, and recoup it later with price increases taking effect after patent term expiration. If the patentee maintains its pricing, the entrant will likely gain market share earlier than would otherwise have been possible, and the patentee will suffer a loss of profits. If the patentee matches the entrant's pricing, it may maintain market share but suffer price erosion and still lose profits. In either case, once the patents expire, the entrant will be free to increase its prices – not as a new market entrant but as an existing supplier with established relationships – contrary to the expectations of the patentee when it invested in developing the product.

Whatever the outcome, the effect of an ongoing-royalty injunction such as the one proposed here would be to put the district court in the position of price czar, establishing price controls in a market based not on government policy and Congressional directive, but instead upon a limited evidentiary record and the exercise of equitable discretion. Not only is this a bad way to set national health care policy, it is unsupported by this Court's precedent and lacks any Congressional authority.

CONCLUSION

For all the foregoing reasons, this Court should affirm the district court's Order granting a preliminary injunction.

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Dated: July 7, 2008

CERTIFICATE OF COMPLIANCE

I, Barbara A. Fiacco, hereby certify under Federal Rule of Appellate Procedure 32(a)(7)(C)(i) that this brief contains 5,756 words as counted by Microsoft Word 2003, the word processing program used to prepare the brief, and therefore complies with Federal Rule of Appellate Procedure 29(d) and the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B)(i).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in 14-point, Times New Roman font.

Dated: July 7, 2008

Barbara A. Fiacco

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