No. ___

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., *et al.*,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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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?

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.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
LIST OF PARTIES	ii
LIST PURSUANT TO RULE 29.6	ii
TABLE OF AUTHORITIES	v
OPINIONS BELOW	1
JURISDICTION	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED	2
STATEMENT	2
A. The License	2
B. District Court Decision	4
C. Court of Appeals Decision	6
REASONS FOR GRANTING THE WRIT	6
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	8
A. The Decision Is Contrary to This Court's Holdings Dating From *Aetna Life Ins. Co.* v. *Haworth*	8
B. The Decision Is Contrary to Declaratory Judgment Holdings in Other Circuits	13
1. Licenses	13
2. Contracts Generally	14

TABLE OF CONTENTS—Continued

Page

II. THE DECISION FRUSTRATES THIS COURT'S DIRECTION IN *LEAR, INC.* V. *ADKINS* 16

III. THE DECISION PARTICULARLY INHIBITS THE INTRODUCTION OF NEW MEDICAL DRUGS AND TREATMENTS 19

CONCLUSION 22

APPENDIX

A. Opinion of the United States Court of Appeals for the Federal Circuit (October 18, 2005) 1a

B. Opinion of the United States District Court for the Central District of California (April 23, 2004) 21a

C. Constitutional and Statutory Provisions. 32a

TABLE OF AUTHORITIES

Cases: *Page*

ACandS, Inc. v. *Aetna Cas. & Surety Co.*, 666 F.2d 819 (3d Cir. 1981) 11, 16, 19
Aetna Life Ins. Co. v. *Haworth*, 300 U.S. 227 (1937) 8, 9, 10, 11, 19
Altvater v. *Freeman*, 319 U.S. 359 (1943) 10, 11
American Machine & Metals, Inc. v. *De Bothezat Impeller Co.*, 166 F.2d 535 (2d Cir. 1948) 15
American Sterilizer Co. v. *Sybron Corp.*, 526 F.2d 542 (3d Cir. 1975) 14
Atlas Chem. Industries, Inc. v. *Moraine Prods.*, 509 F.2d 1 (6th Cir. 1974) 16
Bresnick v. *United States Vitamin Corp.*, 139 F.2d 239 (2d Cir. 1943) 10
C.R. Bard, Inc. v. *Schwartz*, 716 F.2d 874 (Fed. Cir. 1983) 5, 11, 17
Cardinal Chem. Co. v. *Morton Int'l, Inc.*, 508 U.S. 83 (1993) 7, 10, 17, 21
In re Columbia Univ. Patent Litig., 343 F. Supp. 2d 35 (D. Mass. 2004) 7
Continental Cas. Co. v. *Coastal Sav. Bank*, 977 F.2d 734 (2d Cir. 1992) 16
Dewey & Almy Chem. Co. v. *American Anode, Inc.*, 137 F.2d 68 (3d Cir.), *cert. denied*, 320 U.S. 761 (1943) 16
Diamond Scientific Co. v. *Ambico, Inc.*, 848 F.2d 1220 (Fed. Cir.), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988) 17
Doody v. *Ameriquest Mortgage Co.*, 242 F.3d 286 (5th Cir. 2001) 15
E.I. du Pont de Nemours & Co. v. *Great Lakes Chem. Corp.*, 383 F. Supp. 2d 642 (D. Del. 2005) 7

TABLE OF AUTHORITIES—Continued

Page

Fidelity Nat'l Bank & Trust Co. v. *Swope*, 274 U.S. 123 (1927) 10

Gen-Probe Inc. v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 125 S. Ct. 351 (2004) (No. 04-260)..... 4-7, 11, 12, 17-19, 21

Hal Roach Studios, Inc. v. *Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990) 14

Keener Oil & Gas Co. v. *Consolidated Gas Utilities Corp.*, 190 F.2d 985 (10th Cir. 1951).. 15

Laboratory Corp. of America Holdings v. *Metabolite Labs., Inc.*, 74 U.S.L. WEEK 3287 (2005) (No. 04-607)..... 21

Lear, Inc. v. *Adkins*, 395 U.S. 653 (1969).....5, 8, 13, 16-21

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270 (1941) 11

MedImmune, Inc. v. *Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005) 7

Metabolite Labs., Inc. v. *Laboratory Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 74 U.S.L. WEEK 3287 (2005) (No. 04-607)..... 7

Nashville, C. & St. L. Ry. v. *Wallace*, 288 U.S. 249 (1933)..... 10, 19

National Car Rental System, Inc. v. *Computer Assocs. Int'l, Inc.*, 991 F.2d 426 (8th Cir.), *cert. denied*, 510 U.S. 861 (1993)..... 14

Nebraska Engineering Corp. v. *Shivvers*, 557 F.2d 1257 (8th Cir. 1977) 16

NUCOR Corp. v. *Aceros y Maquilas de Occidente, S.A.*, 28 F.3d 572 (7th Cir. 1994) 15

Pope Mfg. Co. v. *Gormully*, 144 U.S. 224 (1892).. 17, 20

TABLE OF AUTHORITIES—Continued

Page

Precision Shooting Equip. Co. v. *Allen*, 646 F.2d 313 (7th Cir.), *cert. denied*, 454 U.S. 964 (1981) 13, 21

S.O.S., Inc. v. *Payday, Inc.*, 886 F.2d 1081 (9th Cir. 1989) 14

Société de Conditionnement v. *Hunter Engineering Co.*, 655 F.2d 938 (9th Cir. 1981) 14

Studiengesellschaft Kohle, m.b.H. v. *Shell Oil Co.*, 112 F.3d 1561 (Fed. Cir.), *cert. denied*, 522 U.S. 996 (1997) 18

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) 7

United Food & Comm'l Workers Local No. 137 v. *Food Employers Council, Inc.*, 827 F.2d 519 (9th Cir. 1987) 16

United States v. *Glaxo Group Ltd.*, 410 U.S. 52 (1973) 17, 20

Venator Group Specialty, Inc. v. *Matthew/Muniot Family, LLC*, 322 F.3d 835 (5th Cir. 2003) 15

Warner-Jenkinson Co. v. *Allied Chem. Corp.*, 567 F.2d 184 (2d Cir. 1977) 14

Constitutional Provisions:

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*

TABLE OF AUTHORITIES—Continued

Page

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

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PETITION FOR A WRIT OF CERTIORARI

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.[1] The opinion of the United States Court of Appeals for the Federal Circuit is not yet reported and is reproduced at A. 1a.

[1] 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.

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®, 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® 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").[2] The invention claimed

[2] After the Boss patent issued in 1989, Genentech initiated a proceeding before the United States Patent and Trademark Office seeking a deter-

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.

