Supreme Court, U.S.
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In the Supreme Court of the United States

INNOVATIVE THERAPIES, INC.,
Petitioner,

v.

KINETIC CONCEPTS, *et al.*,
Respondents.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires a patentee to direct an affirmative act toward a potential infringer for declaratory judgment subject matter jurisdiction to exist.

2. Whether Article III's grant of jurisdiction of "all Cases ... arising under ... the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), requires that a patentee be able to sue a potential infringer before declaratory judgment subject matter jurisdiction can exist.

3. What are the metes and bounds of a district court's discretion to dismiss a declaratory judgment complaint under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), despite the existence of an actual controversy.

PARTIES TO THE PROCEEDING

Petitioner Innovative Therapies, Inc. was the only appellant in the court below. Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. were the appellees in that court.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioner states as follows:

Petitioner Innovative Therapies, Inc. is a privately held corporation. No publicly held entity owns 10% or more of its stock.

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I.
INTRODUCTION

This case presents fundamental questions of declaratory judgment subject matter jurisdiction and the faithful application of this Court's precedents by the United States Court of Appeals for the Federal Circuit ("Federal Circuit"). The Federal Circuit has once again departed from this Court's precedents regarding declaratory judgment subject matter jurisdiction, creating a new rule that requires a patentee to direct an "affirmative act" toward a potential infringer before that potential infringer may bring a declaratory judgment action to clarify its rights regarding the patents-in-question. This Court recently rejected such a formulaic rule for declaratory judgment subject matter jurisdiction. In *MedImmune, Inc. v. Genentech, Inc.*, this Court reconfirmed the time-tested threshold for establishing subject matter jurisdiction in declaratory judgment actions: "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007). In so doing, the Court specifically rejected the Federal Circuit's "reasonable apprehension of suit" test. *Id.* at 132 n.11. Here, the Federal Circuit improperly resurrected the "reasonable apprehension of suit" test through the "affirmative act" rule in direct contravention of *MedImmune*.

This case also presents an issue that this Court has not directly addressed: what are the metes and bounds of a district court's discretion to dismiss a declaratory judgment action involving a patent dispute

where an actual controversy exists? Here, the Federal Circuit affirmed the District Court's discretionary dismissal, focusing solely on whether the pre-suit conduct of petitioner Innovative Therapies, Inc. ("ITI") comported with the objectives of the Declaratory Judgment Act. The Federal Circuit should have instead analyzed whether hearing the case would serve the objective for which the Declaratory Judgment Act was created—relieving the Damoclean threat of suit. Here, there can be no doubt that ITI faced the Damoclean threat of suit from a highly litigious corporation that had sued every competitor with a commercially-viable product.

Now that *MedImmune* has arguably lowered the threshold for establishing an actual controversy sufficient to establish declaratory judgment subject matter jurisdiction, the exercise of discretionary dismissals, such as here, will likely become more common as the number of filed declaratory judgment actions expands. However, unfettered discretionary dismissals would frustrate the objectives of the Declaratory Judgment Act by leaving potentially infringing entities no recourse but to wait for a patentee to sue at the time and place of its choosing.

This Court should grant certiorari to correct the Federal Circuit's application of *MedImmune* and declaratory judgment subject matter jurisdiction principles, and to clarify the discretion of district courts under 28 U.S.C. § 2201(a) to dismiss declaratory judgment actions despite the existence of an actual controversy.

II.
OPINIONS BELOW

The opinion of the Federal Circuit is reported at 599 F.3d 1377 and is reproduced in the Appendix at 1a.[1] The order denying the petition for rehearing en banc is unreported. 44a. The memorandum order of the district judge of the District Court for the District of Delaware was unreported. 17. The report and recommendation of the magistrate judge of the District Court for the District of Delaware was unreported. 22a.

III.
STATEMENT OF THE BASIS FOR JURISDICTION

This Court has jurisdiction over this petition under 28 U.S.C. § 1254(1) because the petition asks the Court to issue a writ of certiorari to review a decision of the United States Court of Appeals for the Federal Circuit. The Court of Appeals issued its decision on April 1, 2010. 1a. The Court of Appeals denied ITI's petition for rehearing en banc on May 26, 2010. 44a. This petition is being filed with the Clerk of this Court within 90 days from the date of the denial of the petition for rehearing en banc.

