No. 05-608

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., *et al.*,

Respondents.

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

BRIEF FOR PETITIONER

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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. Appellees in that Court were Genentech, Inc., City of Hope National Medical Center, and Celltech R & D, Ltd.

LIST PURSUANT TO RULE 29.6

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

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OPINIONS BELOW

The opinion of the United States District Court for the Central District of California is unreported and is reproduced at P.C.A. 21a.[1] The opinion of the United States Court of Appeals for the Federal Circuit is reported at 427 F.3d 958 and is reproduced at P.C.A. 1a.

JURISDICTION

The judgment of the Court of Appeals was entered October 18, 2005. P.C.A. 1a, J.A. 455. The petition for certiorari was filed November 10, 2005, and granted February 21, 2006.

[1] Citations to "P.C.A." are to the appendix to the petition for certiorari. Citations to "J.A." are to the joint appendix.

J.A. 458. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS AND RULE INVOLVED

Article III, § 2, of the Constitution of the United States, and relevant portions of 28 U.S.C. §§ 1331, 1338, 2201 and 2202, 35 U.S.C. §§ 135, 282, 283, 284 and 285, and Rule 57, Fed. R. Civ. P., are reproduced in the addendum.

STATEMENT

Petitioner, MedImmune, Inc., is a biotechnology company in Gaithersburg, Maryland, founded in 1988. Unlike traditional pharmaceutical manufacturers, which develop and market chemical compounds, MedImmune uses "bioengineering" to alter the genetic arrangement of living cells so that they produce antibodies (immunoglobulins) for use as medications targeted specifically at particular harmful viruses and agents that can attack the human body.

A. MedImmune's Development of Synagis®.

After seven years of effort and expense for research, development and many clinical trials, MedImmune in 1998 received approval from the U.S. Food and Drug Administration for Synagis® (palivizumab), a bioengineered antibody that prevents infection from RSV (respiratory syncytial virus), a contagious viral condition dangerous to vulnerable infants. Nearly all young children contract RSV, half of them in the first year of life, and soon recover. But RSV infections are a serious threat to high-risk pediatric patients—particularly to newborns with low birth weight, whose natural immune systems are not sufficiently developed to recognize and combat RSV, and also to children with chronic heart or lung ailments. For such vulnerable infants, RSV infection unless prevented can be fatal.

To develop Synagis®, MedImmune's scientists using recombinant DNA technology reengineered mouse genes that

encoded an RSV antibody in mice, removed most mouse-specific features, and replaced those with human ones. Synagis® is classified as a "humanized monoclonal antibody," *i.e.*, an animal antibody modified into a predominantly human one ("humanized"), and produced as identical copies from a single type of cell ("monoclonal"). When introduced into the human body, Synagis® neutralizes the RSV virus before infection can occur. Synagis® was the first monoclonal antibody successfully developed to combat an infectious disease. In 1998 MedImmune was granted U.S. Patent No. 5,824,307 for the Synagis® antibody and methods of using it. Hospitalization of children for RSV infection has dropped sharply since the introduction of Synagis®.[2]

B. The 1997 License.

Respondent Genentech, Inc., owns U.S. Patent No. 4,816,567 ("the Cabilly I patent"), applied for April 8, 1983, and issued March 28, 1989, to inventors Shmuel Cabilly, *et al.* J.A. 485. The Cabilly I patent was directed to a process for synthesizing monoclonal antibodies that are "chimeric," *i.e.*, containing a relatively high proportion of animal to human components. On June 4, 1997, a year prior to the FDA approval of Synagis®, MedImmune accepted a license from Genentech covering any anti-RSV monoclonal antibody MedImmune might thereafter make, use or sell that would be covered by the Cabilly I "chimeric" patent, J.A. 399, or by "continuations" of the Cabilly I patent, including a pending "coexpression" patent application, the exact claims of which were not disclosed. *Id.* At the time of the license it was

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[2] See National Institutes of Health Office of Technology Transfer, *Synagis® Helping Infants and Parents Breathe Easier: A Case Study* 2 (2002); Meissner *et al.*, *Revised Indications for the Use of Palivizumab and RSV Immune Globulin Intravenous for the Prevention of RSV Infections*, 112 PEDIATRICS 1447 (2003). Synagis® currently is administered annually to approximately 180,000 infants in the United States, and is widely used in other countries.

uncertain whether that pending application ever would be granted, and if it were to be, what would be the scope of its claims. The license called for an initial licensing fee and subsequent quarterly royalties based on revenues from "Licensed Product(s)," defined as those that "would, if not licensed under this Agreement, infringe one or more claims of either or both" of the patents included. J.A. 399, 402-03. The license contained no mention of Synagis®. The license contemplated that the licensed patents and applications might not be valid, and that MedImmune's products might not infringe, in which event no royalty would be due. J.A. 399; see also J.A. 411. The license contained no promise by MedImmune not to sue or to challenge patent validity.

When Synagis® became available in September 1998, MedImmune concluded that respondents' Cabilly I patent—which dealt with chimeric, rather than humanized, antibodies—did not cover Synagis®, so that Synagis® was not a "Licensed Product" under the 1997 license. J.A. 399, 416. Accordingly, MedImmune never paid any royalties to Genentech under the 1997 license of the Cabilly I patent for sales of Synagis®. J.A. 388, 416. The Cabilly I patent expired March 28, 2006.

C. Genentech's 2001 Cabilly II Patent.

Genentech's patent application referred to in the 1997 license agreement, J.A. 399, had been filed in 1988 and shortly thereafter became the subject of a prolonged dispute between Genentech and a British firm, Celltech R&D, Ltd., concerning which firm's scientists were the first inventors. In 1989, Celltech had obtained U.S. Patent No. 4,816,397, naming Michael A. Boss as the first inventor ("the Boss patent"). J.A. 459. Shortly thereafter Genentech amended its pending patent application to add eighteen much broader claims that concededly had been copied essentially verbatim from the Boss patent. *Compare* J.A. 484 *with* J.A. 549-50. These claims purported to cover the process of producing

any type of monoclonal antibody—chimeric, humanized, or other—in one cell using recombinant DNA techniques. Genentech's amendment expectably triggered a contested patent-interference proceeding against Celltech in the U.S. Patent and Trademark Office (PTO), in which Genentech contended that Cabilly, not Boss, was the first inventor, and that its application was entitled to priority over Celltech's Boss Patent.

After seven years of administrative litigation, the PTO in 1998 confirmed that Celltech, not Genentech, was entitled to its patent based on priority of invention. *Cabilly* v. *Boss*, 55 U.S.P.Q.2d 1238 (PTO Bd. Pat. App. & Int. 1998). But in 2001, after Genentech sought judicial review pursuant to 35 U.S.C. § 146, J.A. 276, the two companies settled. J.A. 334. In stipulated findings and judgment drafted by the parties' attorneys, Celltech agreed—disavowing its own victory in the PTO decision—that Genentech had priority of invention, that Celltech's Boss patent (nearing its 2006 expiration date) should be cancelled, and that a new patent based on the broad claims and with an expiration seventeen years in the future should issue to Genentech. J.A. 334, 343-46, 347-48. In return Celltech received money payments and valuable "preferential" rights under the new patent. J.A. 106-08, 228; Ct. Apps. J.A. 1697, 1713. The PTO on remand from the court declared the claims of Celltech's Boss patent void, based on the stipulated court judgment, but commenting on the irregular judicial procedure observed that the effect of that judgment was to grant Genentech a patent with a term of 29 years:

> "We will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991."

Cabilly v. *Boss*, 60 U.S.P.Q.2d 1752, 1755 n.7 (P.T.O. Bd. Pat. App. & Int. 2001). Nevertheless, on December 18, 2001,

the PTO issued to Genentech U.S. Patent 6,331,415 B1 ("the Cabilly II patent"), with a term lasting until 2018. J.A. 509.

Upon that issuance in 2001—four years after the 1997 license agreement—the exact scope of the claims of the Cabilly II patent was publicly disclosed for the first time. Genentech in a press release described its new patent as a "Fundamental U.S. Patent for Antibody Technology" that "covers a principal way that therapeutic and diagnostic antibodies are made by biotechnology and pharmaceutical companies and others using recombinant DNA technology." J.A. 417. The biotechnology press called it "a patent claiming broad rights to fundamental methods for the recombinant expression of antibodies" that "could potentially block the production of antibody products by rival companies or increase their royalty burden." J.A. 423.

D. Genentech's Infringement Charge and Demand for Royalties.

Within days of issuance of the Cabilly II patent on December 18, 2001, a member of Genentech's legal staff telephoned a senior officer at MedImmune to announce that Synagis®, on the market since 1998, infringed the new Cabilly II patent, and that therefore it was a "Licensed Product" for which royalties must be paid under the 1997 license. J.A. 419. By letter of January 7, 2002, Genentech followed up with a written notice

> "to confirm Genentech's expectation that MedImmune will pay royalties on sales of its Synagis® antibody product pursuant to the license granted by Genentech under the recently issued U.S. Patent No. 6,331,415."

Id. MedImmune in response asked to know Genentech's "basis for believing that MedImmune's product would infringe any valid claim of the '415 [Cabilly II] Patent such that royalties would be due." J.A. 421. Receiving no re-

sponse for several weeks, MedImmune explained that it had wired a payment:

> "Such payment, however, was made under protest and with reservation of all of our rights."

J.A. 426. MedImmune also warned that it would "evaluate how further to proceed." *Id.* Genentech reiterated its infringement claim. J.A. 428.

Based on the communications from Genentech asserting that Synagis® infringed the Cabilly II patent and demanding royalties, and also on Genentech's "public statements about the breadth and importance of the Cabilly II patent," J.A. 388; see J.A. 417, MedImmune concluded "that Genentech would terminate the 1997 License Agreement and sue MedImmune for patent infringement based on sales of Synagis® if MedImmune did not make the royalty payments as demanded," J.A. 388. MedImmune "chose not to risk . . . the potential imposition of a preliminary or permanent injunction that would prevent MedImmune from selling the product." J.A. 389. "Accordingly, MedImmune decided to pay royalties under protest . . . and subsequently challenge in court whether the Cabilly II patent was valid, enforceable and/or infringed by MedImmune's Synagis® product." *Id.* The dispute remained unresolved while MedImmune continued to pay the sums demanded for Synagis®, and continued to do business with Genentech on other products. *E.g.*, J.A. 437.

