SAN FRANCISCO BAY AREA INTELLECTUAL PROPERTY
AMERICAN INN OF COURT

Michael A. Molano
President

Neil A. Smith
Vice President

Joshua M. Masur
Secretary/Treasurer

April 2006 Meeting Announcement:

A Double Header: Licensee Challenges to Patent Validity and Tips on Advocacy Before the Federal Circuit

Must a licensee who seeks to challenge the validity of a licensed patent breach the license before filing a declaratory judgment action in order to make the dispute sufficiently definite, concrete and immediate to meet the "case or controversy" requirement of Article III and the related "actual controversy" requirement of the Declaratory Judgment Act? And what is the practical relation, if any, between those jurisdictional requirements and the Court's rejection of "licensee estoppel" in *Lear, Inc. v. Adkins* back in 1969?

The first half of this month's program will be a moot court argument of these issues as presented by *Medimmune v. Genentech*, in which certiorari was granted on February 21, 2006. The "court" will then transform itself into a panel discussion on useful tips when preparing for and presenting arguments to the Federal Circuit (including Jack Russo's exposé on "What *Really* Happens in the Federal Circuit.")

Panelists:	**Stuart Clark**	*Carr & Ferrell*
	Don Falk	*Mayer Brown Rowe & Maw*
	Michael Risch	*Russo & Hale*
	Gary Ritchey	*Townsend & Townsend & Crew*
	Jack Russo	*Russo & Hale*
	Robert Taylor	*Howrey*

Time and Location: April 19, 2006 at 6:00pm
Heller Ehrman
275 Middlefield Road (just North of Willow Road)
Menlo Park
650.324.2000

Dinner to follow

c/o Joshua M. Masur, Mayer Brown Rowe & Maw LLP, Two Palo Alto Square, 3000 El Camino Real, Suite 300, Palo Alto, California 94306-2112
web ipinnofcourt.org *tel* 650 331 2053 *fax* 650 331 4553 *email* inn@ipinnofcourt.org *Tax ID* #77-0387503

2005 WL 3067195 (U.S.)

For opinion see 126 S.Ct. 1329

Briefs and Other Related Documents

Supreme Court of the United States.
MEDIMMUNE, INC., Petitioner,
v.
GENENTECH, INC., et al., Respondents.
No. 05-608.
November 10, 2005.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

Petition for a Writ of Certiorari

John G. Kester, Paul B. Gaffney, Aaron P. Maurer, Williams & Connolly LLP, 725 Twelfth Street, N.W., Washington, D.C. 20005, (202) 434-5000.

Harvey Kurzweil [FN*], Aldo A. Badini, Henry J. Ricardo, Dewey Ballantine LLP, 1301 Avenue of the Americas, New York, New York 10019, (212) 259-8000, Attorneys for Petitioner.

FN* Counsel of Record

*i QUESTION PRESENTED

Does Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?

*ii LIST OF PARTIES

Petitioner was the only appellant in the court below. Respondents are Genentech, Inc., City of Hope, and Celltech R & D, Ltd., appellees in that court.

LIST PURSUANT TO RULE 29.6

Petitioner is a publicly held corporation. No publicly held entity owns 10% or more of its stock.

*iii TABLE OF CONTENTS

***v** TABLE OF AUTHORITIES

Cases:

***vi**

Constitutional Provisions:

2005 WL 3067195 (U.S.)

U.S. Constitution, Article III ... 2, *passim*

Statutes:

28 U.S.C. § 1254 ... 2

28 U.S.C. § 1331 ... 2

28 U.S.C. § 1338 ... 2

28 U.S.C. § 2201 ... 2, *passim*

***viii** *Miscellaneous*:

J. Allison & M. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 Am. Intell. Prop. L.A.Q.J. 185 (1998) ... 20

E. Borchard, Declaratory Judgments (2d ed. 1941) ... 12

S. Rep. No. 1005, 73d Cong., 2d Sess. (1934) ... 12

C. Wright, *et al.*, Federal Practice & Procedure (2d ed. 1983) ... 16

C. Wright, *et al.*, Federal Practice & Procedure (3d ed. 1998) ... 12

***1** Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this case October 18, 2005.

OPINIONS BELOW

The opinion of the United States District Court for the Central District of California is unreported and is reproduced in the Appendix at A. 21a. [FN1] The opinion of the United States Court of Appeals for the Federal Circuit is not yet reported and is reproduced at A. 1a.

FN1. Citations to "A." are to the appendix to this petition. Citations to "C.A.A." are to the joint appendix filed in the Court of Appeals, and to "C." to the first amended complaint.

***2** JURISDICTION

The judgment of the Court of Appeals was entered October 18, 2005. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article III of the Constitution of the United States and 28 U.S.C. §§ 1331, 1338(a) and 2201(a) are reproduced at A. 32a.

STATEMENT

A. The License.

Petitioner, MedImmune, Inc., is a biotechnology company. It manufactures and

markets Synagis(R), the only drug in the United States indicated for prevention of potentially fatal respiratory tract infections caused by respiratory syncytial virus ("RSV") in infants. A. 21a. Synagis(R) is a monoclonal-antibody-based preventative agent.

Respondents Genentech, Inc., and City of Hope (hereinafter collectively "Genentech") hold two related patents directed broadly to methods of manufacturing monoclonal antibodies. The first, United States Patent No. 4,816,567, naming Shmuel Cabilly and others as inventors (the "Cabilly I patent"), issued March 28, 1989, and expires March 28, 2006. C.A.A. 638. The second, United States Patent No. 6,331,415, naming the same inventors (the "Cabilly II patent"), issued December 18, 2001, and following a settlement between Genentech and respondent Celltech - which petitioner challenged in this litigation - -does not expire until 2018. C.A.A. 112. The Cabilly II patent includes claims that are copied from, and are virtually identical to, the claims of a 1989 patent assigned to respondent Celltech (U.S. Patent No. 4,816,397, the "Boss patent"). [FN2] The invention claimed ***3** by the Boss and Cabilly II patents together will receive a total patent-protection period of 29 years. During this time, respondents may demand (and have demanded) licenses and royalty payments for what they describe as a fundamental technology for synthesizing monoclonal-antibody-based products. C. 25-26.

> FN2. After the Boss patent issued in 1989, Genentech initiated a proceeding before the United States Patent and Trademark Office seeking a determination that Genentech had been the first to invent the claimed subject matter. The PTO finally decided in Celltech's favor in 1998. Genentech then commenced litigation in the District Court, seeking to overturn the PTO's determination. The Boss patent was in force during this entire period, and was nearing the end of its 17-year term. But Genentech and Celltech then entered an agreement to settle the litigation. Celltech thereby reversed its position and agreed with Genentech that Genentech had been the first inventor; this removed the barrier that for ten years had prevented Genentech from obtaining the Cabilly II patent, and that patent (with a fresh 17-year term) issued soon afterwards. In return, Celltech received money payments from Genentech through 2006 (when the Boss patent was to expire), plus preferential access to the technology that was once covered by the Boss patent, and as a result of the agreement will be covered until 2018 by the Cabilly II patent.

In 1997, a year prior to first marketing Synagis(R), petitioner agreed to license a group of patents from Genentech. The license carried an obligation to pay royalties for the sale or marketing of any product covered by one of the patents, among which was the Cabilly I patent. A. 4a, 28a-29a, C. 5. Petitioner was a new company unable to afford extended litigation and unwilling to risk crippling infringement judgments, with possible consequences of injunction, treble damages and attorneys' fees. The licensed package also included, in addition to the Cabilly I patent, several patent applications that were pending, among them what became the Cabilly II patent, which at the time of the license was unissued and the scope of whose claims was uncertain.

In December 2001 the Cabilly II patent issued, and its claims were publicly disclosed for the first time. Less than a month later, Genentech notified petitioner of its "expectation *4 that MedImmune will pay royalties on sales of its Synagis(R) antibody product" under the license based on the newly issued and disclosed Cabilly II patent. C. 26. Petitioner disputed that it had any obligation to pay royalties and requested Genentech to explain its "basis for believing that MedImmune's product would infringe any valid claim of the [Cabilly II] Patent such that royalties would be due." C. 27. Genentech ignored the request. In the meantime, fearing possible suit to prohibit its sale of Synagis(R), which accounted for 80% of its revenues, petitioner began making the requested royalty payments, informing Genentech that "[s]uch payment ... was made under protest and with reservation of all of our rights." *Id.*

The following year petitioner brought suit against respondents in the United States District Court for the Central District of California under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), seeking a judgment that the Cabilly II patent - for a number of reasons including failure to disclose prior art and misleading the Patent and Trademark Office - was invalid and unenforceable and was not infringed by Synagis(R). [FN3] A. 4a. To avoid the consequences of an injunction and the penalties of a possible finding of willful infringement, petitioner has continued to pay royalties under protest during the pendency of this litigation.

> FN3. The complaint also claimed damages for antitrust violations and unfair competition under state and federal laws. The District Court dismissed those claims. See A. 22a.

B. District Court Decision.

The District Court (Pfaelzer, J.) in April 2004 dismissed petitioner's suit for lack of subject-matter jurisdiction. The District Court explained that it was bound to do so by a decision of the Federal Circuit announced the previous month, *Gen-Probe Inc. v. Vysis,* Inc., 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed* , 125 S. Ct. 351 (2004) (No. 04-*5 260). That decision held that when a patent licensee had complied with, rather than breached, its royalty obligations, there was no "actual controversy" within the meaning of the Declaratory Judgment Act and the requirements of Article III of the Constitution. The District Court observed that it dismissed with reluctance, explaining:

"In *Gen-Probe* the Federal Circuit determined that controversies over patent validity, enforcement, infringement would not be recognized while license agreements protected the licensee from suit for infringement.

***

"Even if *it has serious misgivings about the panel's conclusion*, this Court is not free to reconsider policy ramifications that *Gen-Probe* rejected.... Because *Gen-Probe* ruled that no subject matter jurisdiction exists under these facts, this Court must grant Genentech's Motion."

A. 29a, 31a (emphasis supplied). The District Court also pointed out that the Federal Circuit's new doctrine was a departure from the Circuit's previous constitutional understanding:

"In the past, the 'actual controversy' requirement has not been interpreted as precluding a licensee from challenging a patent it licenses. *See C.R. Bard Inc. v. Schwartz,* 716 F.2d 874, 875 (Fed. Cir. 1983) ('[A] patent license need not be

terminated before a patent licensee may bring a declaratory judgment action'); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) (holding that a license does not bar the licensee from challenging the validity of the patent).

"In *Gen-Probe*, however, the Federal Circuit limited the ability of licensees to challenge the patents they license. The Court held that no actual controversy existed between a patentee and a licensee in good standing. *Gen-Probe* ... (noting that the 'license, unless *6 materially breached, obliterated any reasonable apprehension of a lawsuit based on the prior circumstances cited by the district court for jurisdiction.')."

A. 24a-25a. Accordingly, the court dismissed the declaratory-judgment claim and entered judgment for respondents. Petitioner appealed.

C. Court of Appeals Decision.

The Federal Circuit, in an opinion by Judge Newman, joined by Judges Mayer and Clevenger, affirmed the dismissal, applying the jurisdictional rule announced in the *Gen-Probe* decision. According to that rule, to sue under Article III and the Declaratory Judgment Act "a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement)." *Gen-Probe*, 359 F.3d at 1381. The Federal Circuit held that "the jurisdictional requirements of a declaratory judgment action are not met when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement." A. 6a. Without such a breach or termination, "there is no discretion to accept an action when there is no controversy of immediacy or reality because there is no reasonable apprehension of suit" when a licensee has not breached a license agreement. A. 8a. [FN4]

> FN4. The Court of Appeals also affirmed the District Court's dismissal of petitioner's other claims. See n. 3, *supra*; A. 9a-17a. Judge Clevenger dissented from that part of the decision, concluding that the appeal of that dismissal should have been transferred to the United States Court of Appeals for the Ninth Circuit. A. 17a-20a.