In 1997, a year prior to first marketing Synagis®, 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

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mination 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.

that MedImmune will pay royalties on sales of its Synagis® 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®, 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®.[3] 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.

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-

[3] 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.

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

> 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.[4]

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 licen-

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[4] 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.

sees 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,[5] and the district courts have obeyed.[6]

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

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[5] 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).

[6] 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.").

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

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

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.[7]

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).

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[7] "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).

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.[8] 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

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[8] 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).

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

> "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,

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

> 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

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

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).

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 circum-

stances 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

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 doubt-

ful 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 peti-

tioner's 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.*[9] 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.

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).

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[9] 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.

CONCLUSION

For the reasons stated, certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

04-1300, -1384

MEDIMMUNE, INC.,
Plaintiff-Appellant,

v.

GENENTECH, INC.,
Defendant-Appellee,

and

CITY OF HOPE,
Defendant-Appellee,

and

CELLTECH R&D, LTD.,
Defendant-Appellee.

DECIDED: October 18, 2005

Before NEWMAN, MAYER, and CLEVENGER, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* NEWMAN. Dissenting in part opinion filed by *Circuit Judge* CLEVENGER.

NEWMAN, *Circuit Judge.*

MedImmune, Inc., a licensee in good standing under a patent owned by Genentech, Inc. and City of Hope (collectively "Genentech"), seeks by declaratory action to challenge the validity and enforceability of the licensed patent on various

grounds flowing from the settlement of a patent interference between Genentech and Celltech R&D, Ltd. The United States District Court for the Central District of California held that because MedImmune continues to comply fully with the license terms, leaving no possibility of infringement suit or license cancellation by Genentech, there is no "case of actual controversy" as required by the Declaratory Judgment Act, 28 U.S.C. §2201. The district court also dismissed MedImmune's antitrust and unfair competition counts. We affirm the judgment.[1]

BACKGROUND

The patented technology relates to the use of cell cultures to manufacture human antibodies. Genentech, Inc. and the City of Hope are the owners of United States Patent No. 4,816,567 (the Cabilly I patent) filed on April 8, 1983, and Patent No. 6,331,415 (the Cabilly II patent), a continuation of Cabilly I, filed on June 10, 1988. Celltech owns United States Patent No. 4,816,397 (the Boss patent), having a British priority date of March 25, 1983. In accordance with 35 U.S.C. §135 the United States Patent and Trademark Office (PTO) declared an interference between the Boss patent and the Cabilly II application. The PTO interference proceedings consumed seven and a half years. The Board of Patent Appeals and Interferences decided priority in favor of the senior party Boss, holding that Cabilly had not established an actual reduction to practice before the Boss patent's British priority date. *Cabilly v. Boss*, 55 USPQ2d 1238 (Bd. Pat. App. & Int. 1988).

Genentech then filed a civil action in the United States District Court for the Northern District of California, in accordance with 35 U.S.C. §146. After various proceedings, the district court concluded that disputed facts concerning con-

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[1] *MedImmune, Inc. v. Genentech, Inc.*, CV 03-2567 (C.D. Cal. Jan. 14, 2004; February 18, 2004; Mar. 15, 2004; April 29, 2004).

ception and reduction to practice required trial and, referring to the complexity of the science, stated that "[t]here appears to be a dispute amongst highly educated and apparently well-qualified experts" as to the interpretation and probative value of the evidence. The court urged Genentech and Celltech to resolve the issue of priority with the aid of mediation. Genentech and Celltech retained a mediation service, and a retired judge served as mediator. A settlement agreement was duly reached, whereby Genentech and Celltech agreed that the Cabilly II application was entitled to priority as against the Boss patent, based in part on new evidence of the content of a draft patent application during the period leading to filing of the Genentech application. Genentech and Celltech also entered into a cross-license agreement that included a formula for sharing of royalties. The district court entered judgment on the parties' resolution of the issue of priority, and directed the PTO to vacate its prior decision, revoke the Boss patent, and issue a patent on the Cabilly II application. *Genentech, Inc. v. Celltech R&D, Ltd.*, No. 3:98cv03929 (N.D. Cal. March 16, 2001).

Genentech and Celltech jointly presented the district court's judgment to the PTO, with a petition requesting that the PTO cancel the Boss patent and issue a patent on the Cabilly II application. The Board entered an order that Cabilly was the prior inventor, but did not precisely follow the requested procedure. The Board stated that the Boss patent was cancelled by operation of law when the district court's judgment became final and was not appealed, and that no further action by the PTO was required. The Board also observed that an Information Disclosure Statement filed by Genentech in 1991 had not been acted upon, and returned the Cabilly II application to the patent examiner for review of any "ground not involved in judicial review." Genentech then cited a large number of additional references to the examiner, and provided various documents from the record of the §146 action. After further examination the Cabilly II patent was issued on

December 18, 2001, eleven years after the inception of the interference.

MedImmune had since 1997 been licensed by Genentech under the Cabilly I patent and, by the terms of that agreement, received a license under the Cabilly II patent. In addition, MedImmune had since 1998 been licensed by Celltech under the Boss patent. After issuance of Cabilly II, Genentech advised MedImmune that a MedImmune product, brand name Synagis®, was covered by Cabilly II and subject to royalties in accordance with the license terms. MedImmune objected, and filed this declaratory judgment action in the Central District of California, requesting a declaration that the Cabilly II patent is invalid or unenforceable. MedImmune paid and continues to pay the license royalties to Genentech, relying on precedent such as *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991 (Fed. Cir. 1985) for the holding that the licensor cannot terminate the license if the royalties are paid to the licensor and the license agreement is not otherwise breached. The district court, applying *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), dismissed the suit as non-justiciable under the Declaratory Judgment Act.

DISCUSSION

I

The district court held that MedImmune, as a licensee in good standing and not in reasonable apprehension of suit, cannot bring a declaratory action to challenge the patent under which it is licensed. MedImmune concedes that it is free of apprehension of suit, stating that the reason it is paying the royalties is to avoid the risk and possible consequences of a successful infringement suit by Genentech. However, MedImmune argues that under *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969) it has the absolute right to challenge the validity or enforceability of the patent, whether or not it breaches the license and whether or not it can be sued by the patentee.

MedImmune states that the *Gen-Probe* decision improperly resurrected the licensee estoppel that was abolished in *Lear*, and should be overturned.[2]

Genentech responds that this is not a question of licensee estoppel under *Lear*, but a question of Article III jurisdiction under the Declaratory Judgment Act. Unlike the situation in *Lear*, MedImmune is paying the license royalties; and unlike the situation in *Lear*, Genentech has no ground on which to cancel the license or otherwise bring suit affecting the licensed subject matter. 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*. In contrast, in *Gen-Probe* the licensee was complying fully with the license terms and could not be sued by the patentee. Similarly, MedImmune is complying fully with the license terms and cannot be sued by the patentee.

