

No. 05-608

IN THE
Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., ET AL.

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

**BRIEF OF THE BOSTON PATENT LAW ASSOCIATION
AS *AMICUS CURIAE* IN SUPPORT OF
GENENTECH, INC., ON THE MERITS**

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INTEREST OF *AMICUS CURIAE*

The Boston Patent Law Association (“BPLA”) is a non-profit association of intellectual property professionals that provides programs and forums for the exchange of ideas and information about patent and other intellectual property rights. The BPLA favors a healthy and balanced patent system, which in turn fosters innovation and bolsters the American economy. Departing from the case or controversy requirement of Article III, however, may ultimately upset the balance in the patent system and, correspondingly, discourage innovation and technology licensing. As such, this case evokes the BPLA’s interest.¹

SUMMARY OF ARGUMENT

The Court of Appeals for the Federal Circuit correctly determined that MedImmune’s mere desire to challenge the Cabilly II patent while still retaining the benefits of its license with Genentech did not create an actual controversy sufficient to trigger Article III jurisdiction. The BPLA agrees with the Federal Circuit’s reasoning in this and other cases holding that a licensee in good standing may not challenge the licensed patents in court. *See, e.g., Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004); *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005).

Rather than repeat or bolster the Federal Circuit’s legal analysis in these cases, the BPLA instead wishes to dispel the impression, advanced by MedImmune, that the patent system is somehow off-kilter, that patents are unsound, and

¹ Pursuant to Supreme Court Rule 37.6, no party or its counsel authored any part of this brief. No person or entity, other than the BPLA and its counsel, Bromberg & Sunstein LLP, contributed money for the preparation or submission of this brief. The parties have consented to the filing of this *amicus* brief. The consent letters have been lodged with the Court.

that the mere hint of an invalid patent justifies a departure from the Article III actual controversy requirements.

In short, contrary to MedImmune's contentions, there is no plague of bad patents threatening licensing, competition, or innovation. As such, there is no need to make an exception to the Article III controversy standard as a way to address a perceived but unsubstantiated problem with the quality of patents. On the other hand, writing a new rule that allows licensees in good standing to challenge licensed patents will upset the balance between licensors and licensees, create uncertainty, and thus cause intellectual property owners to lose faith in licenses as a valid means of (a) profiting from innovation and (b) settling infringement disputes efficiently.

Thus, the BPLA's argument is two-fold. First, the patent system is not broken. Statistics reveal that issued patents are generally sound and deserve their statutory presumption of validity. Accordingly, there is no policy reason to allow licensees in good standing to challenge patents. And even if the statistics were otherwise, even if there were a plague of bad patents infesting the economy, the response should come from Congress or the Executive branch, not from this Court. For example, Congress and the United States Patent and Trademark Office ("PTO") could take steps to improve patent examination so that fewer defective patents issue.

Second, if anything, public policy justifies the Federal Circuit's holding. A policy favoring settlement of litigation through licensing trumps a policy of removing allegedly invalid patents from the economy. Technology licensing generates billions of dollars and is increasingly important to the American economy. Licensing also benefits consumers by ensuring that innovative products, life-saving drugs and medical devices, and other inventions make their way to the market. A ruling that allows an intellectual property user to take a license only to turn around and challenge the

underlying patent when it becomes expedient to do so, however, will ultimately devalue licenses, making them less certain and less efficient as a means for balancing the needs of intellectual property owners and users.

ARGUMENT

I. PATENTS ARE SOUND; THUS, THERE IS NO POLICY REASON FOR UNDERMINING THE ARTICLE III CONTROVERSY STANDARD

There is nothing to suggest that a plague of invalid patents threatens the U.S. economy and that, as MedImmune contends, there is a crisis somehow justifying a ruling that, for the first time, would allow licensees in good standing to challenge allegedly invalid patents. Just the opposite holds true. Statistics suggest that the PTO is doing its job and is, on the whole, issuing valid patents. Thus, there is no urgent reason to disturb the Federal Circuit's refusal to depart from the actual controversy requirement. But even if there were a problem with patent quality, the fix should come from Congress, not from this Court.

A. Patents Are Generally Sound

According to John Dudas, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, the notion that the patent system is broken is based on misperception, not on fact. *See* Neil E. Graham, *Perception Gap Hindering Efforts to Improve Patent System, Dudas Says*, 71 Pat. Trademark, & Copyright J. 374 (2006). In fact, patent quality is improving. For example, Dudas corrects a misperception that the increasing number of patent applications has led to decreasing patent quality. Statistics show that the percentage of applications granted has actually decreased (suggesting that the PTO is being more selective) while the number of patent examiners

has increased to keep up with demand. *Id.* Moreover, despite a perception that up to 40% of all patents are overturned in court, “less than 1/20th of one percent of all patents that issue are actually overturned in court.” *Id.*

Congress has determined that U.S. patents are presumed valid. 35 U.S.C. § 282. That presumption of validity stems, in part, from the presumption that a government agency, such as the PTO, does its job well. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). That presumption is well deserved.