REASONS FOR GRANTING THE WRIT

In an unprecedented reinterpretation of Article III and the Declaratory Judgment Act, the Federal Circuit has written into every patent license a "licensee estoppel" clause. The Federal Circuit has effectively ended actions by patent licensees ***7** to challenge patents, unless those licensees first place themselves in breach, and consequently in jeopardy of license termination, substantial liability and penalties. The Federal Circuit's new and absolute rule, laid down first in *Gen-Probe* last year, and followed undeviatingly once again here, is that any licensee

"must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent."

Gen-Probe, 359 F.3d at 1381. The Federal Circuit already has applied its new Article III rule, without any exception, in at least four decisions thus far, [FN5] and the district courts have obeyed. [FN6]

> FN5. See, in addition to *Gen-Probe* and the present decision, *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005); *Metabolite Labs., Inc. v.*

Laboratory Corp. of America Holdings, 370 F.3d 1354, 1369 (Fed. Cir. 2004) (vacating judgment because "in light of LabCorp's continuing royalty payments on the panel test, LabCorp cannot itself challenge the validity of a claim for which it continues to pay royalties"), *cert. granted*, 74 U.S.L. Week 3287 (2005) (No. 04-607). See also, applying the Federal Circuit interpretation of Article III outside the patent-license context, *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, *rehearing en banc denied*, 405 F.3d 990 (Fed. Cir.), *cert. denied*, 125 S. Ct. 1413 (2005) (No. 05-48).

FN6. See *E.I. du Pont de Nemours & Co. v. Great Lakes Chem. Corp.*, 383 F. Supp. 2d 642 (D. Del. 2005) (applying *Gen-Probe* and dismissing declaratory judgment suit by licensee); *In re Columbia Univ. Patent Litig.*, 343 F. Supp 2d 35, 49 (D. Mass. 2004) ("If Biogen Idec MA and Genzyme pay the annual license fee, any possible case or controversy may be extinguished.").

With particular respect to patents, as this Court explained its grant of certiorari to the Federal Circuit in *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993):

"Because the Federal Circuit has exclusive jurisdiction over appeals from all United States District Courts ***8** in patent litigation, the rule that it applied in this case ... is a matter of special importance to the entire Nation."

So here also. Besides unduly constricting Article III, the decision is contrary to the policy of the patent laws themselves as declared in this Court's decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), which abolished the previous doctrine of licensee estoppel. And because the Federal Circuit is the sole appellate court for patent claims, its new doctrine now governs every United States patent licensee.

The Federal Circuit's decision ignores clear holdings of this Court, and what was heretofore the accepted understanding of the Declaratory Judgment Act in other Circuits, as applied also to copyright licenses, trademark licenses, and licensing contracts of every kind. If the Federal Circuit's constitutional rule is allowed to stand, MedImmune along with many other litigants, particularly small and innovative biotechnology companies, will be forced either to put themselves in material breach of license agreements (agreements often forced upon them) and thereby incur great financial risk, or to forgo any challenge to invalid or overreaching patent claims, even claims that issue after the license. Either way, they are denied the option of declaratory relief that Congress clearly intended to grant when it enacted the Declaratory Judgment Act in 1934.

I. THE FEDERAL CIRCUIT'S NEW INTERPRETATION OF ARTICLE III AND THE DECLARATORY JUDGMENT ACT CONFLICTS WITH DECISIONS OF THIS COURT AND OTHER COURTS OF APPEALS.

A. The Decision Is Contrary to This Court's Holdings Dating From *Aetna Life Ins. Co. v. Haworth*.

1. In its landmark holding in *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937), this Court through Chief Justice Hughes unanimously upheld the constitutionality under Article III of ***9** the 1934 Declaratory Judgment Act, now 28 U.S.C. § 2201(a)

. This Court explained, in constitutional doctrine of general application, that
"Where there is such a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged, the judicial function may be appropriately exercised although the adjudication of the rights of the litigants may not require the award of process or the payment of damages."
300 U.S. at 241. This Court held that a dispute over the meaning of terms of insurance policies presented "a dispute ... manifestly susceptible of judicial determination." *Id.* at 242.

Such is the case here. Just as in *Aetna*,
"There is here a dispute between parties who face each other in an adversary proceeding. The dispute relates to legal rights and obligations arising from the contracts .... The dispute is definite and concrete, not hypothetical or abstract. Prior to this suit, the parties had taken adverse positions with respect to their existing obligations.... It calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts."
300 U.S. at 242. The Cabilly II patent has been issued and is effective until 2018 and petitioner's product is on the market. Petitioner's claims of invalidity, unenforceability and noninfringement all are ripe for determination on a concrete record.

2. Soon after *Aetna* this Court specifically held that the Declaratory Judgment Act applied to a patent-license challenge. Pointing out the immediacy of the dispute, this Court explained that
"certainly the requirements of case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right ***10** to recover the sums paid or to challenge the legality of the claim."
Altvater v. Freeman, 319 U.S. 359, 365 (1943). Further, this Court held:
"It is said that so long as petitioners are paying royalties they are in no position to raise the issue of invalidity - the theory being that as licensees they are estopped to deny the validity of the patents and that, so long as they continue to pay royalties, there is only an academic, not a real controversy, between the parties. ... The fact that *royalties were being paid* did not make this a 'difference or dispute of a hypothetical or abstract character.' "
Id. at 364 (emphasis supplied), quoting in part *Aetna*, 300 U.S. at 240. [FN7]

FN7. "As we said in *Fidelity National Bank* [*& Trust Co. v. Swope*, 274 U.S. 123, 132 (1927)], 'Naturalization proceedings, ... suits to determine a matrimonial or other status; suits for instructions to a trustee or for the construction of a will ... bills of interpleader so far as the shareholder is concerned ... bills to quiet title where the plaintiff rests his claim on adverse possession ... are familiar examples of judicial proceedings which result in an adjudication of the rights of litigants, although execution is not necessary ....' *Nashville, C. & St. L. Ry. v. Wallace*, 288 U.S. 249, 263 (1933).

3. This Court has never deviated from those holdings. In fact, it has pointed out again the particular appropriateness of the Declaratory Judgment Act to patent

litigation. Completely contrary to the Federal Circuit's rejection of jurisdiction here, this Court has held that

"Merely the desire to avoid the threat of a 'scarecrow' patent, in Learned Hand's phrase, may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act."

Cardinal Chemical, 508 U.S. at 96 (footnote omitted), citing *Bresnick v. United States Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943).

***11** 4. In adopting an absolute requirement that bars declaratory judgment suits and permits "no discretion," when "there is no defaulting licensee," A. 6a, 8a, the Federal Circuit has defied this Court's direction, reiterated in many cases, that

"the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Maryland Cas. Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941). Instead, the Federal Circuit has attempted to distinguish the fundamental holdings of this Court on unpersuasive grounds. Faced with the *Aetna* decision, the Federal Circuit rejected it as inapplicable because, although *Aetna* "suggests that a litigant may sue to determine contract rights before a breach," that case "did not involve a declaratory judgment action instituted by a patent licensee in good standing." *Gen-Probe*, 359 F.3d at 1382. Faced with the *Altvater* decision, the Federal Circuit said that that case was inapplicable because the royalties called for by the license there were being paid pursuant to an injunction. *Id.* at 1381-82.

5. The question presented here is certainly "vital to the practice of patent law." *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 878 (Fed. Cir. 1983). But the Federal Circuit has rendered a decision reaching far beyond the patent context, and deep into Article III itself. [FN8] There is no way to confine its reasoning to a single subset of contracts, patent licenses. Contract disputes of all kinds were a primary focus of Congress when it enacted the Declaratory Judgment Act in ***12** 1934: a party who disagrees about the meaning of a contract provision or the obligation imposed by it should not have to put itself in material breach before it can obtain an adjudication of its rights. Congress explained the Act's purpose to

> FN8. The "actual controversy" requirement of the Declaratory Judgment Act extends to the limits of the "Cases" or "Controversies" jurisdiction of Article III. *Aetna*, 300 U.S. at 239-40; *ACandS, Inc. v. Aetna Cas. & Surety Co.*, 666 F.2d 819, 822 (3d Cir. 1981).

"enable[] parties in disputes over their rights over a contract, deed, lease, will, or any other written instrument to sue for a declaration of rights, *without breach of the contract* ...."

S. Rep. No. 1005, 73d Cong., 2d Sess. 2 (1934) (emphasis supplied). Referring to the previous legal situation - under which "it is often necessary to break a contract or lease, or act upon one's own interpretation of his rights when disputed" - the Senate Report explained that with the Declaratory Judgment Act "it is not necessary to bring about such social and economic waste and destruction in

order to obtain a determination of one's rights." *Id.* In the words of a principal author of the Act, it was intended to allow a party disputing a contractual obligation an alternative to the choice of "risking disaster by acting on [its] own assumption or ... not acting because of fear of consequences." E. Borchard, Declaratory Judgments 931 (2d ed. 1941). Its very purpose was to allow parties to litigate contract claims "without the necessity for prior breach." *Id.* at 932. *Accord, e.g.*, 10B C. Wright, *et al.*, Federal Practice & Procedure § 2751, at 457-58 (3d ed. 1998). Yet the Federal Circuit holds just the opposite: that a contracting party to a license agreement "must ... materially breach the agreement ... before bringing suit." *Gen-Probe,* 359 F.3d at 1381; see A. 6a ("there is no defaulting licensee and no possibility of suit").

A holding more contradictory to this Court's long-established construction and constitutional endorsement of the Declaratory Judgment Act, as well as of the patent laws, can scarcely be imagined. And the Federal Circuit, whatever its presumed technical competence in purely patent issues, ***13** has no special expertise in construing Article III of the Constitution or the Declaratory Judgment Act.

B. The Decision Is Contrary to Declaratory Judgment Holdings in Other Circuits.

The Federal Circuit's new line of Article III decisions, of which this is one, is completely at odds with how the Declaratory Judgment Act and Article III are construed in other circuits. Article III does not contain a special rule for patent licenses.

1. *Licenses.*

Prior to the establishment of the Federal Circuit, several courts of appeals had held that patent licensees could bring declaratory judgment actions without first committing a breach of their license agreements. In *Precision Shooting Equip. Co. v. Allen,* 646 F.2d 313 (7th Cir.), *cert. denied,* 454 U.S. 964 (1981), the court pointed out the undesirability of forcing a licensee to "sit back and continue to wonder if it is justly paying royalties or merely paying a bribe to the patentee not to threaten him with business disruption and a possible damage suit if he terminates royalty payments." 646 F.2d at 318. It held that "[w]e see no need to force a party to take some additional act to deepen gray into black and to expand the potential of litigation resulting in further business disruption while we pretend in the meantime that there is no actual controversy." *Id.* at 318-19. It added that "[i]n determining ... whether an 'actual controversy' exists in a particular circumstance, a determination which cannot be mechanically arrived at, the *Lear* rationale deserves to have some influence." *Id.* at 317.

Similarly the Second Circuit, in a frequently cited case, held that

"Addressing the question whether a patent licensee must actually withhold royalty payments before he can ***14** challenge validity, we conclude - as have most courts who have considered the issue - that such repudiation of the licensing agreement should not be precondition to suit."

Warner-Jenkinson Co. v. Allied Chem. Corp., 567 F.2d 184, 187 (2d Cir. 1977) (citing cases). *Accord, Société de Conditionnement v. Hunter Engineering Co.*, 655 F.2d 938, 943-44 (9th Cir. 1981) ("[d]eclaratory relief is 'indisputably

appropriate' to patent cases"); *American Sterilizer Co. v. Sybron Corp.*, 526 F.2d 542, 546 (3d Cir. 1975) (termination of license not a precondition to declaratory suit by licensee).