MedImmune argues that although it has no reasonable apprehension of suit, it meets the requirements of the Declaratory Judgment Act because if it stopped paying royalties it could be sued. MedImmune states that the Cabilly II patent is subject to challenge on several grounds, and that it should not be shielded from such challenge. MedImmune also distinguishes its situation from that in *Gen-Probe* on the ground that the licensee in *Gen-Probe* negotiated for a license and then filed suit to invalidate the licensed patent, having secured its right to operate and the royalty terms should it lose the suit; MedImmune points out that it already had a license to Cabilly II under its license to Cabilly I and that the royalty rate was already set.

The district court was not persuaded by these distinctions, and we agree that they do not create a justiciable controversy.

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[2] Panels of the Federal Circuit are bound by prior decisions of this court unless overturned by the court *en banc*. *See, e.g., Sacco v. Dep't of Justice*, 317 F.3d 1384, 1386 (Fed. Cir. 2003).

Unlike the facts in *Lear*, where the licensee ceased payment and disavowed the license obligation, in *Gen-Probe*, as for MedImmune, breach was assiduously avoided. Thus this case does not raise the question of whether patent invalidity is available as a defense to suit against a defaulting licensee—the licensee estoppel that was laid to rest in *Lear*—for there is no defaulting licensee and no possibility of suit.

Precedent follows this pattern. For example, in *Intermedics Infusaid, Inc. v. Regents of University of Minnesota*, 804 F.2d 129, 131 (Fed. Cir. 1986), where suit was ongoing in state court for royalties under a license agreement, the court held that a federal declaratory judgment action challenging validity was properly stayed. In *Cordis v. Medtronic*, 780 F.2d at 995, the court held that to avoid breach during litigation the royalties were required to be paid to the licensor, not into escrow. In *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 875-76 (Fed. Cir. 1983) the licensee had stopped paying royalties and the licensor was suing for their recovery in state court but had not terminated the license; this court held that this material breach generated an actual controversy for purposes of the federal declaratory judgment challenge to validity. The decision in *Gen-Probe* is in accord with this precedent, in holding 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.

MedImmune stresses the public policy served by permitting it to attack the Genentech patent, and argues that estoppel has been eliminated in the fields of intellectual property as a matter of public policy. However, the issue here is not one of estoppel, but of availability of the declaratory judgment procedure. The purpose of that procedure is to "accommodate[] the practical situation wherein the interest of one side to the dispute may be served by delay in taking legal action," *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977

(Fed. Cir. 1993), by permitting the other side to initiate legal action. *See also, e.g., EMC Corp. v. Norand Corp.*, 89 F.3d 807, 814-15 (Fed. Cir. 1996); *Arrowhead Industrial Water, Inc. v. Ecolochem. Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988). The court in *Gen-Probe* discussed the inequity when the patent owner, having contracted away its right to sue, is in 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. This imbalance distorts the equalizing principles that underlie the Declaratory Judgment Act.

MedImmune states that cases from other circuits hold that a licensee need not terminate its license in order to acquire declaratory standing. However, 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. Contrary to MedImmune's argument, the fact that the licensed subject matter is intellectual property does not create a policy-driven exception to these requirements.

In *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005) the court adhered to *Gen-Probe* in circumstances, like those at bar, where MedImmune had secured a license and then sued to invalidate the licensed patent. The court explained that: "To keep watch over the subtle line between an 'abstract question' and 'a controversy contemplated by the Declaratory Judgment Act' an inquiry has been formulated [whereby] there must be both (1) a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement . . . ." This synthesis of the totality-of-the-

circumstances test for determining whether there is a justiciable controversy is pragmatically useful. *See BP Chemicals*, 4 F.3d at 978 ("The purpose of the two-part test is to determine whether the need for judicial attention is real and immediate, or is prospective and uncertain of occurrence.")

Licensor and licensee always have "adverse legal interests," *Aetna Life Inc. Co. v. Haworth*, 300 U.S. 227, 241 (1937), but that relationship alone does not create a justiciable controversy. The Declaratory Judgment Act requires a "definite and concrete controversy," *id.* at 240, of "sufficient immediacy and reality," *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), to warrant judicial intervention. MedImmune avoided and continues to avoid such a situation, by avoiding breach and avoiding apprehension of suit. Thus although courts have discretion in deciding whether to accept a declaratory action when the constitutional and statutory requirements are met, 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.

MedImmune directs us to the reference to "scarecrow" patents in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 96 (1993). That case concerned the appellate obligation to review a district court's decision concerning patent validity, lest an invalid patent be revived. In *Cardinal Chemical* the trial court had decided the issues of infringement and validity, and the Court held that the Federal Circuit has the power to review both issues on appeal, and should do so, even when the patent is held not infringed. *Cardinal Chemical* was an infringement suit, not a declaratory action. As commented in *Super Sack Manufacturing Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995), "nothing in *Cardinal* undermines our decisions on declaratory justiciability at the trial court level." The present case is unaffected by *Cardinal Chemical.*

The district court did not err in holding that MedImmune, since under no threat or apprehension of suit, did not have standing to bring a declaratory challenge to the Cabilly II patent.

II

MedImmune also argues that the interference settlement between Genentech and Celltech was collusive and fraudulent, and that this provides an independent basis for standing to attack the Cabilly II patent, whether or not the case or controversy requirement of the Declaratory Judgment Act is met. The district court held that the joint action of Genentech and Celltech was protected by the *Noerr-Pennington* doctrine.

MedImmune states that Genentech and Celltech violated federal and state antitrust laws, citing sections 1 and 2 of the Sherman Act (15 U.S.C. §§1,2), and the California antitrust and unfair competition statutes, Cal. Bus. & Prof. Code §16720 and §17200 et seq. MedImmune points out that the Cabilly II patent expires significantly later than the Boss patent (because of the interference delays), and argues that extension of control of the invention was the motivation for the agreement to award priority to Cabilly II. MedImmune also states that Celltech's Boss patent would have retained priority based on its British filing date if the district court had excluded the newly presented evidence of the draft Cabilly patent application. MedImmune states that this evidence, since not before the PTO, should not have been permitted in the district court. However, new evidence may be presented in §146 proceedings, *see* 35 U.S.C. §146 ("without prejudice to the right of the parties to take further testimony"). *See also Abbott Labs. v. Brennan*, 952 F.2d 1346, 1348 (Fed. Cir. 1991).

