No. 05-608

In the Supreme Court of the United States

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., et al.,

Respondents.

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

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

RULE 29.6 STATEMENT

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

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

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STATEMENT OF THE CASE

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

A. The License

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

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

There was a lengthy dispute between Genentech and a British company, Celltech R&D, Ltd., over the U.S. patent rights in the relevant invention. Pet. App. 2a-4a.[1] While that dispute was pending, MedImmune obtained licenses from both Genentech and Celltech. Pet. App. 4a. In June 1997,

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

MedImmune entered into a license agreement with Genentech that permitted MedImmune to practice U.S. Patent No. 4,816,567 ("the '567 patent," claiming related technology), and any patent that issued from a pending Genentech application. Pet. App. 4a. The Genentech application ultimately matured into the '415 patent which claims the invention at issue. Pet. App. 4a. MedImmune has no products covered by the '567 patent and has not paid royalties on the '567 patent.

The '415 patent issued in 2001, after the resolution of the priority dispute between Genentech and Celltech. Pet. App. 3a-4a. Genentech thereafter advised MedImmune of its belief that Synagis® was a "licensed product" for which royalties were due. Pet. App. 4a. MedImmune balked at first, denying that Synagis® was a "licensed product."[2] Pet. App. 4a. But MedImmune subsequently agreed to pay royalties (albeit "under protest"), because, as its General Counsel later testified, MedImmune wanted to retain the benefits of the license – and not be subject to an infringement suit – if its challenge to the patent failed. C.A.A. 314, 3291-92. MedImmune later requested and entered into seven separate agreements to license the '415 patent for products in development. Pet. App. 28a.

Shortly after securing the last of these license agreements, MedImmune filed this declaratory judgment action to invalidate the '415 patent and for a judgment that Synagis® did not infringe the '415 patent. Pet. App. 4a. At all times relevant to this case, however, MedImmune

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

remained a licensee in good standing and made clear its intent not to breach the Synagis® license agreement. C.A.A. 314. It thus retained all benefits of the license, including protection from all of the remedies at law or in equity for patent infringement, such as an injunction, treble damages, and a court-determined, non-contractual royalty rate. Under such circumstances, Genentech could not sue MedImmune for patent infringement, and could not cancel the license agreement.

B. The District Court and Federal Circuit Decisions

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

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

v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941)) (internal citations omitted).

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

The Federal Circuit next addressed MedImmune's argument, recycled here, that "cases from other circuits hold that a licensee need not terminate its license in order to acquire declaratory standing." Pet. App. 7a. The court explained that "in each of the cited cases there was an additional factor, such as money owed on the contract, or the plaintiff or its indemnitee had been threatened with suit, or there was a change in circumstances which affected performance of the contract, meeting the constitutional and statutory requirements that there must be an actual controversy in order to invoke judicial authority." Pet. App. 7a. Thus, there was no conflict with other circuits.

Last, the Federal Circuit rejected MedImmune's policy arguments, in particular the notion that the public interest in challenging potentially invalid patents required giving licensees a one-sided option to litigate licensed patents. The

court stressed two points. First, patent-specific issues could "not create a policy-driven exception" to the constitutional and statutory requirements of an actual controversy. Pet. App. 7a. Second, it would be inequitable for the patent owner, "having contracted away its right to sue," to be under a "continuing risk of attack on the patent whenever the licensee chooses – for example if the product achieves commercial success – while the licensee can preserve its license and royalty rate if the attack fails." Pet. App. 7a. A one-sided option to sue at will, the court reasoned, "distorts the equalizing principles that underlie the Declaratory Judgment Act." Pet. App. 7a.

C. The Pending Reexamination of the '415 Patent

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

REASONS FOR DENYING THE WRIT

The petition should be denied for three reasons. First, the Federal Circuit's decision is consistent with the declaratory judgment jurisprudence of this Court and the courts of appeals. The Declaratory Judgment Act permits persons who anticipate an inevitable lawsuit to come to court first, before damages accrue, for a declaration that they are not liable to the feared opponent. It is nevertheless black letter law that a declaratory judgment action, no less than any other suit, must present a live case or controversy and not seek a merely advisory decree. In enforcing this

requirement, the Federal Circuit and the other courts of appeals ask, among other things, whether a declaratory judgment plaintiff has a "reasonable apprehension" that it will be sued by the declaratory judgment defendant. If not, there is no actionable controversy. Because MedImmune admitted it had no apprehension of suit, and could cite no other case-specific circumstances establishing a live controversy between the parties, the Federal Circuit ruled there was no case or controversy here.