The regional circuits since 1982 no longer pass upon this issue in the context of patent licenses. But those circuits do with regularity construe the Declaratory Judgment Act and Article III in the context of non-patent licenses, as well as other contracts. Although a patent licensee, the Federal Circuit here holds, is required by Article III to put itself in material breach before challenging its licensor, a copyright licensee, for instance, may seek a declaratory judgment without any such burden. The Ninth Circuit, applying patent-license principles to a copyright license, has held that a "licensee need not terminate its license agreement in order to maintain a federal declaratory action for copyright invalidity." *Hal Roach Studios, Inc., v. Richard Feiner & Co.*, 896 F.2d 1543, 1556 n.23 (9th Cir. 1990). Non-patent licensees routinely are permitted to bring declaratory judgment actions without first committing breaches of the licenses. See *National Car Rental System, Inc. v. Computer Assocs. Int'l, Inc.*, 991 F.2d 426, 427-28 (8th Cir.), *cert. denied*, 510 U.S. 861 (1993); *S.O.S., Inc. v. Payday, Inc.*, 886 F.2d 1081, 1083 (9th Cir. 1989).

2. *Contracts Generally.*

The Federal Circuit decision here - holding that there must be a material breach of the license contract in order to present ***15** a constitutional case or controversy under the Declaratory Judgment Act - is entirely in conflict with the numerous decisions in contract cases in other circuits that emphatically hold just the opposite. For many years, the other circuits have held that breach of contract is *not* necessary for jurisdiction of a declaratory-judgment action. *E.g., Keener Oil & Gas Co. v. Consolidated Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951) ("a party to a contract is not compelled to wait until he has committed an act which the other party asserts will constitute a breach, but may seek relief by declaratory judgment and have the controversy adjudicated in order that he may avoid the risk of damages or other untoward consequence"); *American Machine & Metals, Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948) ("The very purpose of the declaratory judgment procedure is to prevent the accrual of ... avoidable damages."). As the Fifth Circuit recently held, the Declaratory Judgment Act is designed "to avoid inequities which might result from a delay in assessing the parties' legal obligations," and "the court ought not require that those contingencies to [*sic*] have occurred at the time relief is sought." *Venator Group Specialty, Inc. v. Matthew/Muniot Family, LLC*, 322 F.3d 835, 840 (5th Cir. 2003) (declaratory judgment concerning obligations under commercial lease). For other examples, see:

- *Doody v. Ameriquest Mortgage Co.*, 242 F.3d 286, 288 (5th Cir. 2001) ("The Declaratory Judgment Act exists to allow litigants to determine an actual controversy such as this one before the dispute grows into a contract violation ....").
- *NUCOR Corp. v. Aceros y Maquilas de Occidente, S.A.*, 28 F.3d 572, 577 (7th Cir. 1994) (Declaratory Judgment Act exists "to avoid accrual of avoidable damages to one not certain of his rights and to afford him an early adjudication, without waiting until his ***16** adversary should see fit to begin suit, after damage had accrued.") (quotations omitted).

- *Continental Cas. Co. v. Coastal Sav. Bank*, 977 F.2d 734, 738 (2d Cir. 1992) ("[D]eclaratory judgment relief was intended to avoid precisely the accrual of avoidable damages to one not certain of his rights.") (quotation omitted).

- *United Food & Comm'l Workers Local No. 137 v. Food Employers Council Inc.*, 827 F.2d 519, 524 (9th Cir. 1987) (Declaratory Judgment Act "is intended to minimize the danger of avoidable loss and the unnecessary accrual of damages and to afford one threatened with liability an early adjudication without waiting until his adversary should see fit to begin an action after the damage has accrued," quoting 10A C. Wright *et al.*, Federal Practice and Procedure § 2751, at 569-71 (2d ed. 1983)).

- *ACandS, Inc. v. Aetna Cas. & Surety Co.*, 666 F.2d 819, 823 (3d Cir. 1981) ("declaratory judgment relief was intended to avoid precisely the 'accrual of avoidable damages to one not certain of his rights' "), quoting *Dewey & Almy Chem. Co. v. American Anode, Inc.*, 137 F.2d 68, 69 (3d Cir.), *cert. denied*, 320 U.S. 761 (1943).

II. THE DECISION FRUSTRATES THIS COURT'S DIRECTION IN *LEAR, INC. V. ADKINS*.

The Federal Circuit's decision also is at war with the policy enacted in the patent laws.

In *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), this Court rejected the doctrine of "licensee estoppel" as "inconsistent with the aims of federal patent policy." 395 U.S. at 673. In *Lear* "[b]y 'unmuzzling' licensees, the Court sought to encourage the prompt adjudication of patent validity." *Nebraska Engineering Corp. v. Shivvers*, 557 F.2d 1257, 1259 (8th Cir. 1977), quoting in part *Atlas Chem. Industries, Inc. v. Moraine Prods.*, 509 F.2d 1, 6 (6th Cir. 1974).

***17** *Lear* recognized that this Court since the Nineteenth Century has held that "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly ...." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892), quoted in *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58 (1973). And exactly a century after *Pope*, this Court reiterated in *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100 (1993), "the importance to the public at large of resolving questions of patent validity." There is an

"important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification."

Lear, 395 U.S. at 670. As this Court held, "We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest." *Id.*

Yet in addressing the *Lear* decision, the Federal Circuit observed - accurately - that "[i]n several instances, this court has declined to apply the *Lear* doctrine." *Gen-Probe*, 359 F.3d at 1381. At first the Federal Circuit had complied with *Lear*. In a 1983 decision it accordingly ruled that "[w]e hold that a patent licensee may bring a federal declaratory judgment action ... without prior termination of the

license." *C.R. Bard, Inc. v. Schwartz,* 716 F.2d 874, 882 (Fed. Cir. 1983). However, in *Diamond Scientific Co. v. Ambico, Inc.,* 848 F.2d 1220, 1224-25 (Fed. Cir.) *pet'n for cert. dismissed,* 487 U.S. 1265 (1988), the Federal Circuit ruled notwithstanding *Lear* that "despite the public policy encouraging people to challenge potentially invalid patents, there are still circumstances ***18** in which the equities of the contractual relationship between parties should deprive one party ... of the right to bring that challenge." Then in 1997 the Federal Circuit characterized this Court's holding in *Lear* as sounding "tones that echo from a past era of skepticism over intellectual property principles." *Studiengesellschaft Kohle, m.b.H, v. Shell Oil Co.,* 112 F.3d 1561, 1567 (Fed. Cir.), *cert. denied,* 522 U.S. 996 (1997). The Federal Circuit candidly acknowledged that after *Lear* "this court nonetheless estopped the assignor from challenging the validity of the patent," and announced that

"a licensee ... cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties ....

112 F.3d at 1567-68.

Gen-Probe and the present decision leave *Lear* virtually a dead letter in the Federal Circuit. In this case, following *Gen-Probe*, the Federal Circuit has resorted to misconstruction of Article III and the Declaratory Judgment Act to reject the patent policy recognized by this Court in *Lear* as something from a "past era." *Studiengesellschaft Kohle,* 112 F.3d at 1567.

The District Court here, reluctantly obeying the Federal Circuit, observed that what was being adopted was the Federal Circuit's own patent policy:

"The *Gen-Probe* panel was concerned by the 'undesirable result' that licensors would bear more risk and be less likely to grant licenses if licensees were permitted to challenge the patents they license.... The panel was apparently more persuaded by this concern than by the potential that invalid or unenforceable patents will stand because licensees will be too risk-averse to challenge them." A. 29a-30a. The District Court also pointed out that this "forces licensees to take a tremendous risk to challenge a ***19** patent, one that some with valid claims will likely be unwilling to take." A. 30a.

Article III does not exist to promote particular substantive policies, but rather sets the parameters of the federal judicial power. Jurisdiction under Article III is not precluded "so long as the case retains the essentials of an adversary proceeding, involving a real, not a hypothetical, controversy, which is finally determined by the judgment below." *Nashville, C. & St. L. Ry. v. Wallace,* 288 U.S. 249, 264 (1933). The Declaratory Judgment Act tracks fully the scope of Article III. *Aetna,* 300 U.S. at 239-40; *ACandS,* 666 F.2d at 822. Nevertheless, as the Federal Circuit recognized, A. 7a, its interpretation of Article III's jurisdictional grant relies on considerations of patent policy it deems persuasive. See A. 7a; see also *Gen-Probe,* 359 F.3d at 1382.

Moreover, even if it were appropriate to reshape Article III in light of such substantive considerations, the Federal Circuit has adopted a policy at odds with the policy of the patent laws as declared by this Court, see *Lear, supra,* and failed to recognize the difficulties its new holding creates.

III. THE DECISION PARTICULARLY INHIBITS THE INTRODUCTION OF NEW MEDICAL DRUGS AND TREATMENTS.

Disallowing licensee challenges to patent validity, as this Court has observed, has an effect "particularly severe in the many scientific fields in which invention is proceeding at a rapid rate." *Lear,* 395 U.S. at 673. It is common in the essential and fast-growing biotechnology industry to license a package of patents, as was done here, in a single license. By prohibiting declaratory challenges to patents unless royalty payments are stopped, the present decision will further encourage patent holders to bundle unrelated "bad" patents with "good" ones, betting that licensees will not risk losing the coverage of the valid patents in order to challenge the doubtful ***20** ones. Also, patents licensed under agreements typically are defined to include "continuations, continuations-in-part, divisionals" and the like. Patent license agreements typically permit the licensor to terminate for any material breach, and treat such a breach as unallocated and applicable to the entire license, so that a licensee faced with a newly-issued invalid patent will be unable to challenge it without risking breach of the entire license and all the patents it includes.

This case presents a striking, but unfortunately all too common, example of how patent-holders can use the threat of litigation to assert claims and exact tributes to which they are not entitled. Here the license for respondent's patent package included an application that, upon its issuance as a patent and publication of its claims, petitioner believed to be invalid and unenforceable.

Such invalid patent claims carry a significant social cost. They inhibit innovation. This Court in *Lear* recognized the "important public interest," 395 U.S. at 670, in challenges to patents. The wisdom of that concern is reflected in the conclusion of recent research that when patents are challenged in litigation, they are held invalid 46% of the time. J. Allison & M. Lemley, *Empirical Evidence on the Validity of Litigated Patents,* 26 Am. Intell. Prop. L.A.Q.J. 185, 205-06 (1998).

Petitioner's attempt to challenge the very broad patent claims Genentech asserted here on basic and important categories of drugs was grounded. Petitioner alleged, for example, that in order to obtain the Cabilly II patent, Genentech had intentionally withheld evidence concerning material prior art from the Patent and Trademark Office, and had obtained a patent monopoly on claims far beyond what experimental submission could support. C. 19-24. Yet in spite of the statutory policy that "competition should not be repressed by worthless patents," *Pope, supra; Glaxo Group, supra,* the Federal Circuit here has effectively enacted just the opposite policy, citing its own conclusion that challenges like petitioner's ***21** would produce "undesirable results." *Gen-Probe,* 359 F.3d at 1382. The Court of Appeals was persuaded that "[a]llowing this action to proceed would effectively defeat those contractual covenants and discourage patentees from granting licenses." *Id.* [FN9] But this Court in *Lear* concluded that "contract doctrine must give way before the demands of the public interest." 395 U.S. at 670. And even if the questionable policy judgment embodied in the present decision were correct, it was not the Federal Circuit's to make, and certainly not by altering the meaning of Article III and the Declaratory Judgment Act.

FN9. By contrast, the Seventh Circuit in *Precision Shooting* was impressed by the undesirability of forcing a licensee to "wonder if it is justly paying royalties or merely paying a bribe." 646 F.2d at 318.