MedImmune refers to *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963), wherein the Court found Sherman Act violation based on interference settlements and other agreements among domestic sewing machine manufacturers for the

purpose of excluding Japanese competitors from the United States market. MedImmune argues that settling interferences "at least in part, to prevent an open fight over validity" of itself violates the Sherman Act, quoting the concurring opinion in *Singer*, 374 U.S. at 199 (White, J., concurring). The settlement of disputes such as priority in patent interferences is not a presumptive violation of antitrust law; such violation requires a showing of market power and other antitrust predicates. A patent does not of itself confer market power or a presumption thereof for purposes of the antitrust laws. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998) ("It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms."); *Abbott Labs.*, 952 F.2d. 396 F.3d 1342, 1348 (Fed. Cir. 2003) ("the Supreme Court has held that there is a presumption of market power in patent tying cases"), *cert. granted*, 125 S. Ct. 2937 (June 20, 2005); Herbert Hovenkamp, at 1354 (Fed. Cir. 1991) ("A patent does not of itself establish a presumption of market power in the antitrust sense."); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1367 (Fed. Cir. 1984) ("patent rights are not legal monopolies in the antitrust sense of the word"); *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 18 (1984) ("any inquiry into the validity of a tying arrangement must focus on the market or markets in which the two products are sold, for that is where the anticompetitive forcing has its impact"); *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1329 (Fed. Cir. 2000) ("patent alone does not demonstrate market power"); *Independent Ink, Inc. v. Illinois Tool Works, Inc.*, 396 F.3d 1342, 1348 (Fed. Cir. 2003) ("the Supreme Court has held that there is a presumption of market power in patent tying cases"), *cert. granted*, 125 S. Ct. 2937 (June 20, 2005); Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and its Practice* §10.3 (3d ed. 2005) ("most patents confer absolutely no market power on their owners").

The antitrust posture that MedImmune urges for patent interferences can discourage if not prevent settlements, placing unnecessary burdens on the courts and the PTO. Priority determinations may raise complex questions of law and scientific fact, and the delays in their resolution by the PTO are notorious; settlement can, as here, expedite resolution of difficult issues. The per se or presumptive illegality urged by MedImmune for interference settlements is contrary to both precedent and policy, as recorded in the *Antitrust Guidelines for the Licensing of Intellectual Property*, 4 Trade. Reg. Rep. (CCH) ¶13,132, §2.2 (1995).

III

MedImmune also argues that Genentech and Celltech colluded in the joint submission of their settlement agreement to the district court, and again in their joint submission of the court's judgment order to the Patent and Trademark Office with the request that the Boss patent be cancelled and the Cabilly II application be granted. The district court dismissed these claims, holding that petitions for governmental action are immune under the *Noerr-Pennington* doctrine that permits collaboration among competitors to petition the government to take an action that may restrain competition, without incurring antitrust liability by the act of collaborating. *See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961) (it is permissible for railroads to act in concert to petition the legislature to take an action that creates a restraint of trade or a monopoly); *United Mine Workers of America v. Pennington*, 381 U.S. 657, 671 (1965) (it is permissible for a combination of workers and their employers to petition the Secretary of Labor to take an action that adversely affects competitors). In *California Motor Transport v. Trucking Unlimited*, 404 U.S. 508 (1972) this immunity was extended to petitions to the courts "respecting resolution of [petitioners'] business and economic interests vis-a-vis their competitors." *Id.* at 511.

A joint communication to a court of the terms of settlement of a matter before the court, and a joint petition to the PTO to implement the court's judgment, are not actions that would be prohibited or tainted absent immunization by *Noerr-Pennington*; thus it was unnecessary for the district court to have relied on *Noerr-Pennington* immunity. Genentech and Celltech, the parties to the litigation in the district court, were obligated to bring their settlement to the court, and to bring the court's judgment to the PTO. Although MedImmune argues that the settlement "contains misrepresentations," the putative misrepresentation was by "representing [to the district court] that Genentech was instead entitled to priority." MedImmune Br. at 48. The district court properly rejected this theory, observing that disputed issues from the underlying litigation cannot be recast as misrepresentations, citing *Kottle v. Northwest Kidney Centers*, 146 F.3d 1056, 1063 (9th Cir. 1998). MedImmune's disagreement with the result of the priority settlement does not convert it into a presumptive violation of the antitrust laws, or grant MedImmune standing to require judicial review of the evidence and the conclusion reached in the settlement.

The ensuing filing of the judgment in the PTO is set by statute, and the joint filing by the parties to the judgment does not require *Noerr-Pennington* protection. *See* 35 U.S.C. §146 (filing in the Patent and Trademark Office of a certified copy of the judgment). The joint request of the litigants that the PTO implement the judgment is not a prohibited collusion.

IV

MedImmune also argues that antitrust violation arose in Genentech's prosecution of the Cabilly II application after it was returned to ex parte examination. MedImmune states that the additional references that Genentech brought to the examiner's attention should have been presented earlier, that Genentech did not tell the examiner about certain patents under which Genentech was licensed, that Genentech made

inconsistent arguments from those it made in an opposition to the Boss patent in the European Patent Office, that Genentech cited so many references that the most important were "buried," and that Genentech did not tell the examiner about challenges to Cabilly II that Celltech had raised during the interference proceeding. Thus MedImmune states that the prosecution was fraudulent, and that enforcement of a fraudulently obtained patent violates the antitrust laws in terms of *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

The district court held that "this argument fails because in its Amended Complaint, MedImmune does not plead fraud" and that "MedImmune's *Walker Process* theory is not supported in the pleadings." Like all fraud-based claims, *Walker* Process allegations are subject to the pleading requirements of Fed. R. Civ. P. 9(b). *See Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003) (claims that are "grounded in fraud" or that "sound in fraud" are subject to Rule 9(b)). MedImmune's counsel emphasized, on questioning by the district court, that he was not charging fraud. The district court correctly held that the pleadings, which charged Genentech with inequitable conduct, not fraud, fell short of alleging a *Walker Process* antitrust violation.

Genentech describes MedImmune's approach as tactical. Whatever its basis, after the grant of summary judgment MedImmune sought to amend its pleadings by filing a Second Amended Complaint, to add the charge of fraud on the grounds that were previously designated as inequitable conduct. The district court denied leave to amend, referring to the litigation history and describing the proposed amendments as "prejudicial and futile." The Ninth Circuit reviews denials of leave to amend under an abuse of discretion standard. *Bowles v. Reade*, 198 F.3d 752, 757 (9th Cir. 1999).[3] MedImmune

[3] Leave to amend is a procedural matter not unique to patent law, and we apply the law of the regional circuit to review denial of leave to amend.

has provided no reasonable basis for deeming this ruling an abuse of the district court's sound discretion. In *Royal Insurance Co. of America v. Southwest Marine*, 194 F.3d 1009, 1017 (9th Cir. 1999) the court affirmed denial of leave to amend when the motion was made after the grant of summary judgment. Although the parties have in their briefs discussed at some length the prosecution aspects challenged by MedImmune, we discern no error in the district court's determination that MedImmune was without a reasonable likelihood of supporting a claim of antitrust violation, and that the proposed redesignation of prosecution issues as constituting fraud was tardy and prejudicial.

