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 OF RESPONDENT GENENTECH, INC.

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QUESTION PRESENTED

Whether the Federal Circuit properly dismissed a suit brought by a patent licensee seeking a declaratory judgment that the patent was invalid or unenforceable, when the licensee's voluntary decision to enter the license agreement compromises those legal issues between the parties and grants the licensee complete immunity from a patent infringement suit?

LIST OF PARTIES

Petitioner MedImmune, Inc. was the only appellant in the Federal Circuit, and Genentech, Inc., City of Hope, and Celltech R&D, Ltd. were appellees. Celltech is not a respondent in this Court, because Petitioner did not seek review of the Federal Circuit's decision concerning this party.

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.

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STATUTES INVOLVED

Relevant constitutional and statutory provisions are set out in the Addendum to this brief.

STATEMENT OF THE CASE

For more than 300 years, the common law and this Court have held that a patent licensee cannot challenge the validity of the patent while retaining the benefits conferred by the license. *E.g.*, *Kinsman v. Parkhurst*, 59 U.S. 289, 292–93 (1856). That rule was premised on the historic understanding of a license as an instrument of compromise. The parties exchange their claims and defenses under the patent laws for the rights and obligations negotiated in the contract, unless and until that contract is repudiated.

MedImmune argues that the Declaratory Judgment Act transforms that settled law by giving it a right to seek judicial advice about the merits of defenses to the potential infringement suit it has already compromised, without giving up the benefits of that compromise. It wants such advice to decide whether to abandon the license and quit paying royalties. But a justiciable controversy requires a dispute about *legal rights*, not simply a legal question that is "concrete" and of practical interest to the parties. MedImmune's legal rights and obligations are now defined by the license, and there is no dispute about them at all. Nor is MedImmune entitled to seek judicial advice about the merits of a settled patent claim by contending that its fear of the potential consequences of an infringement suit render the license a product of "duress." What MedImmune calls "duress" is nothing more than the decision every potential infringer confronts when it decides whether to compromise the risks of patent litigation in exchange for the certainty afforded by a license. The uncontroverted facts establish that MedImmune chose to license Respondents' patent, voluntarily, for the ordinary purpose of managing a legal risk. If the consequences of such a choice are a cognizable legal injury, then every licensee could unilaterally declare a "controversy" about the validity of any patent at any time.

The Federal Circuit correctly recognized that there is no Article III controversy here, but regardless this case must be dismissed as an exercise of the equitable discretion to decline jurisdiction provided in the Declaratory Judgment Act. Indeed, the equitable doctrine of licensee estoppel has foreclosed claims like these for centuries. As the Federal Circuit emphasized, it is "inequit[able]" to subject a patent owner to the "continuing risk of attack on the patent whenever the licensee chooses" while "the licensee can preserve its license and royalty rate if the attack fails," and this record compels that conclusion. Pet. App. 7a.[1]

FACTUAL BACKGROUND

Respondents' Patents. Respondents Genentech, Inc. and City of Hope secured U.S. Patent No. 6,331,415 B1 ("the Cabilly II Patent"), after they invested years of effort and enormous financial resources developing genetic technology to produce antibodies used in, among other things, the diagnosis and treatment of cancer and other diseases. J.A. 109 (Am. Compl. ¶ 21), 417, 485, 509. The Cabilly II Patent relates to processes for the production of antibodies by "coexpression" of immunoglobulin chains in a recombinant host cell (the "coexpression technology"). J.A. 509, 549–50. Genentech uses this technology in a number of its own products, including treatments for breast and colorectal cancer. It also licenses the technology to other companies.

Respondents filed a patent application relating to this technology in 1983, and U.S. Patent No. 4,861,567 ("the Cabilly I Patent") was issued in March 1989. J.A. 109 (Am. Compl. ¶ 21); J.A. 485. The Cabilly I Patent is not the patent in suit. It generally claimed processes for the production of chimeric (genetically engineered) antibodies, but it did not expressly claim the coexpression technology. J.A. 485–505. It expired in March 2006.

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[1] "Pet. App." refers to the Appendix to the Petition for a Writ of Certiorari; "J.A." refers to the Joint Appendix; and "C.A.J.A." refers to the Federal Circuit Joint Appendix.

The PTO did not issue the Cabilly II Patent to Respondents until 2001. J.A. 350–53, 509. The delay was attributable to resolution of a priority dispute between Genentech and a British company, Celltech R&D, Ltd. Pet. App. 2a–4a. Celltech and Respondents had independently developed coexpression technology within weeks of each other. J.A. 344–45. Although Genentech was first to file for U.S. patent protection on April 8, 1983 (J.A. 277, 350), Celltech claimed priority based on a British patent application filed two weeks earlier. J.A. 277–78, 344. Genentech learned of this in 1989 when the PTO issued Celltech a patent for the coexpression technology (the "Boss Patent"). J.A. 459, 484. Believing Respondents had invented the technology, Genentech thereafter challenged the Boss Patent's priority by provoking a PTO interference proceeding. J.A. 278, 345.[2] Seven-and-a-half years after the declaration of interference, the Board of Patent Appeals found that Respondents had not established an actual reduction to practice before the British priority date and granted priority to Celltech. Pet. App. 2a. Respondents contested this decision by filing a civil action in federal court, which resulted in a mediated and judicially endorsed consent decree in Respondents' favor. J.A. 276–80, 343–48.

Although MedImmune contended in its complaint that the consent decree was "collusive" and "fraudulent" (Pet. App. 9a; J.A. 105, 120, 123, 130 (Am. Compl. ¶¶ 10, 66, 76, 106)), the district court rejected that claim on summary judgment (J.A. 357–71), the Federal Circuit affirmed (Pet. App. 9a–17a), and MedImmune did not challenge those rulings in this Court. As the Federal Circuit explained, the district court actively encouraged the parties to settle based on the strength of new evidence supporting Genentech's claim of priority. Pet. App. 2a–3a.[3] The district court

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[2] An interference is a PTO proceeding to determine certain questions of patentability or priority of invention between two or more parties claiming the same invention. 37 C.F.R. § 41.200(a); 35 U.S.C. § 135(a).

[3] During the discovery phase of the district court litigation, Respondents

observed that the new evidence "certainly put [Celltech] on the defensive," and strongly urged the parties to "agree on a mediator" and to "put [their] full effort into it." C.A.J.A. 1666; J.A. 332–33; Pet. App. 3a. The mediation was conducted by a retired judge, and the district court reviewed and approved the settlement, which resulted in a consent judgment that "Genentech is entitled as a matter of law to priority over Celltech to the invention." J.A. 343–48; Pet. App. 3a. The PTO then independently examined Genentech's patent application in light of the district court's judgment, concluded that it met all of the requirements of patentability, and issued the Cabilly II Patent to Genentech on December 18, 2001. J.A. 352–53, 509–51; Pet. App. 3a–4a.

Public Notice Of Respondents' Patent Claims. In 1991, MedImmune began developing Synagis, a monoclonal antibody used to prevent respiratory syncytial virus ("RSV"). J.A. 104 (Am. Compl. ¶5); Pet. Br. 2. As the district court found, MedImmune "utilizes the monoclonal antibody production techniques covered by the patents at issue" to make Synagis. J.A. 349–50; *see* Pet. Br. 2–3. By the time its development was underway, MedImmune was on notice that its use of the coexpression technology to make Synagis would expose it to infringement liability to either Celltech or Genentech for many years into the future.

The Boss Patent expressly claimed the coexpression technology, and became public when issued in 1989. J.A. 459, 484. The public record also demonstrated that Genentech claimed priority to the same invention. On the day the PTO issued the Boss Patent, it also issued the Cabilly I patent to Genentech, which described the coexpression technology but did not expressly claim it. J.A. 485–505; J.A. 109 (Am. Compl. ¶ 24). To provoke the interference, Genentech followed the "permitted and

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discovered a draft of the Cabilly patent application predating Celltech's British priority date and offered testimony from the attorney who drafted that application corroborating conception of the coexpression technology prior to March 25, 1983. J.A. 281–329; C.A.J.A. 1227–57. The parties supplemented the PTO record under 35 U.S.C. § 146. Pet. App. 9a.

standard procedure" of "copy[ing] exactly the claim[s] in Celltech's patent" into a pending continuation application that claimed the benefit of Genentech's 1983 application (the "Cabilly continuation application").[4] When the PTO declared an interference proceeding on February 28, 1991, it issued a public Notice of Declaration of Interference that disclosed that Genentech was asserting priority to the same coexpression technology claimed by the Boss Patent. J.A. 351, 459; 37 C.F.R. § 1.11(a) (1990); Notice of Declaration of Interference, Feb. 28, 1991, *available in* Patent No. 4,816,397 File History, Paper No. 25, at 4 (Cabilly continuation application claims Boss Patent claims 1–18). It was also a straightforward matter of law that Genentech would be entitled to protection for 17 years from the new patent's issuance if it established priority. 35 U.S.C. § 154(a)(2) (1994). As the Federal Circuit noted, PTO delays in the resolution of priority are "notorious." Pet. App. 11a.

MedImmune's Decision to License the Coexpression Technology. In 1997 and 1998, MedImmune acted to eliminate its risk of infringement liability by obtaining licenses to use the coexpression technology for the production of Synagis from both Celltech and Genentech. MedImmune obtained a license from Celltech for the Boss Patent in 1998. J.A. 134 (Am. Compl. ¶ 122). But in 1997 it also elected to secure protection from the known risk that Genentech could prevail in the then-pending interference proceeding by securing a license ("the 1997 License") not only to the Cabilly I Patent (relating to the production of chimeric antibodies), but also to any future patents "relating to the coexpression of immunoglobulin chains in recombinant host cells" (the "Coexpression Patents") that might issue from the Cabilly continuation application, pending at that time. J.A. 399 (Lic. ¶ 1.09). The terms of

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[4] J.A. 345, 351. The patent laws allow an application with new or amended claims—called a "continuation" or "continuing" application—to benefit from the filing date of an earlier application that discloses the claimed invention. *See* 35 U.S.C. §§ 120, 132(a); 37 C.F.R. § 1.121(c).

this license thus demonstrate MedImmune's awareness of the maximum scope of the patent rights Genentech might be granted if it prevailed in the priority dispute.[5] MedImmune was also necessarily agreeing that it desired the protection of the license notwithstanding that it might not know at the time of the license the precise claims of the patent that would ultimately issue. This was plainly a voluntary, uncoerced decision. MedImmune had no present need to license the coexpression technology from Genentech in 1997; Celltech owned the patent. MedImmune could have waited for the outcome of the interference proceeding, and concedes that it was given the option to license the chimeric and coexpression patents separately and was not "coerced" to take a package license. J.A. 402 (Lic. ¶ 2.04). Nonetheless, it chose to negotiate a comprehensive license with Genentech when Synagis was still in development and Genentech had only a prospect of obtaining a patent.

The resulting license terms reflected these advantageous bargaining conditions. The upfront payment was modest, J.A. 402, C.A.J.A. 3585 (Lic. ¶3.01), and the royalty rate was heavily discounted: slightly more than half the top rate that MedImmune later agreed to pay for additional licenses in 2003, *after* Genentech was awarded the Cabilly II patent. *Compare* J.A. 403, C.A.J.A. 3586 (Lic. ¶ 3.03) *with* J.A. 442, C.A.J.A. 3300 (Lic. ¶ 3.03). The 1997 License granted MedImmune "coexclusive" rights, which committed Genentech to granting no more than four additional licenses to practice in the same field and territory, a favorable term that MedImmune was unable to secure in subsequent non-exclusive licenses. *Compare* J.A. 401 (Lic. ¶ 2.01) *with* J.A. 441 (Lic. ¶ 2.01). It also contained a "Most Favored Licensee" provision that gave MedImmune the benefit of the best terms offered to any other party—

[5] In any event, a prospective licensee who has any uncertainty about the scope of the claims covered by the application (and any amendments) can insist on reviewing those documents under a confidentiality agreement prior to executing a license. Licenses need not be taken blind.

another concession MedImmune was unable to secure in licenses negotiated after Cabilly II issued. J.A. 405 (Lic. ¶ 3.07). It also allowed MedImmune to "terminate [the license] in its entirety or with respect to one or more Antigens at any time upon six (6) months written notice." J.A. 409 (License ¶ 7.04).