E. The District Court Proceeding.

With demand for Synagis® growing, and payments to Genentech correspondingly rising, on April 11, 2003, MedImmune brought suit in the United States District Court for the Central District of California under, *inter alia*, 28 U.S.C. §§ 1331 and 1338. J.A. 41, 103. The complaint sought a declaratory judgment under 28 U.S.C. § 2201(a) against respondents Genentech and City of Hope, a co-owner, that the Cabilly II patent was invalid as anticipated, obvious, not adequately described and not enabled (35 U.S.C. §§ 101, 102,

103, 112), J.A. 136-37; unenforceable because Genentech had knowingly failed to disclose material prior art and in other respects misled the Patent and Trademark Office, J.A. 106-30, 137-40; and not infringed by Synagis®, so that royalties were not due under the license. P.C.A. 29a; J.A. 43, 46, 60-63, 105, 136-41, 147.

Neither respondent questioned the District Court's jurisdiction. Genentech said it "admits that, based on the allegations, the Court has jurisdiction to hear this dispute." J.A. 149. City of Hope likewise made no jurisdictional objection. J.A. 183. The complaint also sought damages for federal and state antitrust and unfair-competition violations, based on collusion by Genentech and Celltech to obtain issuance of the Cabilly II patent and share in its benefits, J.A. 63-68, 141-48; those claims were dismissed on grounds of *Noerr-Pennington* immunity.[3] J.A. 349. The case moved towards trial. J.A. 24.

Then, on March 5, 2004, the United States Court of Appeals for the Federal Circuit decided *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004). *Gen-Probe* held that a patent licensee seeking a declaratory judgment "must . . . materially breach the agreement . . . before bringing suit," 359 F.3d at 1381, and that as a matter of law, when a patent licensee continued to pay royalties and did not violate the license, "no actual controversy supports jurisdiction under the Declaratory Judgment Act," *id.* at 1382.

The District Court (Pfaelzer, J.) granted motions by Genentech and City of Hope to dismiss for lack of subject-matter jurisdiction. P.C.A. 31a. The court explained that it

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[3] See *Eastern R.R. Presidents Conference* v. *Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers* v. *Pennington*, 381 U.S. 657 (1965). Judgment on those claims was entered under Fed. R. Civ. P. 54(b), J.A. 380, and separately appealed, J.A. 381. Celltech was a party in the courts below with respect to those claims; it is not a party in this Court.

had "no choice but to dismiss" because "*Gen-Probe* held that a licensee in good standing cannot seek relief under the Declaratory Judgment Act." P.C.A. 28a. At the same time, the District Court observed that it dismissed with reluctance:

> "Even if it has serious misgivings about the panel's conclusion, this Court is not free to reconsider policy ramifications that *Gen-Probe* rejected."

P.C.A. 31a. The District Court characterized the Federal Circuit's new doctrine as a departure from that circuit's and this Court's previous rulings:

> "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)."

P.C.A. 24a. The District Court added that "The public has a strong interest in ferreting out invalid or unenforceable patents," P.C.A. 30a, and it quoted this Court:

> "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."

Id., quoting *Lear*, 395 U.S. at 670. But, obeying *Gen-Probe*, the District Court dismissed, while expressing concern that the Federal Circuit's doctrine "forces licensees to take a tremendous risk to challenge a patent, one that some with valid claims will likely be unwilling to take." P.C.A. 30a.

F. The Court of Appeals Decision.

On appeal the Federal Circuit (Newman, J., joined by Mayer and Clevenger, JJ.) affirmed the dismissal, following its jurisdictional rule stated in *Gen-Probe* and reiterated in

MedImmune, Inc. v. *Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *pet'n for cert. pending*, No. 05-656. P.C.A. 1a.[4] The court held that because MedImmune had continued to pay, albeit under protest, the royalties demanded by Genentech, therefore as a matter of law MedImmune could not have a "reasonable apprehension . . . that it will face an infringement suit," P.C.A. 7a, and therefore there could be no "actual controversy" satisfying "the constitutional and statutory requirements," P.C.A. 7a-8a. In order to constitute an "actual controversy," the Federal Circuit held,

> "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 . . . ."

P.C.A. 7a, quoting *MedImmune, Inc.* v. *Centocor, Inc.*, 409 F.3d at 1379. To permit a declaratory-judgment action, the court believed, would create an "inequity" that would permit the licensee to sue but retain its rights under the license if it lost. P.C.A. 7a.

The Court of Appeals devoted one paragraph to putting aside this Court's decisions construing the Declaratory Judgment Act. P.C.A. 8a. The Court of Appeals also rejected the pertinence of this Court's decision in *Lear, Inc.* v. *Adkins*, which had held that federal patent policy strongly encourages the testing of patent claims, and that a licensee could not be estopped to challenge the validity of a licensed patent. *Lear*, the court said, did not apply because there the patent licensee had stopped paying royalties under the license. P.C.A. 4a-6a. "[T]he issue here is not one of estoppel, but of availability of the declaratory judgment procedure." P.C.A. 6a.

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[4] The Court of Appeals also affirmed summary judgment on the antitrust and unfair-competition claims based on *Noerr-Pennington* immunity. P.C.A. 11a-12a. Judge Clevenger dissented from that part of the decision, reasoning that the appeal of that judgment should have been transferred to the Ninth Circuit pursuant to 28 U.S.C. § 1631. P.C.A. 17a-20a.

The Court of Appeals similarly found no useful guidance in this Court's admonition in *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100, 102 (1993), that the policy enacted in the patent code favors adjudication of the validity of patents, and that validity should be decided under the Declaratory Judgment Act even after a finding of non-infringement, *id.* at 96. Because *Cardinal Chemical* "was an infringement suit, not a declaratory action," the Court of Appeals concluded that "the present case is unaffected by *Cardinal Chemical*." P.C.A. 8a.

SUMMARY OF ARGUMENT

One would have thought that the issue in this case had been settled for almost seventy years. In 1934, encouraged by a unanimous 1933 decision of this Court holding that Article III embraces declaratory judgments in actual, concrete legal controversies,[5] Congress with the support of academics, business enterprises and the bar enacted the Declaratory Judgment Act, now 28 U.S.C. § 2201. A very simple provision, the Act authorizes a federal court to issue a judgment declaring legal rights in a "case of actual controversy." The Act was adopted so that in such a case it would not be "necessary to breach a contract or a lease, or act upon one's own interpretation of his rights when disputed;" instead, under 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." S. Rep. No. 1005, 73d Cong., 2d Sess. 3 (1934).

The Act soon was applied by this Court in three leading cases. In *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 241 (1937), this Court held unanimously that the Act and Article III required simply "a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding." In *Maryland Cas.*

[5] *Nashville, C. & St. L. Ry.* v. *Wallace*, 288 U.S. 249 (1933).

Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), again unanimously, this Court described "the question in each case" as whether there is "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality." And in *Altvater* v. *Freeman*, 319 U.S. 359, 364 (1943)—a challenge to the validity of a patent, brought by licensees paying royalties—this Court held that "[t]he fact that royalties were being paid" did not affect jurisdiction. This Court later summarized, also without dissent, that "[t]he sole requirement for jurisdiction under the Act" is that there be a "real and immediate . . . actual 'controversy.'" *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993), quoting *Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).

Nevertheless, in a recent series of jarring decisions, of which this is the latest, the Federal Circuit has paid little heed to this Court's holdings and has ignored the central purpose of the Declaratory Judgment Act. The Federal Circuit holds that under Article III and the Act, a manufacturer accused by a patentee of liability under a license for an assertedly infringing product cannot seek a declaratory judgment unless it first commits material breach of the license by refusing to pay royalties—thereby placing itself in jeopardy not only of damages for breach of contract, but of an injunction prohibiting sales of its product, treble-damage penalties, interest, attorneys' fees and other costly sanctions for patent infringement under 35 U.S.C. §§ 283, 284 and 285. That absolute rule has no support in the statute's text or history, nor in this Court's precedents.

That new constitutional interpretation would have amazed the drafters of the Declaratory Judgment Act—whose purpose, expressed in a simple, encompassing text and unambiguous explanations by the enactors—was to allow contracting parties to resolve their disputes in court without breach and without risking economic destruction and multiplying damages. The Act, as often recognized and reiterated, was

designed to permit judicial resolution of contract disputes "before or after breach." REPORT OF ADVISORY COMMITTEE ON RULES FOR CIVIL PROCEDURE 145 (1937). That has long been settled law throughout the country. The holding here, besides disregarding decades of contrary appellate decisions and the understanding of leading treatise writers, would on unsupported constitutional grounds disrupt the law of licenses and contracts throughout the economy, essentially undoing the achievement of the reformers of 1934.

Apart from its constitutional error and disregard of precedent, the Federal Circuit also is entirely at odds with a century of decisions of this Court applying federal patent law. This Court repeatedly has emphasized that the patent laws enacted by Congress *favor* and *encourage* and *protect* challenges to patent validity. See *Cardinal Chemical*, 508 U.S. at 100; *Blonder-Tongue Labs.* v. *University of Ill. Foundation*, 402 U.S. 313, 344-45 (1971). This Court has recognized that a licensee often will be the most likely and effective challenger to an invalid patent. *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Yet the Federal Circuit holds that by agreeing to a license—in this case, a license including a broad patent not issued and its claims not disclosed until four years later—the licensee is paralyzed from challenging a patentee's assertion of liability, unless it is willing to jeopardize its principal product, and risk potential financial ruin if a preliminary injunction is entered or its case does not succeed.

The Federal Circuit, citing its own policy judgments, would revive for patent licensees not in breach the discredited doctrine of licensee estoppel, which this Court emphatically rejected in *Lear*. Further, it would write that new barrier into Article III of the Constitution, beyond the corrective power of Congress—the body assigned by Article I to adjust patent policy.