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[1] Citations to "a" are to the appendix to this petition. Citations to "C.A.A." are to the joint appendix filed in the Federal Circuit.

IV.
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED IN THIS CASE

Article III Section 2 of the United States Constitution provides in pertinent part:

> 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(a) provides:

> (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.

V.
STATEMENT OF THE CASE

A. Background

1. ITI's Negative Pressure Wound Therapy System

Petitioner ITI, a start-up medical device company, designed and developed a negative pressure wound therapy ("NPWT")[2] device named the Svedman™ system to treat chronic wounds. Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., and KCI USA, Inc. (collectively, "KCI") manufacture and sell a family of NPWT devices called the Vacuum Assisted Closure (V.A.C.®).

ITI's founders recognized a critical need for an affordable alternative to KCI's patented V.A.C.® NPWT devices. C.A.A.535. Because many health care facilities (such as nursing homes) cannot afford the significant cost of the V.A.C.®, thousands of patients in the United States do not receive the NPWT necessary

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[2] NPWT involves the application of negative pressure to promote healing of chronic wounds typically through a combination of a vacuum and a pressure dressing.

to heal their chronic wounds, and in many cases, avoid amputation. C.A.A.535. ITI endeavored to offer the Svedman™ system at a substantial discount to the current market price for competitive products to meet the needs of patients with serious wounds who had previously been priced out of the NPWT market. C.A.A.535.

KCI has accumulated a portfolio of patents that it claims covers its V.A.C.® devices, including United States Patent Nos. 4,969,880 ("the '880 patent"), 5,645,081 ("the '081 patent"), 5,636,643 ("the '643 patent"), 7,198,046 ("the '046 patent"), and 7,216,651 ("the '651 patent) (collectively, "KCI patents"). C.A.A.332. KCI also claims that those patents broadly cover many other commercially available NPWT devices, and has a well-documented history of aggressively asserting its patent portfolio in litigation to limit competition with its V.A.C.® devices. From 2001 to 2007, KCI sued ten defendants in six different patent infringement lawsuits regarding NPWT devices. C.A.A.335. Those lawsuits included both of KCI's primary NPWT competitors in the chronic wound care treatment market: Medela and BlueSky Medical Corp./Smith & Nephew. C.A.A.335. Furthermore, KCI has even sued a doctor and hospitals that have dared to use NPWT technology other than KCI's V.A.C.® devices to treat patients with chronic wounds. C.A.A.483.

2. ITI Receives FDA Approval and Offers the Svedman™ System for Sale.

The FDA approved both of ITI's 510(k) submissions relating to the Svedman™ system. C.A.A.536. Those submissions took advantage of a FDA procedure that

streamlines the approval process by allowing an applicant to claim that its new medical device "has essentially the same technological characteristics" as a previously approved device, or "predicate device" in FDA lexicon. C.A.A.536-537. One of ITI's 510(k) submissions claimed one of KCI's V.A.C.® devices as a predicate device, asserting that the ITI device "has essentially the same technological characteristics as the previously cleared predicate device." C.A.A.536. The other 510(k) claimed as predicate devices for that 510(k) submission the Medela Invia™ Healing System and the BlueSky Medical Versatile 1™ Wound Vacuum System—both of which have been accused of patent infringement in other lawsuits filed by KCI. C.A.A.334, 536-537.

After receiving FDA approval, ITI proceeded to test the Svedman™ system through clinical evaluations in August 2007. C.A.A.536. During those evaluations, five patients with chronic wounds were successfully healed by the Svedman™ system, and the supervising physician provided testimonials regarding the outstanding chronic wound treatment provided by the Svedman™ system. C.A.A.536. As a result of the successful clinical evaluations, ITI decided to commercialize and market the Svedman™ system.

ITI made its first offer for sale of a Svedman™ system on September 27, 2007, and the first Svedman™ system was placed with a customer in the first week of October 2007. C.A.A.537.