MedImmune did not, however, negotiate any term that would permit it to initiate a judicial proceeding challenging the validity of the patents while retaining the benefits of the license. The 1997 License requires MedImmune to pay royalties unless and until the applicable patent is "held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken." J.A. 399 (Lic. ¶ 1.10). That limitation is common in patent licenses, and this Court has held for 100 years that it does not give the licensee itself any contract right to challenge the validity of the patents; it simply gives the licensee "the benefit of litigation by or against third persons." *United States v. Harvey Steel Co.*, 196 U.S. 310, 317 (1905); *see also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) (collateral estoppel produces the same result). Nothing in the license purported to alter the background rule—well-established by the time of the 1997 License—that unless the licensee repudiates the license it cannot avoid its royalty obligations by denying the patent's validity. *Studiengesellschaft Kohle m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir.), *cert. denied*, 522 U.S. 996 (1997). Indeed, as MedImmune concedes, Genentech "disclaimed any warranty" as to the validity of any licensed patent. Pet. Br. 36 & n.15; J.A. 411 (Lic. ¶ 8.08).

Petitioner's Decisions to Pay Royalties and Secure Additional Licenses. Once the FDA approved Synagis in 1998 and MedImmune began making the product, MedImmune had to decide whether to make the royalty payments required by the licenses it negotiated, or instead repudiate or terminate those licenses. As MedImmune began to develop other products using the coexpression technology, it also had to decide whether to secure

additional licenses. The record leaves no doubt that the decisions MedImmune made with respect to these issues were wholly voluntary. It was not subjected to any pressure beyond its own assessment of the strength of Genentech's and Celltech's patent rights, clearly owed the royalties it elected to pay, and aggressively (and duplicitously) solicited seven new licenses from Genentech.

First, MedImmune elected to pay royalties under its license with Celltech. It did not deny that Synagis infringed the claims of the Boss Patent—the same claims found in the Cabilly II Patent.[6] J.A. 134 (Am. Compl. ¶ 124). This is all the more telling because Genentech requested that it also pay royalties to Genentech under the Cabilly I Patent, but MedImmune refused based on its view that "Synagis falls outside the claims of chimeric antibody patents." J.A. 414–16. (Genentech accepted that explanation and did not threaten suit or take any other adverse action.)

Three years later, in December 2001, the PTO issued the Cabilly II Patent. J.A. 509. Genentech contacted MedImmune in January 2002 "to confirm [its] expectation that MedImmune will pay royalties on sales of its Synagis antibody product." J.A. 419. MedImmune thus had to decide again whether to pay the royalties then due or instead repudiate or terminate the license. Desiring the benefits of its bargain but hoping to evade the price, MedImmune devised another way. As MedImmune would later testify, it decided to sue Genentech to challenge the validity of the patent, but not until it protected its downside by first inducing Genentech to grant it seven additional licenses under the Cabilly II Patent for various other antibody products then under development. J.A. 389, 431, 437. MedImmune began paying royalties under the Cabilly II Patent to maintain its commercial relationship with Genentech and its good standing under the 1997 License.

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[6] But for minor differences in dependent claims, the Cabilly II Patent contains claims identical to the Boss Patent. *Compare* J.A. 484 (claims 1–18 of the Boss Patent) *with* J.A. 550 (claims 1–20 of the Cabilly II Patent).

In the communications that followed the issuance of the Cabilly II Patent, MedImmune never once denied that it owed royalties under the license. J.A. 421–22, 426, 430–31, 434–35. Instead, it merely asked Genentech to explain its "basis for believing that [Synagis] would infringe any valid claim of the [Cabilly II] Patent such that royalties would be due," J.A. 421, and asserted that its March 2002 royalty payment had been made "under protest" while it was "evaluat[ing] [Genentech's] claim that MedImmune owes royalties." J.A. 426. By letter of March 24, 2002, Genentech responded to MedImmune's request and described why it believed that MedImmune was using the coexpression technology to produce Synagis. J.A. 428. The letter asked MedImmune to correct any misunderstanding Genentech had "regarding the structure of Synagis and/or the process by which it is produced." *Id.* MedImmune never responded, never challenged Genentech's understanding, and never offered any reason that royalties were not owed.

Instead, MedImmune continued paying quarterly royalties on Synagis (J.A. 108 (Am. Compl. ¶ 18)), and repeatedly communicated a desire to continue and expand its licensing relationship with Genentech. In a May 23, 2002 letter, for example, MedImmune stated that it was "happy to meet with [Genentech] to discuss whether Genentech is willing to license various MedImmune products in development on commercially reasonable terms." J.A. 434, 431. Genentech expressed "appreciat[ion for] MedImmune's interest in additional licenses under the [Cabilly II] patent" and stated that the company "look[ed] forward … to continuing our commercial relationship." J.A. 429, 433. Based on these communications, and on MedImmune's silence following Genentech's explanatory letter of March 24, 2002, Genentech in good faith entered into negotiations with MedImmune. Those discussions culminated in agreements in January 2003 for seven new licenses to the Cabilly II Patent for MedImmune products in various stages of development. J.A. 439; J.A. 108 (Am. Compl. ¶ 18).

Then, just three months after it had secured the additional covenants not to sue, MedImmune filed this lawsuit challenging the validity and enforceability of the licensed patent. J.A. 1. MedImmune has since admitted that it had made the decision to file this challenge by March 2002. Pet. Br. 7; J.A. 389. It is plain as day why MedImmune waited a year to file and never disclosed its intentions to Genentech until after the new licenses were secured.[7]

PROCEDURAL HISTORY

Nature Of MedImmune's Claims. MedImmune's claims warrant explanation because they bear on the jurisdictional issues. Its Amended Complaint alleged violations of antitrust and unfair competition laws that were dismissed on summary judgment and are no longer at issue. J.A. 141–48; Pet. App. 9a–17a. The remaining claims, as clarified during this litigation, seek a declaratory judgment that the Cabilly II patent is invalid and unenforceable *under the patent laws*. J.A. 115–30, 136–41.

Notwithstanding its inclusion of one cause of action for "Declaratory Judgment on Contractual Rights and Obligations," J.A. 136 (Am. Compl. ¶¶ 131–33), the supporting allegations of the complaint and MedImmune's explanations of its claims establish that MedImmune is not seeking a declaration of rights under the terms of the parties' contract. Its brief in this Court implies that there is a dispute under the contract because its obligation to pay royalties turns on whether Synagis "infringes one or more claims" of the patent, J.A. 399 (Lic. ¶ 1.10), and its complaint alleged "non-infringement." Pet. Br. 3–4; J.A. 108, 136, 141 (Am. Compl. ¶¶ 20, 132, 162–64). That is misleading. Its complaint alleges that Synagis does not infringe any "valid" claim of the patent. J.A. 141 (Am. Compl. ¶ 163). It never alleges that Synagis does not *in fact* utilize the technology

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[7] MedImmune has made a practice of negotiating licenses while intending to immediately challenge the licensed patent. *See MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1377–78 (Fed. Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3336 (U.S. Nov. 22, 2005) (No. 05-656).

claimed by the Cabilly II Patent. MedImmune's Federal Circuit brief explained its "non-infringement" argument in the following terms: "the Cabilly II claims cannot be supported by their limited specification and are invalid in light of prior art" and thus "unenforceable." Appellant's Br. at 2 (Fed. Cir. filed July 6, 2004). That is a challenge to the validity and enforceability of the Cabilly II Patent, not to whether Synagis infringes it according to the claims.

The courts below understood this. The district court found that Synagis *"utilizes the monoclonal antibody production techniques covered by the patents at issue."* J.A. 349–50 (Jan. 12, 2004 Memorandum of Decision) (emphasis added). The Federal Circuit also uniformly characterized MedImmune's claims as "challeng[ing] the validity and enforceability of the licensed patent." Pet. App. 1a; *see id.* at 4a, 6a–7a. Although MedImmune now suggests that the court of appeals should not have "assumed that Synagis was a 'Licensed Product,'" Pet. Br. 27, it did not contest the district court's finding or the Federal Circuit's characterization of its claims in its petition.[8]

MedImmune's alleged injuries are also relevant to the jurisdictional inquiry. First, MedImmune alleges that it has been "damaged" by the "payments to Genentech under the 1997 License Agreement based on sales of Synagis." J.A. 134–35 (Am. Compl. ¶ 125). Second, the complaint alleges that MedImmune "has, as a practical matter, been compelled—at great cost—to enter into the 2003 License Agreements with Genentech to protect its investments" in

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[8] The petition conspicuously asserted only that "the license for respondent's patent package included an application [the Cabilly continuation application] that, upon its issuance as [the Cabilly II Patent] and publication of its claims, petitioner believed to be invalid and unenforceable." Pet. 20. MedImmune's brief in this Court also admits that the Cabilly II Patent claims "the same technology that Celltech (through MRC) had once licensed to [it]," J.A. 134 (Am. Compl. ¶ 124), and therefore "purported to cover the process of producing *any* type of monoclonal antibody." Pet. Br. 4-5 (emphasis added). MedImmune describes Synagis as a "humanized monoclonal antibody." *Id.* at 3.

its pipeline products. J.A. 134 (Am. Compl. ¶ 125). In other words, MedImmune contends it is being injured by its own decisions to execute a license and pay royalties, in exchange for Genentech's covenant not to sue it for infringement.

Proceedings In The District Court. The district court dismissed the action. It first granted summary judgment to Genentech and Celltech on the antitrust and unfair-competition claims under the *Noerr-Pennington* doctrine, and rejected Petitioner's claim that the Cabilly II Patent was secured through fraud on the patent office. J.A. 349–79.

The district court dismissed the remaining declaratory judgment claims for lack of subject matter jurisdiction. Pet. App. 31a. The court found "no relevant facts that distinguish this case from" *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), *pet'n for cert. dismissed*, 543 U.S. 941 (2004), which held that there is no justiciable controversy over the validity of a patent between a patent holder and a licensee in good standing. Pet. App. 24a–31a.

The Decision Of The Federal Circuit. The Federal Circuit affirmed. It construed MedImmune's claims as a "challenge [to] the validity and enforceability of the licensed patent," Pet. App. 1a, and held that MedImmune "did not have standing" to bring claims that had been extinguished by the license. *Id.* at 9a. The panel reasoned that "[t]he Declaratory Judgment Act requires a 'definite and concrete controversy' of 'sufficient immediacy and reality,' to warrant judicial intervention," *id.* at 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)), and that here "there is no controversy of immediacy or reality because there is no reasonable apprehension of suit." *Id.* It observed that here, as in *Gen-Probe* and *Centocor*, "the jurisdictional requirements of a declaratory action are not met when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement." *Id.* at 6a.

The Federal Circuit explained that its holding was compelled by "the equalizing principles that underlie the

Declaratory Judgment Act." *Id.* at 7a. "The purpose of [the declaratory judgment] procedure," the court noted, "is to 'accommodate[] the practical situation wherein the interest of one side to the dispute may be served by delay in taking legal action,' by permitting the other side to initiate legal action." *Id.* at 6a (quoting *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 977 (Fed. Cir. 1993)) (alteration in original). MedImmune's suit "distorts" that balance, and creates "inequity," by placing a patentee who has "contracted away its right to sue … in continuing risk of attack on the patent whenever the licensee chooses—for example, if the product achieves commercial success—while the licensee can preserve its license and royalty rate if the attack fails." *Id.* at 7a. The Federal Circuit held that its decision was consistent with *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), because in *Lear* "the licensee ceased payment and disavowed the license obligation," whereas MedImmune "assiduously avoided" breaching its license. Pet. App. 6a.

