

In The
Supreme Court of the United States

—◆—
MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC. AND CITY OF
HOPE NATIONAL MEDICAL CENTER,

Respondents.

—◆—
**On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit**

—◆—
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INTEREST OF *AMICI CURIAE*

Amici are scholars at American law, business, and education schools who teach, write about, or have an interest in patents and intellectual property law. *Amici* have no stake in the outcome of this case, and we file this brief solely as individuals and not on behalf of the institutions with which we are affiliated.¹ We are, however, interested in assisting this Court to interpret the law in a way that is both consistent with the intent of Congress and that best promotes the development and disclosure of new inventions. A list of *amici* is appended to the signature page. Both petitioner and respondents have consented to the filing of this brief.



SUMMARY OF ARGUMENT

Current law already permits a patent licensee to challenge patent validity when the license has been breached or terminated, or at any time by requesting that the United States Patent and Trademark Office conduct a patent reexamination. It does not permit the licensee to commence a civil action seeking a declaratory judgment of patent invalidity, however, while the license remains in force. We believe that petitioner MedImmune's proposed rule, one that would permit licensees to commence declaratory judgment proceedings at any time, would undermine sound patent policy and decrease consumer welfare by increasing the cost of patent licensing without a commensurate social benefit. We also have grave doubts

¹ Pursuant to Rule 37.6, no party other than the signatories has authored or paid for any part of this brief, except that Farella, Braun + Martel LLP has paid the copying, binding and service costs for this brief.

concerning the existence of a case or controversy in cases in which the licensee continues to perform under the license, but we leave the argument of that issue to the parties and other *amici* and instead focus on the matter most clearly within our own area of expertise, namely patent policy.

The licensing of patent technology is a crucial aspect of any patent system. Licensees are often better positioned than patent owners to efficiently manufacture or market products that incorporate patented inventions. Licensing therefore generally reduces price and increases output, delivering the invention to more consumers at a lower price. Parties to licensing agreements nevertheless often bargain under circumstances of substantial risk, uncertainty, and transaction costs, all of which to some extent reduce the potential gains from trade. Rules that would further increase the cost and uncertainty of patent licensing, such as the rule sought here by petitioner MedImmune, threaten to further impede the efficient exploitation of patented technology, thus potentially making the parties and, more importantly, consumers, worse off.

We further argue that petitioner's proposed rule would generate few if any corresponding social benefits, in terms of increasing the opportunities for challenging invalid patents, to justify the aforementioned social costs. As the law now stands, licensees and others have several options available for challenging patent validity under appropriate circumstances; and Congress may if it chooses enact yet other measures. Modifying the existing case law in the manner proposed by petitioner, however, is required neither by this Court's decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), nor by considerations of sound patent policy.



ARGUMENT

I. Sound Patent Policy Counsels Against a Rule Permitting Licensees to Institute Validity Challenges While Continuing to Perform Under Their Licenses.

We begin our analysis by conceding an obvious point: that the United States Patent Office grants a large number of patents that fail to satisfy one or more of the conditions necessary for patent validity. This observation is borne out by the substantial plurality of litigated patents that are ultimately invalidated. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-07 (1998); Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Look Inside the Black Box*, 99 Mich. L. Rev. 365, 391 (2000). Patentee efforts to exercise rights under invalid patents can impose a variety of social costs, including unnecessary administrative and transaction costs and, in the case of patents that confer a degree of market power, deadweight loss. These costs can have the perverse effect of retarding rather than stimulating innovation, in contravention of the constitutional purpose of “promot[ing] the Progress of . . . the Useful Arts.” U.S. Const., art. I, sec. 8, cl. 8. Nevertheless, we conclude that the rule proposed by petitioner MedImmune – one that would permit patent licensees to institute challenges to patent validity while continuing to enjoy the benefits of their licenses – would be a counterproductive response to the flaws of the current patent regime. By contrast, the rule currently followed by the United States Court of Appeals for the Federal Circuit, which allows licensee challenges only after the license has been breached or terminated, recognizes the procompetitive and proconsumer benefits of enabling the licensing

parties to shift some of the risk of a subsequent determination of patent invalidity from patentee to licensee; the Federal Circuit's rule is, moreover, fully consistent with this Court's decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). We therefore urge this Court to enter a judgment of affirmance.