That the Federal Circuit has nearly exclusive appellate jurisdiction nationally over appeals in cases involving patents is all the more reason not to allow its Article III and patent policy embodied in this decision, so contrary to the holdings of this Court and the reasoning of other circuits - and so powerful in steering the course of American industry - to stand unreviewed. See *Cardinal Chem. Co.*, 508 U.S. at 89. *Cf. Laboratory Corp. of America Holdings v. Metabolite Labs., Inc.*, 74 U.S.L. Week 3287 (2005) (No. 04- 607) (granting certiorari to resolve asserted conflict on patent issue within the Federal Circuit).

***22** CONCLUSION

For the reasons stated, certiorari should be granted.

MedImmune, Inc. v. Genentech, Inc.
2005 WL 3067195

Briefs and Other Related Documents (Back to top)

• 2006 WL 110458 (Appellate Petition, Motion and Filing) Reply to Brief in Opposition (Jan. 12, 2006)Original Image of this Document (PDF)

• 2005 WL 3560572 (Appellate Petition, Motion and Filing) Brief in Opposition (Dec. 27, 2005)

• 05-608 (Docket) (Nov. 15, 2005)

END OF DOCUMENT

2005 WL 3560572 (U.S.)

For opinion see 126 S.Ct. 1329

Briefs and Other Related Documents

Supreme Court of the United States.
MEDIMMUNE, INC., Petitioner,
v.
GENENTECH, INC., et al., Respondents.
No. 05-608.
December 27, 2005.

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

Brief in Opposition

Joseph M. Lipner, Jason Linder, Irell & Manella LLP, 1800 Avenue of the Stars, Suite 900, Los Angeles, CA 90067, (310) 277-1010, Counsel for Respondent, City of Hope.

Roy E. Hofer, Meredith Martin Addy, Brinks Hofer Gilson &, Lione, 455 N. Cityfront Plaza Dr., Suite 3600, Chicago, IL 60611, (312) 321-4200, Counsel for Respondent, Genentech, Inc.

Daniel M. Wall, Counsel of Record, Mark A. Flagel, James K. Lynch, Latham & Watkins LLP, 505 Montgomery Street, Suite 2000, San Francisco, CA 94111, (415) 391-0600.

John W. Keker, Mark A. Lemley, Keker & Van Nest LLP, 710 Sansome Street, San Francisco, CA 94111, (415) 391-5400, Counsel for Respondent, Genentech, Inc.

***i** QUESTION PRESENTED

Whether the Declaratory Judgment Act gives a patent licensee special fights to commence a declaratory judgment action for patent non-infringement and invalidity against its licensor, when such licensee enjoys all benefits and protections of the license, faces no threat of an infringement suit, and indeed is immune from any suit on the patent.

***ii** RULE 29.6 STATEMENT

Approximately 56% of the issued common stock of Respondent Genentech, Inc. is owned by Roche Holdings, Inc. Respondent Genentech, Inc. remains an independent, publicly traded company.

Respondent City of Hope is a non-profit biomedical research, treatment and educational institution. City of Hope has no parent company. No entity owns stock in City of Hope.

*iii TABLE OF CONTENTS

*v TABLE OF AUTHORITIES
CASES

STATUTES

REGULATIONS

OTHER AUTHORITY

***1** STATEMENT OF THE CASE

This case concerns the actions of a party that, for the express purpose of avoiding any risk of an infringement suit, requested and secured licenses to patented technology, and then, after securing the last of the licenses, sued the patent-holder under the Declaratory Judgment Act, claiming there was a live controversy over the validity, enforceability and infringement of the patent.

A. The License

Respondents Genentech, Inc. ("Genentech") and City Hope collaborated over several

years to develop recombinant DNA technology to produce antibody molecules to help treat cancer and other diseases. The results of this collaboration included the patent-in-suit U.S. Patent No. 6,331,415 ("the ' 415 patent"). Genentech uses this technology in five of its marketed products, including treatments for certain types of breast and colorectal cancer. It also licenses this technology to other companies who wish to use it.

Petitioner MedImmune, Inc. ("MedImmune") is biotechnology company whose products include genetically engineered antibodies. Pet. App. 21a-22a. One of its currently marketed products, Synagis(R), and many of its pipeline products, are made using patented technology owned by Genentech and City of Hope. Pet. App. 21a-22a.

There was a lengthy dispute between Genentech and a British company, Celltech R&D, Ltd., over the U.S. patent rights in the relevant invention. Pet. App. 2a-4a. [FN1] While that dispute was pending, MedImmune obtained licenses from both Genentech and Celltech. Pet. App. 4a. In June 1997, ***2** MedImmune entered into a license agreement with Genentech that permitted MedImmune to practice U.S. Patent No. 4,816,567 ("the '567 patent," claiming related technology), and any patent that issued from a pending Genentech application. Pet. App. 4a. The Genentech application ultimately matured into the '415 patent which claims the invention at issue. Pet. App. 4a. MedImmune has no products covered by the '567 patent and has not paid royalties on the ' 567 patent.

> FN1. MedImmune misstates the facts relating to the priority contest in the United States Patent and Trademark Office ("PTO") and the resolution of the district court litigation that followed. Pet. at 2-3 & n.2. The Federal Circuit correctly summarized the undisputed material facts relating to these events. Pet. App. 2a-4a.

The '415 patent issued in 2001, after the resolution of the priority dispute between Genentech and Celltech. Pet. App. 3a-4a. Genentech thereafter advised MedImmune of its belief that Synagis(R) was a "licensed product" for which royalties were due. Pet. App. 4a. MedImmune balked at first, denying that Synagis(R) was a "licensed product." [FN2] Pet. App. 4a. But MedImmune subsequently agreed to pay royalties (albeit "under protest"), because, as its General Counsel later testified, MedImmune wanted to retain the benefits of the license - and not be subject to an infringement suit - if its challenge to the patent failed. C.A.A. 314, 3291-92. MedImmune later requested and entered into seven separate agreements to license the '415 patent for products in development. Pet. App. 28a.

> FN2. The relevant Genentech-MedImmune license granted rights conditionally: if a particular MedImmune product was a "licensed product" (meaning it infringed at least one valid claim of a Genentech patent), MedImmune could secure a license for that product by paying specified royalties. C.A.A. 3584. (Citations to "C.A.A." are to the joint appendix filed in the Court of Appeals.) MedImmune thus could have disputed that Synagis(R) was a "licensed product" under the existing license agreement.

Shortly after securing the last of these license agreements, MedImmune filed this

declaratory judgment action to invalidate the '415 patent and for a judgment that Synagis(R) did not infringe the '415 patent. Pet. App. 4a. At all times relevant to this case, however, MedImmune ***3** remained a licensee in good standing and made clear its intent not to breach the Synagis(R) license agreement. C.A.A. 314. It thus retained all benefits of the license, including protection from all of the remedies at law or in equity for patent infringement, such as an injunction, treble damages, and a court-determined, non-contractual royalty rate. Under such circumstances, Genentech could not sue MedImmune for patent infringement, and could not cancel the license agreement.

B. The District Court and Federal Circuit Decisions

While this case was pending in the District Court, the Federal Circuit issued its decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *cert. dismissed*, 125 S. Ct. 351 (2004), holding that as a general rule a patent licensee in good standing does not have the "reasonable apprehension of a lawsuit" that, under longstanding law, is necessary to maintain a declaratory judgment action. MedImmune acknowledged that it had no reasonable apprehension of suit. Pet. App. 4a. The District Court, by order entered April 27, 2004, dismissed MedImmune's declaratory judgment action for lack of subject matter jurisdiction. Pet. App. 21a-31a.

In the Court of Appeals, MedImmune nominally tried to distinguish *Gen-Probe*. Pet. App. 5a. But MedImmune primarily argued that, although it is "free of apprehension of suit" (Pet. App. 4a), patent licensees have the absolute right under this Court's decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), to bring declaratory judgment actions challenge the validity of licensed patents (Pet. App. 4a-5a). The Federal Circuit disagreed, concluding that the facts of this case do not present "a 'definite and concrete controversy' of 'sufficient immediacy and reality' to warrant judicial intervention." Pet. App. 8a (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937), and ***4***Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (internal citations omitted).

The Federal Circuit explained that in *Lear* this Court eliminated the doctrine of "licensee estoppel," a substantive rule of patent law, and did not consider declaratory judgment standards at all: "In *Lear* the licensee stopped paying royalties and the patentee sued for royalties; there was clearly a justiciable controversy, and that aspect was not an issue in *Lear*." Pet. App. 5a. In contrast, "the issue here is not one of estoppel, but of availability of the declaratory judgment procedure." Pet. App. 6a. The court explained that because in this case "there is no defaulting licensee and no possibility of suit," the fundamental requirements of Article III are not satisfied. Pet. App. 6a. The Federal Circuit grounded its analysis in this Court's precedents concerning when a controversy is sufficiently ripe and concrete to support a declaratory judgment action. Pet. App. 8a (citing *Aetna*, 300 U.S. at 241; *Md. Cas. Co.*, 312 U.S. at 273; *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96(1993)).

The Federal Circuit next addressed MedImmune's argument, recycled here, that "cases from other circuits hold that a licensee need not terminate its license in order to acquire declaratory standing." Pet. App. 7a. The court explained that "in

each of the cited cases there was an additional factor, such as money owed on the contract, or the plaintiff or its indemnitee had been threatened with suit, or there was a change in circumstances which affected performance of the contract, meeting the constitutional and statutory requirements that there must be an actual controversy in order to invoke judicial authority." Pet. App. 7a. Thus, there was no conflict with other circuits.

Last, the Federal Circuit rejected MedImmune's policy arguments, in particular the notion that the public interest in challenging potentially invalid patents required giving licensees a one-sided option to litigate licensed patents. The *5 court stressed two points. First, patent-specific issues could "not create a policy-driven exception" to the constitutional and statutory requirements of an actual controversy. Pet. App. 7a. Second, it would be inequitable for the patent owner, "having contracted away its right to sue," to be under a "continuing risk of attack on the patent whenever the licensee chooses - for example if the product achieves commercial success - while the licensee can preserve its license and royalty rate if the attack fails." Pet. App. 7a. A one-sided option to sue at will, the court reasoned, "distorts the equalizing principles that underlie the Declaratory Judgment Act." Pet. App. 7a.

C. The Pending Reexamination of the '415 Patent

After the District Court dismissed MedImmune's federal lawsuit challenging the '415 patent, a law firm on behalf of an unidentified client filed with the PTO a request for *ex parte* reexamination of the validity of the '415 patent. The PTO granted the request in July 2005, and on September 13, 2005, the PTO issued an Office Action rejecting the claims of the '415 patent for "obviousness-type double patenting." Genentech filed its response to the Office Action on November 25, 2005, and is awaiting further action by the PTO.

REASONS FOR DENYING THE WRIT

The petition should be denied for three reasons. First, the Federal Circuit's decision is consistent with the declaratory judgment jurisprudence of this Court and the courts of appeals. The Declaratory Judgment Act permits persons who anticipate an inevitable lawsuit to come to court first, before damages accrue, for a declaration that they are not liable to the feared opponent. It is nevertheless black letter law that a declaratory judgment action, no less than any other suit, must present a live case or controversy and not seek a merely advisory decree. In enforcing this *6 requirement, the Federal Circuit and the other courts of appeals ask, among other things, whether a declaratory judgment plaintiff has a "reasonable apprehension" that it will be sued by the declaratory judgment defendant. If not, there is no actionable controversy. Because MedImmune admitted it had no apprehension of suit, and could cite no other case-specific circumstances establishing a live controversy between the parties, the Federal Circuit ruled there was no case or controversy here.

That analysis is an unremarkable application of settled law. MedImmune claims, however, that because it is a *patent licensee*, it has special rights under decisions of this Court to challenge licensed patents at any time of its choosing - even if, under ordinary standards, there is no Article III controversy. It

claims patent licensees *may* seek advisory decrees regarding what *would* happen *if* they abandoned the protections of their licenses *and* were sued for infringement. There is no support for that proposition in this Court's Article III cases, nor in *Lear*. Nor is this question close enough to merit review.