SUMMARY OF ARGUMENT

I. This case is about what role a fully negotiated license plays in determining if a justiciable "case or controversy" exists between a licensee and licensor concerning the validity or enforceability of a patent. MedImmune and the United States claim that the license is "immaterial," U.S. Br. 21, but contracts often change the parties' relationship in a way that that brings their controversy to an end. The paradigmatic example is contracts settling an existing dispute, and courts routinely dismiss lawsuits as moot after settlements. A patent license is a contract in the nature of a settlement as well. It resolves a potential (or existing) statutory claim for patent infringement by redefining the parties' rights and obligations under the contract. As part of the bargain, the patent owner promises not to sue for infringement, thereby terminating any threat or uncertainty to the licensee deriving from the patent. Without more—and this case presents nothing more—the license is not only

material; it conclusively resolves any justiciable controversy concerning the patent between the parties to the license.

The Federal Circuit expressed this point through the "reasonable apprehension of suit" test developed in another context. That captures the right concept, because the impossibility of a statutory infringement suit precludes any controversy about the parties' respective legal rights under the patent laws. A fuller explanation is that justiciability has always been tied to an actual or imminent invasion of a legally protected interest, and, under basic legal principles going back 1500 years, voluntary payments to resolve uncertainty about one's legal rights do not constitute injury to any legally protected interest; rather, they terminate any controversy about those rights. Asserting that such payments are made "under protest" changes nothing. As this Court recognized in *Altvater v. Freeman*, it requires an "involuntary or coercive … exaction," such as payments under an injunction, to establish that a royalty payment is an injury to a legally protected interest. 319 U.S. 359, 365 (1943). A compromise of uncertain legal rights is never legally "coerced" by the hazards and expense of litigation; otherwise, no settlement would ever be final.

Nor is MedImmune entitled to litigate the hypothetical question of what its legal rights *would* be *if* it renounced the license and continued selling Synagis. This Court has permitted litigants to challenge statutes or regulations without violating them, on the theory that the consequences of violation coerce the litigants into changing their primary conduct in ways that prevent any action based on actual prosecution from ripening. Equity was flexible enough to accommodate the necessity for early judicial intervention in appropriate circumstances, and Article III can be as well. But no such accommodation is appropriate in this case. MedImmune is not suffering any present injury *because it has voluntarily elected to purchase immunity from the potential cause of such an injury*. It voluntarily opted out of the statutory patent system with a license, and it is free to opt back in at any time by repudiating or terminating that

license. Its curiosity about the wisdom of doing so does not create a dispute about its legal rights. MedImmune is exactly like a party that settles a looming tort suit in exchange for a payment due in six months, and then comes to court for a declaration about the merits of that suit to decide whether to abandon its settlement.

Put another way, mootness, ripeness, and standing principles combine to render this case nonjusticiable. By taking a license, MedImmune mooted any prior controversy between itself and Genentech about their respective rights under the patent laws. It also severed any connection between its own legal rights and the validity of Genentech's patent that could create standing to litigate the validity issue. There is a potential *future* controversy about the validity of the patent, but that controversy will not ripen until MedImmune repudiates or terminates the license.

MedImmune argues at great length that because one purpose of the Declaratory Judgment Act was "to permit judicial resolution of contract disputes 'before or after breach,'" Pet. Br. 12–13 (citation omitted), the Federal Circuit erred by "announc[ing] an absolute rule that no 'actual controversy' can exist without breach of contract." *Id.* at 21. This is misdirection. There is no dispute about the meaning of the license or the parties' legal obligations under it, and the Federal Circuit did not hold that controversies about contract rights can never ripen prior to breach. This case is about whether MedImmune can litigate the merits of a hypothetical infringement suit that cannot arise because of the license—even though no dispute has arisen about the terms of that license—simply because the parties' *economic* interests are adverse and because a favorable decision would clear the way for MedImmune to abandon the contract. The Federal Circuit properly recognized that in these circumstances MedImmune "did not have standing to bring a declaratory challenge to the Cabilly II patent," Pet. App. 9a, because it faces no danger to any legally protected interest. The Declaratory Judgment Act might allow parties to seek clarification of their contractual obligations,

but it does not allow them to seek anticipatory judicial advice about how hypothetical legal rights *outside the contract* might be adjudicated if the contract did not exist.

Applying traditional Article III principles in this case will in no way "[c]onstitutionalize the rejected doctrine of licensee estoppel." Pet. Br. 34. This argument, ostensibly based on *Lear v. Adkins*, is in reality just a plea for a policy-based exception to the case or controversy requirement. *Lear* does not address justiciability and its substantive holding—that a licensee who has repudiated may assert invalidity as a defense to an infringement suit—applies only in circumstances where justiciability is obvious because the patent owner has filed suit or the putative infringer has reason to fear such a suit. This Court should not distort traditional Article III principles to promote MedImmune's particular (and deeply flawed) vision of sound patent policy.

II. This Court has explained that, regardless of whether the requirements of Article III are satisfied, declaratory judgment cases should be dismissed on jurisdictional grounds if it is clear that granting declaratory relief would be inconsistent with equitable principles. Permitting MedImmune to bring this suit while maintaining the down-side protection of its license is inconsistent with at least three centuries of equity jurisprudence directly on point (jurisprudence that was not, as MedImmune claims, rejected in *Lear v. Adkins*). Even leaving licensee estoppel aside, this suit violates fundamental norms of equity, including the principle that a party cannot continue taking the benefits of a contract while attacking it as voidable.

Nor does federal patent policy call for a departure from settled equitable rules. The goals of the patent system are greater than encouraging litigation. Creating incentives to innovation is the primary goal, and it is served by legal rules that promote predictable technology transfers. The new rule MedImmune seeks would encourage challenges to patents by licensees—but only at the expense of distorting market-based pricing and decreasing a license's value as a tool of compromise. That will lead to fewer licenses being

granted and therefore less innovation and less competition. The United States effectively concedes that these results are not required by public policy, by suggesting that licensors contract around them—either by requiring fully paid-up licenses or by inserting a clause making explicit that lawsuits like this one constitute breach. But if this case is just about picking the right contractual default rule then surely the answer is supplied by the common law, which has recognized for centuries that suits like this one are inconsistent with the bargain at the heart of a license.

ARGUMENT

I. THERE IS NO "ACTUAL CONTROVERSY"

MedImmune contends that it is entitled to litigate the merits of a hypothetical patent infringement suit, simply because a favorable decision would give it the confidence to stop purchasing insurance against that lawsuit. But a justiciable controversy requires some injury or threat to legal rights. MedImmune's decision to purchase immunity from suit terminates any controversy about the merits of that suit unless, as in *Altvater*, MedImmune can show that that decision was involuntary or coerced. It clearly cannot.

A. A Justiciable Controversy Requires An Actual Or Imminent Legal Injury, Or A Real Necessity For Anticipatory Judicial Action

This case requires careful attention to the constitutional limits on anticipatory or hypothetical adjudication. MedImmune quotes *Aetna* for the proposition that a declaratory judgment controversy must be "concrete" and not "hypothetical," and must "admit[] of an immediate and definitive determination of the legal rights of the parties," 300 U.S. at 240–41, but then argues as if these phrases come from nowhere—and as if "the legal rights of the parties" embraces any legal question of practical interest to them. *See* Pet. Br. 15. In fact the common law and this Court's standing and ripeness cases lay out a cohesive jurisprudence of when a justiciable controversy can exist prior to an actual violation of legal rights. That jurisprudence *does not* permit

federal courts to opine on any legal question that the parties care about and can state in concrete terms.

First, the controversy must concern the legal rights of the parties. Like any patent licensee, MedImmune would benefit from the declaration it seeks in a practical way, because if the patent were declared invalid it could stop paying royalties. But a federal court may not decide a dispute simply because the plaintiff will benefit from a favorable decision. That much "might be said of someone who has placed a wager upon the outcome." *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000). The party's interest must "consist of obtaining compensation for, or preventing, the violation of a legally protected right." *Id.* MedImmune and its amici misread *Aetna* and *Maryland Casualty* by arguing that Article III requires only a factually concrete dispute with some practical consequence for the parties. *See, e.g.*, Pet. Br. 25; U.S. Br. 10; NRDC Br. 6. As *Aetna* put it, the controversy must be "definite and concrete" but must also "touch[] the legal relations of parties having adverse *legal interests*" and "admit[] of an immediate and definitive determination of the *legal rights* of the parties." 300 U.S. at 240–41 (emphasis added). Similarly, the Declaratory Judgment Act is limited to declarations about "rights and other legal relations." 28 U.S.C. § 2201(a).

Stated differently, in order to establish standing and the existence of a *legal* controversy the plaintiff always bears the burden[9] of tying whatever injury it claims to be suffering to some invasion (or threatened invasion) of an interest protected by common law, statute, or the Constitution.[10] "The alleged injury must be legally and

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[9] *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95 (1993) ("[A] party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy."); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (standing is "part of the plaintiff's case" and "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof").

[10] *See, e.g., Warth v. Seldin*, 422 U.S. 490, 500 (1975) ("Although standing

judicially cognizable," *Raines v. Byrd*, 521 U.S. 811, 819 (1997), which does not require that the claim be *meritorious* but does mean that '[t]he injury must be to the sort of interest that the law protects when it is *wrongfully* invaded," *Aurora Loan Servs. v. Craddieth*, 442 F.3d 1018, 1024 (7th Cir. 2006) (Posner, J.).[11] The case then becomes moot if circumstances change such that "the parties lack a legally cognizable interest in the outcome," even if it remains important to them in some practical sense. *Powell v. McCormack*, 395 U.S. 486, 496 (1969); *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979) (case is moot when "neither party has a legally cognizable interest in the final determination of the underlying questions of fact and law").

Second, in the absence of some special justification an injury to legally protected interests must already have occurred, or at least must be "imminent" or "certainly impending." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992); *see also Whitmore v. Arkansas*, 495 U.S. 149,

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in no way depends on the merits of the plaintiff's contention that particular conduct is illegal, it often turns on the nature and source of the claim asserted.") (citation omitted); *Flast v. Cohen*, 392 U.S. 83, 102 (1968) ("[I]n ruling on standing, it is both appropriate and necessary to look to the substantive issues … to determine whether there is a logical nexus between the status asserted and the claim sought to be adjudicated."); *McConnell v. FEC*, 540 U.S. 93, 227 (2003) ("[T]o satisfy our standing requirements, a plaintiff's alleged injury must be an invasion of a concrete and particularized legally protected interest."); *Int'l Primate Protection League v. Adm'rs of Tulane Educ. Fund*, 500 U.S. 72, 77 (1991) ("[S]tanding is gauged by the specific common-law, statutory, or constitutional claims that a party presents."); William A. Fletcher, *The Structure of Standing*, 98 Yale L.J. 221, 229 (1988) ("The essence of a true standing question is the following: Does the plaintiff have a legal right to judicial enforcement of an asserted legal duty? This question should be seen as a question of substantive law, answerable by reference to the statutory or constitutional provision whose protection is invoked.").

[11] Ordinarily the litigant must claim an injury to *his own* legal rights, although in some instances it may be permitted to complain about what would ordinarily be regarded as a violation of the legal rights of a third party. 'In such instances, the Court has found, in effect, that the constitutional or statutory provision in question implies a right of action in the plaintiff." *Warth*, 422 U.S. at 501.