In addition, MedImmune's charge of fraud during ex parte patent examination does not establish standing to bring a declaratory action to invalidate a patent not involved in a case or controversy between the parties. The standards for determining jurisdiction in a declaratory judgment action of patent invalidity do not change when the declaration raises a *Walker Process* claim. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1357-58 (Fed. Cir. 2004) (as for other declaratory challenges to patent validity, reasonable apprehension of suit is a prerequisite for standing to bring an antitrust challenge to the patent prosecution). A person not under reasonable apprehension of suit cannot overcome the absence of declaratory standing simply by challenging the patent prosecution and asserting fraud. There is neither statutory nor precedential authority for collateral attack on patent examination procedures, by a person who does not meet the requirements of declaratory judgment standing.

MedImmune also states that it should have been permitted to file the Second Amended Complaint after the summary judgment, to add a charge of fraud in the tardy filing of the

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See Ferguson Beauregard/Logic Controls Div. of Dover Resources, Inc. v. Mega Sys. LLC, 350 F.3d 1327, 1342 (Fed. Cir. 2003).

interference settlement agreement. The PTO accepted the filing, as authorized by 35 U.S.C. §135(c). MedImmune challenges the sufficiency of Genentech's reason for its tardiness. The district court held that "MedImmune has pled no facts sufficient to assert that the PTO acted inappropriately in accepting the settlement documents from Genentech." No abuse of the district court's discretion has been shown, and no basis whatsoever for opening to collateral attack a discretionary decision of the PTO to accept a document in accordance with the rules of the PTO.

V

MedImmune states that if this court affirms the district court on the patent counts, the antitrust and unfair competition counts should be transferred to the Ninth Circuit. That procedure would violate the jurisdictional assignment to the Federal Circuit. In *Texas American Oil Co. v. Department of Energy*, 44 F.3d 1557, 1564 (Fed. Cir. 1995) (en banc) the court explained the assignment to the Federal Circuit of "case" jurisdiction, in recognition of the burdens of "issue" jurisdiction on litigants and on the courts.

As discussed in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988), the jurisdiction of the Federal Circuit is established by the well-pleaded complaint in the district court, whereupon the Federal Circuit must exercise jurisdiction of all of the issues in the case. In *United States v. Hohri*, 482 U.S. 64 (1987) the Court explained that the Federal Circuit must take jurisdiction of the appeal of all issues when the complaint includes any issue exclusively assigned to the Federal Circuit, in *Hohri* a nontax claim under the Little Tucker Act. *See also Atari, Inc. v. JS & A Group, Inc.*, 747 F.2d 1422, 1431 (Fed. Cir. 1984) (*en banc*) (Federal Circuit must exercise jurisdiction although only copyright issue was appealed). In *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826, 829 (2002) the Court confirmed that the jurisdiction of the Federal Circuit arises from the

complaint, and that the entire appeal is directed to the regional circuit when the patent count arose only by counterclaim. Similarly, when patent claims are included in order to manipulate the direction of the appeal, or are eliminated at the threshold of the pleading stage, the entire appeal is properly taken to the regional circuit. *E.g., Chamberlain Group, Inc. v. Skylink Techs. Inc.*, 381 F.3d 1178, 1189-90 (Fed. Cir. 2004); *Schwartzopf Dev. Corp. v. Ti-Coating, Inc.*, 800 F.2d 240, 245 (Fed. Cir. 1986) (referring to "the transient appearance of the [patent] counterclaim"). In all cases, the purpose is to avoid the burdens of dividing the appeal between two circuits. *See Texas American Oil*, 44 F.3d at 1564. It would be contrary to this careful balance and efficient design for the Federal Circuit to decide part of an appeal and then, depending on the outcome of that part, to ship the residue to another circuit.[4] The request to transfer part of this appeal to the Ninth Circuit is denied.

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[4] We take note of the dissent's argument that the case should now be sent to the Ninth Circuit for decision of the *Walker Process* and other patent/antitrust issues raised by the appellant, on the theory that the complaint should, after this appellate decision, be deemed to have been "constructively amended" to have been filed without the patent counts of the complaint. Neither statute nor precedent provides support for such a procedure, and indeed they weigh heavily against it. In none of the "authority" mentioned by the dissent was the complaint subject to retrospective amendment of well-pleaded issues after the legal status of the parties had been altered. The Court in *Christianson v. Colt* confirmed that jurisdiction "is determined by reference to the well-pleaded complaint, not the well tried case." 486 U.S. at 814; *see also Holmes Group v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 832, n.3 (2002). The purpose of the rule is to determine jurisdiction at the outset of litigation, to avoid throwing the parties into "a perpetual game of jurisdictional ping-pong." *Id.* at 818. To bifurcate an appeal after some of the issues are decided offers the worst of all possibilities, for it would not be known whether some issues would be shipped elsewhere, to be redocketed and rebriefed and reargued and reappealed, until after the Federal Circuit decided other issues. Such a situation is devoid of support.

We have considered all of the arguments raised by MedImmune. The decision of the district court is

AFFIRMED.

CLEVENGER, *Circuit Judge*, dissenting in part.

MedImmune, Inc. ("MedImmune") paid, and continues to pay, royalties under a 1997 licensing agreement with Genentech, Inc. ("Genentech"), which entitles MedImmune to produce and sell its humanized monoclonal antibody, Synagis®, free from liability under U.S. Patent No. 6,331,415 ("Cabilly II" or "the '415 patent"). Because MedImmune's good standing under the agreement necessarily quells any reasonable apprehension of an infringement suit brought by Genentech pursuant to the '415 patent, I agree with the court that the declaratory judgment claims properly were dismissed for want of jurisdiction. Indeed, the district court's dismissal is required by our prior decisions in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004) and *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005). I write separately, however, to voice my disagreement with the court's refusal to transfer the remainder of the case to the Court of Appeals for the Ninth Circuit, pursuant to 28 U.S.C. § 1631, for a determination as to whether the district court properly granted summary judgment regarding MedImmune's antitrust and unfair competition claims.