No declaratory judgment case of this Court has featured a plaintiff immune from suit, as MedImmune is here by virtue of its license to the '415 patent. Hence, none of the Federal Circuit's rulings could be in any direct conflict with this Court's cases. Since *Ashwander v. Tennessee Valley Authority*, 297 U.S. 288 (1936), moreover, this Court consistently has held that federal courts do not have jurisdiction to issue merely advisory opinions under the Declaratory Judgment Act. All of this Court's cases have involved a "definite and concrete controversy" (*Aetna*, 300 U.S. at 240) of "sufficient immediacy and reality" (*Md. Cas. Co.*, 312 U.S. at 273) to warrant judicial intervention.

As for the circuit cases cited in the petition, they typically involved some "additional factor" beyond the mere existence of a license or contract between the parties that demonstrated the existence of a live controversy. Pet. App. ***7** 7a. Variations in the outcomes of these cases reflect the factbound application of settled law to different circumstances, not any disagreement over the governing legal principles.

Second, the Federal Circuit's decision does not conflict with *Lear*. *Lear* was not a declaratory judgment action; it was a royalty collection action that presented a justiciable controversy. Accordingly, *Lear* neither holds nor says anything about when a declaratory judgment action is appropriate. *Lear* instead eliminated the substantive patent law "licensee estoppel" doctrine that prevented licensees from ever disputing the validity of a patent - even if the licensee had ceased paying royalties and had already been sued by the licensor. Nothing about *Lear* requires the extraordinary further leap urged by MedImmune: that licensees must *always* be free to challenge the validity of patents irrespective of the "actual controversy" requirement of the Declaratory Judgment Act and Article III.

Third, MedImmune's policy arguments do not, and could not, justify making an exception to bedrock Article III principles for patent licensees. The "case or controversy" requirement is a limitation on the constitutional jurisdiction of the federal courts, which cannot be exceeded no matter the asserted justification. Regardless, neither the integrity of the patent system nor the progress of medical science depends on allowing licensees in good standing to challenge the validity of licensed patents. So-called "weak" patents can be challenged in a variety of ways and settings, including through the administrative "reexamination" process by which the PTO is presently reviewing the very patent at issue in this case. The "need" to create a heretofore unknown exception to the case or controversy requirement is not nearly as great as MedImmune claims.

MedImmune identifies no genuine conflict and offers no persuasive justification for the expansion of settled precedent that it seeks. The petition should be denied.

A claim under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), must present "a

concrete case admitting of immediate and definitive determination of the legal rights of the parties in an adversary proceeding." *Aetna*, 300 U.S. at 241. To determine whether a declaratory judgment case is sufficiently concrete, courts adjudicating patent cases have long applied the "reasonable apprehension of suit" test, which inquires whether a declaratory judgment plaintiff faces a threat of suit from the patent owner. *See Japan Gas Lighter Ass'n v. Ronson Corp.*, 257 F. Supp. 219, 237 (D.N.J. 1966) (first formulating test). The Federal Circuit has applied that test for decades in cases where the plaintiff seeks a declaration that a competitor's patent is invalid, or not infringed. [FN3] The "reasonable apprehension" test also has been employed by every circuit and in many analogous circumstances, including copyright, trademark, trade secrets, "right of publicity," unfair trade practices, unfair labor practices, and breach of contract cases. [FN4]

FN3. *See Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1398-99 (Fed. Cir. 1984) (explaining that the defendant "must have engaged in conduct that created on the part of the declaratory plaintiff a reasonable apprehension that it will face an infringement suit if it commences or continues the activity in question"); *see also Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1334 (Fed. Cir.) (holding that the declaratory judgment plaintiff was "unable to demonstrate a reasonable apprehension of imminent suit on the part of [the declaratory judgment defendant] for [patent] infringement"), *cert. denied*, 126 S. Ct. 473 (2005).

FN4. *See, e.g., Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001) ("The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit."); *Starter Corp. v. Converse, Inc.*, 84 F.3d 592 (2d Cir. 1996) (applying Federal Circuit's "reasonable apprehension" test to trademark case); *Interdynamics, Inc. v. Wolf*, 698 F.2d 157, 166 (3d Cir. 1982) (applying the legal principles set forth the Seventh Circuit in *International Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210-11 (7th Cir. 1980), and noting that the standard "provides what is perhaps the most comprehensive formulation of the test that a court should apply in determining whether [the court has jurisdiction] to grant declaratory relief in a patent case"); *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581,593-94 (4th Cir. 2004) (holding that declaratory judgment jurisdiction existed because plaintiff "possessed a reasonable apprehension of a multiplicity of litigation and of liability for ongoing damages"); *Texas v. West Publ'g Co.*, 882 F.2d 171, 175 (5th Cir. 1989) (applying Federal Circuit's "basic declaratory judgment principles [that] are well settled" to copyright case); *Robin Prods. Co. v. Tomocek*, 465 F.2d 1193, 1196 (6th Cir. 1972) (phrasing the test as whether a "reasonable man" would regard the threatened action as a "charge of infringement"); *Int'l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210-11 (7th Cir. 1980) (referenced above); *Crown Drug Co. v. Revlon, Inc.*, 703 F.2d 240, 243 (7th Cir. 1983) (applying reasonable apprehension test to dismiss plaintiff's action for a declaration that it was not liable for unfair trade practices); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 728-29 (8th Cir. 1975) (holding that a combination of factors gave rise to reasonable apprehension

of infringement litigation); *Nat'l Basketball Ass'n v. SDC Basketball Club, Inc.*, 815 F.2d 562, 566 (9th Cir. 1987) (applying the reasonable apprehension test to a contract dispute between NBA and a franchisee); *Cardtoons, L.C. v. Major League Baseball Players Ass'n*, 95 F.3d 959, 965-66 (10th Cir. 1996) (applying reasonable apprehension of litigation test to "right of publicity" case and citing with approval several Federal Circuit declaratory judgment jurisdiction cases); *GTE Directories Publ'g Corp. v. Trimen Am.*, 67 F.3d 1563, 1569 (11th Cir. 1995) (applying reasonable apprehension of suit test); *United Christian Scientists v. Christian Sci. Bd. of Dir.*, 829 F.2d 1152, 1159 (D.C. Cir. 1987) (applying reasonable apprehension of litigation test copyright dispute and citing with approval the application of the test in the Federal Circuit and other circuits); *Fed. Express Corp. v. Air Line Pilots Ass'n*, 67 F.3d 961,964-65 (D.C. Cir. 1995) (applying the test determine whether the court could rule on an assertion of unfair labor practices).

***9** A straightforward application of the reasonable apprehension rule to the facts of this case leads to the conclusion that no case or controversy exists. MedImmune ***10** admitted that it runs *no* risk of suit and that it intends to remain a licensee in good standing precisely to avoid the risk of suit. Pet. App. 4a. Thus, MedImmune has no apprehension of suit whatsoever, reasonable or otherwise. Nor can MedImmune point to any unique facts here that establish a justiciable controversy notwithstanding the immunity from suit it enjoys as a licensee. Notably, MedImmune does not in its petition ask this Court to review or reject the "reasonable apprehension of suit" test. It seeks instead a patent licensee exception to that test - and to Article III itself.

MedImmune argues that there is a justiciable controversy because it *would* have a reasonable apprehension of suit/f it stopped paying license royalties. Pet. App. 5a. MedImmune thus seeks to base Article III jurisdiction on an entirely hypothetical controversy, while it continues to pay royalties precisely to ensure that no *actual* controversy can arise. That is not sufficient. This Court long ago declared that federal courts have no jurisdiction to issue "an opinion advising what the law would be upon a hypothetical set of facts." *Aetna*, 300 U.S. at 241.

Courts of appeals hold the same. In *Hendrix v. Poonai*, 662 F.2d 719 (11th Cir. 1981), for example, the Eleventh Circuit, in denying declaratory judgment jurisdiction, explained that Article III courts are not empowered to advise litigants regarding such strategic business decisions:

> Persons occupying positions of responsibility, like the appellants, often must make difficult decisions that can have adverse consequences for others. The possibility of being sued by those adversely affected is an inherent risk faced by the decisionmakers. Needless to say, the decisionmakers would benefit greatly by having guidance as to the potential legal ramifications of their decisions. Furnishing ***11** such guidance prior to the making of the decision, however, is the role of counsel, not of the courts.

Id. at 722.

In *Crowley Cutlery Co. v. United States*, 849 F.2d 273 (7th Cir. 1988), Judge Posner made the same point, explaining that

intentions alone do not make a case or controversy in the constitutional sense. You cannot go to a federal court for advice on the legality of a proposed course of action. You must be a party to an existing legal dispute. This is true whether you are seeking a declaratory judgment or any other form of relief; the declaratory-judgment statute cannot amend Article III.

Id. at 276. [FN5] MedImmune's claim does not meet the basic legal requirements for establishing a case or controversy.

> FN5. *See also, e.g., Harris Trust &Sav. Bank v. E-II Holdings, Inc.*, 926 F.2d 636, 640 n.14 (7th Cir. 1991) (explaining that the Declaratory Judgment Act "was never intended as a device for relegating to the courts responsibilities reposed initially in private parties" (internal quotation marks and citation omitted)); *Brown & Root, Inc. v. Big Rock Corp.*, 383 F.2d 662, 666 (5th Cir. 1967) ("However desirable such a decision be to the parties, and however much the Court may sympathize with their desires, it is fundamental that the question of Federal jurisdiction is always present and if there be no jurisdiction the courts must decline to act.").

Furthermore, MedImmune argues for a rule that would be unprecedented in the annals of declaratory relief law: that patent licensees should have the *unilateral* right to declare a justiciable controversy and sue the patent owner even though the license bars any infringement suit by the patent owner against the licensee. It is well established that a patent-***12** holder who has licensed its patents has given up its right to file suit against the licensee for infringement of those patents. *See Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed. Cir. 1987) ("A "patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee."). Thus MedImmune proposes a one-sided rule that would destroy the *mutuality* of access to the courts that is the very reason for the existence of the Declaratory Judgment Act.

As the Federal Circuit has observed,

> The purpose of the [Declaratory Judgment] Act is to enable a person who is reasonably at legal risk because of an unresolved dispute, to obtain judicial resolution of that dispute without having to await the commencement of legal action by the other side. It accommodates the practical situation wherein the interests of one side to the dispute may be served by delay in taking legal action.

BP Chem. Ltd. v. Union Carbide Corp., 4 F.3d 975, 977 (Fed. Cir. 1993); *see also EMC Corp. v. Norand Corp.*, 89 F.3d 807, 814-15 (Fed. Cir. 1996). The Declaratory Judgment Act equalizes the parties' positions by giving both sides access to the courts under the same standards. If one party has a cause of action, the other party can sue as well and "clear the air." *EMC Corp.*, 89 F.3d at 815 (internal quotation marks and citation omitted). The contrary regime MedImmune urges, with unilateral rights of suit for patent licensees only, has no support in the law.

A. The Federal Circuit's Decision Does Not Conflict With This Court's Declaratory Judgment Jurisprudence.

The Federal Circuit's determination that there is no justiciable controversy

under the facts of this case is consistent with this Court's declaratory judgment jurisprudence. In each case in which this Court has found a declaratory relief action proper, the declaratory judgment plaintiff faced a very real and often imminent threat of litigation, or other facts established the existence of a ripe controversy. None involved a declaratory judgment plaintiff, like the one in this case, who had no present controversy and who was *immune* from suit.

