No. 05-608

In the Supreme Court of the United States

MEDIMMUNE, INC.

Petitioner,

v.

GENENTECH, INC., *ET AL.*,

Respondents

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

BRIEF OF AMICUS CURIAE MEDTRONIC, INC. IN SUPPORT OF PETITIONER

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Interest of the *Amicus*

This brief is filed with the consent of the parties[1] on behalf of Medtronic, Inc. Medtronic is the world leader in medical technology providing lifelong solutions for people with chronic disease. It offers a variety of medical products, therapies and services that enhance or extend the lives of millions of people. Each year, patients benefit from Medtronic's technology, used to treat conditions such as diabetes, heart disease, neurological disorders, and vascular illnesses. Because the medical devices industry has a large number of patents, many of them overlapping. Medtronic is frequently a party to patent litigation.

Medtronic's interest in this case arises from one of those litigations. As the Court knows, patent litigation involves issues that are often very complicated, both from a technical and a legal perspective. Medtronic sometimes finds that the most reasonable business solution to patent litigation is to enter into a licensing agreement, despite continuing differences between the parties as to the scope or validity of the claims. Medtronic believes that the standing decisions that have recently emerged from the Court of Appeals for the Federal Circuit are inconsistent with this Court's well-established case-and-controversy principles and

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[1] The parties' letters of consent have been filed with the Clerk in compliance with Rule 37.3. This brief was not authored in whole or in part by counsel for any party. No person or entity other than the *amicus* made a monetary contribution to the preparation or submission of this brief.

will prevent parties from reaching the most efficient business solution to patent disputes.

Medtronic has an appeal pending before the Federal Circuit that touches on the Question Presented in this case.[2] Medtronic believes that the facts of that case and of a similar prior Medtronic appeal to that court serve as a useful backdrop for illustrating the legal and practical problems raised by the decision under review in this case.

Summary of Argument

The Federal Circuit's rule of decision that precludes a patent licensee in good standing from seeking a declaratory judgment that the patent is invalid fails to follow the principles established by this Court in *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227 (1937) and *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). The circuit's rule appears to draw a distinction between cases where disputed royalty payments are escrowed and cases where the licensee continues to pay royalties on a current basis. There is no valid reason in either situation to dismiss invalidity claims brought by licensees on the ground that there is no case or controversy within the Article III jurisdiction of the federal courts.

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[2] The pending appeal is *Medtronic v. Guidant, et al.*, CAFC No. 05-1515. The case was argued and submitted to the Federal Circuit on May 4, 2006.

Argument

I. Medtronic's Experience in Litigating Declaratory Judgment Actions as a Patent Licensee Before the Federal Circuit May Assist the Court To Decide this Case

The declaratory judgment issue presented in this case has arisen in two cases Medtronic has argued before the Court of Appeals for the Federal Circuit, one of which is pending there now. Those two cases present a factual variation on licensee standing that the Federal Circuit has previously found significant. In both cases a licensee in good standing did not merely dispute the scope or validity of its license, it ceased paying royalties to the licensor and instead paid them into an escrow pending final determination of a declaratory judgment action to resolve the dispute. Medtronic agrees with the Petitioner that the recent Federal Circuit decisions on this issue were wrongly decided, but believes this Court may wish to consider the significance of a contemporaneous royalty escrow when it decides this case.

The Question Presented has its roots in the Federal Circuit's decision in *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). The panel opinion in that case did discuss this Court's highly decisions in *Aetna* and *Lear*, although it failed to properly apply them. The *Gen-Probe* decision did not, however, discuss that court's own prior decision in *Cordis, Corp. v. Medtronic, Inc.*, 835 F.2d 859 (Fed. Cir. 1987) which found that there was a case and controversy sufficient to sustain jurisdiction to issue a declaratory judgment in a case brought by a Medtronic licensee in good standing.

Cordis arose from a patent license Medtronic had

granted to Cordis for pacemaker leads. Cordis was manufacturing one variety of leads under that license and was paying royalties on those leads. Cordis later developed a new lead that it claimed was not covered by the patent; Medtronic disagreed and said it would cancel the license agreement if Cordis refused to pay royalties on future sales of the new leads. Medtronic also reserved a claim to sue for past infringement from prior sales. In light of those assertions, Cordis instituted a declaratory judgment action seeking a preliminary injunction to prevent Medtronic from canceling the license and asking for a declaration that the new leads were not covered by the patent or the license agreement. Cordis also immediately "moved for an order to establish an escrow account into which the royalty payments due Medtronic on the [new] leads could be deposited during the litigation . . . ." 835 F.2d at 861. On those facts the Federal Circuit found that there was a case and controversy within the meaning of Article III. *Cordis* 835 F.2d at 863. The panel relied on prior decisions in concluding that Cordis was "under a reasonable apprehension or threat of being sued for infringement." *Id.* at 862.