3. KCI Makes Clear That It Will Aggressively Assert Its Intellectual Property Rights Against ITI.

Prior to offering the Svedman™ system for sale, Richard Vogel—ITI Chief Executive Officer and former KCI Vice President and Executive Committee member— and David Tumey—ITI's Chief Technology Officer and former KCI Director of Research & Development—decided to approach KCI regarding the Svedman™ system. As former KCI insiders, Vogel and Tumey had first hand experience with KCI's litigation decision-making process and tactics. C.A.A.509, 536. On the eve of their new company's launch of a device that would compete directly with KCI's V.A.C.® devices, they faced the almost certain prospect of being the next target of KCI's aggressive litigation tactics. C.A.A.509. Therefore, Tumey decided to contact some of his former colleagues at KCI to assess the potential for avoiding litigation by consummating a business relationship between the parties. C.A.A.510-511.

On September 12, 2007, Tumey called his former colleague, Michael Girouard, because he believed that, as KCI's Director of Marketing, Girouard would understand KCI's current institutional attitude toward patent enforcement against competitive products. C.A.A.510. During the call, Tumey asked Girouard if he was aware of the two 510(k) submissions filed by ITI that the FDA had recently approved. C.A.A.504, 507, 510, 526. Girouard replied that he was aware of one of the 510(k) submissions based upon discussions at KCI's regular "Competitive Intelligence" meetings. C.A.A.504-505, 510. Tumey explained to Mr. Girouard that his new company had been developing and was considering launching a chronic wound healing system

that utilized negative pressure and a polyurethane foam dressing. C.A.A.505, 510-511. When asked how he thought KCI might react to the introduction of such a product, Girouard responded, "KCI will act aggressively. You know that." C.A.A.505, 507, 510-511, 528.

On September 17, 2007, Tumey called KCI's Senior Vice President of Manufacturing, Michael Burke, a corporate officer and Executive Committee[3] member. Tumey called Burke—his former supervisor at KCI—to determine, as with Girouard, whether the parties could develop a business relationship regarding the Svedman™ system, and alternatively, to determine the litigation risk associated with launching the Svedman™ system. C.A.A.511.

Tumey explained to Burke that he was working on the launch of a new NPWT wound healing system utilizing polyurethane foam dressing, and asked Burke how he thought KCI would react to the release of such a product. C.A.A.511-512. Burke replied, "KCI will aggressively go after [you]", "particularly if it is foam-based." C.A.A.512, 530. When asked whether KCI and ITI could peacefully coexist regarding the Svedman™ system, Burke replied that there was "no way to coexist" and that it would not happen. C.A.A.512, 530. Tumey also queried Burke about the odds of a KCI suit if ITI launched the Svedman™ system; Mr. Burke replied that the odds were "very big" "100% no doubt about it," and that any product that "scratches the surface of [KCI's] patents" would be

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[3] KCI is run by an Executive Committee comprised of approximately ten officers.

the subject of a lawsuit. C.A.A.512, 530. Burke concluded by warning Tumey to steer clear of a NPWT device that is foam-based. C.A.A.512, 530.

4. KCI Documents Underscore the Significance of Girouard's and Burke's Statements.

The significance of Messrs. Girouard's and Burke's statements was confirmed by pre-suit awareness documents belatedly produced by KCI in the district court proceedings. Those documents show that KCI was aware of both of ITI's 510(k) submissions prior to ITI's conversations with both gentlemen, and that those submissions were discussed at no fewer than seven KCI Competitive Intelligence meetings in the Spring and Summer of 2007. *See generally* C.A.A.1318, 1426, 1462-1463, 1533-1534, 1600-1601, 1625-1626. The documents also show that ITI's use of a foam dressing became the subject of a KCI investigation in which KCI's Senior Marketing Manager concluded that the use of foam dressings in conjunction with NPWT is covered by KCI's patent estate. C.A.A.763.

B. The District Court Proceedings

On September 25, 2010, two days before the commercial launch of its Svedman™ system, ITI filed a declaratory judgment complaint in the United States District Court for the District of Delaware, where ITI and two of the three KCI respondents are incorporated. C.A.A.37. ITI's Original Complaint sought declarations that the KCI patents are invalid and not infringed by ITI's first product. C.A.A.41-45. KCI filed a motion to dismiss the Original Complaint.