Aetna, for example, involved a declaratory judgment suit by an insurer against an insured *who had stopped paying premiums* on the ground that his disability relieved him of the obligation to make such payments. *Aetna*, 300 U.S. at 242. The Court held this cessation of premium payments created an immediate controversy. The insurer's position that the insured had wrongfully breached the policy required immediate resolution to determine whether the insurer needed to maintain financial reserves for the policy. *Id.* at 239, 242. This Court also emphasized that the insured had the right to sue at any time to demand payment of the policy's cash value. *Id.* at 243-44.

Nor is there any conflict with *Altvater v. Freeman*, 319 U.S. 359 (1943). In *Altvater*, there was a "raging" dispute between the parties, reflected in a history of multiple claims and counterclaims. *Id.* at 361-62, 364. This Court held that where the counterclaimant was paying royalties "under compulsion of an injunction decree" from a prior case, the ***14** royalty payments did not defeat justiciability. *Id.* at 365-66. The Court stressed that "the involuntary or coercive nature of the exaction" - *i.e.*, the injunction, which gave the counterclaimant no option but to pay the royalties - "*preserve[d] the right ... to challenge the legality of the claim.*" *Id.* at 365 (emphasis added). In other words, *Altvater* found justiciability notwithstanding royalty payments only because the licensee did not have the option of stopping payment. Here, by contrast, MedImmune *chose* to pay royalties; it could have ceased paying royalties at any time to challenge the patent.

Similarly, MedImmune's suggestion that under this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), a plaintiff can invoke Declaratory Judgment Act jurisdiction " '[m]erely ... to avoid the threat of a 'scarecrow' patent' " is just wrong. Pet. at 10 (quoting *Cardinal Chem.*, 508 U.S. at 96). *Cardinal Chemical* involved a ripe dispute worthy of adjudication because in that case a patentee sued the defendant for infringement and the defendant asserted a declaratory judgment *counterclaim*. *Cardinal Chem.*, 508 U.S. at 95-96. Because there was plainly a live controversy between the parties, *Cardinal Chemical* does not inform the analysis here. [FN6] Indeed, subsequent decisions recognize that *Cardinal Chemical* did not alter well settled justiciability analysis in patent cases. *See, e.g., Super Sack Mfg. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995) (rejecting notion that *Cardinal Chemical* "cut[s] [the] two-step justiciability analysis off at the pass" and concluding that the decision ***15** "does not revolutionize the justiciability of declaratory judgment actions attacking a patent's validity").

FN6. *Bresnick v. U.S. Vitamin Corp.*, 139 F.2d 239 (2d Cir. 1943), which MedImmune cites for Judge Hand's reference to a "scarecrow" patent (Pet. at 10), is equally inapplicable because that case similarly involved an infringement suit by a patentee and did not address jurisdictional issues.

The Federal Circuit's application of the "reasonable apprehension" test in licensee cases like this one also does not present an overly broad and inflexible "absolute requirement" at odds with this Court's direction that Declaratory Judgment Act jurisdiction requires consideration of "all the circumstances." Pet. at 11 (citing *Md. Cas. Co.*, 312 U.S. at 273). The Federal Circuit merely recognized that a license, the essence of which is a covenant not to sue on the licensed patents, is in most instances inconsistent with a reasonable apprehension of litigation. *See Ortho Pharm. Corp. v. Genetics Inst.*, 52 F.3d 1026, 1031 (Fed. Cir. 1995) (a patent license is "a covenant by the patentee not to sue the licensee"). The Federal Circuit's observation reflects its understanding of the critical "circumstance" in this case: a covenant not to sue. Such a covenant typically *should* be dispositive. However, if a licensee can show what MedImmune could not - facts and circumstances demonstrating a reasonable apprehension of suit - declaratory judgment jurisprudence will not stand in its way. The Federal Circuit explicitly retained the "totality-of-the-circumstances test" (Pet. App. 7a-8a), preserving the flexibility needed to deal with unusual facts not present in this case. [FN7] To be sure, the Federal Circuit's decisions in *Gen-Probe* and subsequent cases, including this case, have drawn attention to the inherent tension between obtaining a patent license and then later claiming to have a reasonable ***16** fear of suit. [FN8] But the point itself is unassailable, and undeserving of this Court's review.

> FN7. One can imagine, for example, a live dispute over a patent arising just before a license expired, but where the patent term still had some years to run. If the patent-holder threatened suit unless the licensee agreed to an extension, there very well could be an actionable controversy. *See, e.g., Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990). Of course, a live dispute might also exist where the licensee withheld royalty payments, or violated some other express contractual provision.
>
> FN8. Cases applying *Gen-Probe* include *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3336 (U.S. Nov. 22, 2005) (No. 05-656), which concerns same MedImmune practice at issue here.

Here, the Federal Circuit correctly refused to hold that the desire to be released from the obligations of a license, without more, is enough to create a cognizable case or controversy between the parties. There is no conflict between the Federal Circuit's decision and this Court's precedent.

B. The Federal Circuit's Decision Does Not Conflict With Circuit Court Precedent.

MedImmune cites an array of circuit court decisions, some involving licenses but others not, that it argues conflict with the decision below. None of MedImmune's cases rejects or even questions the reasonable apprehension of suit test applied in this case. Thus, none of the cases presents a conflict in legal standards. Of course, there are differing *outcomes*, but that will always be the case when a totality-of-the-circumstances test is applied to different facts. However, there is no disagreement among the circuits concerning the fundamental principle that

Declaratory Judgment Act jurisdiction exists only if the plaintiff can show a "reasonable apprehension of suit" by the defendant.

1. Non-License Cases

MedImmune's non-license cases merit little attention. Precisely because they do not involve licenses, these cases do not consider the key question of how a *covenant not to sue* affects justiciability. The Federal Circuit's reasoning in this case turns on the nature of a license, and is inherently ***17** confined to licenses - or, if one prefers, covenants not to sue generally. [FN9] Cases without this feature offer little value.

> FN9. MedImmune is therefore wrong when it claims that "[t]here is no way to confine [the Federal Circuit's] reasoning to a single subset of contracts, patent licenses." Pet. at 11. There is no reason whatsoever to think that courts are unable to distinguish between the effects of an uncontested covenant not to sue and other, ordinary kinds of contracts when determining justiciability.

MedImmune mistakenly relies on such cases to contest the proposition "that there must be a material breach of the license contract in order to present a constitutional case or controversy." Pet. at 14-15. There are two problems with MedImmune's position. First, because those cases do not involve licenses, they could not possibly address that point. Second, the Federal Circuit did *not* hold that *all* licensees must breach to establish jurisdiction. Rather, the court held that a licensee, like every other declaratory judgment plaintiff, must identify *some* "actual controversy." In MedImmune's cited cases, in contrast to this case, the parties were committed to, or in some cases forced into, courses of conduct that made a breach by one party highly likely. *See, e.g., Keener Oil & Gas Co. v. Consol. Gas Util. Corp.*, 190 F.2d 985, 988-90 (10th Cir. 1951) (the declaratory judgment plaintiff, a gas utility company, had no choice but to switch gas suppliers and the defendant, a pipeline operator, disputed its ability to do so); *Am. Mach. & Metals, Inc. v. De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948) (actual controversy present where plaintiff expressed that it "desires and intends" to terminate the contract and continue manufacturing allegedly infringing products, and defendant "has led plaintiff to believe that upon termination of the contract defendant will sue plaintiff if it does not cease manufacture and sale" of the products (internal quotation marks and citation omitted)); *Venator Group Specialty, Inc. v. Matthew/Muniot Family, LLC*, 322 F.3d 835, 840-41 (5th Cir. 2003) (conflict over the validity of a lease provision that ***18** required property to be restored to pre-lease condition at end of lease was "very likely" because "the lease term *will* end" and adjoining property would be rendered unmarketable were plaintiff's position sustained). Cases concerning "very likely" breaches are simply not helpful. [FN10]

> FN10. MedImmune's reliance on the remaining non-license cases is equally puzzling. In each case, there was either a change in circumstances, or one of the parties had created an actual prospect of litigation or breach of contract. *See, e.g., NUCOR Corp. v. Aceros y Maquilas de Occidente, S.A. de C.V.*, 28 F.3d 572, 575, 578 (7th Cir. 1994) (declaratory judgment defendant

"demanded payment of $685,000 in damages within 60 days" and had "clearly threatened suit"). None of those factors is present here.

2. License Cases

Most of the pre-Federal Circuit patent cases MedImmune cites are distinguishable because an "actual controversy" was apparent. In *Precision Shooting Equipment Co. v. Allen,* 646 F.2d 313 (7th Cir. 1981), the licensee tendered its license payments to the court rather than to the licensor. *Id.* at 314, 318. The licensee thus was not in "good standing," and the parties had a sufficient conflict to create a justiciable controversy. *See id.* at 318 ("if not for the injunction it is obvious [the declaratory judgment defendant] would seek to terminate the license because it does not have possession of the escrowed royalties"). In *Societe de Conditionnement v. Hunter Engineering Co.*, 655 F.2d 938 (9th Cir. 1981), the plaintiff was not a licensee, was not immunized by a contractual covenant not to sue, and therefore could demonstrate a real and concrete fear of suit if it continued to manufacture the allegedly infringing product. *Id.* at 944-45. In *American Sterilizer Co. v. Sybron Corp.*, 526 F.2d 542 (3d Cir. 1975), the licensee had refused to pay ***19** royalties on the grounds that its product did not infringe the patent. [FN11] *Id.* at 544.

FN11. Furthermore, like several of the cases MedImmune cites, *American Sterilizer* does not even discuss this jurisdiction issue and therefore cannot be cited for the proposition that jurisdiction was present. *See, e.g., Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 91 (1998) ("drive by" jurisdictional rulings are entitled to no precedential weight).

Similarly distinguishable are the non-patent license cases MedImmune cites. Pet. at 14. These cases each involved additional facts that, under the totality of the circumstances, supported a reasonable apprehension of suit on the part of the declaratory judgment plaintiff. In *National Car Rental System, Inc. v. Computer Associates International, Inc.*, 991 F.2d 426 (8th Cir. 1993), for example, the copyright licensee sued under the Declaratory Judgment Act after the licensor had threatened to sue for allegedly breaching the scope of the license, *Id.* at 428. In *S.O.S., Inc. v. Payday, Inc.*, 886 F.2d 1081 (9th Cir. 1989), the licensee raised a declaratory judgment *counterclaim* after the licensor had sued the licensee for copyright infringement alleging a breach of the license. *Id.* at 1084-85. In *Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990), the copyright licensee had explicitly threatened to continue using the copyrighted material after expiration of the license, which was imminent. *Id.* at 1556. The Ninth Circuit applied the "reasonable apprehension" test and concluded that under the totality of the circumstances there was a sufficient present controversy to support jurisdiction. *Id.* at 1555-56.

The only case MedImmune cites that could arguably be read as disagreeing with the Federal Circuit's decision is the 1977 decision of the Second Circuit in *Warner-Jenkinson Co. v. Allied Chemical Corp.*, 567 F.2d 184 (2d Cir. 1977). It is questionable whether *Warner-Jenkinson* is followed on this issue even in the Second Circuit, which routinely applies ***20** the "reasonable apprehension of suit" test. *See, e.g., Starter Corp. v. Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996)

(declaratory judgment plaintiff must have a "real and reasonable apprehension of litigation" and "must have engaged in a course of conduct which brought it into adversarial conflict with the declaratory defendant"); *Matthew Bender & Co. v. West Publ'g Co.*, 240 F.3d 116, 119 (2d Cir. 2001) (discussing the district court's appropriate application of the reasonable apprehension test for determining declaratory judgment jurisdiction in a copyright case). In *Atlantic Richfield Co. v. Alcan Aluminum Holdings Ltd.*, 12 F. Supp. 2d 460 (S.D.N.Y. 1998), for example, district court applying Second Circuit law concluded that a declaratory judgment case was not justiciable because the plaintiff only sought a declaration to assure the availability of breaching a contract as an option "if economic analysis shows that it would be the most profitable course." *Id.* at 460-61. Such relief, of course, is precisely what MedImmune seeks here - a declaration that *if* it chose to breach its license it would have a valid defense to any subsequent infringement lawsuit Genentech *might* bring.