A. Efficient Licensing is Essential to the Proper Functioning of the Patent System.

As this Court has recognized on many occasions, a fundamental premise of the patent system is that the granting of exclusive rights in inventions and discoveries for a limited time stimulates both the creation of new technology and its disclosure to the general public. *See, e.g., Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). Absent a patent system or some other market correcting mechanism, inventors would be less willing to invest either in the production or disclosure of new inventions, due to the threat posed by free riders. At the same time, a variety of patent doctrines reflect the need to balance the social benefits provided by exclusive rights against the social costs, including transaction and monopoly costs, to which an overly expansive regime of patent rights would give rise. Ideally, the patent system strives to achieve the maximum surplus of benefits over costs and thus to fulfill the constitutional mandate of promoting the progress of the useful arts. In large part, and despite many imperfections, the U.S. patent system has distinguished itself in its efforts to attain this goal.

An important subset of patent doctrine relates to the licensing of patented inventions. Many patentees lack the capability of efficiently exploiting their patented inventions

by means of their own manufacture, use, or sale of the patented technology. For example, a patent owner may be able to manufacture or market products embodying its invention only at higher cost, or on a smaller scale, than could a firm that specializes in the manufacture or sale of a specific type of product. The ability to license patented inventions therefore promises a higher return on investment to the patentee, who is thereby better able to exploit the value of the invention, and renders better off those firms that can specialize in the manufacture, sale, or use of the relevant technology. *See, e.g.*, Roger D. Blair & Thomas F. Cotter, *The Elusive Logic of Standing Doctrine in Intellectual Property Law*, 74 *Tulane L. Rev.* 1323, 1333-34 (2000). More importantly, patent licensing in general makes consumers better off, by lowering the cost (and thus the price) of manufacturing and marketing products embodying patented inventions, by expanding output, and – as a matter of economic logic, since a reduction in price and expansion of output necessarily increases consumer surplus beyond what it otherwise would be – by reducing deadweight loss. It follows that, in general, legal rules that promote and enable technology licensing are a social good, at least in the absence of antitrust problems or other countervailing considerations that on occasion may arise. This point has not been lost on legal policymakers. Over the past twenty to thirty years, for example, federal antitrust enforcers have come to recognize the proconsumer benefits of licensing and thus are much less apt to challenge licensing arrangements in the absence of compelling proof of anticompetitive harm. *See generally* U.S. Dep’t of Justice & Federal Trade Comm’n, *Antitrust Guidelines for the Licensing of Intellectual Property* (Apr. 6, 1995).

Even so, licensing remains an undertaking that is fraught with peril. On the one hand, when a technology is new, no one may yet have a clear idea how it is best utilized, whether consumers will respond favorably to it, or whether other competing technologies will prove superior; in short, no one may appreciate just how valuable (or valueless) the technology is likely to be. On the other hand, even when a technology is more mature, no one may be able to predict whether it will yet be put to hitherto undiscovered uses – or, alternatively, how quickly it will obsolesce. This uncertainty can reduce the gains from trade that might otherwise be available to the licensing parties. *See, e.g.*, Richard E. Caves et al., *The Imperfect Market for Technology Licenses*, 45 *Oxford Bull. Econ. & Stat.* 249 (1983) (discussing various market imperfections in the licensing of technology); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 *Tex. L. Rev.* 989, 1053-54 (1997) (discussing high transaction costs associated with licensing). Legal rules that make it more difficult to license patented inventions therefore are likely, on average, to decrease rather than increase consumer welfare, absent clear proof of anticompetitive or other countervailing harm.

B. Allowing Patent Licensees to Institute Validity Challenges While Still Enjoying the Benefits of Their Licenses Would Likely Raise the Cost of Patent Licensing, and Thus Decrease Consumer Welfare.

As the law now stands, a party considering the manufacture, use, or sale of technology that is covered by another's existing patent has several options. First, it may decide to make, use, or sell despite the existence of the

patent, and if sued or threatened with suit to defend on the ground of invalidity or noninfringement. Second, it may decide to “design around” the patent so as to achieve the same end result without use of the claimed invention. Third, it may decide to license the invention from the patent owner on terms that take into account both the value that the licensee expects to extract from the invention and the probability that the patent is both valid and “reads on” the licensee’s proposed conduct. To illustrate by means of a simple example, assume that a potential licensee’s use of the patented invention is expected to bring in \$1,000 of profit, over a given time period, above that which could be gained from the use of the next-best alternative; thus if the would-be licensee were to use the invention without permission, its expected profit would consist of this \$1,000 minus the expected costs of litigation. These costs would include, among other things, an estimate of the user’s potential damages liability, based upon its assessment of the probability of patent validity and infringement, and attorney’s fees. If the would-be user estimates (1) the probability of patent validity and infringement to be 50%; (2) its damages in the event it is found to have infringed to be \$600; and (3) its attorneys’ fees to be \$100, its expected gain from unauthorized use equals \$600. A risk-neutral user therefore would agree to pay no more than \$400 (\$1,000 minus \$600) for permission to use the invention. Presumably the patent owner will make its own cost-benefit calculation in determining how much it is willing to accept in exchange for granting a license; if this amount is no more than \$400, the parties will find it in their mutual interest to agree to a license, absent prohibitive transaction costs or other bargaining obstacles.