158 (1990) ("Each of these cases demonstrates what we have said many times before and reiterate today: Allegations of possible future injury do not satisfy the requirements of Art. III. A threatened injury must be 'certainly impending' to constitute injury in fact.") (citations omitted). That rule essentially tracks the traditional common law requirements for relief at law or in equity, which is not surprising or accidental. Justiciability at common law was defined by the system of writs; the "jurisdictional" question was whether the plaintiff had averred sufficient facts to show that it was entitled to relief under the particular writ it asserted.[12] And the "case or controversy" limitation was designed, in part, to confine the federal courts to disputes "of the sort traditionally amenable to, and resolved by, the judicial process." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998); *see also, e.g., Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 150 (1951) (Frankfurter, J., concurring) (disputes "consonant with what was, generally speaking, the business of the Colonial courts and the courts of Westminster when the Constitution was framed"); *Vt. Agency*, 529 U.S. at 774.

The vast majority of declaratory judgment cases easily satisfy the requirement of an actual or imminent injury to legally protected rights. In "alternative relief" cases, for example, the declaratory judgment plaintiff has suffered an actionable injury and has a ripe cause of action for damages or an injunction, but instead chooses to seek a declaration. *See, e.g., Nashville, Chattanooga & St. Louis Ry. Co. v. Wallace*, 288 U.S. 249, 263 (1933) ("While the ordinary course of judicial procedure results in a judgment requiring

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[12] *See, e.g.*, Joseph Vining, *Legal Identity: The Coming of Age of Public Law* 55 (1978) ("Courts, whose jurisdiction was defined by the system of writs, did not need to speak of standing. The question was whether a challenger was entitled to a writ, whether he had a cause of action, whether the writ lay."); Fleming James, Jr., *Civil Procedure* § 1.3 (1965) (standing in king's court determined by whether plaintiff had proved a case in a particular cause of action); Theodore F. T. Plucknett, *A Concise History of the Common Law* 354 (5th ed. 1956).

an award of process or execution to carry it into effect, such relief is not an indispensable adjunct to the exercise of the judicial function."). In a "mirror image" suit like *Aetna*, the *other* party has suffered a legally cognizable injury but has not yet filed a lawsuit—and the likely defendant seeks a declaration in order to resolve the uncertainty. *See Aetna*, 300 U.S. at 244. As this Court stressed in both *Aetna* and *Maryland Casualty*, declaratory relief is permitted in these cases because "[i]t is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative." *Id.*; *Md. Cas.*, 312 U.S. at 273 ("It is immaterial that frequently, in the declaratory judgment suit, the positions of the parties in the conventional suit are reversed; the inquiry is the same in either case.").[13] The key point in both the "alternative relief" and "mirror image" situations is that the existence of a ripe traditional cause of action between the parties makes it clear that a justiciable "controversy" exists.

It is "anticipatory" cases, where a party seeks a declaration prior to the point at which a cognizable injury has been suffered or is "imminent," that push the outer boundary of the case or controversy limitation. Such cases threaten to bring into court disputes that would never have been ripe prior to the Declaratory Judgment Act, in conflict with this Court's repeated assurance that the Act is "procedural" and does not expand the jurisdiction of the federal courts. *See, e.g.*, *Aetna*, 300 U.S. at 240. Both the common law and this Court have authorized judicial intervention before the feared injury to legally protected interests is "imminent" or "certainly impending," but only in limited circumstances and with very special justification.

The common law recognized a limited, and sparingly applied, category of equitable relief known as bills *quia*

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[13] Although under state procedure, the tort plaintiff in *Maryland Cas.* may have been unable to sue the insurer prior to obtaining a judgment against the insured, under *federal* procedure either party could have joined the insurance company to avoid the risk of inconsistent judgments.

timet ("because he fears"), which were "ordinarily applied to prevent wrongs or anticipated mischiefs, and not merely to redress them when done."[14] An individual could, for example, bring a *quia timet* suit at common law claiming that its future property interests were in danger of being diverted or squandered, and courts had discretion to appoint a receiver or to require security in order to protect the plaintiff's future property rights. The test was that the threatened injury must either be "so imminent that no one can doubt that, if the remedy is delayed, the damage will be suffered" or "it must be shown that … it will be impossible for the plaintiff to protect himself against [injury] if relief is denied to him in a *quia timet* action." *Fletcher v. Bealey*, 28 Ch.D. 688, 698 (1885). Legal uncertainty alone was never enough.[15] This Court has recognized that a request "for an adjudication of rights in anticipation of their threatened infringement" under the Declaratory Judgment Act is constitutionally justified in part by "analog[y] to the equity jurisdiction in suits *quia timet* or for a decree quieting title." *Great Lakes Dredge & Dock Co. v. Huffman*, 319 U.S. 293, 300 (1943); *see also, e.g.*, *Am. Auto. Ins. Co. v. Freundt*, 103 F.2d 613, 617 (7th Cir. 1939) ("The roots of the declaratory

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[14] 2 Joseph Story, *Commentaries on Equity Jurisprudence: As Administered in England and America* 156–57 (1886); *see also*, *e.g.*, 27A Am. Jur. 2d Equity § 93 (1996); *City of New Orleans v. Christmas*, 131 U.S. 191, 212 (1889) ("'A court of equity will also prevent injury in some cases by interposing before any actual injury has been suffered, by a bill which has sometimes been called a bill *quia timet* ….'") (citation omitted); *Flight v. Cook*, 2 Ves. Sen. 619, 619–20 (Eng. Ch. 1755) (*quia timet* relief should be cautiously invoked).

[15] *See, e.g.*, *Willing v. Chicago Auditorium Ass'n*, 277 U.S. 274, 289–90 (1928) (There is no action in equity to remove "plaintiff's … own doubts," where "[n]o defendant has wronged the plaintiff or has threatened to do so." Such an action "was unknown to either English or American courts at the time of the adoption of the Constitution and for more than a half a century thereafter."); *Edison Elec. Light Co. v. Kaelber*, 76 F. 804, 806 (C.C.N.D.N.Y. 1896) ("A *quia timet* action will not lie unless there is something to fear.").

judgment procedure are found in equity procedure, chiefly in the *quia timet* relief.").

Both the common law and this Court have also permitted litigants to challenge official action believed to be contrary to law, without necessarily exposing themselves to the risk of enforcement. *See, e.g.*, *Ex Parte Young*, 209 U.S. 123 (1908); *Steffel v. Thompson*, 415 U.S. 452 (1974); *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 107 (1977). Such pre-enforcement review is justified if the litigant is being "coerced" to alter its primary conduct by the threat of enforcement. As the treatise this Court cited in *Altvater* makes clear, the common law regarded threats under color of official authority as inherently coercive. *See* Frederic Campbell Woodward, *The Law of Quasi Contracts* 348 (1913) ("[I]n the case of a refusal by a public officer to perform a duty, the courts, recognizing the inherent advantage of his position and the importance of protecting those who deal with him, require no additional evidence that the act is coercive."). In *Steffel*, for example, this Court observed that refusing pre-enforcement review of a criminal statute would "place the hapless plaintiff between the Scylla of intentionally flouting state law and the Charybdis of forgoing what he believes to be constitutionally protected activity in order to avoid becoming enmeshed in a criminal proceeding." 415 U.S. at 462. On the other hand, "a justiciable controversy does not exist where 'compliance with [challenged] statutes is uncoerced by the risk of their enforcement.'" *Lake Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 507 (1972) (citation omitted). Absent a real threat of enforcement, there is no coercion and no necessity for judicial intervention before a litigant's legally protected interests are invaded. [16]

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[16] City of Hope shows that cases like *Steffel* and *Ex Parte Young* might also be read as involving fully realized injury to a distinct legal right (a right to be free from threats of unlawful action by state officials that compel abandonment of constitutionally protected rights), such that

The common thread in all of these cases is that a litigant cannot claim a justiciable "controversy" over a potential future injury *that the litigant itself is preventing* unless the law is prepared to regard that preventive behavior as involuntary or coerced. The common law *quia timet* cases captured that concept by saying that anticipatory relief was generally unavailable if it was possible "for the Plaintiff to protect himself against [the harm]." *Fletcher*, 28 Ch.D. at 698. This Court explained in *Lujan* that the constitutional requirement of an "imminent" injury is "stretched beyond the breaking point" when "the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partially within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2. If the plaintiff itself can prevent any injury from occurring, without surrendering its legal rights, then that injury is ordinarily neither sufficiently "imminent" nor "'fairly … trace[able] to the challenged action of the defendant.'" *Id.* at 560 (citations omitted) (alterations in original). Or, in the language of this Court's ripeness cases, there is not sufficient "hardship to the parties of withholding court consideration" to justify anticipatory relief. *Abbott Labs.*, 387 U.S. at 149. Considerations of hardship and necessity have similarly justified exceptions from ordinary mootness principles when the mootness is beyond the litigant's control (such as when injuries are capable of repetition yet evading review), but this Court has made it clear that *voluntary* action mooting a case destroys the controversy and renders it non-justiciable. *U.S. Bancorp Mortgage Corp. v. Bonner Mall P'ship*, 513 U.S. 18, 25 (1994) ("Where mootness results from settlement, … the losing party has voluntarily

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they do not involve or justify "anticipatory" declaratory relief. In contrast to the reading above, that would foreclose adjudication of truly anticipatory cases (such as suits to interpret a contract prior to actual or imminent breach, or to test the scope or validity of a patent prior to actual or imminent infringement). *Compare supra* at 21–23 *with* Resp. City of Hope Br. 19–22. This Court need not choose between these readings here because this suit is non-justiciable under either view.

forfeited his legal remedy by the ordinary processes of appeal or certiorari, thereby surrendering his claim to the equitable remedy of vacatur.").[17]

MedImmune is therefore wrong to suggest that Article III is satisfied simply by a disagreement over a point of law that the parties care about, and that is factually concrete enough to permit a definite answer. MedImmune must identify some injury *to legal rights or legally protected interests*, and it must show that the alleged injury has occurred, is "imminent" or "certainly impending," or otherwise presents a compelling necessity for review prior to the point at which judicial intervention has traditionally been available. If the injury it claims to fear will likely never occur because of uncoerced choices MedImmune is making, then there is no justiciable controversy.

B. There Is No Cognizable Injury Or Coercion Creating A Justiciable Controversy In This Case

1. Voluntary Royalty Payments Are Not An Injury To MedImmune's Legal Rights

MedImmune bears the burden of tying the injury it claims to be suffering to the violation of some alleged legal right or legally protected interest. To the extent MedImmune addresses that central question at all, it simply assumes that paying royalties on a patent it believes to be invalid is a violation of its legal rights. But MedImmune utterly fails to identify any statutory or other source for such a right—because no right exists. MedImmune's assumption is inconsistent with a basic legal principle so venerable that it predates the common law itself: *volenti*

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[17] The concerns underlying the doctrines of standing, mootness, and ripeness often coincide. *See, e.g.*, 13 Charles Alan Wright et al., *Federal Practice and Procedure* § 3531, at 350 (2d ed. 1984) ("Both ripeness and mootness, indeed, could be seen as providing time-bound perspectives on the injury inquiry of standing."); *Warth*, 422 U.S. at 499 n.10 ("The standing question thus bears close affinity to questions of ripeness—whether the harm asserted has matured sufficiently to warrant judicial intervention—and of mootness—whether the occasion for judicial intervention persists.").

non fit injuria, or "to a willing person it is not wrong." *Black's Law Dictionary* 1605 (8th ed. 2004). That formulation comes from the *Liber Sextus* of Pope Boniface VIII in the late thirteenth century, but as a legal principle it actually dates back at least to the Codex of Justinian in 529 AD, and philosophically back to Aristotle. *See* Terence Ingman, *A History of the Defence of* Volenti Non Fit Injuria, 26 Jurid. Rev. 1, 1–3 (1981); N.G.L. Child, "*Volenti Non Fit Injuria*," 17 Jurid. Rev. 43 (1905); Aristotle, Nichomachean Ethics, V. ix. 1136b ("no one can suffer injustice voluntarily, because no one can wish to be harmed"). In the absence of coercion or a public policy precluding consent, a voluntary payment is not an injury to legal rights, and is no business of the courts. *See, e.g.*, Restatement (Third) of Restitution and Unjust Enrichment § 6 cmt. d (T.D. No. 1, 2001) ("A transfer pursuant to a valid agreement of the parties cannot be nonconsensual, nor can it result in the unjustified enrichment of the recipient.").