The crux of MedImmune's argument is its flawed construction of *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). Yet the petition does not allege any actual conflict with *Lear*, and with good reason. *Lear* had nothing to do with the case or controversy requirement under Article III and the Declaratory Judgment Act, and it arose in a context in which a justiciable controversy was clearly present. *Lear* addressed whether a licensee, *sued by its licensor* for non-payment of royalties, could defend the suit by attacking the patent's validity. *Id.* at 660, 670-71. Prior cases had held that licensees were estopped, as a matter of substantive law, from denying the validity of the patent in any litigation context. ***21** *Id.* at 663-64. *Lear* eliminated that "licensee estoppel" doctrine and leveled the playing field between licensors and licensees by permitting a licensee *who had stopped paying royalties* to defend a suit by the licensor for non-payment on the grounds that the licensed patent was invalid.

Lear thus stands for a point of substantive patent law: licensing a patent does not concede its validity and forever bar the licensee from attacking the patent's validity. It is an important point, but it has nothing to do with Article III jurisdiction. As the Federal Circuit pointed out over twenty years ago, "*Lear* ... left unresolved the question when a federal court has jurisdiction of a licensee's claim of patent invalidity." *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 878 (Fed. Cir. 1983).

MedImmune nevertheless claims that the decision below "adopted a policy at odds with the policy of the patent laws as declared by this Court" in *Lear*. Pet. at 19. It did no such thing. The Federal Circuit's decision in this case conflicts with *Lear* only if one reads *Lear*'s general observations about the public interest in challenging weak or invalid patents to *require* giving licensees unfettered rights to commence litigation at any time, irrespective of whether there is an Article III controversy. Nothing remotely like that is found in the Court's decision. Indeed, a key principle for the *Lear* Court was balance between the rights of the licensor and licensee. The "licensee estoppel" doctrine plainly favored licensors by forever estopping licensees from challenging the validity of a patent - even if they ceased paying royalties under the license. This Court sought to "balance the claims of promisor and promisee in accord with the requirements of good faith." *Lear*, 395 U.S. at 670. Thus, if the licensor sued under the license, it was only

fair that the licensee could assert all relevant defenses, including invalidity.

MedImmune's theory would upset that balance by skewing it overwhelmingly in favor of licensees. Under ***22** MedImmune's view, a licensee can negotiate a patent license on the best available economic terms - terms that cap the licensee's risk and inherently reflect any existing uncertainty about the patent's validity [FN12] - and then, the next day, sue to invalidate the same patent. The licensor has no parallel fight, for as long as the licensee continues to pay royalties, the licensee could bind the licensor's hands and prevent it from terminating the license. This would not "balance the claims of promisor and promisee in accord with the requirements of good faith," *Lear*, 395 U.S. at 670; it would give licensees an undeserved second bite at the apple with everything to gain and nothing to lose. Neither *Lear* nor any other holding of this Court supports such a disproportionate imposition of risk upon the patent-holder.

> FN12. It is widely recognized that patent licenses implicitly take into account the licensing parties' views as to the validity of the patents, whether they are infringed, and whether there are work-arounds. *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 392 (2003) ("Virtually every patent license can be viewed as settlement of a patent dispute: the royalty rate presumably reflects the two parties' strengths or weaknesses in patent litigation in conjunction with the licensee's ability to invent around the patent.").

It is, in any event, impossible for the Congress or a decision of this Court to have created a policy-based exception to Article III's "case or controversy" requirement. That is a fundamental limitation on the constitutional power of the federal courts, designed to protect the separation of powers and the integrity of the judicial role. Congress could not, for any policy reason, authorize the federal courts to hear a hypothetical controversy. This Court has never created a policy-based exception to the case or controversy requirement. And if this were to be the first such instance, there would be no way to confine the exception MedImmune seeks just to patent cases. The message to the legal community would be that with a good enough policy argument one indeed may, as Judge Posner put it in *Crowley* ***23** *Cutlery*, come to federal court simply "for advice on the legality of a proposed course of action." *Crowley Cutlery*, 849 F.2d at 276. Neither policy arguments generally nor anything found in *Lear* can justify such a radical change in settled Article III jurisprudence.

MedImmune closes its petition with the doomsday prediction that, unless patent licensees are allowed to file suit for what would effectively be advisory opinions, the pace of innovation in "new medical drugs and treatments" will be inhibited. Pet. at 19. This policy argument is irrelevant for the reasons just discussed. In addition, it is wholly lacking in substance.

MedImmune's assertion that the public can only be protected from invalid patents by allowing licensees in good standing to sue their licensors (or allowing non-licensees who have never been threatened with suit by a patentee to sue, for that matter) - is wrong. There are at least three different ways the validity of a patent may be tested (and through one of these procedures the '415 patent is

currently under review). First, a licensee such as MedImmune may refuse to pay or cease paying royalties and, as in *Lear*, induce an infringement suit. Second, anyone who is not licensed and is threatened with suit may challenge the patent under the Declaratory Judgment Act. Third, any member of the public, even a patent licensee in good standing, may seek reexamination of a patent by the PTO at any time. [FN13] In fact, ***24** the '415 patent currently is being reexamined. Indeed, this ongoing PTO reexamination has the potential to moot the issues that MedImmune is asking to litigate, which is a further reason to deny review.

> FN13. The federal patent statutes permit anyone to ask the PTO to reconsider the validity of an issued patent based on prior art. 35 U.S.C. §§ 302, 311(b) ; *see also id.* § 301. The patent statutes provide for two different types of reexamination. For patents issuing from an application filed on or after November 29, 1999, the requesting party may request either an *inter partes* or an *ex parte* reexamination. *See id.* § 311; 37 C.F.R. § 1.913. If the PTO grants an *inter partes* reexamination request, the third party requesting reexamination retains the ability to remain substantively involved throughout the reexamination process. The requesting party may continue to make arguments about validity throughout the reexamination process, and may appeal any outcome in favor of validity to the Board of Patent Appeals and Interferences and then to the Federal Circuit. *See* 35 U.S.C. §§ 306, 314(b), 315. If the PTO grants an *ex parte* reexamination request, the requesting party is not substantively involved in the reexamination process. *Ex parte* reexamination has been a part of the patent statute since 1980. For the '415 patent, the PTO has granted an *ex parte* request for reexamination, and the proceeding is currently ongoing.

Given the various options for challenging the validity of patents, the courts need not, under the guise of protecting the public, disregard the constitutional requirement of an actual controversy and allow licensees who are immune from suit to challenge the validity of licensed patents in court. The patent system is more robust than that, as the facts of this case prove.

MedImmune's proposed rule would also make it difficult, if not impossible, for parties to a licensing negotiation to allocate risk. The agreed royalty rate in a license agreement reflects the perceived strength of the patent (among other factors). But if the licensor has protection from an invalidity attack as soon as the license is signed, risk cannot be allocated. It makes no sense to think that impairing contractual certainty in this manner will promote innovation. The opposite is more likely correct.

MedImmune also asserts that it was the victim of an "all too common" package licensing strategy in which a ***25** putatively "bad" patent (the '415 patent) was licensed as part of a "bundle" with other patents. Pet. at 19-20. That argument is wrong. MedImmune, "for reasons of convenience," expressly elected not to license the '415 patent alone. C.A.A. 3585. Moreover, MedImmune has no products covered by the '567 patent it licensed along with the '415 patent, and thus could not fear losing license rights to the ' 567 patent by challenging the '415 patent. *See* C.A.A. 3312, 3316-17. At any rate, the answer to this supposed issue lies in the parties' license negotiations, not a wholesale revision of Article III

jurisprudence. A licensee may negotiate for the right to challenge one licensed patent without risking a breach of other patent license rights. *See, e.g., Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368-69 (Fed. Cir. 2004) (patent licensee stopped paying royalties on one licensed product; all parties agreed the license agreement was still in effect as to other licensed product), *cert. granted on other grounds*, 126 S. Ct. 601 (2005). This solution is at least as "common" MedImmune contends bundling is (Pet. at 19), and does not require this Court to change Article III doctrine to address MedImmune's policy concerns.

CONCLUSION

Sound policy does not justify limitless encouragement of no-risk, roll-the-dice lawsuits seeking to invalidate licensed patents. The Federal Circuit's unexceptional application of the case or controversy requirement correctly strikes the right balance: allow licensees, like any other litigant, to seek declaratory relief when they have a reasonable apprehension of suit; but forbid licensees, like any other litigant, from seeking declaratory relief when they lack such apprehension.

The petition for a writ of certiorari should be denied.

MedImmune, Inc. v. Genentech, Inc.
2005 WL 3560572

Briefs and Other Related Documents (Back to top)

- 2006 WL 110458 (Appellate Petition, Motion and Filing) Reply to Brief in Opposition (Jan. 12, 2006)Original Image of this Document (PDF)

- 05-608 (Docket) (Nov. 15, 2005)

- 2005 WL 3067195 (Appellate Petition, Motion and Filing) Petition for a Writ of Certiorari (Nov. 10, 2005)

END OF DOCUMENT

JAN 12 2006

No. 05-608

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

GENENTECH, INC., *et al.*,
Respondents.

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

REPLY TO BRIEF IN OPPOSITION

JOHN G. KESTER
PAUL B. GAFFNEY
AARON P. MAURER

WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000

HARVEY KURZWEIL *
ALDO A. BADINI
HENRY J. RICARDO

DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

* Counsel of Record

Attorneys for Petitioner

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

BLANK PAGE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES

IN THE

Supreme Court of the United States

No. 05-608

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., *et al.*,

Respondents.

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

REPLY TO BRIEF IN OPPOSITION

The Federal Circuit after *Gen-Probe*[1] now requires that patent licensees commit a material breach of contract before they can sue under the Declaratory Judgment Act, 28 U.S.C. § 2201, to challenge validity, enforceability, or infringement. Unless material breach has occurred, the Federal Circuit now banishes

[1] *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004). *Gen-Probe* and the decisions following it contradict prior Federal Circuit law. See *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874, 882 (Fed. Cir. 1983) ("we hold that a patent licensee may bring a federal declaratory judgment action . . . without prior termination of the license"); see also *Gen-Probe Inc.* v. *Vysis*, No. 99-CV-2668H (S.D. Cal. Mar. 12, 2002) ("It is settled law that an effective license between the parties does not preclude federal question jurisdiction over a licensee's declaratory judgment action."), *rev'd*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004) (reprinted in Petition for Certiorari, *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 04-260, at 25a).

such disputes from the avenue of relief Congress provided in the Declaratory Judgment Act. Certiorari is appropriate because the Federal Circuit has acted contrary to the established understanding of Article III and the Declaratory Judgment Act, and also contrary to the policy of the patent laws as held in *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969).

A. "Reasonable Apprehension of Suit."

The Declaratory Judgment Act extends to the limits of Article III. *Ashwander* v. *TVA*, 297 U.S. 288, 325 (1936); see Pet. Cert. 11 n.8. The simple jurisdictional requirement is that there be a dispute as to legal rights that is—as here—"definite and concrete." *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 242 (1937).

> "The sole requirement for jurisdiction under the Act is that the conflict be real and immediate, i.e., that there be a true, actual 'controversy' required by the Act."

Cardinal Chem. Co. v. *Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993), quoting *Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).[2]

That constitutional requirement was fully satisfied in this case. Petitioner sought resolution of "a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged." *Aetna*, 300 U.S. at 241. Respondents have never wavered in asserting that the licensed patent is valid and infringed by petitioner's Synagis®; and petitioner equally has never wavered in disputing those assertions. The fact that petitioner has not in addition committed a material breach does not convert this mature and concrete dispute into what respondents call "a hypothetical" set of facts. Br. Opp. 10, quoting *Aetna*, 300 U.S. at 241.