That analysis is an unremarkable application of settled law. MedImmune claims, however, that because it is a *patent licensee*, it has special rights under decisions of this Court to challenge licensed patents at any time of its choosing – even if, under ordinary standards, there is no Article III controversy. It claims patent licensees *may* seek advisory decrees regarding what *would* happen *if* they abandoned the protections of their licenses *and* were sued for infringement. There is no support for that proposition in this Court's Article III cases, nor in *Lear*. Nor is this question close enough to merit review.

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

As for the circuit cases cited in the petition, they typically involved some "additional factor" beyond the mere existence of a license or contract between the parties that demonstrated the existence of a live controversy. Pet. App.

7a. Variations in the outcomes of these cases reflect the fact-bound application of settled law to different circumstances, not any disagreement over the governing legal principles.

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

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

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

I. THE FEDERAL CIRCUIT'S DECISION APPLIES WELL ESTABLISHED PRINCIPLES TO FACTS THAT PRESENT NO CASE OR CONTROVERSY.

A claim under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), must present "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. To determine whether a declaratory judgment case is sufficiently concrete, courts adjudicating patent cases have long applied the "reasonable apprehension of suit" test, which inquires whether a declaratory judgment plaintiff faces a threat of suit from the patent owner. *See Japan Gas Lighter Ass'n v. Ronson Corp.*, 257 F. Supp. 219, 237 (D.N.J. 1966) (first formulating test). The Federal Circuit has applied that test for decades in cases where the plaintiff seeks a declaration that a competitor's patent is invalid, or not infringed.[3] The "reasonable apprehension" test also has been employed by every circuit and in many analogous circumstances, including copyright, trademark, trade secrets, "right of publicity," unfair trade practices, unfair labor practices, and breach of contract cases.[4]

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

[4] *See, e.g., Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 25 (1st Cir. 2001) ("The reasonable apprehension of suit doctrine exists to cabin declaratory judgment actions where the only controversy surrounds a potential, future lawsuit."); *Starter Corp. v. Converse, Inc.*, 84 F.3d 592 (2d Cir. 1996) (applying Federal Circuit's "reasonable apprehension" test to trademark case); *Interdynamics, Inc. v. Wolf*, 698

A straightforward application of the reasonable apprehension rule to the facts of this case leads to the conclusion that no case or controversy exists. MedImmune

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F.2d 157, 166 (3d Cir. 1982) (applying the legal principles set forth by the Seventh Circuit in *International Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210-11 (7th Cir. 1980), and noting that the standard "provides what is perhaps the most comprehensive formulation of the test that a court should apply in determining whether [the court has jurisdiction] to grant declaratory relief in a patent case"); *Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co.*, 386 F.3d 581, 593-94 (4th Cir. 2004) (holding that declaratory judgment jurisdiction existed because plaintiff "possessed a reasonable apprehension of a multiplicity of litigation and of liability for ongoing damages"); *Texas v. West Publ'g Co.*, 882 F.2d 171, 175 (5th Cir. 1989) (applying Federal Circuit's "basic declaratory judgment principles [that] are well settled" to copyright case); *Robin Prods. Co. v. Tomocek*, 465 F.2d 1193, 1196 (6th Cir. 1972) (phrasing the test as whether a "reasonable man" would regard the threatened action as a "charge of infringement"); *Int'l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210-11 (7th Cir. 1980) (referenced above); *Crown Drug Co. v. Revlon, Inc.*, 703 F.2d 240, 243 (7th Cir. 1983) (applying reasonable apprehension test to dismiss plaintiff's action for a declaration that it was not liable for unfair trade practices); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 728-29 (8th Cir. 1975) (holding that a combination of factors gave rise to a reasonable apprehension of infringement litigation); *Nat'l Basketball Ass'n v. SDC Basketball Club, Inc.*, 815 F.2d 562, 566 (9th Cir. 1987) (applying the reasonable apprehension test to a contract dispute between NBA and a franchisee); *Cardtoons, L.C. v. Major League Baseball Players Ass'n*, 95 F.3d 959, 965-66 (10th Cir. 1996) (applying reasonable apprehension of litigation test to "right of publicity" case and citing with approval several Federal Circuit declaratory judgment jurisdiction cases); *GTE Directories Publ'g Corp. v. Trimen Am.*, 67 F.3d 1563, 1569 (11th Cir. 1995) (applying reasonable apprehension of suit test); *United Christian Scientists v. Christian Sci. Bd. of Dir.*, 829 F.2d 1152, 1159 (D.C. Cir. 1987) (applying reasonable apprehension of litigation test to copyright dispute and citing with approval the application of the test in the Federal Circuit and other circuits); *Fed. Express Corp. v. Air Line Pilots Ass'n*, 67 F.3d 961, 964-65 (D.C. Cir. 1995) (applying the test to determine whether the court could rule on an assertion of unfair labor practices).