MedImmune's voluntary payment of royalties therefore bears no resemblance to the payments that were made in *Altvater* and does not constitute injury sufficient to support jurisdiction. In *Altvater*, this Court rested its jurisdictional analysis on the same coercion principles, discussed above, that explain why a federal court has jurisdiction to evaluate pre-enforcement challenges to statutes and regulations. The patent owner had argued that, so long as the petitioner continued to pay royalties, there was not a justiciable controversy concerning the validity of the patent. 319 U.S. at 364.[18] This Court concluded that there was an actual controversy over the counterclaim because the royalties were being paid "under the compulsion of an injunction decree" from prior litigation between the parties, and "the

[18] MedImmune wrongly suggests that the declaratory plaintiffs in *Altvater* were "licensees in good standing" not different from MedImmune. Pet. Br. 16. But in *Altvater* "both the District Court and the Circuit Court of Appeals have found that the license agreement was terminated on the surrender of the original patent and was not renewed and extended to cover the reissue patents." 319 U.S. at 364.

only other course" available was to "defy [an injunction]." *Id.* at 364–65. It reasoned that "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.* at 365 (emphasis added). This Court cited a treatise on quasi-contract and a string of its own cases, all making clear that a demand by a public official acting under color of law (*colore officii*) is inherently coercive, and that payments made under official pressure do not terminate the controversy over whether that demand was wrongful.[19]

MedImmune's payments are, by contrast, not an injury inflicted upon it, but simply the price of an insurance policy voluntarily purchased in 1997—and voluntarily renewed with each quarterly royalty payment—because MedImmune continues to regard that policy as worth the price. MedImmune has not repudiated that policy, does not genuinely contest its terms, and in fact took seven additional licenses after the Cabilly II Patent issued in order to insulate additional products in development from any risk under the patent laws. It has not been injured; it has gotten exactly what it paid for. MedImmune's curiosity about whether to abandon its license is not a controversy about legal rights; it is a request for judicial advice about the wisdom of a proposed business decision.

MedImmune has not repudiated the license or exercised its absolute right to terminate that agreement because doing so would expose it to the risk of the infringement suit. Managing that risk is the point of a license. If MedImmune

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[19] MedImmune misreads *Cardinal* and its discussion of *Altvater*. The only issue in *Cardinal* was whether a declaration of invalidity obtained by counterclaim when a "controversy" was plainly present should be vacated on appeal simply because the licensee also prevailed on the alternative ground of non-infringement. This Court simply held that it would not require the licensee to prove that it intended to "continue to violate the patentee's alleged rights" by making new, potentially infringing, products in order to retain the judgment it had already won. 508 U.S. at 100 n.22.

lost that suit it would (at a minimum) have to pay "reasonable royalty" damages that would be substantially higher than the highly favorable license rate it negotiated back in 1997 when Synagis had not been approved and Genentech had not been awarded the patent. (MedImmune itself agreed to a top royalty rate almost twice as high in the seven additional licenses to this patent that it negotiated in 2003. *Supra* at 6.) Nevertheless, MedImmune cannot retain all the benefits of its 1997 compromise while at the same time alleging that the payments it agreed to make constitute harm. That is contrary not only to *volenti non fit injuria* but also to the basic equitable principle that a party cannot take benefits under a contract and still challenge it as voidable. *Infra* at 42–44. If ever there were a claimed "injury" that is not cognizable in a court of law, this is it.[20]

For similar reasons, any injury MedImmune claims to be suffering from its payments is not "fairly traceable" to Genentech, but is instead self-inflicted and "traceable" only to MedImmune's own desire to avoid any risk under the patent laws. *Lujan*, 504 U.S. at 560; *see also McConnell*, 540 U.S. at 228 (candidates' claim of "competitive injury" was not fairly traceable to challenged statute because their "alleged inability to compete stems not from the operation of § 307, but from their own personal 'wish' not to solicit or accept large contributions, *i.e.*, their personal choice.").

2. MedImmune Has Not Been Coerced

The only way that MedImmune could characterize its royalty payments as an invasion of a legally protected interest would be to prove that those payments are coerced or involuntary. That is also precisely the showing it would have to make in order to establish the necessity that would

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[20] *Compare, e.g., McConnell*, 540 U.S. at 227 (an interest in competing in an election with equal resources is not cognizable injury); *Allen v. Wright*, 468 U.S. 737, 755–56 (1984) ("stigmatic injury" of racial discrimination "not judicially cognizable"); *United States v. Hays*, 515 U.S. 737, 746 (1995) (injury associated with living in segregated district not cognizable); *Lewis v. Casey*, 518 U.S. 343, 350–53 (1996) (rejecting prisoners' suit because injuries alleged did not pertain to any legal right).

justify an anticipatory "mirror image" declaration about the merits of the lawsuit that might result if it gave up its license. So MedImmune and the United States both implicitly acknowledge the correct analysis by arguing that MedImmune's royalty payments are "under protest" or are "coerced" by the consequences it could face if it gave up its license. Pet. Br. 24–25. Neither identifies anything special about this particular license; MedImmune and the United States assert that *all* patent licenses are legally coerced by "the inherently coercive backdrop of the presumption of validity and the powerful remedies afforded by the law to the patentee." U.S. Br. 21 & n. 10; *see also* Pet. Br. 24–25.

That assertion cannot withstand serious scrutiny. The concept of legal coercion has been liberalized over time, but the one immutable certainty in this area of the law is that a payment made to resolve uncertain legal rights is never "coerced" by that uncertainty. As the 2005 draft of the Restatement (Third) of Unjust Enrichment explains (at § 6 cmt. d), any allegation of duress or mistake "disappears if the payment in question was made pursuant to a valid agreement of the parties allocating between them the risk of a perceived uncertainty as to the underlying obligation." This Court observed in *United States v. Child & Co.*, 79 U.S. 232, 245 (1871), that "[i]t is of the very essence of such adjustments of disputed rights that the contest shall be closed." If a party were permitted to challenge its own voluntary resolution of a potential legal dispute on the ground that it was "coerced" by the uncertain outcome of that suit, then "no party [could] safely pay [or accept] by way of compromise any sum less than what is claimed …, for the compromise [would] be void as obtained by duress." *Id.* at 244. The same treatise and cases that this Court relied upon in *Altvater* make it perfectly clear that the potential consequences associated with losing an infringement suit could not possibly "coerce" MedImmune into purchasing immunity from suit by taking a license, and that "[p]rotest will not make an otherwise voluntary payment involuntary." Woodward, *supra*, at 388; *id* at 362–63 ("[P]ayment of a

claim under such circumstances would be an idle ceremony if the only effect were to reverse the parties as plaintiff and defendant ….”). The common law coercion cases MedImmune cites, Pet. Br. 24, are just the cases cited in *Altvater*, and all involved demands under color of official authority that the law regards as inherently coercive.

Patent licenses are squarely within the traditional rule that a contract designed to resolve uncertain legal rights cannot be “coerced” by that very uncertainty. A patent gives its owner “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.” 35 U.S.C. § 154(a)(1). The patent laws grant patent holders a cause of action for infringement, and potential infringers various countervailing rights and defenses. The fundamental purpose and effect of a patent license is to resolve and compromise uncertainty concerning the parties’ preexisting statutory rights under those laws. A license is therefore “an agreement manifestly intended to adjust conflicting rights” under the law. *Eureka Co. v. Bailey Co.*, 78 U.S. (11 Wall.) 488, 491 (1871); *see also, e.g.*, 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 ….”); *Blonder-Tongue*, 402 U.S. at 338 (“[P]rospective defendants will often decide that paying royalties under a license or other settlement is preferable to the costly burden of challenging the patent.”); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (“[T]he amount of leverage arising from a patent application depends on how likely the parties consider it to be that a valid patent will issue.”). The nature of that bargain precludes, as a matter of law, any claim that the license was “coerced” by the licensee’s fear that the patent might be valid. MedImmune’s complaint that the parties’ *ex ante* bargaining position was somehow coercive or unfair is simply disagreement with the statutory rights that Congress has chosen to give to patent holders.

Put another way, a license is no different from any other informal settlement of uncertain legal rights. This Court has repeatedly recognized that settlements render already-filed cases moot, requiring dismissal for lack of jurisdiction.[21] That is true "even if the parties remain at odds over the particular issue they are litigating." *ITT Rayonier Inc. v. United States*, 651 F.2d 343, 345 (5th Cir. 1983). A settlement reached *prior* to injury similarly prevents the incipient dispute from ripening into a justiciable controversy in the first place. There is no principled reason to treat a contract resolving a dispute *after a lawsuit is filed* as a jurisdictional termination of the controversy, but a contract resolving the same dispute before it ever ripens as a constitutional nullity.[22] Nor is there any reason to treat agreements labeled "settlements" differently from "licenses" that accomplish the same thing. The United States' suggestion that the license is "evidence of (not an obstacle to) a concrete controversy," U.S. Br. 21, is exactly backwards. A license resolves disputes about the parties' rights under the patent laws; it does not create them.

3. *Lear v. Adkins* Did Not Give Licensees A New Right To Challenge Validity Before Repudiating the License Agreement

As the Federal Circuit recognized, MedImmune's true argument must be that "under *Lear* it has the absolute right to challenge the validity or enforceability of the patent" even without repudiating its license. Pet. App. 4a. This suit is justiciable, in other words, only if *Lear* either creates a substantive right of challenge unknown at common law and not found in any statute, or abrogates basic *volenti non fit injuria* principles as inconsistent with patent policy.

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[21] *See Lake Coal Co. v. Roberts & Schaefer Co.*, 474 U.S. 120 (1985); *Bonner Mall*, 513 U.S. at 20; *see also, e.g.*, Charles Alan Wright, *Law of Federal Courts* § 12, at 62–63 (5th ed. 1994) ("There is no case or controversy once [a] matter has been resolved.").

[22] Unlike a pre-litigation resolution of legal uncertainty, a settlement procured after litigation has ensued may have *res judicata* effect. But that is no reason to treat them differently for justiciability purposes.

Neither theory is plausible. The common law held that the central purpose of a license is to terminate any dispute or uncertainty between the parties about their respective rights under the patent laws—including, most importantly, the validity of the patent—unless and until the licensee repudiated its benefits. Nothing in *Lear* is inconsistent with that understanding. *Lear* involved a licensee who had repudiated the benefits of the license and been sued by the licensor. *See* ABA Br. 3–4. It said nothing about a licensee, like MedImmune, who insists on keeping all the benefits of the license while challenging its basic premise.