ARGUMENT

I. THE COMPLAINT STATED A "CASE OF ACTUAL CONTROVERSY" UNDER THE DECLARATORY JUDGMENT ACT AND ARTICLE III.

The Declaratory Judgment Act has been a useful part of the federal judicial code for more than seventy years. Enacted in 1934, its text provides:

> "In a case of actual controversy within its jurisdiction [with specified exceptions] . . . 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 declaration, whether or not further relief is or could be sought. . . ."

28 U.S.C. § 2201(a). The Act, it has been recognized since its beginning, reaches to the full scope of the federal judicial power of Article III. *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 239-40 (1937); *Ashwander* v. *TVA*, 297 U.S. 288, 325 (1936).

A. The Declaratory Judgment Act and Article III Do Not Exclude Patent Licensees Paying Royalties Under Protest.

1. *A "Case of Actual Controversy" Is a Concrete Legal Dispute Between Parties With Adverse Interests*.

(a) Early Decisions.—Aetna Life Ins. Co. v. Haworth.— The requirements for a "case of actual controversy" under the 1934 Act were soon explained by this Court unanimously through Chief Justice Hughes:

> "A justiciable controversy is . . . *distinguished from* a difference or dispute of a *hypothetical or abstract* character; from one that is academic or moot. . . . The controversy *must be definite and concrete*, touching the

> legal relations of parties having *adverse legal interests*. . . . It must be *a real and substantial controversy admitting of specific relief* through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."

Aetna Life Ins. Co. v. *Haworth*, 300 U.S. 227, 240-41 (1937) (emphasis supplied). In *Aetna*, a policyholder of five life insurance policies gave notice that he was permanently disabled and so entitled to benefits under two of them, and also that he was no longer obliged to pay premiums but that the insurance company would be liable at his death. Although the company refused to recognize his claims, he did not bring suit. *Id*. at 238. The insurance company then sought relief under the Declaratory Judgment Act, alleging that without a resolution of the dispute, evidence might be lost, and that it would need to set aside a reserve for potential liability. *Id*. at 239. This Court held that the requirements of the Act and the Constitution were satisfied. The complaint "calls, not for an advisory opinion upon a hypothetical basis, but for an adjudication of present right upon established facts." *Id.* at 242. This Court reaffirmed, as it had in *Nashville, C. & St. L. Ry.* v. *Wallace*, 288 U.S. 249 (1933), that what Article III requires is

> "a concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding."

Aetna, 300 U.S. at 241—a dispute that "is definite and concrete, not hypothetical or abstract," *id.* at 242.

Maryland Casualty.—Four years after *Aetna* this Court emphasized that the Declaratory Judgment Act prescribes no rigid or mechanical formula for a "case of actual controversy," as long as the essentials of a concrete, adversarial legal dispute are present. In language often quoted since, this

Court held that the Act calls for examing the particular circumstances:

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

Altvater v. Freeman.—Completing the trilogy of this Court's foundational decisions construing the Declaratory Judgment Act was a case like this one—a declaratory claim of patent invalidity by patent licensees paying royalties. *Altvater* v. *Freeman*, 319 U.S. 359 (1943), decided the same jurisdictional issue before this Court today. The petitioners, patent licensees in good standing who were sued for making unauthorized sales, filed a counterclaim for a declaratory judgment that the licensed patents were invalid. The licensees did not "cancel[] the license agreement" or "refuse[] to pay any royalties under it," because if they did "they would be subject to infringement suits." *Id.* at 361. Just as here, the patentee-licensors denied that there was an "actual controversy," arguing that "so long as they continue to pay royalties, there is only an academic, not a real controversy, between the parties." *Id.* at 364. This Court squarely rejected that argument:

> "The fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.' *Aetna* . . . . That controversy was 'definite

> and concrete, touching the legal relations of parties having adverse legal interests.' *Aetna* . . . ."

Id. This Court emphasized that if the royalties, which were paid "under protest and under the compulsion of an injunction decree," had not been paid, the licensees faced a "risk . . . [of] treble damages in infringement suits." *Id.* at 365. They sought a declaratory judgment "to lift the heavy hand of that [royalty] tribute from the business." *Id.*

> "It was the function of the Declaratory Judgments Act to afford relief against such peril and insecurity . . . . And 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."

Id. Further, this Court later explained that in *Altvater* "we nowhere stated that a [licensee] counterclaimant could seek the affirmance of a declaratory judgment only if it ensured that its future actions would continue to violate the patentee's alleged rights." *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100 n.22 (1993).

Contemporaneous decisions authored by distinguished appellate judges underscored the seminal holdings of this Court. Six months after *Aetna*, Judge Parker explained that the Declaratory Judgment Act was enacted "to settle legal rights and remove uncertainty and insecurity from legal relationships without awaiting a violation of the rights or a disturbance of the relationships." *Aetna Cas. & Sur. Co.* v. *Quarles*, 92 F.2d 321, 325 (4th Cir. 1937). Judge Magruder wrote that "[t]his constitutional requirement [Article III], as applied to declaratory judgments, is not interpreted in any narrow or technical sense." *Dewey & Almy Chem. Co.* v. *American Anode, Inc.*, 137 F.2d 68, 70 (3d Cir.), *cert. denied*, 320 U.S. 761 (1943). Judge Swan explained that if a patent licensee were required to terminate the contract before seek-

ing declaratory judgment, "it will be too late to avoid an action for damages," yet "[t]he very purpose of the declaratory judgment procedure is to prevent the accrual of such avoidable damages," *American Machine & Metals, Inc.* v. *De Bothezat Impeller Co.*, 166 F.2d 535, 536 (2d Cir. 1948). Rather than requiring a licensee to "risk an otherwise profitable business in order to present a justiciable 'controversy[,]' [t]he Declaratory Judgments Act was designed to obviate just this sort of peril." *Id.* at 537.

(b) Subsequent Decisions.—This Court in later decisions explained that a dispute as to whether one is under a legal obligation with which one must comply is a classic "actual controversy": "if appellants are now under such an obligation, that in and of itself makes their attack on the validity of the law a live controversy, and not an attempt to obtain an advisory opinion." *Lake Carriers' Ass'n* v. *MacMullan*, 406 U.S. 498, 507 (1972). What matters is that—as here—

> "[t]he disagreement must not be nebulous or contingent but must have taken on fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them."

Public Serv. Comm'n v. *Wycoff Co.*, 344 U.S. 237, 244 (1952). In *Cardinal Chemical* this Court confirmed that "a party may . . . seek a declaratory judgment, even if the patentee has not filed an infringement action," and held that Article III jurisdiction persisted on appeal "as long as the parties continued to dispute the issue of validity." 508 U.S. at 95, 97.

The regional courts of appeals when they had jurisdiction of patent cases held on several occasions that a "case of actual controversy" under the Declaratory Judgment Act does not require a patent licensee to withhold royalties or terminate a license. Otherwise the licensee would be forced 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."

Precision Shooting Equip. Co. v. *Allen*, 646 F.2d 313, 318 (7th Cir.), *cert. denied*, 454 U.S. 964 (1981). The Second Circuit 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) (emphasis supplied). "There is clearly a case and controversy here since the plaintiffs-licensees have an interest in proving patent invalidity and thereby escaping liability for royalties." *Id.* at 187 n.4. *Accord, American Sterilizer Co.* v. *Sybron Corp.*, 526 F.2d 542, 543 (3d Cir. 1975). The Moore treatise summarized:

> "In general, the fact that a declaratory relief plaintiff holds a valid license to use the allegedly patented item is irrelevant; the licensee need not terminate the license in order to maintain a federal declaratory relief action for patent invalidity."

12 J. MOORE *et al.*, MOORE'S FEDERAL PRACTICE § 57.22[8][c][i] at 57-80 (3d ed. 2005).

The jurisdictional principle of course is not confined to patent licenses. For instance, 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 1542, 1556 n.23 (9th Cir. 1990). Parties to all kinds of contracts are permitted to bring declaratory-judgment actions without first committing material breaches. "[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." *Keener Oil & Gas Co.* v. *Consolidated Gas Utilities Corp.*, 190 F.2d 985, 989 (10th Cir. 1951). Last year the Second Circuit "easily rejected" a challenge to declaratory jurisdiction when parties not in breach disputed the scope of coverage of an insurance policy. *Duane Reade, Inc.* v. *St. Paul Fire & Marine Ins. Co.*, 411 F.3d 384, 389 (2d Cir. 2005). In a suit challenging liability on a commercial lease, the same court held:

> "We agree with the plaintiff's implicit premise that it need not fail to make payments in violation of its lease or mortgage obligations in order to have a justiciable controversy concerning its obligation to make such payments."

118 East 60th Owners, Inc. v. *Bonner Properties, Inc.*, 677 F.2d 200, 202 n.1 (2d Cir. 1982). "The Declaratory Judgment Act exists to allow litigants to determine an actual controversy . . . before the dispute grows into a contract violation . . . ." *Doody* v. *Ameriquest Mortgage Co.*, 242 F.3d 286, 288 (5th Cir. 2001).[6]

2. *The Federal Circuit Disregarded the Decisions of This Court.*

The Federal Circuit offered no convincing way to escape the declaratory-judgment holdings of this Court. In *Gen-Probe* it had acknowledged this Court's *Aetna* decision but denied its authority on this basis:

> "While this language [in *Aetna*] suggests that a litigant may sue to determine contract rights before a breach, this 1937 Supreme Court case did not involve a de-

[6] See also, *e.g.*, *Venator Group Specialty, Inc.* v. *Matthew/Muniot Family, LLC*, 322 F.3d 835, 840 (5th Cir. 2003); *Continental Cas. Co.* v. *Coastal Sav. Bank*, 977 F.2d 734, 738 (2d Cir. 1992).

> claratory judgment action instituted by a patent licensee in good standing."

359 F.3d at 1382. But "this 1937 Supreme Court case" stated a fundamental constitutionally-based rule of general application. There is no separate constitutional rule for patent-license cases that specially limits a federal court's jurisdiction under the Declaratory Judgment Act and Article III.