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

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

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

> Persons occupying positions of responsibility, like the appellants, often must make difficult decisions that can have adverse consequences for others. The possibility of being sued by those adversely affected is an inherent risk faced by the decisionmakers. Needless to say, the decisionmakers would benefit greatly by having guidance as to the potential legal ramifications of their decisions. Furnishing

> such guidance prior to the making of the decision, however, is the role of counsel, not of the courts.

Id. at 722.

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

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

Id. at 276.[5] MedImmune's claim does not meet the basic legal requirements for establishing a case or controversy.

Furthermore, MedImmune argues for a rule that would be unprecedented in the annals of declaratory relief law: that patent licensees should have the *unilateral* right to declare a justiciable controversy and sue the patent owner even though the license bars any infringement suit by the patent owner against the licensee. It is well established that a patent-

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

holder who has licensed its patents has given up its right to file suit against the licensee for infringement of those patents. *See Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft*, 829 F.2d 1075, 1081 (Fed. Cir. 1987) (A "patent license agreement is in essence nothing more than a promise by the licensor not to sue the licensee."). Thus MedImmune proposes a one-sided rule that would destroy the *mutuality* of access to the courts that is the very reason for the existence of the Declaratory Judgment Act.

As the Federal Circuit has observed,

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

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

II. THE FEDERAL CIRCUIT'S DECISION DOES NOT CONFLICT WITH THE CASES CITED BY MEDIMMUNE.

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

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

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

Nor is there any conflict with *Altvater v. Freeman*, 319 U.S. 359 (1943). In *Altvater*, there was a "raging" dispute between the parties, reflected in a history of multiple claims and counterclaims. *Id.* at 361-62, 364. This Court held that where the counterclaimant was paying royalties "under compulsion of an injunction decree" from a prior case, the

royalty payments did not defeat justiciability. *Id.* at 365-66. The Court stressed that "the involuntary or coercive nature of the exaction" – *i.e.,* the injunction, which gave the counterclaimant no option but to pay the royalties – "*preserve[d] the right . . . to challenge the legality of the claim.*" *Id.* at 365 (emphasis added). In other words, *Altvater* found justiciability notwithstanding royalty payments only because the licensee did not have the option of stopping payment. Here, by contrast, MedImmune *chose* to pay royalties; it could have ceased paying royalties at any time to challenge the patent.

Similarly, MedImmune's suggestion that under this Court's decision in *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83 (1993), a plaintiff can invoke Declaratory Judgment Act jurisdiction "'[m]erely . . . to avoid the threat of a "scarecrow" patent'" is just wrong. Pet. at 10 (quoting *Cardinal Chem.*, 508 U.S. at 96). *Cardinal Chemical* involved a ripe dispute worthy of adjudication because in that case a patentee sued the defendant for infringement and the defendant asserted a declaratory judgment *counterclaim*. *Cardinal Chem.*, 508 U.S. at 95-96. Because there was plainly a live controversy between the parties, *Cardinal Chemical* does not inform the analysis here.[6] Indeed, subsequent decisions recognize that *Cardinal Chemical* did not alter well settled justiciability analysis in patent cases. *See, e.g., Super Sack Mfg. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995) (rejecting notion that *Cardinal Chemical* "cut[s] [the] two-step justiciability analysis off at the pass" and concluding that the decision

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

"does not revolutionize the justiciability of declaratory judgment actions attacking a patent's validity").