The licensee estoppel doctrine discussed in *Lear* began at least three centuries ago as a principle of landlord-tenant law.[23] So long as a lessee retained quiet enjoyment of his property, common law courts held that he was estopped from challenging the title of his landlord. The principle goes back to Roman law, which held that a person could not refuse to return borrowed property on the ground that his lender had stolen it from someone else. *See Wilder v. Adams*, 29 F. Cas. 1216, 1218 (D. Mass 1846) (citing *inter alia* Dom. Civil Law. Pt 13, tit. 6; *Story on Bailments*, §§ 120, 230, 266). English and American courts soon extended this rule to hold that a licensee could not contest the validity of a licensed patent. The early cases rested in part on the equitable principle that a licensee cannot take the benefits of the license while challenging its fundamental premises, and also in part on a recognition that the patent's validity is simply irrelevant to the terms of the typical license bargain. Rooklidge, 8D-4 to -7, -12 n.57 & n.58. So long as the licensee retained "quiet enjoyment" of the benefits of the license (i.e., use of a presumptively valid patent free from fear of an infringement suit), the licensee

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[23] An appendix to the leading treatise on intellectual property licensing consolidates and reprints three articles that provide a scholarly overview of the early case law and its development. *See* William C. Rooklidge, *Licensee Validity Challenges and the Obligation to Pay Accrued Royalties: Lear v. Adkins Revisited, reprinted in* 2 Roger M. Milgrim, *Milgrim on Licensing* Appendix 8-D (1994) (hereafter "Rooklidge").

got what it paid for. *See, e.g.*, *Bartlett v. Holbrook*, 67 Mass. 114, 118 (1854); *Marston v. Swett*, 66 N.Y. 206, 212 (1876).

The common law always recognized, however, that the estoppel ended if the licensee was "evicted" from quiet enjoyment (by a third-party decision declaring the patent invalid, or by widespread infringement) or if the licensee "evicted" itself by repudiating the benefits of the license. Rooklidge at 8D-10 to –11. Courts throughout the United States and England consistently applied the common law rule, including its exception for repudiating licensees, for more than a century and a half. *See, e.g.*, *Willison v. Watkins*, 28 U.S. 43, 48 (1830); *Kinsman v. Parkhurst*, 59 U.S. 289, 293 (1856); *Eureka Co.*, 78 U.S. (11 Wall.) at 491–92; ABA Br. 5–6.[24] Some doctrinal confusion crept in after this Court recognized in *St. Paul Plow Works v. Starling*, 140 U.S. 184 (1891), that a licensee's repudiation did not necessarily *terminate* the license as a contractual matter. The trial court in *St. Paul* correctly held that because of his repudiation the licensee was nonetheless permitted to raise invalidity as a defense, and this Court approved that holding *sub silentio*. But after *St. Paul* some courts lost sight of the equitable foundations of licensee estoppel and began to hold that the estoppel continued until the license terminated according to its terms—even if the licensee had clearly repudiated the benefits of the license. Rooklidge, 8D-16 & n.80 (collecting cases). And in *Automatic Radio Mfg. Co. v. Hazeltine*, 339 U.S. 827, 836 (1950), this Court stated that the "general rule is that the licensee under a patent license agreement may not challenge the validity of the licensed patent" without acknowledging a possibility of repudiation.

This pervasive confusion led to the California Supreme Court's holding in *Adkins v. Lear, Inc.*, 67 Cal. 2d 882 (1967),

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[24] MedImmune wrongly suggests that *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224 (1892), rejected the common law rule. Pet. Br. 34. *Pope* held that a provision barring the licensee from challenging validity *after the license ended* violated public policy. *Pope* was fully consistent with the common law rule, as illustrated by this Court's continued application of estoppel to licensees who had not repudiated the license.

that a licensee is estopped from challenging validity despite clear repudiation of the license. This Court reacted very strongly against that holding in *Lear*, but it was only rejecting a deviation from the common law mainstream. Lear had clearly repudiated the agreement, was no longer accepting any benefits under the license, and had been sued for unpaid royalties. In that circumstance this Court concluded that "the equities of the licensor do not weigh very heavily." 395 U.S. at 670. The traditional common law agreed entirely.

Once it is understood that *Lear* was consistent with traditional limitations on the scope of licensee estoppel, the case for extending *Lear* to permit validity challenges by licensees, such as MedImmune, *that have not repudiated and wish to maintain all the benefits of the license* vanishes completely. That situation was not presented in *Lear*, and indeed Lear itself "conceded that it would be estopped to contest the validity of any patent issued to Adkins … so long as it continued to operate under that agreement." *Id.* at 679 n.1 (White, J., concurring). This Court's statement that it was overruling the "*Hazeltine* rule" is as ambiguous as the *Hazeltine* opinion itself, and need not be read as rejecting centuries of common law jurisprudence that were not presented in *Lear* and that even Lear conceded. As this Court has explained, *Lear* "permits an accused infringer to accept a license, pay royalties for a time, and cease paying when financially able to litigate validity, secure in the knowledge that invalidity may be urged when the patentee-licensor sues for unpaid royalties." *Blonder-Tongue*, 402 U.S. at 346. There is no reason to read *Lear* more expansively when the lower courts have not done so,[25] and

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[25] Although one court initially concluded that *Lear* allowed a licensee to challenge the patent while still retaining its license, *see Warner-Jenkinson Co. v. Allied Chem. Corp.*, 567 F.2d 184 (2d Cir. 1977), most courts soon reaffirmed the common law distinction between licensees who repudiated and those who attempted to maintain the license. *See* ABA Br. 13. In *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 880–81 (Fed. Cir. 1983), decided well before the current crop of patents were issued, the

when that decision's broader rhetoric rests on premises that this Court has largely rejected. *See generally* Br. of Richard L. Donaldson *et al.* And certainly there is no justification for reading *Lear* to create a new substantive right to challenge patents, or to be free from voluntary royalty payments associated with invalid patents, when nothing in the patent laws suggests that Congress intended to create such a right and it would be inconsistent with basic common law principles. *See Mowry v. Whitney*, 81 U.S. 434, 441 (1872) (noting that the patent laws do not create a freestanding right for private persons to challenge patents); *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles.").

MedImmune wrongly suggests that the Federal Circuit's decision somehow constitutionalizes the licensee estoppel doctrine, or makes it impossible for Congress to grant licensees a right to challenge patents. But Congress can always create new substantive rights in patent law, the invasion of which would confer standing and form the basis of a justiciable controversy. Congress could, for example, provide that patent licenses contain an implied warranty that the patent underlying the agreement is valid. (In this License Genentech expressly disclaimed any warranties.)

Federal Circuit held that an Article III controversy existed in a validity challenge only because the licensee had "ceased payment of royalties," which was a "material breach of the agreement that … enabled [the licensor] to terminate the agreement." And in 1997, before this license was signed, the Federal Circuit held that "a licensee … cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." *Studiengesellschaft*, 112 F.3d at 1568. MedImmune's suggestion that the Federal Circuit's pre-*Gen-Probe* cases permitted suits like this is plainly incorrect. MedImmune's citation to 12 James W. Moore et el., *Moore's Federal Practice* § 57.22[8][c][i] (3d ed. 2005), Pet. Br. 19, adds nothing because *Moore's* merely cites *Warner-Jenkinson* and *C.R. Bard* and fails even to acknowledge that the Federal Circuit has long recognized that a non-repudiating licensee cannot sue for invalidity.

But MedImmune offers no serious argument that Congress has given it any legal right that is invaded either by its own royalty payments or by the bare existence of the patent.

C. This Case Has Little In Common With Breach Of Contract Or Typical Patent Declaratory Cases

MedImmune labors to connect itself to cases granting declarations interpreting ambiguous contracts prior to breach. Its amici criticize the Federal Circuit's treatment of cases in which non-licensees seek a declaration about the scope or validity of a patent prior to infringement. None of these issues are relevant to the dispute in this case.

1. This Is Not A Contract Dispute

MedImmune builds its argument around the idea that "patent-license controversies are a subset" of "[c]ontract disputes," Pet. Br. 30, and that the Declaratory Judgment Act was designed to permit interpretation of contracts prior to breach. The cases MedImmune discusses (Pet. Br. 20) are "mirror image" suits anticipating potential breach of contract actions, and seeking clarification of uncertainty about the parties' present legal rights and obligations under the contract. The lower courts have entertained such cases, although they are rarer than MedImmune implies and the courts often struggle with concerns about justiciability. Most of the decided cases have involved an imminent or "certainly impending" breach, and are therefore easy to justify on traditional principles. Contrary to MedImmune's implication, the analysis is never that because it is a contract case and no breach is required, anything goes.

Absent an imminent or reasonably certain breach, judicial intervention in contract disputes would have to be justified by the necessity or coercion principles at work in the pre-enforcement review cases or in the common law *quia timet* writ. That may or may not justify every decision on the books; the common law did not recognize the threat of private contract damages as legal coercion or as creating any necessity for early judicial intervention. In an appropriate case this Court might find a permissible extension of traditional principles, or it might not.

But this case is another kettle of fish. MedImmune does not even claim to fear contract damages, and there is no real dispute about its contract rights and obligations. Genentech expressly disclaimed any warranty that the patent is valid and MedImmune promised to pay royalties nonetheless. *Supra* at 6–7. MedImmune is not seeking an interpretation of its present contractual obligations at all; it wants a declaration of what its legal obligations *would be* if it chose to abandon its contract and opt into an entirely different legal regime. That has nothing to do with cases interpreting rights under a contract prior to breach.

At certain points MedImmune implies that there might be a contractual dispute over whether Synagis infringes the claims of the patent irrespective of validity, *i.e.*, whether Synagis is covered by the royalty-triggering language of the license. There is no genuine dispute on that issue, and if there ever was MedImmune has waived it. *Supra* at 9–11. Regardless, even if there were a genuine contractual dispute about non-infringement, that would not create a controversy over the issues of validity and enforceability.[26]

Any such claim also would not be sufficiently concrete or immediate to justify declaratory relief, because MedImmune never brought such concerns to Genentech to make sure it would disagree. Something like the "reasonable apprehension of suit" test is required by this Court's repeated holdings that there is no "necessity" for anticipatory adjudication of defenses to lawsuits or government enforcement actions that are unlikely to materialize.[27] All "mirror image" declaratory actions

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[26] *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) ("[A] plaintiff must demonstrate standing separately for each form of relief sought."); *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996) ("[S]tanding is not dispensed in gross.").

[27] *See, e.g., Poe v. Ullman*, 367 U.S. 497, 506 (1961) (stating that declaratory judgment procedure "does not permit litigants to invoke the power of this Court to obtain constitutional rulings in advance of necessity"). Understanding the precise nature of the suit the plaintiff fears is also essential to determining if federal question jurisdiction

therefore require a "reasonable apprehension of suit," although in many non-patent contexts it is fairly presumed. The basic insight behind the particular focus on "reasonable apprehension" in patent cases is that when a new product is marketed it may arguably infringe thousands of patent claims, although the vast majority of those claims will never be asserted. Hence, even the chief academic proponent of the Declaratory Judgment Act recognized that in patent cases some sharpening of the dispute between the parties is necessary to ensure that there is a real need for declaratory relief. *See, e.g.*, Edwin Borchard, *Declaratory Judgments* 807 (2d ed. 1941). When Genentech asserted that Synagis infringed its Cabilly I patent, MedImmune disagreed and produced evidence that convinced Genentech not to sue. *Supra* at 8. When Genentech asked MedImmune to clarify whether it believed Synagis infringed the Cabilly II patent, and if not then why, MedImmune declined to respond or to provide any explanation for its purported "protest." There is no necessity for "mirror image" declaratory relief when the plaintiff has not even procured a clear answer from the defendant. *Willing*, 277 U.S. at 288.

2. Patent Declaratory Actions Brought By Non-Licensees Raise Different Concerns

MedImmune and its amici also devote considerable ink to discussing cases in which a declaratory judgment plaintiff without a license seeks a "mirror image" declaration that a product it plans to sell does not infringe a patent, or that the patent in question is invalid. For over 40 years the lower courts have held that such cases are justiciable only if the declaratory plaintiff has put itself in a position to infringe the patent imminently, and has a "reasonable apprehension" that it will then be sued for infringement. Declaratory relief in the absence of imminent or "certainly impending" injury would, again, have to be justified by reference to coercion, necessity, and traditional equitable principles, and in an

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exists. Suits to enforce a license usually arise under state law. *See, e.g.*, *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 672 (1950).

appropriate case this Court could strike that balance. *See, e.g.*, *Woodworth v. Stone*, 30 F. Cas. 593, 594 (C.C.D. Mass. 1845) (Story, Circuit Justice) (noting that *quia timet* was available "upon well grounded proof of an apprehended intention of the defendant to violate the patent right"). But there certainly is no justification for an exception from ordinary justiciability rules when the prospective infringer has negotiated immunity from the suit it claims to fear.