The Federal Circuit in the present case acknowledged *Maryland Casualty*, P.C.A. 8a, which looked to whether "under all the circumstances" there was a "substantial controversy" with "immediacy and reality" between parties with "adverse legal interests," 312 U.S. at 273. But the Federal Circuit, to the contrary, has announced an absolute rule that no "actual controversy" can exist without breach of contract. It maintained that its automatic rule was not a departure from *Maryland Casualty*, but simply a "synthesis of the totality-of-the-circumstances test for determining whether there is a justiciable controversy." P.C.A. 7a-8a.

The Federal Circuit here made no mention of *Altvater*, which approved a declaratory-judgment claim by patent licensees not in breach. In *Gen-Probe* (which was settled soon after a petition for certiorari was filed) the Federal Circuit had held *Altvater* inapplicable because "[t]he royalty payments in *Altvater* were paid not under the terms of a license agreement; rather, they were paid 'under the compulsion of an injunction decree,'" 359 F.3d at 1382, quoting *Altvater*, 319 U.S. at 365—even though this Court in *Altvater* had equally noted that, as here, the royalties also were paid "under protest," 319 U.S. at 365, and this Court explicitly held that ongoing royalty payments and absence of breach did not preclude an "actual controversy" under the Declaratory Judgment Act. *Id*.

Cardinal Chemical was previously dismissed by the Federal Circuit as a decision that "did not concern the jurisdiction of federal district courts" (as opposed to appellate courts) and

therefore was "inapposite," and should be "limited to the specific facts of that case." *MedImmune, Inc.* v. *Centocor, Inc.*, 409 F.3d at 1380, quoting in part *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*, 78 F.3d 540, 546 (Fed. Cir. 1996). In the present case once again the Federal Circuit concluded that "nothing in *Cardinal* undermines our decisions on declaratory justiciability at the trial court level." P.C.A. 8a, quoting *Super Sack Mfg. Corp.* v. *Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995). It has called *Cardinal Chemical*'s applicability "twice rejected" by its own prior decisions, *MedImmune*, 409 F.3d at 1380, and held that "[t]he present case is unaffected by *Cardinal Chemical*." P.C.A. 8a.

B. This Is a "Case of Actual Controversy."

The judgment on review here endorses a rule that as a matter of law there can be no "actual controversy" in a patent challenge by a licensee unless the licensee has a "reasonable apprehension of suit"—and that, also as a matter of law, as long as royalties are being paid and no breach has occurred, "reasonable apprehension of suit" cannot exist.[7] The statute, however, speaks of "case of actual controversy." The phrase "reasonable apprehension of suit" is not to be found in the text or history of the statute, nor has this Court ever used it.

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

Cardinal Chemical, 508 U.S. at 96, quoting *Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 734-35 (Fed. Cir. 1988). However, under either formulation—"actual controversy" or "reasonable apprehension of suit"—the Act is satisfied here.

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[7] In one case the Federal Circuit escalated its requirement to "reasonable apprehension of *imminent* suit." *Teva Pharmaceuticals USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir.) (emphasis in original), *cert. denied*, 126 S. Ct. 473 (2005).

1. *"Actual Controversy" Is Not Limited to "Reasonable Apprehension of Suit."*

"Reasonable apprehension of suit" first appeared in the context of the typical action for declaration of invalidity and non-infringement brought by a potential infringer against a patentee. In such suits "reasonable apprehension of suit," along with likelihood of producing the disputed item (here already produced and sold for four years) could establish a concrete legal controversy. See *Société de Conditionnement* v. *Hunter Engineering Co.*, 655 F.2d 938, 944 (9th Cir. 1981); *Japan Gas Lighter Ass'n* v. *Ronson Corp.*, 257 F. Supp. 219, 237 (D.N.J. 1966).

A "reasonable apprehension of suit" certainly can be significant, and often may be *sufficient* in the circumstances to establish an "actual controversy." But apprehension of suit is not a *necessary* condition, and this Court has never suggested such a thing. It scarcely would have, given that in *Aetna* this Court noted that the plaintiff was suing precisely *because* the adverse party had declined to bring its asserted claim to court; the insurance company properly sought a declaratory judgment when the insured and beneficiary

> "have not instituted any action wherein the plaintiff would have an opportunity to prove the absence of the alleged disability."

300 U.S. at 239.

Courts of appeals have confirmed that apprehension of a lawsuit "is not the only way to establish the existence of a case for purposes of Article III." *Sallen* v. *Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001). In *Precision Shooting*, 646 F.2d at 314, the Seventh Circuit recognized that an "actual controversy" existed even if a patent licensee paying royalties had "no reasonable apprehension of liability in an infringement suit." The appropriate

question, the court held, was whether there was "a reasonable apprehension that the patentee will bring an infringement suit against [the licensee] *if there is non-compliance with the license*." 646 F.2d at 318 (emphasis supplied). This Court explained:

> "If . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint . . . under the Act."

Cardinal Chemical, 508 U.S. at 96 (emphasis in original). This Court in *Cardinal Chemical* further observed that an "actual controversy" under the Declaratory Judgment Act could include a challenge to a patent's validity even without a prior charge of infringement:

> "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."

Id. (footnote omitted), quoting *Bresnick* v. *United States Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943). See also *Hanes Corp.* v. *Millard*, 531 F.2d 585, 592 (D.C. Cir. 1976).

Certainly payment under protest, as occurred here, does not negate an "actual controversy" under the Act. See *Altvater*, 319 U.S. at 365. This Court never has abided the argument that a payment made under threat of financial ruin is voluntary and waives judicial relief. As explained through Justice Holmes,

> "It always is for the interest of a party under duress to choose the lesser of two evils. But the fact that a choice was made according to interest does not exclude duress. It is the characteristic of duress properly so called."

Union P.R.R. v. *Public Serv. Comm'n*, 248 U.S. 67, 70 (1918). See also, *e.g.*, *Swift Co.* v. *United States*, 111 U.S. 22, 28-29 (1884) ("The appellant had no choice. The only

alternative was to submit to an illegal exaction, or discontinue its business."); *Atchison, T. & S.F. Ry.* v. *O'Connor*, 223 U.S. 280, 286-87 (1912) (Holmes, J.) (when party paying tax "had no certainty of ultimate success," and chose not "to take the risk of having its contracts disputed and its business injured and of finding the tax more or less nearly doubled," then "the payment was made under duress").

2. *Petitioner Presented an "Actual Controversy."*

The statutory requirements are satisfied here. The court acknowledged that the parties had "adverse legal interests." P.C.A. 8a, quoting *Aetna*, 300 U.S. at 241. The dispute was as to the parties' "rights and other legal relations." 28 U.S.C. § 2201(a). And there was an "actual controversy within its jurisdiction," in which the material facts are concrete rather than speculative, and a court ruling can resolve the dispute. That statutory template is not affected by whether in addition MedImmune "take[s] some additional act to deepen gray into black," *Precision Shooting*, 646 F.2d at 318, by putting itself in breach of the license agreement to which Genentech asserted it was subject.

A central concern when Article III was first applied to declaratory judgments was that the facts and issues be actual, adverse and concrete. *Nashville Ry.*, 288 U.S. at 264; *Aetna*, 300 U.S. at 240-41. MedImmune was not a stranger with no interest. Here the uncontroverted record shows a specific assertion of liability based on infringement of a patent by sales of a product approved by the FDA and on the market; a demand for royalties; denial of infringement and liability; denial of the validity and enforceability of the patent; and payment under protest. For MedImmune to commit breach of the license would not make this case any more concrete and "admitting of an immediate and definitive determination of the legal rights of the parties." *Aetna*, 300 U.S. at 241. All that breach would accomplish would be to heighten the risks

and consequences—exactly what the Declaratory Judgment Act was enacted to avoid.

This dispute fits easily within this Court's decisions. As in *Aetna*, it is a dispute about legal obligations that "is definite and concrete, not hypothetical or abstract." 300 U.S. at 242. As in *Maryland Casualty*, it is "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality." 312 U.S. at 273. And if the Federal Circuit decision here is correct, *Altvater* could not have been decided as it was.

3. *Petitioner Presented a "Reasonable Apprehension of Suit."*

Even if "reasonable apprehension of suit," rather than "actual controversy" were the only constitutional and statutory test, the undisputed facts here amply demonstrated not only an "actual controversy," but a "reasonable apprehension of suit" as well.[8]

Beginning in the 1930s, countless decisions have allowed declaratory-judgment actions by manufacturers which have been accused by a patentee of infringement, but have not been sued for it. Those cases have held that such accusation creates a "reasonable apprehension of suit" sufficient for an "actual controversy." That assertion of infringement is exactly what occurred here, with Genentech also asserting that therefore Synagis® upon the issuance of the Cabilly II patent in 2001 became a "Licensed Product" that "would, if not licensed under this Agreement, infringe," J.A. 399, so that royalties were due under the 1997 license. J.A. 419, 428. MedImmune did not agree, and paid royalties only "under

[8] The Court of Appeals incorrectly stated that "MedImmune concedes that it is free of apprehension of suit." P.C.A. 4a. MedImmune specifically declared, J.A. 389, and argued in the Court of Appeals that "Genentech's demands for royalties under an existing license for a new patent created a reasonable apprehension of an infringement suit." Brief of Plaintiff-Appellant, U.S. Ct. Apps., Fed. Cir., at 30.

protest." J.A. 389, 426. Genentech did not deny its "clear threat to enforce the Cabilly II patent against MedImmune." J.A. 388; see pp. 6-7, *supra*. MedImmune sought a declaration that Synagis® did not infringe, that it therefore was not covered by the license, and that the Cabilly II patent was both invalid and unenforceable. J.A. 60-63, 136-41. It was exactly "to lift the heavy hand of . . . tribute" without having to defend infringement actions that the Declaratory Judgment Act was enacted. *Altvater*, 319 U.S. at 365. The communications here went well beyond the minimum for "reasonable apprehension of suit;" "[t]he [patentee's] claim need not be formally asserted; it is not necessary that notice be given directly to the plaintiff or that any threat be made to sue the plaintiff." *Aralac, Inc.* v. *Hat Corp.*, 166 F.2d 286, 292 (3d Cir. 1948); see also *Dewey & Almy Chem. Co.* v. *American Anode, Inc.*, 137 F.2d 68, 70 (3d Cir.), *cert. denied*, 320 U.S. 761 (1943).