A review of the patent application process shows that PTO examiners are far from bored clerks rubber-stamping applications until the clock strikes five. Contrary to MedImmune’s contention, the PTO does not grant every application it receives. Rather, the PTO does its job conscientiously and scrutinizes each application for compliance with all statutory requirements for patentability.

Specifically, when an inventor files an application for patent, the PTO assigns the application to an examiner versed in the technology of the claimed invention. After reviewing the application and searching for relevant prior art, the examiner typically rejects the application for one or more alleged defects and states his or her reasons in a so-called “office action.” A patent application often receives not just one but two rounds of office actions. To overcome a rejection, the applicant must justify the patentability of the invention (*e.g.*, by distinguishing prior art cited by the examiner). In some instances, the applicant must narrow the scope of the claims to overcome the rejection.

The PTO issues office actions rejecting patent claims roughly 90% of the time. Indeed, a patent almost never issues on the first pass. *See, e.g.*, Andrew T. Zidel, *Patent Claim Construction in the Trial Courts: A Study Showing the*

Need for Clear Guidance from the Federal Circuit, 33 Seton Hall L. Rev. 711, 717–18, n.49 (2003) (giving an overview of patent prosecution and positing that claims are initially rejected 75–100% of the time); Procedure for Obtaining U.S. Patent, at http://www.angenehm.com/pat_faqs4.html (last visited July 23, 2006) (“The USPTO examines the application and in about 90% of the cases finds reason why the patent should not issue”); Larry J. Guffey, *Business Method Patents: What They Are — Why Clients and Service Providers Should Care*, 33 Md. B.J., July/Aug. 2000, at 25, 28 (2000) (initial rejection of patent claims occurs about 80% of the time and there are usually two rounds of office actions per application); Ronald E. Smith, *The Ten Commandments of Inventing*, at www.library.okstate.edu/patents/tencmds.htm (last updated June 26, 2006) (“According to PTO statistics, about 90 percent of all patent applications are initially rejected”).

Not every application results in a patent. Rather, contrary to MedImmune’s claim that 74% to 98% of all patent applications are granted, currently only about 50% of applications mature into patents. As seen in Figure 1 below, the percentage of patents granted has declined over the years. Moreover, as seen in Figure 2 below, the number of patents granted has leveled off at 180,000 per year, even as the number of applications has risen.²

² The BPLA based Figures 1 and 2 on statistics compiled by the PTO. See U.S. Pat. & Trademark Office, *U.S. Patent Statistics Chart: Calendar Years 1963–2004*, available at http://www.uspto.gov/go/taf/us_stat.htm (last visited July 23, 2006) [hereafter *USPTO Patent Statistics*].

Figure 1. Percentage of Patents Granted Per Year

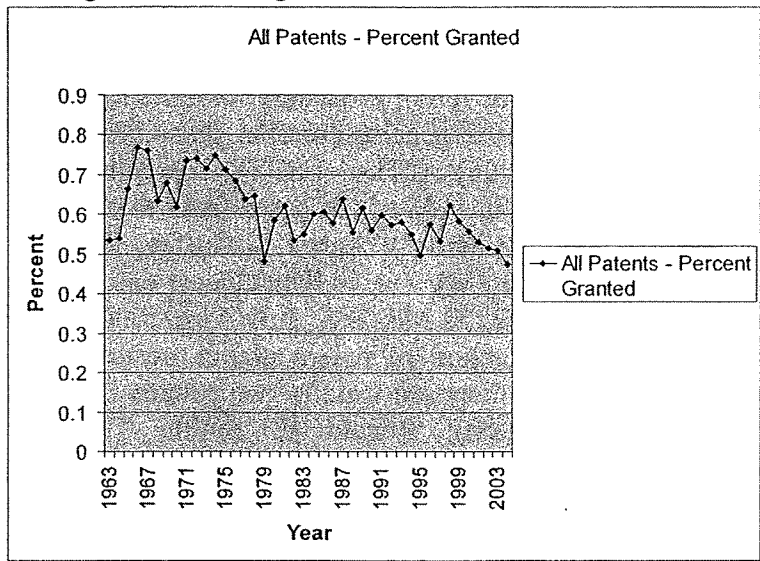
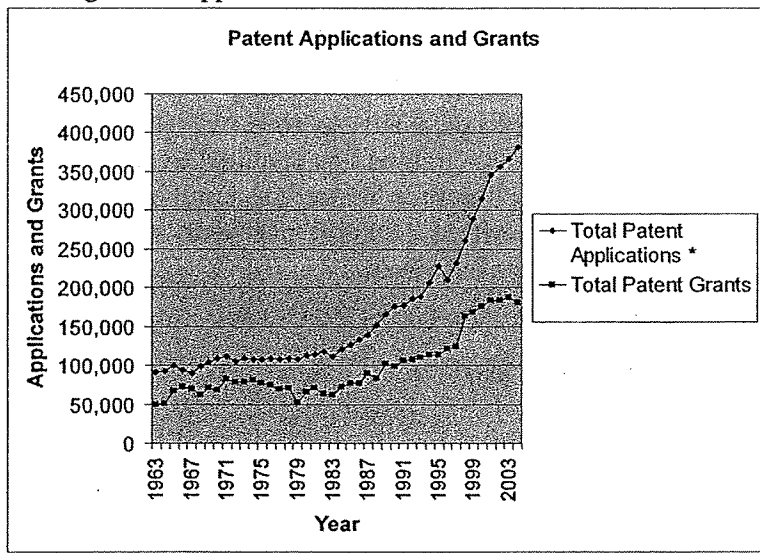