MedImmune and its amici criticize the Federal Circuit's application of the reasonable apprehension test in patent cases brought by non-licensees, arguing for example that suits seeking a declaration of invalidity should not be dismissed simply because the patent holder has remained silent in the face of inquiries, or has chosen its words carefully to avoid any overt threat of an infringement suit. That is an interesting jurisprudential problem, but it is not remotely presented in this case. The party being coy about its intentions here was MedImmune, not Genentech. The basic issue in this case is not factual uncertainty over whether an infringement suit will materialize, but whether MedImmune should be allowed to seek a defensive declaration against an infringement suit that by definition *cannot* materialize unless MedImmune repudiates the license. In a case actually presenting the different problem identified by MedImmune's amici, this Court could adopt a rule that a "reasonable apprehension" exists whenever a prospective infringer directly asks the patent holder whether it intends to claim infringement, and gives the patent holder the information necessary to assess that question, and does not get a clear negative answer. *See Clair v. Kastar, Inc.*, 148 F.2d 644, 646 (2d Cir.) (L. Hand, J.) ("[I]f a manufacturer fears that he will be charged to infringe, he can always inquire of the patentee, and if the answer is unsatisfactory, he can bring an action for a declaratory judgment."), *cert. denied*, 326 U.S. 762 (1945). But a party cannot fear, or be legally coerced by, the threat of a lawsuit from which it has purchased immunity.

II. THIS COURT SHOULD EXERCISE EQUITABLE DISCRETION TO DISMISS THIS SUIT

A. The Declaratory Judgment Act Provides Broad Discretion To Decline Jurisdiction Based On Equitable Considerations

Even if this Court concludes that this case satisfies the minimum requirements for a constitutional controversy, or alternatively if it chooses to avoid that issue, it can and should direct dismissal on discretionary or prudential grounds. *See Steel Co.*, 523 U.S. at 97 & n.2; *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11 (2004). In *Cardinal Chemical*, 508 U.S. at 99–102, this Court rejected the Federal Circuit's Article III reasoning but then addressed possible equitable arguments for reaching the same result that were not raised by either side. Because the Federal Circuit's Article III reasoning in *Gen-Probe* so clearly required dismissal, there was no cause or justification for Respondents to urge alternative arguments for the same result.[28] Regardless, the equitable and patent policy issues have been fully briefed at all stages of this case, and the Federal Circuit's jurisdictional reasoning (here as in *Gen-Probe*) was shaped in large part by those arguments.

Jurisdiction in declaratory judgment cases is always discretionary.[29] This Court has repeatedly held that courts should consider a broad range of equitable factors in striking "a proper balance between the needs of the plaintiff and the

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[28] *See Grosso v. United States*, 390 U.S. 62, 70–71 (1968) (failure to raise claim excused because of its futility in light of prevailing law). Genentech is entitled to raise alternative arguments for dismissing this case for lack of jurisdiction, under the "traditional rule" permitting parties to raise a "new argument in support of what has been [its] consistent claim" throughout the litigation. *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995); *see also Yee v. City of Escondido*, 503 U.S. 519, 535 (1992).

[29] 28 U.S.C. § 2201(a) (court "may" grant declaratory relief); *Pub. Serv. Comm'n v. Wycoff*, 344 U.S. 237, 241 (1952) ("an enabling Act, which confers a discretion on the courts rather than an absolute right upon the litigant"); *Pub. Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962) (same); 10B Charles Alan Wright et al., *Federal Practice and Procedure* § 2759 (3d ed. 1998) (same).

consequences of giving the desired relief," *Eccles v. Peoples Bank of Lakewood Vill.*, 333 U.S. 426, 431 (1948), including traditional equitable defenses but also the broader public interest implicated by the suit.[30] As this Court observed in *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995), if a court "know[s] at the commencement of litigation that it will exercise its broad statutory discretion to decline declaratory relief" on equitable grounds, it need not "go through the futile exercise of hearing [the] case on the merits first" and should simply decline jurisdiction at the outset. *See also Samuels v. Mackell*, 401 U.S. 66, 70 (1971).

Although this Court has indicated that discretion should ordinarily be exercised by district courts in the first instance, a remand in this case is unnecessary. The traditional equitable principles governing situations like this one are clear and categorical; this is a textbook case for the maxim that in appropriate circumstances equitable discretion may be "'hardened by experience into rule.'" *Wilton*, 515 U.S. at 289 (quoting Borchard, *Declaratory Judgments* 293); *see also Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 710 (2005) ("Discretion is not whim, and limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike."). The Federal Circuit has already made clear that it believes suits like this one are inequitable. A

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[30] *See Abbott Labs*, 387 U.S. at 155 (because the Act provides equitable relief, "other equitable defenses may be interposed"); *Green v. Mansour*, 474 U.S. 64, 72 (1985) ("propriety of issuing a declaratory judgment may depend on equitable considerations"); *Great Lakes*, 319 U.S. at 300 ("The Declaratory Judgment Act was not devised to deprive courts of their equity powers or of their freedom to withhold relief upon established equitable principles."); *Ala. State Fed'n of Labor v. McAdory*, 325 U.S. 450, 462, 471 (1945) (relief must advance "the interests of justice" and serve the "public interest"); *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545 (1987) (observing "the important role of the "public interest" in the exercise of equitable discretion"). This Court has similarly advised against exercising jurisdiction over unripe claims, like MedImmune's, that are used to harass or to gain a procedural advantage. *See Wycoff*, 344 U.S. at 243; *Calderon v. Ashmus*, 523 U.S. 740, 747–48 (1998).

remand would serve no purpose but confusion. *See Pope*, 144 U.S. at 236–38 (dismissing patent license action on federal equitable principles); *City of Sherrill v. Oneida Indian Nation*, 544 U.S. 197 (2005) (applying equitable principles in the first instance to limit relief available); *Agostini v. Felton*, 521 U.S. 203 (1997) (applying equitable principles in the first instance to dissolve an injunction).

B. This Suit Violates Basic Equitable Principles

"As this Court has long recognized, 'a major departure from the long tradition of equity practice should not be lightly implied.'" *Ebay Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1839 (2006) (citation omitted). MedImmune's suit violates settled canons of equity and at least three centuries of equitable tradition directly on point.

First, MedImmune's duplicitous "license and then sue" strategy violates the basic equitable principle that a party cannot accept benefits under an agreement while simultaneously attacking it as voidable. If a party to a contract learns that the contract was procured by fraud, for example, it must immediately choose between continuing to perform and to accept performance, or renouncing the contract and suing for fraud and rescission.[31] There is no

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[31] *See, e.g.*, Restatement (Second) of Contracts §380 cmt. a (1981) ("A party who has the power of avoidance may lose it by action that manifests a willingness to go on with the contract. Such action is known as 'affirmance' and has the effect of ratifying the contract."); 27 Richard M. Lord, *Williston on Contracts* § 69:59 (4th ed. 2003) ("The defrauded party may lose his or her right of rescission by any act done after discovery of the fraud that indicates a willingness to allow the transaction to stand, such as the acceptance or demand of any benefit under the transaction."); Restatement (First) of Restitution § 68 cmt. b (1937) ("[A] person who receives or retains things to which he is entitled only if the transaction is binding thereby affirms it, if he knows the facts …."); *Commodity Credit Corp. v. Rosenberg Bros. & Co.*, 243 F.2d 504, 512 (9th Cir.) ("[I]f, after full knowledge of the fraud or deceit, he goes forward and executes it notwithstanding such fraud, the damage which he thereby sustains is voluntarily incurred."), *cert. denied*, 355 U.S. 837 (1957); *Kingman & Co. v. Stoddard*, 85 F. 740, 745 (7th Cir. 1898) ("With respect to an executory contract, one may not, after knowledge of the fraud, continue to carry it out, exacting performance from the other party to it, receive its benefits,

reason to treat a licensee who contends that his license is unenforceable because the patent is invalid more generously than a licensee who contends that his license was procured by outright fraud. In either case the ancient and obviously correct principle is that the challenging party cannot have its cake and eat it too, but must choose whether it prefers the bargain or the *status quo ante*. If the licensee commits a material breach, the licensor always must elect between maintaining the license and suing for royalties, or terminating it and suing for infringement. *See, e.g.*, *St. Paul*, 140 U.S. at 196; *United Mfg. & Serv. Co. v. Holwin Corp.*, 187 F.2d 902, 905 (7th Cir. 1951) ("[W]hile the license agreement is still in effect the owner of the patent cannot sue for infringement. He is limited to the enforcement of his rights and remedies under the license agreement.").

MedImmune wants to avoid that choice, keeping the favorable royalty rate it received from Genentech in exchange for early "patent peace" while destroying the premises of that bargain. Its own conduct makes clear that MedImmune understands the inherent duplicity of this strategy. After deciding to file this lawsuit, it kept silent about that decision and spent the better part of a year sewing up seven additional licenses to cover other products then in development. Only after obtaining those licenses did MedImmune file this suit less than three months later. J.A. 437; *supra* at 9–10. Its parallel conduct with Centocor vividly illustrates that MedImmune's conduct is part of a broader and deliberate strategy. *Supra* at 10 n.7. That behavior is not clever; it is fundamentally inequitable.[32] Its only real excuse—that it could not know the claims of the

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and still pursue an action for deceit ….").

[32] In a similar vein, courts have repeatedly dismissed patent declaratory judgment actions when it appears that the licensee signed a licensing agreement only to buy itself more time to forum shop and prepare litigation papers before breaching the license. *See, e.g.*, *Mission Ins. Co. v. Puritan Fashions Corp.*, 706 F.2d 599, 602 n.3 (5th Cir. 1983); *Charles Schwab & Co. v. Duffy*, 49 U.S.P.Q.2d (BNA) 1862 (N.D. Cal. 1998).

patent at the time it agreed to the license—is both factually unsupportable, *supra* at 4–5, and legally irrelevant.[33]

Second, MedImmune's suit is obviously inconsistent with the even more specific, and directly on point, equitable tradition of licensee estoppel. As noted, *supra* at 32–33, common law judges thought long and hard about whether a licensee in good standing could bring a validity challenge consistent with equitable principles while continuing to enjoy the benefits of the license. For at least three centuries they answered with a consistent and emphatic "no." The common law was not blind to the public policies that favor (within limits) judicial challenges to patents that may be invalid, but sensibly balanced the relevant policies in the same way this Court did on the facts of *Lear* itself: by giving licensees an option to repudiate the license and defend any resulting suit on the ground that the patent was invalid. MedImmune's only refuge is to argue that under *Lear* all considerations of equity and tradition must be ignored in deference to a particular conception of patent policy in which nothing matters but encouraging patent litigation. *Lear* does not remotely require that result.