The Federal Circuit not only mistakenly narrowed the statute's "actual controversy" to "reasonable apprehension of suit." The court also assumed that Synagis® was a "Licensed Product" under the contract, which would be so only if it infringed the Cabilly II patent. The court then redefined and narrowed apprehension of suit to require material breach of contract. Even the Federal Circuit's own prior holdings do not support this. *E.g., Arrowhead Indus. Water*, 846 F.2d at 735, quoted in *Cardinal Chemical*, 508 U.S. at 96; *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874, 880 (Fed. Cir. 1983) ("We reject the blanket approach . . . that there can never be an apprehension of a federal infringement suit and thus no controversy when a license is still in effect."); *Cordis Corp.* v. *Medtronic, Inc.*, 780 F.2d 991, 994 (Fed. Cir. 1985) ("In *C.R. Bard* . . . this court held that a patent licensee may seek a federal declaratory judgment to declare a patent, subject to a

license, invalid without prior termination of the license."), *cert. denied*, 476 U.S. 1115 (1986).[9]

C. A Requirement To Commit Breach of Contract Would Be Contrary to the Text and Purpose of the Declaratory Judgment Act.

Few familiar federal laws have a clearer text and legislative history than the Declaratory Judgment Act. Declaratory judgments were recognized in England in 1883[10] and in the United States by a New Jersey statute in 1915, followed by several other states.[11] A federal declaratory judgment act was first proposed in Congress in 1919, and bills were reintroduced thereafter. See Borchard, *The Federal Declaratory Judgments Act*, 21 VA. L. REV. 35, 36 (1936). During the 1920s, however, there had been uncertainty whether an action for declaratory relief, which some opinions addressing state laws suggested would amount to an "advisory opinion," could satisfy the requirements of Article III.[12] The constitutional doubt was dispelled in 1933 when this Court through Justice

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[9] See also *Teva Pharmaceuticals USA, Inc.* v. *Pfizer Inc.*, 405 F.3d 990, 997 (Fed. Cir.) (Dyk, J., dissenting as to rehearing *en banc*) ("In my view, the First Circuit [in *Sallen*, *supra*] is correct: the proper test under Article III is whether there is a present concrete controversy, and the panel here applied an incorrect test [reasonable apprehension of suit]."), *cert. denied*, 126 S. Ct. 473 (2005).

[10] Supreme Court of Judicature, Order XXV, § 5 (1883), 7 STATUTORY RULES AND ORDERS REVISED 54 (1904). See E. BORCHARD, DECLARATORY JUDGMENTS 129-130 (2d ed. 1941).

[11] N.J. Laws, 1915, ch. 116, § 7, called "the first effective statute" of this kind in a country. E. BORCHARD at 132. Professor Edwin Borchard was recognized as the "author of the Federal Declaratory Judgment Act." *Steffel* v. *Thompson*, 415 U.S. 452, 468 n.19 (1974). His treatise continues to be cited regularly in decisions construing the Act. *E.g.*, *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 288, 289 (1995).

[12] See E. BORCHARD at 134; *Willing* v. *Chicago Auditorium Ass'n*, 277 U.S. 274, 289 (1928); *Liberty Warehouse Co.* v. *Burley Tobacco Growers' Co-op. Marketing Ass'n*, 276 U.S. 71, 89 (1928).

Stone unanimously held that Article III did not stand in the way of reviewing a Tennessee declaratory judgment

> "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) (emphasis supplied). Article III, this Court held, is satisfied

> "when the complainant asserts rights which are challenged by the defendant, and presents for decision an actual controversy to which he is a party, capable of final adjudication by the judgment or decree to be rendered."

Id. at 260. That explanation of what Article III requires cleared the way for enactment of the Declaratory Judgment Act the following year. See S. Rep. No. 1005, 73d Cong., 2d Sess. 5 (1934); *Public Serv. Comm'n* v. *Wycoff Co.*, 344 U.S. at 241-42.

1. *The Declaratory Judgment Act Was Adopted To Make Breach of Contract Unnecessary.*

To demand that a declaratory-judgment plaintiff first commit a contractual breach, risking injunction of its major product, substantial damages and penalties, is the last thing that Congress in 1934 thought it was doing. The Declaratory Judgment Act applies by its terms to a "case of actual controversy." 28 U.S.C. § 2201(a).[13] The express purpose of

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[13] Article III, § 2, extends the federal judicial power to *inter alia* "all Cases, in Law and Equity, arising under . . . the Laws of the United States" and "Controversies . . . between Citizens of different States." See also *Calderon* v. *Ashmus*, 523 U.S. 740, 746 (1998). The phrase "case of actual controversy" was borrowed from contemporaneous state declaratory-judgment statutes, *e.g.*, Kan. Laws, 1921, ch. 168, § 1 ("cases of actual controversy"); Cal. Stats., 1921, p. 689 (same); Va. Laws, 1922, p.

the Act was to authorize the adjudication of real and concrete disagreements without forcing a party first to put itself in jeopardy of paying damages or other penalties if its legal claim ultimately did not succeed. The Senate report quoted with approval a supporter in a previous Congress:

> "Under the present law you take a step in the dark and then turn on the light to see if you have stepped into a hole. Under the declaratory judgment law you turn on the light and then take the step."

S. Rep. No. 1005 at 3, quoting 69 CONG. REC. 2108 (1928) (Rep. Gilbert). See also Hearings on H.R. 5623 Before Subcomm. of Senate Comm. on Judiciary, 70th Cong., 1st Sess. 55 (1928) (letter of Chief Judge Benjamin N. Cardozo) ("useful expedient to litigants who would otherwise have acted at their peril, or at best would have been exposed to harrowing delay").

Contract disputes, of which patent-license controversies are a subset, were a primary focus of Congress when it enacted the Declaratory Judgment Act in 1934. Congress explained its 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 at 2 (emphasis supplied). Citing states' experience, the drafters observed:

> "The [declaratory judgment] procedure has been especially useful in *avoiding the necessity*, now so often present, *of having to act at one's peril* or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring damages. . . . Persons now often have to act at their peril, a danger which could be

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902 (same). See Borchard, 21 VA. L. REV. at 44. "The word 'actual' is one of emphasis rather than of definition." *Aetna*, 300 U.S. at 240.

> frequently avoided by the ability to sue for a declaratory judgment as to their rights or duties."

Id. at 2-3 (emphasis supplied), quoted in *Steffel* v. *Thompson*, 415 U.S. 452, 480 n.1 (1974) (Rehnquist, J., concurring). See also, *e.g.*, *Abbott Labs.* v. *Gardner*, 387 U.S. 136, 152 (1967) (risk of potential penalties before adjudication was "a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate").

The understanding from the beginning has been that the Declaratory Judgment Act "enable[s] a party who is challenged, threatened or endangered in the enjoyment of what he claims to be his rights, to initiate the proceedings against his tormentor and remove the cloud." *United States* v. *Doherty*, 786 F.2d 491, 498-99 (2d Cir. 1986) (Friendly, J.), quoting E. BORCHARD, DECLARATORY JUDGMENTS 280 (2d ed. 1941). One accused of patent infringement "should not be compelled to act at its peril when it has the foresight to seek declaratory relief." *Broadview Chem. Corp.* v. *Loctite Corp.*, 417 F.2d 998, 1001 (2d Cir. 1969), *cert. denied*, 397 U.S. 1064 (1970). "The purpose of the Declaratory Judgment Act is to enable parties to adjudicate their disputes before either suffers great damage." 12 J. MOORE *et al.* § 57.03[2] at 57-11; see also 5 C. WRIGHT *et al*., FEDERAL PRACTICE & PROCEDURE § 1238 at 411 (3d ed. 2004).

To require breach of the contract as a condition to suit would not make the present dispute any more clear or concrete. But it would place petitioner in a "very real dilemma" and "quite clearly exposed to the imposition of strong sanctions." *Abbott Labs.*, 387 U.S. at 153, 154. "[T]he declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity." *Steffel*, 415 U.S. at 480 & n.1 (Rehnquist, J., concurring). See also *Evers* v. *Dwyer*, 358 U.S. 202, 204 (1958) ("We do not believe that appellant, in order to demonstrate the existence of an 'actual controversy' over the validity of the statute here challenged, was bound to continue to ride the Memphis buses at the risk of arrest if he

refused to seat himself in the space in such vehicles assigned to colored passengers."); *Gardner* v. *Toilet Goods Ass'n*, 387 U.S. 167, 172 (1967) (alternative to declaratory-judgment action is "beset with penalties and other impediments").

Declaratory judgments, it has been noted, are particularly appropriate for patent litigation. *Hanes Corp.* v. *Millard*, 531 F.2d 585, 592 (D.C. Cir. 1976) ("indisputably appropriate"); *Société de Conditionnement*, 655 F.2d at 943 (same); The practical risks of being held liable for infringement are particularly serious. See 35 U.S.C. §§ 283 (injunction), 284 (treble damages), 285 (attorneys' fees). Absent prompt judicial resolution of disputes about patent validity and infringement, the licensee's only alternative is "to risk not only actual but treble damages in infringement suits . . . . It was the function of the Declaratory Judgments Act to afford relief against such peril and insecurity." *Altvater*, 319 U.S. at 365.

The enactors of the Declaratory Judgment Act also had in mind the situation in which

> "the plaintiff, desiring not to sunder the economic or social relations involved, which a 'fight to the finish' might entail, contents himself with a suit for a judgment declaring his rights in the premises, enabling him thus to proceed to adjust his established legal relations accordingly."

Borchard, 21 VA. L. REV. at 39. In *Gen-Probe*, for example, "Gen-Probe expressly acknowledged its desire to maintain the status quo and remain a faithful licensee. Moreover, Gen-Probe exercised options to extend the duration of the license . . . ." 359 F.3d at 1380. Similarly, in the present case petitioner in 2003 sought and negotiated with respondent Genentech licenses for additional products, even though the dispute concerning alleged infringement of the Cabilly II patent by Synagis® and its validity remained unresolved. See J.A. 429, 431, 433, 434, 437. "[T]he declaratory judgment . . .

enables litigants to . . . settle the controversy before an accumulation of differences and hostility has engendered a wide and general conflict, involving numerous collateral issues." S. Rep. No. 1005 at 3.