Under 28 U.S.C. § 1295(a)(1), this court has exclusive jurisdiction over an appeal from a final decision of a district court, so long as the district court's jurisdiction was based in whole or in part upon 28 U.S.C. § 1338. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1342 (Fed. Cir. 2003) (stating that if the district court had jurisdiction over at least one claim in the case under section 1338, then this court has appellate jurisdiction over the entire case). Section 1338(a) in turn provides that a district court shall have original jurisdiction over any civil action arising under an Act of Congress relat-

ing to patents. The "well-pleaded complaint" rule defines what "arising under" means. *See Holmes Group v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 833-34 (2002). "Under the well-pleaded complaint rule, as appropriately adapted to § 1338(a), whether a claim 'arises under' patent law must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 809 (1988) (internal quotation marks omitted). The focus of our jurisdictional inquiry should thus be upon MedImmune's complaint and whether, as ultimately amended, it arises under an Act of Congress relating to patents. *See Chamberlain Group v. Skylink Tech., Inc.*, 381 F.3d 1178, 1189 (Fed. Cir. 2004). As ultimately amended, I would hold that it does not.

Our precedent mandates this conclusion. First, we have stated that a dismissal for lack of subject matter jurisdiction is usually one without prejudice because the dismissing court has no power to render a judgment on the merits of the dismissed claim. *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1486 (Fed. Cir. 1998). Such is the case here, and nothing about the district court's dismissal bars MedImmune from refiling its complaint. *See Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 505-06 (2001) ("The primary meaning of 'dismissal without prejudice,' we think, is dismissal without barring the defendant from returning later, to the same court, with the same underlying claim."). Second, we have held, in a decision that binds this panel, that dismissals without prejudice are "de facto amendments," or "constructive amendments," to the complaint. *See Nilssen v. Motorola, Inc.*, 203 F.3d 782, 784-85 (Fed. Cir. 2000) (noting that regardless of whether the patent claims were dismissed without prejudice or extinguished by amendment, the effect is the same because in either case the parties are left in the same legal position with respect to the patent claims as if they had never

been filed); *Gronholz v. Sears, Roebuck & Co.*, 836 F.2d 515, 516, 518 (Fed. Cir. 1987) (holding that plaintiff's voluntary dismissal of the patent claim without prejudice constituted an amendment to the complaint and that the suit no longer arose under the patent laws for jurisdictional purposes). Third, for jurisdictional determinations, we do not differentiate be tween actual and constructive amendments—"both divest us of jurisdiction if they eliminate all issues of patent law." *Chamberlain Group*, 381 F.3d at 1189.

Therefore, because the district court's dismissal of MedImmune's declaratory judgment claims without prejudice is equivalent for jurisdictional purposes to an amendment removing the declaratory judgment claims from the complaint, and because no other claims in MedImmune's complaint "arise under" patent law, the district court's dismissal eliminates all issues of patent law from MedImmune's well-pleaded complaint and thus divests this court of jurisdiction over the case. Where a plaintiff lacks standing to pursue a patent law claim, as in this case, we have no jurisdiction over the remaining claims and must transfer the case to an appropriate court of appeals. *See Fieldturf v. Southwest Recreational Indus.*, 357 F.3d 1266, 1267 (Fed. Cir. 2004). Indeed, MedImmune itself understands that a transfer is required if we affirm the absence of jurisdiction over the declaratory judgment claims. (Appellant's Reply Br. at 12 n.8.)

Finding no jurisdiction, I would transfer the case to the Court of Appeals for the Ninth Circuit, pursuant to 28 U.S.C. § 1631, for a determination as to whether the district court properly granted summary judgment regarding MedImmune's antitrust and unfair competition claims. *See Christianson*, 486 U.S. at 818-19 (noting that the Federal Circuit erred in deciding to reach the merits of plaintiff's antitrust claims after concluding that it lacked jurisdiction).

As the majority correctly notes, our jurisdiction is determined by the complaint. Where a patent law issue permeates

the complaint, the "case" is ours, and all "issues," including non-patent law issues, remain with us for decision. But when the complaint contains nary a whiff of patent law, as is the situation with the amended complaint in this case, we are powerless to adjudicate the other issues in the case.

To be sure, transfer to another circuit court involves some inconvenience to the parties and a burden on the courts. But inconvenience and burden are insufficient reasons to violate a fundamental limitation on federal courts: the power of judicial review vests only where jurisdiction lies.

APPENDIX B

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Apr. 26, 2004]

Case No. CV 03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., *et al.*

Defendants.

AMENDED MEMORANDUM OF DECISION
AND ORDER RE: Motion to Dismiss for
Lack of Subject Matter Jurisdiction

The Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction came on for hearing on April 19, 2004 and this Court took the matter under submission. Having considered the parties' written and oral argument this court hereby GRANTS the Defendant' motion.

INTRODUCTION

I. Summary of Dispute

Plaintiff MedImmune is a biotechnology company whose most successful product is Synagis, a drug used to prevent serious lower respiratory tract disease in children. Amended Complaint ¶¶ 4-5. The Defendants are a biotechnology company, Genentech, Inc. ("Genentech") and a nonprofit organization, City of Hope, who are co-assignees of the patent in

dispute.[1] U.S. Patent No. 6,331,415B1 (issued December 18, 2001) ("'415 patent").

The '415 patent describes a method of producing monoclonal antibodies using recombinant deoxiribonuclic acid ("DNA") technology. *Id.* Synagis is a monoclonal antibody; MedImmune licenses the '415 patent for the production of its Synagis product. Amended Complaint, ¶ 18. Although MedImmune continues to fulfill its obligations under the license agreement, MedImmune asserts that the '415 patent is invalid, unenforceable and not infringed, and that MedImmune therefore does not owe the royalties it is paying to Genentech. Amended Complaint, ¶ 20, ¶¶ 131-64.

II. Status of Case

MedImmune originally made antitrust and unfair competition claims in addition to seeking declaratory judgment of invalidity, unenforceability, non-infringement, and lack of royalty obligation under the license agreement. Amended Complaint, ¶¶ 131-201. The antitrust and unfair competition claims were dismissed on summary judgment holding that the *Noerr-Pennington* doctrine applied to these claims. Memorandum of Decision and Order (filed Dec. 23, 2004, amended January 14, 2004). Consequently, the only claims remaining in this case are claims for declaratory judgment.

The parties fully briefed the issue of claim construction and this Court was prepared to hold the *Markman* hearing scheduled for March 15, 2004. However, prior to the *Markman* hearing a March 5, 2004 Federal Circuit decision suggested that this Court does not have subject matter jurisdiction. *See Gen-Probe, Inc. v. Vysis, Inc.*, 2004 WL 405737, *3 (Fed. Cir. 2004). On March 12, 2004, this Court stayed all other matters, including claim construction, until

[1] References to Genentech in the remainder of this memorandum are intended to indicate both Genentech and City of Hope.

the issue of subject matter jurisdiction could be resolved. Telephonic Status Conference (held March 12, 2004).