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

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[7] One can imagine, for example, a live dispute over a patent arising just before a license expired, but where the patent term still had some years to run. If the patent-holder threatened suit unless the licensee agreed to an extension, there very well could be an actionable controversy. *See, e.g., Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542 (9th Cir. 1990). Of course, a live dispute might also exist where the licensee withheld royalty payments, or violated some other express contractual provision.

fear of suit.[8] But the point itself is unassailable, and undeserving of this Court's review.

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

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

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

1. Non-License Cases

MedImmune's non-license cases merit little attention. Precisely because they do not involve licenses, these cases do not consider the key question of how a *covenant not to sue* affects justiciability. The Federal Circuit's reasoning in this case turns on the nature of a license, and is inherently

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[8] Cases applying *Gen-Probe* include *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3336 (U.S. Nov. 22, 2005) (No. 05-656), which concerns the same MedImmune practice at issue here.

confined to licenses – or, if one prefers, covenants not to sue generally.[9] Cases without this feature offer little value.

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

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

required property to be restored to pre-lease condition at end of lease was "very likely" because "the lease term *will* end" and adjoining property would be rendered unmarketable were plaintiff's position sustained). Cases concerning "very likely" breaches are simply not helpful.[10]

2. License Cases

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

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[10] MedImmune's reliance on the remaining non-license cases is equally puzzling. In each case, there was either a change in circumstances, or one of the parties had created an actual prospect of litigation or breach of contract. *See, e.g., NUCOR Corp. v. Aceros y Maquilas de Occidente, S.A. de C.V.*, 28 F.3d 572, 575, 578 (7th Cir. 1994) (declaratory judgment defendant "demanded payment of $685,000 in damages within 60 days" and had "clearly threatened suit"). None of those factors is present here.

royalties on the grounds that its product did not infringe the patent.[11] *Id.* at 544.

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

The only case MedImmune cites that could arguably be read as disagreeing with the Federal Circuit's decision is the 1977 decision of the Second Circuit in *Warner-Jenkinson Co. v. Allied Chemical Corp.*, 567 F.2d 184 (2d Cir. 1977). It is questionable whether *Warner-Jenkinson* is followed on this issue even in the Second Circuit, which routinely applies

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

the "reasonable apprehension of suit" test. *See, e.g., Starter Corp. v. Converse, Inc.*, 84 F.3d 592, 595 (2d Cir. 1996) (declaratory judgment plaintiff must have a "real and reasonable apprehension of litigation" and "must have engaged in a course of conduct which brought it into adversarial conflict with the declaratory defendant"); *Matthew Bender & Co. v. West Publ'g Co.*, 240 F.3d 116, 119 (2d Cir. 2001) (discussing the district court's appropriate application of the reasonable apprehension test for determining declaratory judgment jurisdiction in a copyright case). In *Atlantic Richfield Co. v. Alcan Aluminum Holdings Ltd.*, 12 F. Supp. 2d 460 (S.D.N.Y. 1998), for example, a district court applying Second Circuit law concluded that a declaratory judgment case was not justiciable because the plaintiff only sought a declaration to assure the availability of breaching a contract as an option "if economic analysis shows that it would be the most profitable course." *Id.* at 460-61. Such relief, of course, is precisely what MedImmune seeks here – a declaration that *if* it chose to breach its license it would have a valid defense to any subsequent infringement lawsuit Genentech *might* bring.

III. THE DECISION BELOW HARMONIZES WITH *LEAR*.

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

Id. at 663-64. *Lear* eliminated that "licensee estoppel" doctrine and leveled the playing field between licensors and licensees by permitting a licensee *who had stopped paying royalties* to defend a suit by the licensor for non-payment on the grounds that the licensed patent was invalid.

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

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

MedImmune's theory would upset that balance by skewing it overwhelmingly in favor of licensees. Under

MedImmune's view, a licensee can negotiate a patent license on the best available economic terms – terms that cap the licensee's risk and inherently reflect any existing uncertainty about the patent's validity[12] – and then, the next day, sue to invalidate the same patent. The licensor has no parallel right, for as long as the licensee continues to pay royalties, the licensee could bind the licensor's hands and prevent it from terminating the license. This would not "balance the claims of promisor and promisee in accord with the requirements of good faith," *Lear*, 395 U.S. at 670; it would give licensees an undeserved second bite at the apple with everything to gain and nothing to lose. Neither *Lear* nor any other holding of this Court supports such a disproportionate imposition of risk upon the patent-holder.