It would confound the goal of the Declaratory Judgment Act to hold, as the Federal Circuit did here, that petitioner needed to commit breach of contract and place itself in great jeopardy before seeking judicial resolution of a clear legal dispute. The whole purpose of the Act was to eliminate the need for such risk-taking, commercial uncertainty, and piling on of potential damages.

2. *Rule 57 Contemplates Declaratory Judgments "Before or After Breach."*

The same year *Aetna* was decided, this Court also adopted the new Federal Rules of Civil Procedure. Order, 302 U.S. 783 (1937). Rule 57, unchanged in substance today, provided for declaratory judgments. Order, 308 U.S. 645, 736 (1938). The distinguished Advisory Committee this Court appointed summarized concisely the requirements for seeking declaratory relief: the plaintiff "must have a practical interest in the declaration sought," which may be as to "[t]he existence or non-existence of any right, duty, power, liability, privilege, disability, or immunity or of any fact upon which . . . legal relations depend." REPORT OF THE ADVISORY COMMITTEE ON RULES FOR CIVIL PROCEDURE 145 (1937) (Rule 58, later renumbered 57). The Advisory Committee's explanation specified that in declaratory actions

> "Written instruments, including ordinances and statutes, may be construed *before or after breach* at the petition of a properly interested party . . . ."

Id. (emphasis supplied). Yet the Federal Circuit's recent decisions hold just the opposite—as if Rule 57 instead had meant, to the contrary, that "written instruments . . . may be construed *only after breach*." The Federal Circuit, unlike any

other, explicitly holds as an absolute rule that a licensee "must . . . materially breach the agreement . . . before bringing suit." *Gen-Probe*, 359 F.3d at 1381. The notion that a litigant must first commit breach of the contract at issue—negating the very purpose of the Rule and the Act—surely would have puzzled the drafters both of the Act and of the Rule.

II. TO BAR PETITIONER FROM DECLARATORY RELIEF WOULD CONSTITUTIONALIZE THE REJECTED DOCTRINE OF LICENSEE ESTOPPEL.

The Federal Circuit's new jurisdictional holding would write into Article III of the Constitution a policy that this Court has repeatedly held the patent laws reject.

A. *Pope Mfg. Co.* v. *Gormully* Rejected Contractual Prohibitions of Patent Challenges.

In 1892 this Court held that a licensee's promise in a patent license not to challenge the patent's validity would be unenforceable in equity, because the right to challenge a patent "is not only a private right to the individual, but it is founded on public policy." *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 235 (1892).

> "It 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 . . . ."

Id. at 234. See also *Haughey* v. *Lee*, 151 U.S. 282, 285 (1894) ("relieve the public from an asserted monopoly"). Therefore a patent license could "not operate to estop the defendants from contesting the validity of these patents." *Pope Mfg. Co.* v. *Gormully & Jeffery Mfg. Co. (No. 4)*, 144 U.S. 254, 255 (1892).

Many decisions of this Court since 1892 have reiterated

> "the importance to the public at large of resolving questions of patent validity."

Cardinal Chemical, 508 U.S. at 100, citing *Blonder-Tongue Labs., Inc.* v. *University of Ill. Foundation*, 402 U.S. 313 (1971). "It is the public interest which is dominant in the patent system." *Mercoid Corp.* v. *Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1944). "The possession and assertion of patent rights are 'issues of great moment to the public.'" *Precision Instrument Mfg. Co.* v. *Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815 (1945), quoting in part *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co.*, 322 U.S. 238, 246 (1944). Federal patent policy is generally to "encourage authoritative testing of patent validity," "eliminating obstacles to suit by those disposed to challenge the validity of a patent," *Blonder-Tongue*, 402 U.S. at 344-45 (citing cases), "keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid." *Edward Katzinger Co.* v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947). "[W]hat will usually be the better practice [is] inquiring fully into the validity of this patent." *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 330 (1945), quoted in *Cardinal Chemical*, 508 U.S. at 100. See also *United States* v. *Glaxo Group Ltd.*, 410 U.S. 52, 57 (1973) (this Court has "repeatedly held that the private licensee-plaintiff in an antitrust suit may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license").[14]

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[14] The concern of the patent laws extends not just to the validity of the patent itself, but also to whether, as the complaint here alleged, J.A. 53-54, 137-40, the patent had been deceptively or fraudulently obtained. "The far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope." *Walker Process*

The Federal Circuit's holding that a license *per se* prevents an accused infringer not in breach from challenging patent validity is irreconcilable with *Pope Mfg. Co.* v. *Gormully* and a century of this Court's patent decisions. The Federal Circuit would imply as a matter of law a contract provision against challenging validity which not only was entirely absent here,[15] but would have been void and unenforceable if it had been present.

B. *Lear, Inc.* v. *Adkins* Rejected Barring Suits by Patent Licensees.

In *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), this Court through Justice Harlan rejected the doctrine of "licensee estoppel" as "inconsistent with the aims of federal patent policy." 395 U.S. at 673. The patent code, in 35 U.S.C. §§ 101, 102, 103 and 112, prescribes standards of utility, novelty, non-obviousness and specificity required for a patent to be valid. But the PTO, with limited staff and resources and a flood of applications, and acting *ex parte*, is in no position to assure that the statutory limitations always are honored. See FEDERAL TRADE COMM'N, TO PROMOTE INNOVATION, Exec. Sum. at 8-9, ch. 5 at 5-6 (2003) ("FTC Report"). "If [licensees] 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; see also *Panther Pumps & Equip. Co.* v. *Hydrocraft, Inc.*, 468 F.2d 225, 231 (7th Cir. 1972) (Stevens, J.) (after *Lear*, "the 'no contest' provision in the LEMCO license is plainly unenforceable"), *cert. denied*, 411 U.S. 965 (1973).

Equip., Inc. v. *Food Machinery & Chem. Corp.*, 382 U.S. 172, 177 (1965), quoting *Precision Instrument*, 324 U.S. at 816.

[15] The license contract in fact provided that royalties would not be due on any patent held invalid, and Genentech disclaimed any warranty. J.A. 399, 411.

For the same reasons, it was recognized soon after *Lear* that a promise not to challenge patent validity is unenforceable when contained in a settlement agreement. *Business Forms Finishing Service, Inc.* v. *Carson*, 452 F.2d 70, 73-75 (7th Cir. 1971) (Stevens, J.). The Federal Circuit, however, has not shared that view. Thus the Federal Circuit held in *Flex-Foot, Inc.* v. *CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001), that *Lear*'s "holding with respect to licensee estoppel is meaningfully distinguishable from the present case concerning a settlement agreement." See also *Diversey Lever, Inc.* v. *Ecolab, Inc.*, 191 F.3d 1350, 1352 (Fed. Cir. 1999) (permitting agreement in consent decree not to challenge patent validity).

Indeed, the Federal Circuit long has expressed and demonstrated hostility to *Lear*. It has characterized *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). It has acknowledged that "[i]n several instances, this court has declined to apply the *Lear* doctrine." *Gen-Probe*, 359 F.3d at 1381. See also, *e.g.*, *Diamond Scientific Co.* v. *Ambico, Inc.*, 848 F.2d 1220, 1224-25 (Fed. Cir.) (*Lear* does not bar assignor estoppel), *id*. at 1228 (concurring opinion) (*Lear* rests on "outmoded theory" that "disserves the national interest"), *pet'n for cert. dismissed*, 487 U.S. 1265 (1988); *Foster* v. *Hallco Mfg. Co.*, 947 F.2d 469, 476 (Fed. Cir. 1991) ("[t]he Supreme Court in *Lear* did not consider the policy concerns" affecting a consent decree); *Flex-Foot*, 238 F.3d at 1368 ("this court has in the past distinguished a number of other cases from *Lear*"). But whether or not it agrees with this Court, the Federal Circuit is not at liberty to "ignore[] the guidance" of decisions of this Court. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

Now the Federal Circuit has invoked Article III to eliminate *Lear* itself, and effectively to revive licensee estoppel except for those licensees willing to commit breach of contract with all the accompanying risks as a precondition to challenging a patent. Unable to overturn *Lear* frontally under the patent laws, the Federal Circuit has adopted a constitutional holding that serves a policy exactly opposite to *Lear*—explaining that challenges like petitioner's would produce "undesirable results," *Gen-Probe*, 359 F.3d at 1382, "inequity," P.C.A. 7a. Already the present case has been recognized as holding that a licensee paying royalties "is estopped to challenge the validity of the patents in suit." *Advanced Card Technologies LLC* v. *Versatile Card Technology, Inc.*, 410 F. Supp. 2d 158, 161 (S.D.N.Y. 2006). And even if a patent license in spite of *Lear* could block a claim of invalidity or non-infringement, that still would be only a defense for the licensor, not a jurisdictional defect. "[A]bsence of a valid . . . cause of action does not implicate subject-matter jurisdiction." *Steel Co.* v. *Citizens for a Better Environment*, 523 U.S. 83, 89 (1998).

III. ARTICLE III SHOULD NOT BE REINTERPRETED TO FREEZE FEDERAL PATENT POLICY.

The decision under review would reinterpret Article III of the Constitution, as implemented in the Declaratory Judgment Act. Even if the Federal Circuit were authorized to adopt its own patent policy contrary to *Lear*, there certainly was no basis or authority for that court to turn its view of desirable patent policy into an Article III holding. Most immediately, the present decision would disrupt a basic tenet of federal patent policy—encouragement of challenges to patent validity—and then elevate that revision to a constitutional ruling, beyond Congress's power to correct. *Cf. Seminole Tribe* v. *Florida*, 517 U.S. 44, 63 (1996) (for constitutional decisions "correction through legislative action is practically impossible"), quoting *Burnet* v. *Coronado Oil & Gas Co.*,

285 U.S. 393, 407 (1932) (Brandeis, J., dissenting). More broadly, the decision would excise from the Declaratory Judgment Act the heart of what Congress enacted, and call into question prior decisions of this Court.