III. Motion to Dismiss

In the Motion at issue here, Genentech seeks dismissal of all remaining causes of action based on lack of subject matter jurisdictions. Specifically, Genentech requests that the First Cause of Action (Declaratory Judgment on Contractual Rights and Obligations), the Second Cause of Action (Patent Invalidity), the Third Cause of Action (Patent Unenforceability), and the Fourth Cause of Action (Non-Infringement) be dismissed. Genentech's Notice of Motion and Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed March 22, 2004) ("Motion").

The parties have briefed this issue for the Court. City of Hope joined Genentech's Motion to Dismiss but did not file a separate motion. City of Hope's Notice of Motion and Motion for Joinder in the Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed March 23, 2004). MedImmune filed an Opposition and supported it with two Declarations. Plaintiff MedImmune, Inc's Opposition to Genentech, Inc.'s Motion to Dismiss (filed under seal, March 29, 2004) ("Opposition"); Declaration of David M. Scott in Support of Opposition to Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed under seal, March 29, 2004); Declaration of Tanya Hunter in Support of Opposition to Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed under seal, March 29, 2004). Genentech and City of Hope filed separate Reply memoranda. Genentech's Reply Brief in Support of Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed April 5, 2004); Genentech's Request for Judicial Notice in Support of Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed April 5, 2004) ("Notice Request"); Defendant City of Hope's Reply Brief in Support of Motion to Dismiss for Lack of Subject Matter Jurisdiction (filed April 5, 2004). This Court heard argument on April 19, 2004.

LEGAL STANDARD

Genentech brings this Motion under Rules 12(b)(1) and 12(h)(3) of the Federal Rules of Civil Procedure ("FRCP"). Rule 12(b)(1) gives a party the option of presenting the defense of lack of subject matter jurisdiction by motion rather than asserting it in the responsive pleading. Rule 12(h)(3) makes it clear that subject matter jurisdiction is a defense that is never waived: "Whenever it appears by suggestion of the parties or otherwise that the Court lacks jurisdiction of the subject matter, the court *shall* dismiss the action." FRCP Rule 12(h)(3) (emphasis added). If a court lacks subject matter jurisdiction, dismissal of the action is mandatory. *See Ex parte McCardle*, 74 U.S. 506, 514 (1868).

DISCUSSION

I. The Gen-Probe Decision

Article III of the Constitution authorizes the federal judiciary to hear justiciable cases and controversies. To effectuate this requirement, the Declaratory Judgment Act requires that there be an "actual controversy" between the parties. 28 U.S.C. § 2201(a); see also *Gen-Probe*, 2004 WL 405737, *3. It is therefore the rule that a declaratory judgment plaintiff must establish that the "totality of the circumstances" demonstrates that an actual controversy exists. *Gen-Probe*, 2004 WL 405737 at *3.

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*, 2004 WL 405737 at *4 (noting that the "license, unless materially breached, obliterated any reasonable apprehension of a lawsuit based on the prior circumstances cited by the district court for jurisdiction.").

Gen-Probe distinguished prior cases as involving plaintiff-licensees who were not in good standing. The plaintiff-licensee in Gen-Probe, like MedImmune in this case, sought declaratory judgment of patent invalidity, unenforceability or non-infringement. *See Gen-Probe*, 2004 WL 405737. As is true of the plaintiff in this case, the plaintiff in *Gen-Probe* made these challenges while continuing to: fulfill its obligations under the license agreement. *Gen-Probe*, 2004 WL 405737 at *4. The Federal Circuit found the Gen-Probe plaintiff's continued performance of the license agreement to be a critical factor that destroyed jurisdiction by eliminating any reasonable apprehension of suit by the licensor for infringement.

II. Controlling Law

MedImmune essentially admits that under *Gen-Probe* this Court does not have jurisdiction, but argues that *Gen-Probe* is not controlling. MedImmune contends that this Court has jurisdiction because Ninth Circuit precedent does not require that a license be breached before the licensee can seek declaratory relief. Opposition at 10 (citing *Hal Roach Studios, Inc. v. Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1987)).

For issues not unique to patent law, this Court must apply the law of the Ninth Circuit. MedImmune seeks to characterize subject matter jurisdiction as a procedural matter that is unrelated to patent law and thus to have this Court apply Ninth Circuit law rather than that of the Federal Circuit.

Opposition at 5-7 (citing *Toxgon Corp. v. ENFL, Inc.*, 213 F.3d 1379, 1380 (Fed. Cir. 2002; *Molins PLC v. Quigg*, 837 F.2d 1064, 1066 (Fed. Cir. 1988); *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249, 1254 (Fed. Cir. 2002)).

Federal Circuit precedent controls the Court's decision in this case. Determination of whether an actual controversy exists under these facts requires evaluation of whether a licensee has a reasonable apprehension of a claim of infringement. This decision clearly implicates patent law, and is well within the purview of the Federal Circuit. See *Shell Oil Company v. Amoco Corp.*, 970 F.2d 885, 887-888 (Fed. Cir. 1992) ("The reasonable apprehension of a threat of patent infringement "clearly implicates" the patent law; the law of this circuit therefore applies.").

The cases that MedImmune cites do not support the application of anything other than the law of the Federal Circuit. *Toxgon, Molins*, and *Vanguard Research* do indicate that the law of the regional circuit should govern procedural issues, but they also support the proposition that when jurisdictional questions are intertwined with patent law considerations, the law of the Federal Circuit applies.

In *Toxgon* the Federal Circuit reviews a District Court's decision to dismiss the case for lack of subject matter jurisdiction. The court applies Ninth Circuit law to decide the correct standard under which it will review the dismissal; regional circuit law is applied to this procedural question. 312 F.3d at 1380-81. However, when deciding whether the District Court correctly interpreted the jurisdictional implications of a statute immunizing federal contractors from patent infringement suits, the *Toxgon* Court looked to Supreme Court and Federal Circuit precedent. 312 F.3d at 1381-82. When resolving a jurisdictional issue that involved patent concerns, the *Toxgon* court used the law of the Federal Circuit.

Like *Toxgon*, *Vanguard Research* states that the regional circuit is the appropriate source of law for "procedural issues not unique to patent law." 304 F.3d at 1254. However, in considering whether the plaintiff had a reasonable apprehension of suit that would create an actual controversy, the question at issue before this Court, the *Vanguard Research* court applied Federal Circuit law. 304 F.3d at 1254-55. When the *Vanguard Research* Court faced the situation that this Court now faces—determining whether a plaintiff has an actual controversy with a patentee—the *Vanguard Research* Court looked to the law of the Federal Circuit.