While its motion to dismiss the Delaware action was pending, KCI filed a patent infringement lawsuit against ITI in the District Court for the Middle District of North Carolina, claiming that the Svedman™ system infringes three of the KCI patents, and a Texas state court trade secret and business tort suit against ITI and its principals. ITI subsequently filed an Amended Complaint incorporating, *inter alia*, the facts of that patent infringement suit and KCI's Texas state court suit. KCI withdrew its original motion to dismiss and refiled a new motion to dismiss.

The Magistrate Judge issued a Report and Recommendation ("Report") on July 14, 2008, recommending that the District Court grant KCI's motion and dismiss ITI's declaratory judgment action. 22a. The Report examined this Court's decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. 118 (2007), and the Federal Circuit's subsequent application of that decision in *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007). 34a-35a. The Magistrate Judge seized upon the Federal Circuit's statement in *SanDisk* that "declaratory judgment jurisdiction generally will not arise ... without some affirmative act by the patentee" and concluded that the District Court lacked subject matter jurisdiction because ITI had not demonstrated any "affirmative act" by KCI towards ITI. 37a-38a.

ITI timely filed objections to the Magistrate Judge's Report. The District Court disagreed with the reasoning set forth in the Report, rejecting the notion that declaratory judgment jurisdiction cannot arise without an "affirmative act" by the patentee towards the declaratory judgment plaintiff. 21a. Nonetheless, the District Court exercised its discretion to grant

KCI's motion to dismiss the entirety of the Amended Complaint. *Id.* The District Court summarily concluded that the exercise of its jurisdiction would not serve the objectives of the Declaratory Judgment Act: "I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." *Id.* The District Court accordingly dismissed ITI's declaratory judgment action and entered judgment for respondents. ITI appealed.

C. Court of Appeals Decision

The Federal Circuit, in an opinion by Judge Newman, joined by then-Chief Judge Michel and Judge Prost, affirmed the District Court's dismissal, applying the "affirmative act" jurisdictional rule announced in the *SanDisk* decision. 9a. According to that rule, "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *SanDisk*, 480 F.3d at 1380-81. The Federal Circuit held that the facts and circumstances of the case did not "meet the minimum standard discussed in *MedImmune*" "in the absence of any act directed toward ITI." 9a. The Federal Circuit also affirmed the District Court's discretionary dismissal. 12a (quoting District Court opinion).

VI.
REASONS FOR GRANTING THE WRIT

A. A Patentee Need Not Direct an Affirmative Act Toward a Potential Declaratory Judgment Plaintiff for Declaratory Judgment Subject Matter Jurisdiction to Exist Under Article III or the Declaratory Judgment Act.

In the wake of *MedImmune* and its rejection of the "reasonable apprehension of suit" standard for declaratory judgment subject matter jurisdiction, the Federal Circuit in *SanDisk* established a new rule for establishing such jurisdiction. Namely, the Federal Circuit held that "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some ***affirmative act*** by the patentee." *SanDisk*, 480 F.3d at 1380-81 (emphasis added). In contravention of *MedImmune*, the Federal Circuit erroneously applied the "affirmative act" test in this case, concluding that the facts and circumstances of the case did not "meet the minimum standard discussed in *MedImmune*" "in the absence of any act directed toward ITI." 9a.

1. This Court Rejected the "Reasonable Apprehension of Suit" Test, Which Included an Affirmative Act Requirement.

In creating the "affirmative act" test, the Federal Circuit erroneously sought to resurrect the "reasonable apprehension of suit" test under a different moniker,

ignoring this Court's unambiguous rejection of that test in *MedImmune*. Indeed, the Federal Circuit previously required an affirmative act to satisfy the "reasonable apprehension of suit" test: "***an explicit threat or other action by the patentee*** which creates a ***reasonable apprehension*** on the part of the declaratory judgment plaintiff that it will face an infringement suit." *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005) (emphases added). This Court in *MedImmune* not only rejected the "reasonable apprehension" test itself, but also the very formulation of the test enunciated in *Teva* that required an affirmative act. 549 U.S. at 132 n.11 (rejecting both the "reasonable apprehension of suit" test and what it called the "'reasonable apprehension of imminent suit' test [of] *Teva*") (citation omitted). Thus, the Federal Circuit's use of the "affirmative act" test in this case flies in the face of this Court's clear rejection of that requirement in *MedImmune*.