Not surprisingly, the real world often presents many additional complications. For one thing, patent litigation is notoriously expensive. *See, e.g.*, American Intellectual Property Law Association, 2005 Report of the Economic Survey 22-23 (reporting estimated mean and median costs for small, middle, and high stakes patent litigation, with high stakes litigation resulting in estimated mean total costs of more than \$5 million and median total costs in excess of \$4 million). It is, therefore, often in both parties' interest to avoid litigation by agreeing to a license – which thus can be thought of as a prelitigation settlement of a hypothetical future patent dispute. (Of course, licenses often arise later on as well, as part of an actual settlement of an actual dispute). In addition, both the inherent value of the invention and the probability of validity and infringement may be uncertain; either or both parties may be risk-averse, meaning that they would turn down an actuarially fair “bet” on future events unless offered a sufficient risk premium; and each party's evaluation of its own and the other party's likely costs and benefits may differ due to asymmetric information. Financial constraints also may limit either or both parties' options in various ways. A licensee, for example, may prefer a smaller initial royalty coupled with future payments based on use, due to liquidity constraints; the licensor, on the other hand, may prefer a larger down payment and a fixed rather than per-use royalty that does not discourage the licensee from optimal future use. The existence of so many uncertain variables can lead to a wide variety of rational licensing arrangements, including exclusive and nonexclusive licenses, lump-sum and running royalty rates, and other permutations. *See Blair & Cotter, supra*, at 1380-1402.

Suppose, then, that a patentee and potential licensee are considering the licensing of an invention; that both parties have the good-faith belief that the patent is valid and would be infringed by the licensee's proposed use; but that, as is virtually always the case, the probability that a future decisionmaker would find both validity and infringement is less than 100%. As noted above, both parties can be expected to take their subjective estimates of validity and noninfringement into account in setting the "price" at which they would be willing to proceed. Now consider the likely consequences of a rule (from which the parties may not deviate by contract) permitting the licensee to challenge patent validity while enjoying the benefits of the patent license, versus a rule that does not permit the licensee to do so (but that does allow the licensee to challenge validity in the event the patentee sues for infringement or breach of contract). The former rule – that is, the rule espoused by petitioner here – requires the patentee to bear the incremental risk that the licensee will mount a successful challenge during the pendency of the license. The latter rule (the rule adopted by the Federal Circuit) would instead shift some of the risk of invalidity to the licensee – though not all of that risk, since a licensee who subsequently becomes convinced that the patent is in fact invalid could stop paying royalties and then assert invalidity if the patentee sues or threatens to sue. The former rule thus creates an incentive for the patentee to demand either more royalties upfront, or higher royalties overall, as compensation for this additional risk. Put another way, the patentee has an incentive to charge each licensee a higher price than would otherwise be the case, insofar as the use of the patent comes coupled with an inalienable option to challenge validity at any time. Licensees who do not expect to mount a validity challenge

and who would prefer to pay a lower rate in exchange for assuming some of the risk of invalidity are therefore rendered worse off, absent some alternative way for them to credibly signal their belief that the patent is valid. At the margin, some licensees may be priced out of the market, or at best will respond to the higher royalty rate by charging more and producing less. Both parties therefore may be worse off than if they had been able to allocate risk in accordance with their own preferences and liquidity constraints.

Another way of thinking about the matter is that petitioner's proposed rule effectively permits one party unilaterally to unravel the pre- or post-litigation settlement of a patent infringement suit that might have arisen, or did arise, absent the license. Unsurprisingly, patent owners may be marginally less willing to enter into such vulnerable settlements in the first instance, or may demand a higher premium in response to the increased uncertainty. A rule that encourages such results runs counter to the general federal policy favoring settlement – a policy that itself is based on many sound considerations, including the high private and public cost of litigation (particularly patent litigation). One might also take note of the potential inequity of allowing one party, but not the other, to do the unraveling of the settlement; the patent owner could not sue the licensee for infringement unless and until the licensee exceeded the scope of the license or the license terminated. On a fairness basis, if not on a purely economic rationale, this asymmetry is troubling.