Similarly, in *Molins* the court held that the law of the regional circuit will apply to a question, like the ripeness question being considered in *Molins*, "which does not pertain to patent law issues and has no effect on this court's jurisdiction." 837 F.2d at 1066. Far from indicating that regional law applies in this case, the above-quoted statement in *Molins* suggests its converse: that application of regional law is inappropriate when considering questions that do pertain to patent law issues.[2] *Molins* thus further supports the conclusion that when a jurisdictional issue involves patent law concerns—such as the threat of infringement litigation between a patentee and a licensee—Federal Circuit law controls.

This Court's jurisdiction over this case depends on whether a patent licensee in good standing has an actual controversy with a patentholder whose patent the plaintiff-licensee believes is invalid, unenforceable, or not infringed. This jurisdictional issue is intertwined with patent law considerations, thus the law of the Federal Circuit controls. 28 U.S.C. § 1295 (giving the Federal Jurisdiction over appeals if

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[2] Ripeness was also the issue in *Shell Oil*; because the ripeness question in that case depended on interpretation of a statute relevant to patent law, the *Shell Oil* Court applied the law of the Federal Circuit. *Shell Oil*, 970 F.2d at 888, n.10.

the jurisdiction of the District Court was based on 28 U.S.C. § 1338, which grants exclusive jurisdiction to the federal courts in cases arising under the patent laws).

III. Subject Matter Jurisdiction

Federal Circuit precedent dictates that this case be dismissed. *Gen-Probe* held that a licensee in good standing cannot seek relief under the Declaratory Judgment Act. 2004 WL 405737 at *6. Because MedImmune is a licensee in good standing, and because the relief MedImmune seeks is for declaratory judgment, this Court has no choice but to dismiss this case for lack of subject matter jurisdiction.

A. MedImmune is a Licensee in Good Standing

MedImmune is a licensee of the '415 patent and is in good standing. MedImmune's First Amended Complaint says:

> With its New Cabilly Patent in hand, Genentech immediately exercised its illegally obtained monopoly by advising MedImmune that the New Cabilly Patent covers MedImmune's Synagis® product. As a consequence of this assertion, MedImmune began to make and continues to make significant payments to Genentech under an agreement entered into by MedImmune and Genentech on or about June 5, 1997 (the "1997 License Agreement"). This 1997 License Agreement provided rights to various intellectual property, including the patent application that later matured into the New Cabilly patent. After issuance of the New Cabilly Patent, MedImmune was forced to obtain additional license agreements from Genentech on or about February 7, 2003—at substantial cost—to cover seven new products that MedImmune has been developing (the "2003

> License Agreements") (collectively the 1997 and 2003 License Agreements are referred to herein as the "License Agreements").

FAC ¶ 18. There is no dispute that MedImmune is a licensee in good standing of the patent it seeks to challenge.

B. MedImmune Seeks Declaratory Judgment

Each of the claims remaining in this case are for declaratory judgment. The First Amended Complaint ("FAC") states:

> MedImmune also seeks a declaration that: (a) the New Cabilly Patent (which is co-owned by Genentech and COH) is invalid; (b) the New Cabilly Patent is unenforceable; (c) MedImmune's sales of its Synagis® product do not infringe any valid claim of the New Cabilly Patent; and (d) MedImmune owes no payments to Genentech under the License Agreements.

FAC ¶ 20; see also ¶¶ 131-33 (seeking declaratory judgment on contractual rights and obligations); ¶¶ 134-39 (seeking declaratory judgment that the New Cabilly patent is invalid); ¶¶ 140-61 (seeking declaratory judgment that the New Cabilly patent is unenforceable); ¶¶ 162-64 (seeking declaratory judgment that the Synagis® product does not infringe any valid and enforceable claim of the New Cabilly patent). As is indicated by the foregoing, the claims that remain at issue in this case are all claims for declaratory judgment.

C. Mandatory Dismissal

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. 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. 2004 WL 405737, *6. 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.

Requiring licensees to violate their license agreements and subject themselves to infringement suits before recognizing that they have an actual controversy with their licensors forces licensees to take a tremendous risk to challenge a patent, one that some with valid claims will likely be unwilling to take. The Federal Circuit has commented on the chilling effect this will have on patent challenges:

> To always require the termination of a license agreement as a precondition to suit would mean that a licensee must then bear the risk of liability of infringement. This would discourage licensees from contesting patent validity and would be contrary to the policies expressed in Lear.

C.R. Bard, Inc. v. Schwartz, 716 F.2d 874, 880 (Fed. Cir. 1983).

The public has a strong interest in ferreting out invalid or unenforceable patents and in ensuring that the owners of valid patents monopolize only the technology claimed by the patent. The Supreme Court has described the importance of allowing licensees to challenge the patents they license:

> Surely the equities of the licensor do not weigh very heavily when they are balanced against the 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 v. Adkins, 395 U.S. 653 (1969). Licensees may cham-

pion the public interest in eliminating the monopoly over subject matter that is not rightfully acquired; stifling their challenges risks losing to private parties property that actually belongs to the public.

Even if it has serious misgivings about the panel's conclusion, this Court is not free to reconsider policy ramifications that *Gen-Probe* rejected. There are no relevant facts that distinguish this case from the facts of *Gen-Probe*. *Gen-Probe* is controlling law, and it dictates that this case be dismissed for lack of an actual controversy. Because *Gen-Probe* ruled that no subject matter jurisdiction exists under these facts, this Court must grant Genentech's Motion. FRCP Rule 12(b)(3).

CONCLUSION

Because the *Gen-Probe* decision dictates that this Court does not have subject matter jurisdiction over MedImmune's suit for declaratory judgment, Genentech's Motion is GRANTED and the First, Second, Third, and Fourth Causes of Actions are dismissed as to both Genentech and City of Hope.

IT IS SO ORDERED.

DATED: April 23, 2004

/s/ Mariana R. Pfaelzer
HONORABLE MARIANA R. PFAELZER
United States District Judge

APPENDIX C

CONSTITUTIONAL AND STATUTORY PROVISIONS

Article III of the Constitution of the United States provides in relevant part:

> SECTION 2. The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States . . . .

Title 28 U.S.C. § 1331 provides:

> The district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.

Title 28 U.S.C. § 1338(a) provides:

> The district courts shall have original jurisdiction of any civil action arising under any act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

Title 28 U.S.C. § 2201(a) provides:

> In any case of actual controversy within its jurisdiction, except . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such a declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.