The Federal Circuit's application of an "affirmative act" test also conflicts with the United States' position in its Amicus Brief supporting the petitioner in *MedImmune*. The United States argued that the "reasonable apprehension of suit test" through its "overt act or other action by the patentee" requirement improperly required "the declaratory judgment plaintiff [to] already have taken steps that expose it to a risk of suit," "impermissibly limit[ing] the broad power of the federal courts to hear and decide concrete disputes between adverse parties in appropriate declaratory judgment actions." United States Amicus Br. at 15-16, *MedImmune, Inc. v. Genentech Inc.*, No. 05-608 (May 2006). Indeed, the Federal Circuit's application of the "affirmative act" test plainly subjects ITI and future declaratory judgment plaintiffs to the

Hobson's choice about which the United States warned. ITI was acutely aware of KCI's litigious history in the NPWT field and had already been warned by senior KCI decision-makers that KCI would sue if ITI launched its NPWT product. Yet under the Federal Circuit's ruling, ITI could not properly seek a declaratory judgment unless and until it received a letter from KCI's president or general counsel expressly threatening litigation. 7a ("these informal conversations did not constitute a threat of suit"). Waiting for such an affirmative act would needlessly expose ITI and other similarly situated declaratory judgment plaintiffs to the risk of suit and prevent federal courts from adjudicating actual controversies.

In short, the Federal Circuit's application of an "affirmative act" test contravenes the *MedImmune* Court's rejection of the "reasonable apprehension of suit" test.

2. The "Affirmative Act" Test Contravenes the "All the Circumstances" Standard For Determining Whether a Case or Controversy Exists.

The "affirmative act" rule also conflicts with this Court's rejection of rigid and formulaic jurisdictional tests in *MedImmune*. This Court made clear that the reasonable apprehension of suit standard was overly restrictive and thus inconsistent with the standards for Article III jurisdiction and the historical purpose of the Declaratory Judgment Act—to provide a challenger with an alternative to the Hobson's choice between "abandoning his rights or risking prosecution." *MedImmune*, 549 U.S. at 129-34; *see also id.* at 129 (Article III "d[oes] not require ... that

the plaintiff bet the farm, so to speak, by taking the violative action."). Furthermore, the Court specifically explained that there is no bright line test for determining the existence of an actual controversy. *Id.* at 127 ("*Aetna* and the cases following it do not draw the brightest of lines between declaratory-judgment actions that satisfy the case-or-controversy requirement and those that do not."). Indeed, this Court in *MedImmune* did not enunciate any specific factors that would tend to establish an actual controversy, much less articulate an "affirmative act" requirement.

This Court made clear that to establish subject matter jurisdiction, the declaratory judgment plaintiff need only satisfy the case-or-controversy requirements of Article III—standing and ripeness. *MedImmune,* 549 U.S. at 128 & n.8. The doctrines of standing and ripeness are pragmatic and look to the totality of circumstances surrounding a particular dispute:

> [T]he question in each case is whether the facts alleged, under ***all the circumstances***, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Id. at 127 (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)) (emphasis added). Thus, the Federal Circuit's singular focus on an "affirmative act" plainly contravenes *MedImmune*'s and its predecessors' consideration of "all the circumstances" when analyzing whether Article III's case or controversy requirement has been satisfied in the context of a declaratory judgment action.

Here, when considered together, all the circumstances demonstrate that an actual controversy existed at the time ITI filed its declaratory judgment action:

- A member of KCI's Executive Committee confirmed that the odds were 100% that KCI would sue if ITI launched a foam-based, NPWT device, which ITI made clear it intended to do (*supra* at 8-9);

- KCI had publicly articulated its corporate policy to aggressively enforce its patents in its 10-K filings, as well as its belief that its patents have broad applicability to NPWT devices (C.A.A. 192);

- KCI had previously sued all of its primary competitors in the chronic wound care market that had offered NPWT devices (*supra* at 5);

- KCI was aware of both of ITI's FDA submissions based upon discussions at KCI's regular Competitive Intelligence meetings (*supra* at 9);

- Two key KCI decision-makers, including a member of KCI's Executive Committee, had confirmed that KCI was not interested in a business relationship with ITI (*supra* at 7-9); and

- ITI was only days away from launching its new product, having received FDA approval, successfully completed clinical evaluations, entered into non-disclosure agreements with prospective purchasers and investors, and pre-marketed the device to prospective purchasers (C.A.A. 536-37, 1307).