C. Adjudication Of Licensee Challenges To Validity Prior To Repudiation Frustrates The Core Purposes Of The Patent Laws

MedImmune's policy arguments collapse into a belief that licensors and licensees should be forced to internalize risks they are currently choosing to share and bear costs they are currently contracting to avoid, and that more of our country's productive resources should be devoted to patent litigation and less toward research and development of new

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[33] Restatement (Second) of Contracts §154 (1981) (party to a contract always bears the risk of mistake if "he is aware, at the time the contract is made, that he has only limited knowledge with respect to the facts to which the mistake relates but treats his limited knowledge as sufficient"); William A. Keener, *A Treatise on the Law of Quasi-Contracts* § 42 (1926) ("[I]f one is conscious of a doubt as to his legal rights or duties, and with or without deliberation, with or without advice, chooses and enters upon a course of action, he should not be permitted to repudiate his choice.").

technologies. It urges this Court to be the agent of such a revolution on the premise that the system Congress established for reviewing patent applications is fundamentally broken, that most issued patents are invalid, and that therefore the public interest cannot tolerate licensees bargaining away (even temporarily and with regard to themselves alone) the ability to file lawsuits like this one. This agitation should be directed to Congress. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 168 (1989) ("It is for Congress to determine if the present system of design and utility patents is ineffectual in promoting the useful arts in the context of industrial design."). Congress has considered policy arguments like these for decades, and has repeatedly declined to codify any statutory extension of *Lear*, to create any general cause of action to challenge the validity of a patent, or even to modify the rule that all patents are to be presumed valid, 35 U.S.C. § 282.[34] What Congress has done instead is to create a cost-efficient, expeditious new *administrative* process for reexamination of patents before the PTO. 35 U.S.C. § 303(a).[35] MedImmune admits that it has not only invoked that procedure in this case, but that the reexamination process has allowed it to present the challenges to the Cabilly II patent that it attempts to raise in this declaratory judgment suit. *See* Pet. Br. 48 n.18. Against that backdrop, MedImmune's rhetoric about the need for this Court to save the country from a plague of invalid patents rings hollow.

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[34] *See* Resp. City of Hope Br. at 41. As one of MedImmune's amici notes, a bill is pending before the House of Representatives that would provide a system of post-grant review of issued patents, including the right of any dissatisfied party to appeal the determination to the Federal Circuit. *See* H.R. 2795, 109th Cong. § 9 (introduced June 8, 2005).

[35] Even the Federal Trade Commission, which regulates anticompetitive conduct, has not recommended what MedImmune proposes here. In 2003, it suggested changes to *the administrative process* for reexamination; it did not suggest Congress give licensees a cause of action to challenge a patent's validity. *See* FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 5, at 23–24 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

Regardless, MedImmune's policy analysis considers only the potential benefits that would be produced by taking some invalid patents off the books, but completely ignores the associated costs—in the form of greatly increased litigation expenses, decreased licensing, and decreased use of the patent system. It would encourage more challenges to patents by licensees, at the expense of decreasing the number of licensees and the number of productive collaborations facilitated by licensing, as well as overall use of the patent system and investments in research and innovation. *See* John W. Schlicher, *Judicial Regulation of Patent Licensing, Litigation and Settlement Under Judicial Policies Created in* Lear v. Adkins, *in* American Intellectual Property Law Association, *Selected Legal Papers*, Vol. III, No. 1, I-8 to -13 (June 1985). Those trade-offs are complex and not well suited to judicial resolution.

First, MedImmune's proposal would inflict enormous deadweight social costs. The effects on price and output are explained in detail in the literature,[36] but the basic principles are simple. Under the common law rule, a licensor's freedom from the risk and expense of patent litigation (limited, of course, by the licensee's right to repudiate) creates value for the licensor and decreases the price at which it will grant a license. MedImmune's proposed rule encourages licensees to sue whenever expected future royalties multiplied by the chance of establishing invalidity exceed the likely litigation costs. Where as here the royalties are many multiples of the litigation costs, a licensee would arguably breach its fiduciary duty to its shareholders by not taking a shot at suit. MedImmune's proposed rule would also have the perverse effect of encouraging patent holders to file infringement suits against prospective licensees and then explicitly "settle" the litigation via a license, to achieve res judicata protection from any subsequent validity challenge.

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[36] *E.g.*, John W. Schlicher, *A Lear v. Adkins Allegory*, 68 J. Pat. & Trademark Off. Soc'y 427, 429–35 (1986); Schlicher, *Judicial Regulation of Patent Licensing*, I–8 to –13.

As MedImmune concedes, the patent litigation its rule would instigate would be enormously expensive. Pet. Br. 44–45 (estimating legal costs of challenge at $5–$7 million). If licensees can no longer credibly promise to pay royalties in exchange for "patent peace," the licensor has no choice but to factor litigation costs into the profit maximizing royalty rate. That will necessarily discourage some licensees from taking a license, and decrease the output of the rest. *See* Schlicher, *Judicial Regulation of Patent Licensing* at I–8 to –11. Licenses are socially beneficial because they encourage production and innovation that might not otherwise occur, or that might otherwise remain with a less efficient firm (such as the patent holder itself). *Id.* at I–11 to –12 (increase in licensing costs will lead to "monopolistic exploitation at higher costs"); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 487 (1974). The sharing of technology under patent licenses is also essential to the collaborative research environment that has made the past decades' dramatic advances in medicine and biotechnology possible. Individual firms, each exploiting only their own patented techniques, would never produce innovation at the current breakneck pace.

MedImmune misses the point by arguing that small start-up companies often agree to licenses only because they are initially "unable to afford the high cost of patent litigation." Pet. Br. 45. MedImmune's proposed rule would force patent holders to internalize projected litigation costs into the price of a license, and the entrepreneurs it purports to be concerned about would then be unable to afford a license. The United States concedes as much by acknowledging that patent holders would inevitably respond to MedImmune's rule by requiring paid-in-full up-front licenses, U.S. Br. 28–29, which will price many prospective licensees (and particularly cash-poor startup companies) out of the license market entirely. And in many industries, parties structure patent licenses to defer royalty payments until the point where the licensee actually markets a product or service subject to the license. The ability to

defer royalty payments therefore provides the licensee with more discretion over the decision to use the patented invention in its products. A license agreement that frontloads payments necessarily requires licensees to decide prior to entering the license whether they will proceed all the way with development in a manner that uses the patent.

Second, by greatly decreasing the value of licensing to both parties, MedImmune's rule also decreases the net expected value of a patent itself, with predictably negative consequences for use of the patent system and perhaps for overall investments in innovation. An inventor considering whether to invest in research and development faces enormous risks associated with whether that investment can ultimately be recouped. If a patent is applied for and granted, the patent system requires complete public disclosure of the invention. If that patent is later set aside as invalid, then the public gets a free ride on the inventor's efforts and investment. Traditional licenses make it possible to share that risk. But MedImmune's proposed rule forces the inventor to bear it all alone, and also imposes a large and unavoidable risk of expensive litigation on anyone brash enough to apply for a patent. The predictable result is to make the patent system less appealing, giving inventors an incentive to either decrease their innovative activities or maintain those efforts but opt-out of the patent system and rely on state trade secret law—which is a far inferior outcome from the standpoint of public policy.

MedImmune's real complaint in this litigation is that the bargaining leverage Genentech had before MedImmune took a license, and that Genentech would have again if MedImmune repudiated that license, is unfair and should be regarded as legal coercion. MedImmune fears that if it repudiated the license, sued for a declaration of invalidity, and lost, Genentech would not give it a new license at the same favorable royalty rate it now enjoys. But Congress gave patent holders "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention

into the United States." 35 U.S.C. § 154(a)(1). There is no public policy demanding that MedImmune have a license from Genentech, or that it retain the favorable royalty rate it negotiated back in 1997. As this Court has often observed, compulsory licensing "is a rarity in our patent system." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 & n.21 (1980). Although "[c]ompulsory licensing of patents often has been proposed," it "has never been enacted on a broad scale."[37] So, like it or not, MedImmune must choose between litigating or licensing.

The United States concedes that MedImmune's proposal to increase patent litigation is bad policy, by suggesting that it will not work,[38] by conspicuously emphasizing that it will not apply to the United States' *own* patents in any event, U.S. Br. 23 n.11, and by suggesting various ways that inventors might be able to contract to avoid it, such as "requir[ing] prospective licensees to purchase a fully paid-up license" or including a provision making explicit that lawsuits like MedImmune's constitute a material breach of the license. U.S. Br. 28–29. The United States is, of course, correct that licensors would inevitably respond to a victory by MedImmune in this case by demanding large up-front payments rather than ongoing royalties, but that shift will just discourage licensing without even encouraging validity challenges. A licensee that has already paid in full has *no incentive to challenge validity*, ever.

More broadly, the United States' suggestion cuts the heart out of its (and MedImmune's) arguments on the merits. If public policy somehow demands that licensees be unfettered and have a strong incentive to challenge validity,

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[37] 448 U.S. at 215 n.21; *see Hartford-Empire Co. v. United States*, 323 U.S. 386, 417 (1945) (observing that "Congress was asked as early as 1877, and frequently since, to adopt a system of compulsory licensing of patents" but "[i]t has failed to enact these proposals into law"); *Dawson Chem.*, 448 U.S. at 215 n.21 ("compulsory licensing provisions were considered for possible incorporation into the 1952 revision of the patent laws").

[38] U.S. Br. 26 (arguing that litigation costs will deter challenges and "[m]any patents are clearly valid, and thus are unlikely to be challenged").

then why hypothesize or permit ways that the parties could evade that policy? The answer, of course, is that the United States recognizes that MedImmune's rule may be inefficient and undesirable, and does not want to limit the parties' contractual freedom. But if this case just boils down to determining what the right presumption or contractual default rule should be, then surely the right choice is the common law rule that Congress has never altered, which for centuries has recognized that suits like this one are fundamentally inconsistent with the bargain at the heart of a license, and which notwithstanding the confusion briefly introduced by *Lear* has been reaffirmed as sound precedent. The patent system does not need the United States' various suggestions, particularly since it simultaneously invites decades of litigation and confusion by speculating that its proposals might or might not be unenforceable for public policy reasons. *See* Licensing Exec. Society Br. 12.

There is no justiciable controversy in this case, but even if there were, it is not a case that any court of equity should reach out to hear. MedImmune is trying simultaneously to receive and challenge the benefit of its bargain, in direct conflict with centuries of equitable jurisprudence directly on point. In this area as in many others, "a page of history is worth a volume of logic." *N.Y. Trust Co. v. Eisner*, 256 U.S. 345, 349 (1921) (Holmes, J.). The traditional understanding that a license resolves any cognizable dispute over the validity of the patent, unless and until the licensee is willing to repudiate the benefits of its bargain, strikes a sensible balance both as a matter of equity and public policy. If that traditional presumption needs to change, the change should come from Congress.

CONCLUSION

For the reasons set forth, this Court should affirm the judgment of the Court of Appeals.

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ADDENDUM

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Const. Art. III, § 2, cl. 1

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction;—to Controversies to which the United States shall be a Party;—to Controversies between two or more States;—between a State and Citizens of another State;—between Citizens of different States;—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

28 U.S.C. § 2201. Creation of remedy

(a) 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 declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

35 U.S.C. § 120. Benefit of earlier filing date in the United States

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

35 U.S.C. § 132(a). Notice of rejection; reexamination

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement,

together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 135(a). Interferences

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.

35 U.S.C. § 146. Civil action in case of interference

Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141

of this title, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

Such suit may be instituted against the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision complained of, but any party in interest may become a party to the action. If there be adverse parties residing in a plurality of districts not embraced within the same state, or an adverse party residing in a foreign country, the United States District Court for the District of Columbia shall have jurisdiction and may issue summons against the adverse parties directed to the marshal of any district in which any adverse party resides. Summons against adverse parties residing in foreign countries may be served by publication or otherwise as the court directs. The Director shall not be a necessary party but he shall be notified of the filing of the suit by the clerk of the court in which it is filed and shall have the right to intervene. Judgment of the court in favor of the right of an applicant to a patent shall authorize the Director to issue such patent on the filing in the Patent and Trademark Office of a certified copy of the judgment and on compliance with the requirements of law.

35 U.S.C. § 154(a)(1). Contents and term of patent; provisional rights

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to

exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

35 U.S.C. § 282. 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.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure—

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

35 U.S.C. § 303. Determination of issue by Director

(a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this

title, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Director may determine whether a substantia l new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 of this title. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.