But it is not only the parties who may be rendered worse off by the inclusion of an unwanted, but mandatory, term permitting licensees to challenge patents pre-breach. The public also may be worse off to the extent the mandatory

term raises the cost to licensees of using patented technology. Economic analysis predicts that the price of goods embodying such technology will increase and that output will decline, thus decreasing consumer surplus. Indeed, consumers may be worse off both short-term, as a result of higher costs and lower output, and in the long run as well, to the extent that the mandatory term marginally decreases the value of patents generally and thus the incentive to invent and disclose. We submit that these potential social costs are not trivial; and that this Court should decline to adopt petitioner's proposed rule absent clear proof of some potentially weightier social benefit.

C. The Potential Benefits of Petitioner's Proposed Rule Do Not Outweigh the Social Costs.

In response to the preceding argument, we anticipate the argument that the social costs we have identified above, as flowing from the adoption of petitioner's proposed rule, nevertheless could be worth incurring if the social benefits of increased patent invalidation were sufficiently large and could not be achieved in other ways. But the premises of this response seem doubtful, for several reasons.

First, even in the absence of petitioner's proposed rule, potential and former licensees and other would-be users of patented inventions retain other means of challenging possibly invalid patents. As noted, persons who wish to use inventions that are arguably covered by existing patents may do so and then defend themselves, in litigation, on the ground of invalidity – or may institute declaratory judgment actions for invalidity under appropriate circumstances. Any final judgment of patent invalidity is, moreover, binding on

the patent owner vis-à-vis any other possible future disputants. See *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313, 350 (1971). Alternatively, and consistent with *Lear, Inc. v. Adkins*, licensees themselves may challenge validity when they are sued or threatened with suit for infringement (for example, for continuing to use the patent after license termination) or for breach of contract (e.g., for refusing to pay promised royalties). See *Lear*, 395 U.S. at 660-71. To be sure, the result in *Lear* can be defended on the ground that it would be inequitable to permit a patentee to pursue a claim against its former licensee without permitting the licensee to defend by challenging patent validity. But the balance struck by *Lear* would be upset by MedImmune's rule here. In contrast to the rule in *Lear*, MedImmune's proposed rule would allow the licensee to use a license both as a shield and sword, insulating the licensee from infringement claims while at the same time permitting it to challenge validity, absent any provocation from the patentee.

Second, the Patent Act already permits “[a]ny person at any time” to seek reexamination of an issued patent – that is, to request that the Patent Office reconsider patent validity in light of some overlooked prior art. See 35 U.S.C. §§ 301, 302 (2000). As the statute implies, “there are no persons who are excluded from being able to seek reexamination.” Manual of Patent Examining Procedure § 2212 (8th ed. 2005); see also *id.* § 2612 (no standing requirement for inter partes reexaminations); 37 C.F.R. §§ 1.510(a), 1.913 (2005) (same); *Vitronics Corp. v. Conceptronic, Inc.*, 36 F. Supp. 2d 440, 441 (D.N.H. 1997). The statute even permits requests for ex parte reexamination to be made anonymously. See 35 U.S.C. § 301.

Third, it is clearly within the power of Congress – and to a lesser extent, the courts and the Patent Office itself, in articulating and developing patent policy in accordance with their constitutional powers – to develop yet other effective ways of reducing the number of invalid patents. Patent lawyers and scholars have suggested many possible methods for accomplishing this goal, including greater upfront scrutiny of patent applications for conformity with, among other things, the nonobviousness requirement; extending bounties to persons who come forward with prior art demonstrating that a patent lacks novelty or is obvious; and the adoption of post-grant opposition procedures of the type commonly used within the European Patent Office and in other countries to facilitate early, low-cost resolution of validity disputes. For that matter, Congress could, if it so chose and if such proceedings are permissible under article III of the Constitution, explicitly to allow licensee challenges of the type espoused by petitioner here. The fact remains that Congress has not expressly opted to do so, however; and we submit that Congress’s inaction, coupled with the possibility that it may prefer one or more of these other alternatives – or none of them – provides further reason for this Court to stay its hand.



CONCLUSION

For the reasons stated above, we urge this Court to affirm the judgment of Court of Appeals for the Federal Circuit.

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