Under these facts, there can be no doubt that, from the onset, ITI faced the *in terrorem* choice that the Declaratory Judgment Act was designed to relieve.

The Court should grant this petition to correct the Federal Circuit's failure to adhere to *MedImmune* and its disregard of the *MedImmune* Court's rejection of any affirmative act requirement for establishing declaratory judgment subject matter jurisdiction.

3. The Federal Circuit's Affirmative Act Rule Conflicts with Other Circuits' Correct Application of the Declaratory Judgment Subject Matter Jurisdiction Jurisprudence of this Court.

The Federal Circuit's application of the "affirmative act" rule for establishing declaratory judgment subject matter jurisdiction diverges from the well-traveled paths of other Circuits in applying the fundamental jurisdictional principles of *MedImmune* and its predecessors. In *MedImmune*, this Court reaffirmed the "all circumstances" standard first announced in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). This Court also explained that Congress intended the Declaratory Judgment Act to "ameliorate" the declaratory judgment plaintiff's "dilemma" posed by "cho[osing] between abandoning his rights or risking prosecution," and accordingly, that such plaintiffs need not "bet the farm" before seeking declaratory relief. *MedImmune*, 549 U.S. at 129, 134. In sharp contrast to these fundamental principles and their application by other Circuits, the Federal Circuit's "affirmative act" rule prevents a declaratory judgment plaintiff from clarifying his

rights when a patentee stops just short of an explicit threat of litigation.

In *Dewey & Almy Chemical Co. v. American Anode, Inc.*, 137 F.2d 68 (1943), the Third Circuit applied *Maryland Casualty* to resolve a strikingly similar patent dispute. Dewey engaged in certain commercial methods of producing rubber goods from latex that potentially infringed two of Anode's patents. *Id.* at 68-69. Anode had previously sued other manufacturers who used similar methods for infringement of the same patents. *Id.* at 70. Dewey sought a declaration of non-infringement under the Declaratory Judgment Act. However, the district court dismissed the suit for lack of jurisdiction, noting that Anode had not accused Dewey of infringement or threatened litigation. *Id.* In fact, American Anode purportedly did not even know that Dewey potentially infringed its patents until it read its complaint for declaratory relief. *Id.*

Reversing the district court, the Third Circuit disregarded Anode's lack of any affirmative act towards Dewey, explaining that "the fact that Anode had never made any direct threat to sue Dewey ... is not conclusive of the problem." *Id.* at 70. Instead, the Third Circuit focused on the patent owner's long history of infringement litigation as an "economic weapon." *Id.* In concluding that an actual controversy did indeed exist, the Third Circuit reasoned that the patent owner's prior litigation, which asserted a broad scope for its patent claims, constituted "equally effective notice to whom it may concern that they practise [sic] [the patented process] at their peril." *Id.* at 71.

The Fifth Circuit has also concluded that an affirmative act is not a predicate for declaratory judgment subject matter jurisdiction. In *Venator Group Specialty, Inc. v. Matthew / Muniot Family, LLC*, 322 F.3d 835 (5th Cir. 2003), a tenant sought declaratory relief three years before the termination of a lease to clarify whether it was required to make expensive alterations to the leased property. The terms of that lease obligated the tenant to make the alterations if the landlord so requested in writing sixty days before the lease terminated. The district court dismissed the declaratory judgment complaint for lack of jurisdiction, concluding that there was no controversy until the landlord requested the alterations to be made—an affirmative act. But the Fifth Circuit reversed, explaining that the district court must "necessarily assess the likelihood that future events will occur" and determine "whether an injury that has not yet occurred is significantly likely to happen to justify judicial intervention." *Id.* at 840. The Fifth Circuit held that the controversy was sufficiently immediate and real because the circumstances made it "very likely" that the landlord would invoke the challenged lease provision. *Id.* at 839-41.