Gen-Probe arose from a somewhat similar fact pattern, but it differed from *Cordis* in that it did not involve any escrow of disputed royalties. Gen-Probe and Vysis were adversaries in litigation involving a number of patents. During that litigation, Vysis obtained ownership of an unrelated patent which it claimed covered certain Gen-Probe products. Gen-Probe took a license under that patent, but then initiated a declaratory judgment action that the patent did not cover the products and was invalid. Throughout the pendency of that suit Gen-Probe "fulfilled its obligations [under the license] and continued paying royalties." *Gen-Probe*, 359 F.3d at 1379. In that case the Federal Circuit held that there was no case and controversy and dismissed the appeal, finding "there is not a reasonable

apprehension of suit." *Id.* at 1382.[3]

Medtronic's more recent experience before the Federal Circuit involving this issue arose in the context of a dispute over the scope and validity of certain cardiac pacemaker patents. Medtronic was a party to six separate litigations where the owner and exclusive licensee of the numerous patents contended that certain Medtronic pacemakers and defibrillators infringed several patents. In 1991, Medtronic settled those lawsuits and took a license, while specifically reserving the right to contest the application, validity and enforceability in subsequent declaratory judgment actions. When a dispute later arose over one of the licensed patents, Medtronic denied any obligation to pay royalties, in part on the basis of a claim of invalidity because claims surrendered in the prosecution of the original patent had been improperly recaptured in a reissue of that patent. Medtronic filed a complaint seeking a declaratory judgment in the United States District Court for the District of Delaware as provided for in the settlement agreement. Prior to institution of the action, the parties agreed to escrow all royalty payments the owner asserted were due by virtue of the reissue claims. That escrow continues to this day and the amount on deposit exceeds $5,000,000.

The District Court concluded that it did have jurisdiction and issued a final judgment on July 19, 2005 finding the patent valid. *Medtronic, Inc. v. Guidant Corp.*,

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[3] The Federal Circuit relied on and followed the *Gen-Probe* decision in dismissing this case and a similar one, *MedImmune v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005), *cert. pending* in 05-656.

378 F. Supp 2d 503 (D. Del. 2005). That case differed from *Gen-Probe* and this case because of the escrow of royalties. On appeal Medtronic contended that the case was substantially similar to its prior dispute with Cordis because of the presence of an escrow and the prior litigation between the same parties involving the same patent. The jurisdictional issue presented here was raised and discussed in Medtronic's briefs and oral argument in the Federal Circuit where the case remains under consideration by the panel as of the filing of this *amicus* brief.

II. The Declaratory Judgment Action Is An Important Alternative that Potential Licensees Need to Avoid Excessive Infringement Litigation

Unless this Court reverses the Federal Circuit and clarifies the law to make it clear that patent licensees can bring declaratory judgments to challenge the validity of questionable patents, potential licensees will be forced to defend more patent litigations, a result that will increase docket congestion. This reality is particularly acute in the technology and medical device industries that are characterized by a multiplicity of patents.

The license agreement that is involved in the pending Medtronic/Guidant case is typical of agreements in the medical device and technology industries today. That settlement and licensing agreement licensed over 500 US patents and pending applications. In many industries, the single patent license agreement is the exception and not the rule. More often, companies cross-license dozens or hundreds of patents to a defined set of licensed products or in a licensed field of use. This is particularly true of cross-license agreements resulting from settlement of patent

litigation. If a company cannot enter into a comprehensive settlement and licensing agreement except at the cost of being unable to challenge the validity of individual questionable patents, it will face the Hobson's choice of foregoing a settlement in order to preserve challenges to some of the patents, or accept a settlement that precludes judicial determination of the validity of those patents.

Neither of those alternatives serves the public or private interests. Under the present Federal Circuit rule patents of dubious validity will remain unchallenged if the affected entity enters into a comprehensive patent licensing agreement. On the other hand, if that party declines to enter into such an agreement in order to maintain the ability to challenge those patents, it is likely to become a defendant in suits brought on other patents in the patentee's portfolio, suits that could be avoided or resolved through a comprehensive settlement. The realities of today's technology driven society present the multi-patent licensing concept as the norm in many industries. If the Federal Circuit's rule stands, parties in Medtronic's position are put at risk of losing all patents included in a license agreement to challenge a dispute over one or a few patents. As a practical matter, the licensee has no remedy whatsoever if the parties cannot enter into a comprehensive settlement while agreeing to continue resolving genuine disputes involving a small number of the patents through the courts

III. The Precedent in the Court of Appeals for the Federal Circuit Are Inconsistent with This Court's Decisions

The recent Federal Circuit cases that have refused to find jurisdiction when a licensee in good standing contests the claim scope or validity of its license are inconsistent with

this Court's fundamental declaratory judgment decisions, as well as the policy rationale that undergirds the decision in *Lear v. Adkins, supra.*

A. The Federal Circuit Decisions Fail to Follow the Well-Established Principle that a Case and Controversy Sufficient to Sustain Jurisdiction Exists When the Parties to a Contract Have a Bona Fide Dispute Over its Proper Interpretation.