Figure 2. Applications and Grants Per Year



These trends suggests that the PTO is exercising appropriate selectivity. Indeed, the PTO appears to be getting stingier in granting patents. Perhaps, given the emergence of better

prior art searching capabilities (specifically, the use of computer and Internet prior art databases), the PTO is becoming even better at its job of rigorously examining patent applications.³

In some industries, the percentage of patent grants is significantly below the 50% level. For example, business method patents, frequently a target of criticism (most recently in the *eBay v. MercExchange* case), have been maligned as too easy to obtain. In March 2000, the PTO moved to address such criticism and thus hired and trained additional examiners and instituted a second level of patent review. See John R. Allison & Emerson H. Tiller, *The Business Method Patent Myth*, 18 Berkeley Tech. L.J. 987, 995 (2003). As a result of these and other improvements at the PTO, the percentage of business method patents granted fell from 56% to 36% in one year alone. *Business Method Patents: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 107th Cong. 58 (2001) (statement of Ronald E. Myrick, President, Intellectual Property Owners Association). Under Secretary Dudas notes that the current allowance rate for business method patents is only about 11%. Graham, 71 Pat., Trademark & Copyright J. at 374.

The PTO has also put in place a second level of review. After the patent examiner allows an application, PTO supervisors test the allowed claims for patentability and thus exercise quality control. The patent allowance error rate

³ Figures 1 and 2 track the results of all patent applications from 1963 to 2004, including utility, design, and plant patents. But when utility patents only are examined (*i.e.*, the type of patent involved in this case), the numbers are even more telling. For example, in 2004, U.S.-based inventors filed 189,536 applications for utility patents. In that same year, only 84,271 patents were granted to U.S.-based applicants. That grant rate was only 44%. See *USPTO Patent Statistics*.

(i.e., the percentage of allowed patents rejected after this second level of review) in 2005 was only about 4%, down from 5.32% in 2004. U.S. Pat. & Trademark Office, Proposed Rule Changes to Focus the Patent Process Involving Continuations, Double Patenting and Claims (Mar. 29, 2006), at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/connipla032906v1_text.html.

But that is not the end of PTO review. Patents can also be subjected to reexamination, either at the request of the patentee or, more often, an opponent. Indeed, in this case, MedImmune has requested reexamination of the Cabilly II patent (and thus does not even need to challenge the patent in court). In a reexamination, the requestor submits to the PTO prior art references and arguments against patentability that the PTO had not considered the first time. No presumption of validity applies. Even so, reexamination results in cancellation of the patent in only about 9.2% of the cases. That statistic alone confirms that the PTO generally did its job well the first time. In about 23% of the cases, the patent claims remain unscathed. In the rest of the cases, some claims are amended or some are cancelled but the patent as a whole survives. See Stuart J. Graham *et al.*, Post-Issue Patent "Quality Control": A Comparative Study of US Patent Re-examinations and European Patent Oppositions, 34 (2002), available at <http://repositories.cdlib.org/iber/econ/E02-321> (analyzing all U.S. patents reexamined from 1980 to 1999).

As noted above, MedImmune claims that 74% to 98% of all applications are granted. *Brief for Petitioner* at 47. MedImmune derives these figures from a 2003 report by the Federal Trade Commission ("The FTC Report"). Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003). MedImmune fails to mention, however, that the FTC Report itself notes that there is a dispute over these figures and that,

for example, recent research has cast doubt on the 98% figure. See *id.* at ch. 5, 6 & nn.41–42; see also Robert A. Clarke, *U.S. Continuity Law and its Impact on the Comparative Patenting Rates of the US, Japan and the European Patent Office*, 85 J. Pat. & Trademark Off. Soc’y 335, 337–38 (2003) (noting that the 98% figure results from double counting errors).

The FTC Report proves only that the numbers can be deceiving. Thus, to test the BPLA’s own calculations, the BPLA recalculated a subset of patents (utility patents, which is the category of patent involved in this case) and applied a two-year lag to account for the average length of patent prosecution. That is, an application filed in, say, 2002, will, on average, not be granted until 2004 or later. As seen in Figure 3 below, however, the trend is the same: the patent grant rate has steadily declined since the late 1990s, dipping to roughly 50% in recent years.

Figure 3. Percentage of Utility Patents Granted