Relying upon *Maryland Casualty*, the Ninth Circuit recently concluded that subject-matter jurisdiction existed over an employee's suit for declaratory relief from discriminatory practices, despite the fact that the employer had not specifically directed an affirmative act towards the employee. *Hulteen v. AT&T Corp.*, 498 F.3d 1001, 1004 n.1 (9th Cir. 2007) (en banc), *rev'd on other grounds*, 129 S. Ct. 1962 (2009). The Ninth Circuit reasoned that a sufficiently real and immediate controversy existed based on the employer's behavior

towards other employees. Thus, the employee faced a "real and immediate threat" of discrimination "given [her employer's] truculent refusal to credit [other] employees for their pre-PDA pregnancy leave in its benefits calculations." *Id.* Other Ninth Circuit cases have reached similar results. *See, e.g., Yahoo! Inc. v. La Ligue Contre Le Racisme Et L'Antisemitisme*, 433 F.3d 1199, 1211 (9th Cir. 2006) (per curiam) (declaratory challenge to enforceability of French court injunction was constitutionally ripe even though the French government had not sought to enforce it in the United States); *see also NBA v. SDC Basketball Club, Inc.*, 815 F.2d 562, 566 (9th Cir. 1987) (rejecting formulation of case and controversy requirement that would require the NBA to actually impose a fine or sanction before a declaratory judgment action could accrue, calling it the "type of Damoclean threat that the Declaratory Judgment Act is designed to avoid").

The Federal Circuit's "affirmative act" rule perpetuates the Hobson's choice that the Declaratory Judgment Act was intended to remedy. It permits a defendant to constrain otherwise lawful conduct while safely knowing its target cannot seek redress through declaratory relief. This result conflicts with other Circuits' faithful application of this Court's Article III jurisprudence set forth in *MedImmune* and its predecessor *Maryland Casualty*. Accordingly, the Court should grant the petition.

B. *MedImmune* and Its Predecessors Make Clear that an Actual Controversy Exists Even If a Patentee Purportedly Could Not Have Sued the Declaratory Judgment Plaintiff

The Federal Circuit incorrectly concluded that there was no actual controversy based upon the District Court's finding and KCI's argument that KCI could not have sued ITI for patent infringement at the time ITI filed its declaratory judgment action because KCI had never physically seen ITI's product. 4a ("KCI had not seen any device produced or intended to be produced by ITI ... and KCI had not charged ITI with infringement as to any such device"), 7a ("informal conversations did not constitute a threat of suit ... against a device that had not been seen and evaluated for infringement"). But, as explained above, this Court in *MedImmune* rejected such categorical rules, concluding instead that a declaratory judgment plaintiff need only satisfy the constitutional requirement to show the existence of a real and imminent dispute. 549 U.S. at 127. Moreover, this Court in *MedImmune* and predecessor cases made clear that the existence of an actual controversy is not predicated upon a patentee's ability or intent to bring a cause of action against the declaratory judgment plaintiff.

In abrogating the reasonable apprehension of suit test, this Court in *MedImmune* specifically rejected the argument that a case or controversy cannot exist where a patentee is unable to sue the declaratory judgment plaintiff. *Id.* at 132 n.11. Indeed, the patentee in *MedImmune* argued that declaratory judgment jurisdiction did not exist because the

declaratory judgment plaintiff had continued to pay royalties under a patent licensing agreement, and therefore, the patentee could not have filed suit for patent infringement. *Id.* at 134-35. This Court relied on its previous precedent to show that no such requirement existed, explaining that in *Maryland Casualty*, 312 U.S. at 273, "jurisdiction obtained even though the collision-victim defendant could not have sued the declaratory-judgment plaintiff-insurer without first obtaining a judgment against the insured." *MedImmune*, 549 U.S. at 132 n.11. Similarly, this Court has also made clear that declaratory judgment jurisdiction can exist even if there is no indication that a declaratory judgment defendant intends to file suit. For example, in *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 239 (1937), "jurisdiction obtained even though the very reason the insurer sought declaratory relief was that the insured had given no indication that he would file suit." *MedImmune*, 549 U.S. at 132 n.11.