A. As a Constitutional Holding, the Decision Is Unsound and Disruptive.

Since its enactment in 1934 the declaratory judgment remedy has been a valuable resource in federal litigation to resolve a wide range of controversies, from commercial contracts to civil rights cases to insurance-coverage disputes, and its utility and role are well-recognized, "to enable parties to adjudicate their disputes before either suffers great damage." *Starter Corp.* v. *Converse, Inc.*, 84 F.3d 592, 596 (2d Cir. 1996) (declaratory "actions are particularly useful in resolving trademark disputes"); *Allstate Ins. Co.* v. *Green*, 825 F.2d 1061, 1064 (6th Cir. 1987) ("an extremely useful procedural device for adjudicating disputes concerning insurance"); see also, *e.g.*, *Hamlin Inc.* v. *Hartford Accident & Indem. Co.*, 86 F.3d 93, 94 (7th Cir. 1996) (Posner, C.J.) (insurance companies "often seek a declaratory judgment of noncoverage" in order "to avoid liability for breach"); *Whetstone Candy Co.* v. *Kraft Foods, Inc.*, 351 F.3d 1067, 1072 (11th Cir. 2003) (settlement agreement). To hold that Article III requires a party as a prerequisite to a declaratory judgment to perform the very act of which it wishes to ascertain the legality, would upset the law in many contexts beyond patents.

In so doing it would also disrupt the expectations of both patent licensees and licensors. Heretofore there has been no constitutional barrier to licensees' challenging patents while paying royalties under protest. The Federal Circuit soon after its creation in 1982 confirmed that established view. In *C.R. Bard, Inc.* v. *Schwartz*, 716 F.2d 874 (Fed. Cir. 1983)—which

the District Court here noted was controlling until *Gen-Probe*, see P.C.A. 24a—the Federal Circuit held:

> "We reject the blanket approach . . . that there can never be an apprehension of a federal infringement suit and thus no controversy when a license is still in effect."

716 F.2d at 880. That has been the law relied on by the district courts. *E.g.*, *Grid Systems Corp.* v. *Texas Instruments, Inc.*, 771 F. Supp. 1033, 1042 (N.D. Cal. 1991) (citing *C.R. Bard*); *Research Inst. for Med. Chemistry, Inc*. v. *Wisconsin Alumni Res. Found., Inc*., 647 F. Supp. 761, 767 n.5 (W.D. Wis. 1986) (same). The district court that was reversed in *Gen-Probe* had thought it "settled law that an effective license between the parties does not preclude federal question jurisdiction over a licensee's declaratory judgment action."[16] Another district court likewise had held that "[a]lthough the parties are under license, there is a clear and concrete dispute between them about whether Synagis® infringes," but then overruled itself after *Gen-Probe*. *Med-Immune, Inc.* v. *Centocor, Inc*., 271 F. Supp. 2d 762, 768 (D. Md. 2003), *overruled*, 2004 U.S. Dist. Lexis 28800 (D. Md. June 17, 2004), *aff'd*, 409 F.3d 1376 (Fed. Cir. 2005), *pet'n for cert. pending* (No. 05-656). In this case as well, such was the understanding of the sophisticated attorneys representing respondents, who until *Gen-Probe* suddenly appeared had not challenged the subject-matter jurisdiction of the District Court. J.A. 149, 183; p. 8, *supra*.

Patent applications now approach 300,000 per year, and lately have been increasing 10% annually. See FTC Report, Exec. Sum. at 9. The number of patents tested in court is relatively small, and likely to remain so. Most patent licenses now in effect were negotiated and entered on the assumption that the pre-*Gen-Probe* understanding of the Declaratory

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[16] *Gen-Probe Inc.* v. *Vysis, Inc.*, No. 99-CV-2668, at 10 (S.D. Cal., Mar. 12, 2002), reprinted in Pet. Cert. in *Gen-Probe*, No. 04-260 (2004), at 25a.

Judgment Act, allowing declaratory suits by licensees, applied. "[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 535 U.S. at 739.

B. As Patent Policy, the Decision Is Unsound and Unauthorized.

Constitutional rules of general application concerning federal jurisdiction, like Article III's "Case" or "Controversy" requirement, should not be reconstructed to fit a patent policy. Even if that were permissible, the policy chosen by the Federal Circuit is not consistent with this Court's past interpretations of the patent laws. Although this Court repeatedly has emphasized that federal patent policy favors judicial testing of whether patents are valid, pp. 34-37, *supra*, the Federal Circuit instead has created a new, constitutionally entrenched, obstacle. And that Article III barrier would be erected at a time when commentators observe that the number of overbroad and invalid patents has grown far beyond the ability and resources of the PTO to control, and when practical inhibitions to such suits already are formidable.

1. *Declaratory Actions by Licensees Do Not Unfairly Disadvantage Licensors*.

The Federal Circuit denounced "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." P.C.A. 7a. It called this "undesirable." *Gen-Probe*, 359 F.3d at 1382.

However, this Court in *Lear* announced exactly the opposite judgment. Emphasizing "the demands of the public interest," 395 U.S. at 670, this Court addressed head-on and rejected "[t]he theory . . . that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent which forms the basis of the agreement is void." *Id.* at 656.

> "[I]t does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue, especially since the licensor's case is buttressed by the presumption of validity which attaches to his patent."

Id. at 670. "[T]he seeming inequity of allowing a licensee to keep his license while he attacks the validity of the licensor's patent is outweighed by the public interest in placing no impediment in the way of those in the best position to contest the validity of the underlying patent." *Warner-Jenkinson Co. v. Allied Chem. Corp*., 567 F.2d 184, 188 (2d Cir. 1977); see also *American Sterilizer Co.* v. *Sybron Corp.*, 526 F.2d 542, 546-47 (3d Cir. 1975) ("We read the Supreme Court's opinion in *Lear* as resolving the competing equities between the licensee and the licensor in favor of the licensee.").

The Federal Circuit's policy argument forgets this Court's conclusion that

> "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."

Lear, 395 U.S. at 670. "A patent by its very nature is affected with a public interest" that is "recognized by the Constitution." *Precision Instrument*, 324 U.S. at 816. The public is a silent party in all patent-validity litigation.

Moreover, there is no rule that a patentee may not seek a declaratory judgment; enjoying the presumption of validity, however, few have reason to do so. See *Talbot* v. *Quaker State Ref. Co*., 104 F.2d 967, 968 (3d Cir. 1939); see also *Lang* v. *Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990) ("no reason why a patentee should be unable to seek a declaration of infringement against a future infringer"); *Metabolite Labs., Inc.* v. *Laboratory Corp. of America Holdings*, 370 F.3d 1354, 1369 (Fed. Cir. 2004) (same), *cert. granted on another point*, 126 S. Ct. 601 (2005)

(No. 04-607); 10B C. WRIGHT, *et al*., FEDERAL PRACTICE & PROCEDURE § 2761 at 572 (1998).

It is quite correct that licensor and licensee do not stand on equal footing—but the advantages are on the side of the licensor. "[P]atentees are heavily favored as a class of litigants by the patent statute." *Blonder-Tongue*, 402 U.S. at 335. Patents—and every claim within those patents—are statutorily *presumed* valid and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. Further, this presumption of validity cannot be overcome except by "clear and convincing evidence." *State Contracting & Engineering Corp.* v. *Condotte America, Inc.*, 346 F.3d 1057, 1067 (Fed. Cir. 2003). Given the powerful presumption of validity, there is little need for a licensor to obtain further confirmation of its patent's validity outside an infringement action.

The Court of Appeals also opined that "[a]llowing this action to proceed would . . . discourage patentees from granting licenses." *Gen-Probe*, 359 F.3d at 1382. But that speculation is unsupported. There is no evidence that patent-licensing abated after *Lear*, nor that such would occur if jurisdictional law returns to the pre-*Gen-Probe* norm. Nor is the assumption logical. Patentees grant licenses to generate royalties. Their financial incentive to do so is not altered by whether licensees can sue without breach. If a patentee preferred instead not to license, but rather to use its patent to prevent competition, it would not have licensed in the first place. Removing the licensee's ability to challenge validity in a declaratory action would simply add to the economic power of the patent.

Also, any attempt to weigh fairness would consider that patent licenses often are entered under economic constraint, and sometimes without full information. "[C]ompanies and individuals must constantly fear that their research and product development may come to naught, because someone is going to assert an as-yet unknown or untested patent

against them." A. JAFFE & J. LERNER, INNOVATION AND ITS DISCONTENTS 172 (2004). This "often leads either to abandonment of the allegedly infringing technology, or to an agreement to pay possibly unnecessary royalties." *Id.* Sometimes, too, as here, a patentee's potentially invalid claims may not be known when the license is entered. The Cabilly II application claimed an invention date of 1983, was not filed until 1988, was vastly broadened in 1989, provoking a lengthy interference proceeding, and was not issued as a patent and its claims revealed until its issuance (to the consternation of the PTO Board, p. 5, *supra*) in 2001—four years after MedImmune's license.

Finally, if in a particular case declaratory relief really would involve unfairness, the Act itself provides a solution. Declaratory relief, like an injunction, is discretionary. *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 286-88 (1995); *Cardinal Chemical*, 508 U.S. at 95 n.17; *Brillhart* v. *Excess Ins. Co.*, 316 U.S. 491, 494 (1942). Discretion looks, for example, to "whether the judgment will serve a useful purpose in clarifying or settling the legal issues involved" and "finalize the controversy and offer relief from uncertainty." *Duane Reade, Inc*. v. *St. Paul Fire & Marine Ins. Co.*, 411 F.3d 384, 389 (2d Cir. 2005). The Federal Circuit, however, would deny district courts the jurisdiction to exercise that discretion. Accordingly, here the District Court obediently dismissed for lack of subject-matter jurisdiction, with no opportunity "to exercise *any discretion at all*." *Cardinal Chemical*, 508 U.S. at 103 (Scalia, J., concurring in part) (emphasis in original).