---

[2] Of course no one disputes the familiar proposition, see Br. Opp. 10-11, that if there is no actual controversy, federal courts may not issue advisory opinions as to purely hypothetical situations.

The "reasonable apprehension of suit" formulation, which courts have applied in varying situations, is not an exclusive determinant of Article III jurisdiction in every instance, nor does it overrule this Court's decisions going back to *Aetna*. It is simply a sometimes convenient proxy for the Article III and DJA requirement of "actual controversy." As the First Circuit has explained, "reasonable apprehension of suit"

> "is not the only way to establish the existence of a case for purposes of Article III."

Sallen v. *Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001). An actual and concrete dispute as to legal rights between adverse parties satisfies Article III and the Declaratory Judgment Act, whether or not described as "apprehension of suit." *Id.*

The issue presented in the petition is not the phrase "reasonable apprehension of suit." Rather, it is that the Federal Circuit now has *redefined* "reasonable apprehension of suit" —and with it Article III and the statutory term "actual controversy"—to require absolutely that before a patent licensee can seek a declaratory judgment, it must place itself in material breach—and at risk of treble damages, penalties, and injunction—contrary to the Declaratory Judgment Act's central purpose. P.C.A. 5a-6a, citing *Gen-Probe*. But this Court held long ago that a patent licensee should not have to choose between paying "the heavy hand of . . . tribute" or

> "risk[ing] not only actual but treble damages in infringement suits. . . . It was the function of the Declaratory Judgments Act to afford relief against such peril and insecurity."

Altvater v. *Freeman*, 319 U.S. 359, 365 (1943).[3]

---

[3] Only by assuming the validity of *Gen-Probe*'s new definition could the Federal Circuit say that "MedImmune concedes that it is free of apprehension of suit." P.C.A. 4a, cited at Br. Opp. 3. MedImmune expressly asserted apprehension that it would be sued for treble damages

B. Conflict With Other Circuits.

The petition discussed a number of decisions in other Circuits that place the Federal Circuit's constitutional interpretation diametrically at odds with the application of Article III and the Declaratory Judgment Act in other courts of appeals. Pet. Cert. 14-16. Several of those decisions the Brief in Opposition does not mention.[4] Others it brushes aside with the comment that "[c]ases concerning 'very likely' breaches are simply not helpful." Br. Opp. 18.

To play down the conflict with other Circuits, respondents rely instead on a long string of opinions that have used the phrase "reasonable apprehension of suit." Br. Opp. 8-9 n.4. But none of the cases respondents cite used the phrase "reasonable apprehension of suit" to mean what the Federal Circuit redefined it to mean in *Gen-Probe* and here: material breach as a precondition to suit. Indeed, not a single one involved an enforceable patent license, or a license of any other kind. Most were ordinary determinations of whether a threat of infringement, not involving a license, was immediate enough or too speculative to be an "actual controversy." Many antedated the Federal Circuit and further confirm, as the petition already has demonstrated, that the law was firmly established that licensees were not required to commit material breach before seeking declaratory relief. Pet. Cert. 13-14.

---

and onerous penalties if it ceased to pay royalties—which was what the Federal Circuit then ruled under *Gen-Probe* was no longer jurisdictionally sufficient.

[4] *E.g.*, *Doody* v. *Ameriquest Mortgage Co.*, 242 F.3d 286, 288 (5th Cir. 2001) (DJA authorizes suits "before the dispute grows into a contract violation"); *Continental Cas. Co.* v. *Coastal Sav. Bank*, 977 F.2d 734, 738 (2d Cir. 1992) (DJA "intended to avoid precisely the 'accrual of avoidable damages to one not certain of his rights'"); *ACandS, Inc.* v. *Aetna Cas. & Surety Co.*, 666 F.2d 819, 823 (3d Cir. 1981) (quoting *Continental*); see Pet. Cert. 14-16.

Not only do the opinions respondents cite provide no support for the Federal Circuit rule: several are in fact antithetical to it. In *National Basketball Ass'n* v. *SDC Basketball Club, Inc.*, 815 F.2d 562 (9th Cir. 1987), cited Br. Opp. 9 n.4, the court held that a party to a joint venture agreement could bring an action under the Declaratory Judgment Act without first exposing itself to risk of liability:

> "The . . . alternative formulation of case and controversy would force the NBA to impose a fine or sanction on the Clippers before an action could accrue. *This is the type of Damoclean threat that the Declaratory Judgment Act is designed to avoid.* . . . Since the NBA's 'real and reasonable apprehension' . . . was that any action on the Clippers' move could result in antitrust liability, the case is justiciable."

Id. at 566 (emphasis supplied). Similarly, in *GTE Directories Pub. Corp.* v. *Trimen America, Inc.*, 67 F.3d 1563 (11th Cir. 1995), the court rejected a supposed requirement to risk or incur potential liability:

> "The practical effect of finding no case or controversy in the instant case would be to force GTEDPC to contact Trimen's clients thereby subjecting itself to potential liability before allowing it to receive a declaratory judgment. GTEDPC is not required to take such action for an actual case or controversy to exist."

Id. at 1568.

Crowley Cutlery Co. v. *United States*, 849 F.2d 273, 276 (7th Cir. 1988), quoted at Br. Opp. 11, required simply that there be "an existing legal dispute"—as there is here. In fact, the court's relevant jurisdictional holding (dismissing on other grounds) was that the plaintiff's stated fear of prosecution for importing switchblade knives was sufficient to "satisfy the requirements of Article III." *Id.*

Presented with the exact issue raised here, the Second Circuit held that licensees need not withhold royalty payments, because "such repudiation of the licensing agreement should not be precondition to suit." *Warner-Jenkinson Co.* v. *Allied Chem. Corp.*, 567 F.2d 184, 187 (2d Cir. 1977) (citing "most courts who have considered the issue"). Respondents acknowledge *Warner-Jenkinson* as "arguably . . . disagreeing with the Federal Circuit's decision." Br. Opp. 19.[5] And in *Precision Shooting Equip. Co.* v. *Allen*, 646 F.2d 313 (7th Cir.), *cert. denied*, 454 U.S. 964 (1981), the Seventh Circuit held sufficient under Article III that the licensee alleged "a reasonable apprehension that the patentee will bring an infringement suit against him *if* there is non-compliance with the license." *Id.* at 318 (emphasis supplied); see Pet. Cert. 13. Those jurisdictional principles apply no less in the regional Circuits today. *E.g.*, *Starter Corp.* v. *Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996), cited at Br. Opp. 20 (jurisdiction satisfied based on communication of "intent" "to bring an infringement suit should Starter engage in the sale.").

C. The Federal Circuit's Jurisdictional Rule.

Gen-Probe has declared an absolute jurisdictional rule that hereafter the

> "license, unless materially breached, *obliterated any reasonable apprehension of a lawsuit*."

359 F.3d at 1381 (emphasis supplied). As the District Court pointedly recognized, until *Gen-Probe*,

---

[5] Respondents assert that *Warner-Jenkinson* somehow was challenged *sub silentio* by decisions using the phrase "reasonable apprehension of suit." Br. Opp. 18-19. That is not correct. Moreover, a plaintiff "need not prove that [the defendant] expressly has threatened to take legal action." *Interdynamics, Inc.* v. *Wolf*, 698 F.2d 157, 167 (3d Cir. 1982), cited at Br. Opp. 9 n.4.

> "In the past, the 'actual controversy' requirement has not been interpreted by precluding a licensee from challenging a patent it licenses."

P.C.A. 24a. The Federal Circuit's absolute rule also contradicts this Court:

> "The difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and *it would be difficult*, if it would be possible, *to fashion a precise test* for determining in every case whether there is such a controversy."

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941) (emphasis supplied).

Respondents at one point pretend that the Federal Circuit nevertheless "retained the totality-of-the-circumstances test." Br. Opp. 15. That is plainly not so in any meaningful sense. What the Federal Circuit unambiguously held, both in *Gen-Probe* and here, was that "the jurisdictional requirements of a declaratory action are not met when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement." P.C.A. 6a. The Federal Circuit described its mechanical *Gen-Probe* rule as its "synthesis of the totality-of-the-circumstances test for determining whether there is a justiciable controversy." P.C.A. 7a-8a. Citing *Gen-Probe*, the Federal Circuit reiterated that without breach "there is no defaulting licensee and *no possibility of suit*." P.C.A. 6a (emphasis supplied).

On that basis the Federal Circuit in the present case held that "as a licensee in good standing" petitioner "cannot bring a declaratory action to challenge the patent under which it is licensed" because there is "no justiciable controversy." P.C.A. 4a-5a. There has not been a Federal Circuit case since *Gen-Probe* that has held otherwise. The Federal Circuit has followed *Gen-Probe* four times and declined four petitions

for rehearing *en banc*,[6] and the 94 district courts in patent cases are obediently applying, however skeptically,[7] this new Article III jurisdictional rule.

D. *Lear, Inc.* v. *Adkins*.

For several years, the Federal Circuit has been issuing decisions critical of this Court's holding in *Lear*, and seeking every possible way to escape it. See, *e.g.*, *Studiengesellschaft Kohle, m.b.H.* v. *Shell Oil Co.*, 112 F.3d 1561, 1567 (Fed. Cir.) (*Lear* sounds "tones that echo from a past era"), *cert. denied*, 522 U.S. 966 (1997); *Gen-Probe*, 359 F.3d at 1381 ("In several instances, this court has declined to apply the *Lear* doctrine."); cases cited at Pet. Cert. 17-18.

With *Gen-Probe* and the present case, the Federal Circuit now has effectively done away with *Lear* completely for licensees not in material breach. Being unable frontally to overturn this Court's *Lear* holding under the patent laws—which was reiterated in *Cardinal Chem. Co.*, 508 U.S. at 96, 100—it has achieved nearly the same result by an unprecedented rereading of Article III and the Declaratory Judgment Act. Moreover, by invoking the Constitution, it has placed its revival of licensee estoppel beyond the power of

---

[6] In *Gen-Probe*; in *MedImmune, Inc.* v. *Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *pet'n for cert. pending* (No. 05-656); in *Metabolite Labs., Inc.* v. *Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004), *cert. granted on another question*, 126 S. Ct. 601 (2005) (No. 04-607); and in *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir.) (three judges dissenting), *cert. denied*, 126 S. Ct. 473 (2005).

[7] *E.g.*, P.C.A. 31a ("serious misgivings"), noting that the Federal Circuit now

> "forces licensees to take tremendous risk to challenge a patent, one that some with valid claims will likely be unwilling to take."

P.C.A. 30a.

Congress to correct. The only body in a position effectively to do so is now this Court.

CONCLUSION

For the reasons stated herein and in the petition, certiorari should be granted.[8]

Respectfully submitted,

JOHN G. KESTER
PAUL B. GAFFNEY
AARON P. MAURER
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
(202) 434-5000

HARVEY KURZWEIL *
ALDO A. BADINI
HENRY J. RICARDO
DEWEY BALLANTINE LLP
1301 Avenue of the Americas
New York, New York 10019
(212) 259-8000

* Counsel of Record

Attorneys for Petitioner

January 12, 2006

[8] Respondents note that some patents can receive narrow reexamination by the U.S. Patent and Trademark Office pursuant to 35 U.S.C. §§ 302 and 311. Br. Opp. 23-24. That very limited procedure, however, is not nearly equivalent to challenge of a patent in an adversarial judicial proceeding, and is limited to prior printed publications and patents. 35 U.S.C. § 302. Petitioner's challenges—based on inequitable conduct, fraud on the Patent Office, lack of adequate support in the patent for the invention, non-infringement, and other fundamental violations—cannot be raised in such a proceeding.