The Declaratory Judgment Act was enacted in 1934 in part to facilitate parties' ability to resolve legal disputes. Prior to creation of the declaratory judgment remedy, disputes could arise where someone asserted a legal right but declined to enforce it through litigation seeking a money judgment or injunction. The declaratory judgment remedy met the need that the putative defendant in a coercive action had to resolve that legal dispute. An essential part of the federal remedy was the requirement that it can only be invoked where there is an actual case or controversy.

The lower federal courts were not uniformly receptive to the declaratory judgment procedure. One of the earliest cases involving the Act that the Court considered is one of the most pertinent for the decision in this case.

Aetna v. Haworth arose from a dispute between an insurance carrier and its insured over the coverage of disability benefits. The insured had ceased making payments, claiming he was totally disabled and entitled to the benefits without paying any additional premiums. The carrier disputed the validity of the disability claim. The insured never brought an action to recover the claimed benefits, so the carrier instituted an action in federal court seeking a declaratory judgment that there was no disability.

The trial court dismissed the carrier's complaint finding there was no controversy within the meaning of Article III. 200 U.S. at 236. The Circuit Court affirmed. *Id.* This Court, in a unanimous opinion authored by Chief Justice Hughes, reversed and held that there was a case and controversy that sustained federal jurisdiction and was within the scope of the then recently-enacted Federal Declaratory Judgment Act. The Court's rationale was succinct and unambiguous:

> There is here a dispute between parties who face each other in an adversary proceeding. The dispute relates to legal rights and obligations arising from the contracts of insurance. The dispute is definite and concrete, not hypothetical or abstract.

200 U.S. at 242

Aetna remains a cornerstone of declaratory judgment precedents. When the Federal Circuit decided *Gen-Probe* it discussed *Aetna* and distinguished it on the grounds that it was an insurance dispute and "did not involve a declaratory judgment action instituted by a patent licensee in good standing." *Gen-Probe*, 359 F.3d at 1382. That statement is a classic "distinction without a difference." The Federal Circuit failed to apply the principle on which the *Aetna* decision was based – the existence of a genuine dispute as to legal rights under a contract is sufficient to satisfy the case and controversy requirement – and instead dismissed the case because of immaterial factual differences. That error should be corrected in this case.

B. The Federal Circuit Fails to Follow this Court's Decision that the Public Interest is Best Served by Allowing Patent Licensees to Contest the Validity of the Licensed Patent.

The Federal Circuit apparently believes that patent cases are categorically different from other contract disputes and thus not subject to the same standards for determining whether there is a federal case and controversy. The Circuit Court is wrong in that belief. Not only is there no valid analytical reason for a different rule in patent license cases, there is a strong public policy that supports application of the same principle applied to other types of commercial and contract disputes. That public policy is one that favors opening the judicial doors to issues of patent validity in order to protect the public interest from the adverse market consequences of invalid patents.

In *Lear v. Adkins* the Court reconsidered the estoppel doctrine that had developed in patent law and concluded that it was an unsound limitation. The Court had previously adopted a rule that estopped a licensee from attacking the validity of the patent in *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, 339 U.S. 827 (1950). Upon reconsideration of that case, the Court held that it should be overruled. *Lear* rested on the realization that because patents have the effect of a limited monopoly, the public interest is better served by allowing licensees to contest the validity of the patent on which the license was based.

In *Gen-Probe*, the Federal Circuit, relying on a number of its own prior decisions, construed *Lear* narrowly and said that it "does not grant every licensee in every circumstance the right to challenge the validity of the patent." 359 F.3d at 1381. Here again the Federal Circuit failed to follow the principle that sustains the *Lear* precedent

and chose to follow its own precedent instead of this Court's controlling decision.

It is not clear why the Federal Circuit reached the result it did in *Gen-Probe* or in this case. Perhaps those decisions reflect an excessively rigid view of the general rule that decisions of a prior panel of the circuit control a subsequent panel – even if wrongly decided – until and unless overruled by the circuit sitting *en banc*. *See, e.g., Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1366 (Fed. Cir. 2002) (panels of the Federal Circuit are bound by a prior panel ruling on the issue until and unless the prior decision is set aside by the court sitting *en banc*). Perhaps they reflect a pro-patent-validity policy of that court. Regardless of the reason, the rejection of *Lear* and *Aetna* by the circuit court was wrong then and remains wrong today. The Court should reject the narrow view of case and controversy jurisdiction that has been adopted by the Federal Circuit. The same public interest analysis applied to the issue of equitable estoppel in *Lear*, also applies in the context of case and controversy analysis. The analysis of equitable estoppel by this Court and the regional circuits shows that there is no constitutional issue that requires dismissal of declaratory judgment complaints filed by licensees.

Conclusion

For the reasons stated, the Court should reverse the judgment of the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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