2. *The Federal Circuit's Decision Would Add Another Disincentive to Patent Challenges.*

To establish a patent's invalidity is likely to demand "great effort and expense." *Cardinal Chemical*, 508 U.S. at 99, quoting *Morton Int'l, Inc.* v. *Cardinal Chem. Co.*, 967 F.2d 1571, 1577 (Fed. Cir. 1992) (Nies, J., dissenting from denial of rehearing *en banc*), *vacated*, 508 U.S. 83 (1993). It has

been estimated that to challenge a patent can cost in legal fees $5-7 million. See FTC Report, Ex. Sum. at 6, ch. 3 at 22; see also Lerner, *Patenting in the Shadow of Competitors*, 38 J.L. & ECON. 463, 470 (1995). A challenger faces also the statutory presumption of validity, 35 U.S.C. § 282, which lets a patentee "easily put the alleged infringer to his expensive proof," so that "prospective defendants will often decide that paying royalties under a license or other settlement is preferable to the costly burden of challenging the patent." *Cardinal Chemical*, 508 U.S. at 101 n.24, quoting *Blonder-Tongue*, 402 U.S. at 338.

Licensees often enter licenses reluctantly. Small, start-up companies, particularly in the pharmaceutical and biotechnology industries, may agree to be bound by licenses for patents of uncertain scope and validity because the licensee may be unable to afford the high cost of patent litigation. As this Court observed in *Lear*, "by accepting a license and paying royalties for a time, the licensee may have avoided the necessity of defending an expensive infringement action during the period when he may be least able to afford one." 395 U.S. at 669. Small start-up companies and even larger ones may, like MedImmune, depend on a single product for most of their revenue.[17] Quite understandably, such entrepreneurs may find it imprudent to forgo a license and risk an injunction of their principal product, which could effectively put them out of business. MedImmune, of course, was acutely aware of the risks of defying Genentech's demand, by stopping payments in a bet-the-company legal judgment jeopardizing its principal product, instead of resolving the matter by declaratory adjudication. J.A. 389, 393.

Licensees may not be sure what a license ultimately will purport to include. Here MedImmune agreed to the license from Genentech in 1997. The Cabilly II patent was not

[17] More than 80% of MedImmune's revenues from 1999 to 2003 depended on Synagis®, J.A. 387, and the same is true since then.

issued and its claims disclosed until late in 2001. Genentech's demand for royalty payments followed in a matter of days. J.A. 414. Given the high cost of litigation to test the validity of a patent, a small company is unlikely to undertake such a challenge unless and until the product is successful enough to generate large revenues, carrying a correspondingly increasing burden of royalty payments. See FTC Report, ch. 3 at 29 (observations that "litigation is too expensive and time-consuming for small biotechnology companies"). At the time of the 1997 license, Synagis® had not been approved by the FDA. By the time MedImmune sought a declaratory judgment, royalties demanded had risen to millions of dollars per year.

Licensees often agree to a single license for several patents and products together, and with a provision that failure to pay any royalty due is a material breach of the entire contract. The prudent licensee very likely will be unwilling to lose its license to all the patents or products, if that is the consequence of challenging a demand based on one patent it believes invalid or not infringed. The licensee's dilemma is heightened in a case like the present one, in which not all the licensed claims are known at the time of licensing, and later there appears a broad "continuation" patent, the claims of which the licensee does not learn until years after agreeing to the license.

3. *Preventing Licensee Patent Challenges Would Disserve a Rapidly Evolving Technological Economy.*

Presciently this Court warned in *Lear* that to disallow licensee challenges to patent validity would have an effect "particularly severe in the many scientific fields in which invention is proceeding at a rapid rate." 395 U.S. at 673. A "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention . . . ." *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996), quoting *United Carbon*

Co. v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942), and citing *Merrill* v. *Yeomans*, 94 U.S. 568, 573 (1877). That is certainly true for biotechnology, and also for active fields like electronic information, communications, medicine and others of highest innovation. "Firms in the biotechnology industry reported that they avoid infringing even questionable patents and therefore refrain from entering or continuing with a particular field of research." FTC Report, ch. 3 at 21. Also, "invalid patents" are "hampering pharmaceutical innovation." Derzko, *The Impact of Recent Reforms*, 45 IDEA: J.L. & TECH. 165, 265 (2005). "[T]he pattern of costly litigation—or payments to forestall litigation—are leading to reductions or distortions in innovative investments, particularly for small firms." Lerner at 471.

Burdens on challenging patents are less appropriate today than ever. The increasingly ineffective scrutiny applied in issuing patents has been widely criticized. *E.g.*, A. JAFFE & J. LERNER at 34 (PTO is "so overtaxed, and its incentives have become so skewed towards granting patents"); FTC Report, Exec. Sum. at 8-10, ch. 3 at 19, ch. 5 at 5-8. By various estimates the PTO grants 74% to 98% of all patent applications, which now approach 300,000 per year. *Id.*, Exec. Sum. at 9, ch. 5 at 6; NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 52-55 (2004). "[T]he ultimate granting of some patent from each original application has become almost a sure thing." A. JAFFE & J. LERNER at 171. But when validity is challenged and litigated to final judgment, about 45% of patents are held invalid. FTC Report, ch. 5 at 6. Such "an indiscriminate creation of exclusive privileges tends rather to obstruct than to stimulate invention." *Atlantic Works* v. *Brady*, 107 U.S. 192, 200 (1883). See also *Lear*, 395 U.S. at 674 n.19 ("public's interest in the elimination of specious patents").

This Court has pointed out that patents are granted "in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." *Lear*, 395 U.S. at 670.[18] The public's interest is not only to reward useful innovation, but also to ensure that unpatentable ideas remain in the public domain, encouraging innovation, investment, competition, and lower costs to consumers. It is also to prevent higher prices of medicines and other commodities resulting from royalties paid to holders of invalid patents. FTC Report, Exec. Sum. at 6-7.

"Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery." *Lear*, 395 U.S. at 670. If licensees are prevented from testing validity without giving up their licenses and risking ruin, there will be fewer challengers to step forward to undertake that role.

C. Patent Policy Should Be Revised by Congress Legislating Under Article I, Not by Courts Reinterpreting Article III.

If changes in the legal relationships of licensors and licensees of patents are to be adopted, such adjustments are constitutionally assigned to Congress by Article I. See

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[18] The narrow and limited procedure of patent reexamination under 35 U.S.C. §§ 301-302 is *ex parte* and considers only prior printed publications and patents. Reexamination is not available for other fundamental violations raised here, such as lack of enablement or written description, fraud on the Patent Office, prior acts evidencing invention by another, non-infringement, etc. The PTO has granted two requests for reexamination of the Cabilly II patent under § 302, one by petitioner. A preliminary ruling has held the Cabilly II patent invalid for obviousness-type double-patenting. (Reexamination under 35 U.S.C. § 311, not pertinent here, is not *ex parte*, but otherwise suffers from the same limitations, plus a number of others.) See generally A. JAFFE & J. LERNER at 186-88; FTC Report, ch. 3 at 21 (reexamination mechanisms "are generally inadequate").

Diamond v. *Chakrabarty*, 447 U.S. 303, 317 (1980) (in addressing scope of patentable subject matter, "the contentions now pressed on us should be addressed to the political branches of the Government"); *cf. Hartford Underwriters Ins. Co.* v. *Union Planters Bank, N.A.*, 530 U.S. 1, 13-14 (2000) (bankruptcy policy); *Turner Broadcasting System, Inc.* v. *FCC*, 520 U.S. 180, 224 (1997) (communications policy). Congress, for its part, pays active and frequent attention to adjusting patent provisions: "our patent and copyright statutes have been amended repeatedly." *Sony Corp.* v. *Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984).[19] Revising intellectual-property policy falls "inside the domain the Constitution assigns to the First Branch." *Eldred* v. *Ashcroft*, 537 U.S. 186, 222 (2003). So, for that matter, does revising the statutory jurisdiction of the federal courts within Article III. *Sheldon* v. *Sill*, 8 How. 441, 449 (1850). "Congress can legislate" on those subjects "any time it chooses." *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997).

[19] "[T]he Patent Act was amended, revised or codified some 50 times between 1790 and 1950," *Graham* v. *John Deere Co.*, 383 U.S. 1, 10 (1966), and in recent years the pace of amendment has not slackened. See 118 Stat. 3596 (2004); 117 Stat. 2066 (2003); 116 Stat. 1758 (2002); 114 Stat. 1742 (2000); 113 Stat. 1501 (1999); 112 Stat. 2780 (1998); 109 Stat. 351 (1995); 108 Stat. 4809 (1994); 107 Stat. 2057 (1993).

CONCLUSION

For the reasons stated, the judgment of the Court of Appeals should be reversed.

Respectfully submitted,

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ADDENDUM

CONSTITUTIONAL AND STATUTORY PROVISIONS AND RULE

Article III, § 2, of the Constitution of the United States provides in part:

> "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 a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, 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 decla-

ration, 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.

Title 28 U.S.C. § 2202 provides:

Further relief

Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

Title 35 U.S.C. § 135(a) provides:

Interferences

(a) Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be. The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability. Any final decision, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office of the claims involved, and the Director may issue a patent to the applicant who is adjudged the prior inventor. A final judgment adverse to a patentee from which no appeal or other review has been or can be taken or had shall constitute cancellation of the claims involved in the patent, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation by the Patent and Trademark Office.

Title 35 U.S.C. § 282 provides in part:

> Presumption of validity; defenses
>
> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.
>
> The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:
>
> (1) Noninfringement, absence of liability for infringement or unenforceability,
>
> (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,
>
> (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
>
> (4) Any other fact or act made a defense by this title. . . .

Title 35 U.S.C. § 283 provides:

> Injunction
>
> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the

principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

Title 35 U.S.C. § 284 provides:

Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

Title 35 U.S.C. § 285 provides:

Attorneys Fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

Rule 57, Federal Rules of Civil Procedure, provides:

Declaratory Judgments.

The procedure for obtaining a declaratory judgment pursuant to Title 28, U.S.C., § 2201, shall be in accordance with these rules, and the right to trial by jury may be demanded under the circumstances and in the manner provided in Rules 38 and 39. The existence of

another adequate remedy does not preclude a judgment for declaratory relief in cases where it is appropriate. The court may order a speedy hearing of an action for a declaratory judgment and may advance it on the calendar.