It is, in any event, impossible for the Congress or a decision of this Court to have created a policy-based exception to Article III's "case or controversy" requirement. That is a fundamental limitation on the constitutional power of the federal courts, designed to protect the separation of powers and the integrity of the judicial role. Congress could not, for any policy reason, authorize the federal courts to hear a hypothetical controversy. This Court has never created a policy-based exception to the case or controversy requirement. And if this were to be the first such instance, there would be no way to confine the exception MedImmune seeks just to patent cases. The message to the legal community would be that with a good enough policy argument one indeed may, as Judge Posner put it in *Crowley*

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

Cutlery, come to federal court simply "for advice on the legality of a proposed course of action." *Crowley Cutlery*, 849 F.2d at 276. Neither policy arguments generally nor anything found in *Lear* can justify such a radical change in settled Article III jurisprudence.

IV. THE FEDERAL CIRCUIT'S DECISION RAISES NO ISSUES OF NATIONAL IMPORTANCE AND DOES NOT THREATEN THE PACE OF INNOVATION IN MEDICAL PRODUCTS.

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

MedImmune's assertion that the public can only be protected from invalid patents by allowing licensees in good standing to sue their licensors (or allowing non-licensees who have never been threatened with suit by a patentee to sue, for that matter) – is wrong. There are at least three different ways the validity of a patent may be tested (and through one of these procedures the '415 patent is currently under review). First, a licensee such as MedImmune may refuse to pay or cease paying royalties and, as in *Lear*, induce an infringement suit. Second, anyone who is not licensed and is threatened with suit may challenge the patent under the Declaratory Judgment Act. Third, any member of the public, even a patent licensee in good standing, may seek reexamination of a patent by the PTO at any time.[13] In fact,

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[13] The federal patent statutes permit anyone to ask the PTO to reconsider the validity of an issued patent based on prior art. 35 U.S.C. §§ 302, 311(b); *see also id.* § 301. The patent statutes provide for two different types of reexamination. For patents issuing from an application

the '415 patent currently is being reexamined. Indeed, this ongoing PTO reexamination has the potential to moot the issues that MedImmune is asking to litigate, which is a further reason to deny review.

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

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

MedImmune also asserts that it was the victim of an "all too common" package licensing strategy in which a

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filed on or after November 29, 1999, the requesting party may request either an *inter partes* or an *ex parte* reexamination. *See id.* § 311; 37 C.F.R. § 1.913. If the PTO grants an *inter partes* reexamination request, the third party requesting reexamination retains the ability to remain substantively involved throughout the reexamination process. The requesting party may continue to make arguments about validity throughout the reexamination process, and may appeal any outcome in favor of validity to the Board of Patent Appeals and Interferences and then to the Federal Circuit. *See* 35 U.S.C. §§ 306, 314(b), 315. If the PTO grants an *ex parte* reexamination request, the requesting party is not substantively involved in the reexamination process. *Ex parte* reexamination has been a part of the patent statute since 1980. For the '415 patent, the PTO has granted an *ex parte* request for reexamination, and the proceeding is currently ongoing.

putatively "bad" patent (the '415 patent) was licensed as part of a "bundle" with other patents. Pet. at 19-20. That argument is wrong. MedImmune, "for reasons of convenience," expressly elected not to license the '415 patent alone. C.A.A. 3585. Moreover, MedImmune has no products covered by the '567 patent it licensed along with the '415 patent, and thus could not fear losing license rights to the '567 patent by challenging the '415 patent. *See* C.A.A. 3312, 3316-17. At any rate, the answer to this supposed issue lies in the parties' license negotiations, not a wholesale revision of Article III jurisprudence. A licensee may negotiate for the right to challenge one licensed patent without risking a breach of other patent license rights. *See, e.g., Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1368-69 (Fed. Cir. 2004) (patent licensee stopped paying royalties on one licensed product; all parties agreed the license agreement was still in effect as to other licensed product), *cert. granted on other grounds*, 126 S. Ct. 601 (2005). This solution is at least as "common" as MedImmune contends bundling is (Pet. at 19), and does not require this Court to change Article III doctrine to address MedImmune's policy concerns.

CONCLUSION

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

The petition for a writ of certiorari should be denied.

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