This Court should grant this petition to reject any notion that the existence of an actual controversy depends on whether the patentee has the present ability or intent to sue the declaratory judgment plaintiff for patent infringement. Such a requirement could be easily manipulated by patentees. For example, a patentee could delay filing suit in purposeful ignorance of a potentially infringing product and allow significant damages to accrue while the potential infringer would have no recourse to bring a declaratory judgment action. That result would be antithetical to the purpose of the Declaratory Judgment Act—to remove the Damoclean threat of suit by providing a potential infringer with relief from uncertainty and delay regarding its legal rights. A

potential infringer should be able to take the initiative by filing a declaratory judgment complaint to resolve its conflict with a patentee without waiting for the patentee to initiate an action at a time and in a manner that the patentee deems suitable. *MedImmune*, 549 U.S. at 132 n.11.

C. District Courts Do Not Have Unfettered Discretion to Dismiss Declaratory Judgment Actions Where an Actual Controversy Exists

The Declaratory Judgment Act provides that a district court "***may*** declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a) (emphasis added). Although the Declaratory Judgment Act confers upon a district court a measure of discretion in deciding whether to hear a declaratory judgment action, that discretion is not unbounded. Here, the District Court abused its discretion in dismissing ITI's declaratory judgment complaint, and the Federal Circuit erred in affirming the discretionary dismissal.

This Court has not spoken directly on the issue of the proper exercise of discretion in dismissing a declaratory judgment action involving a purely federal question, or more specifically, a patent dispute. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 290 (1995) ("We do not attempt at this time to delineate the outer boundaries of ... discretion in other cases, for example, cases raising issue of federal law."); *MedImmune*, 549 U.S. at 136 ("leav[ing] the equitable, prudential, and policy arguments in favor of ... a discretionary dismissal" in a declaratory judgment patent action to the district court in the first instance). However, the

legislative history and jurisprudence of this Court and the Courts of Appeals provide a framework for assessing the District Court's discretionary dismissal.

The Report of the Senate Judiciary Committee analyzing the then soon-to-be-enacted Declaratory Judgment Act stated that courts would have discretion not to entertain a declaratory judgment "'if it will not finally settle the rights of the parties.'" *Aetna Cas. & Sur. Co. v. Quarles*, 92 F.2d 321, 324 (4th Cir. 1937) (quoting Senate Report No. 1005, 73d Cong., 2d Sess. (May 10, 1934)). Over the years, this Court has delineated the bounds of discretion to dismiss a declaratory judgment action. As an initial matter, a court "cannot decline to entertain such an action as a matter of whim or personal disinclination." *Pub. Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962). This Court has affirmed courts' exercise of discretion to dismiss declaratory judgment actions that would involve "futile or premature interventions," *Public Service Comm'n v. Wycoff Co.*, 344 U.S. 237, 243 (1952), or where a dispute could "better be settled in the proceeding pending in [a] state court," *Brillhart v. Excess Ins. Co.*, 316 U.S. 495 (1942). And, certain Courts of Appeals have analyzed discretionary dismissals under the rubric of whether the declaratory judgment action in question would serve the objectives of the Declaratory Judgment Act. *See, e.g.*, *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) ("[W]hether hearing the case would serve the objectives for which the Declaratory Judgment Act was created.") (internal quotation omitted); *Quarles*, 92 F.2d at 324 ("[D]iscretion should be liberally exercised to effectuate the purposes of the statute and thereby afford relief from uncertainty and insecurity.").

In this case, the District Court summarily concluded that the exercise of its jurisdiction would not serve the objectives of the Declaratory Judgment Act: "I am not convinced that the objectives of the Declaratory Judgment Act are being served by allowing such a plaintiff to plead uncertainty and delay." 14a. Significantly, that conclusion cannot be squared with the opening sentence of the District Court's opinion that "[t]his case arguably presents a situation meant to be addressed by the Declaratory Judgment Act," and the District Court failed to provide any explanation for its decision. 18a. Thus, the District Court's unexplained discretionary dismissal plainly falls into the category of "whim[sical]" dismissal, *Rickover*, 369 U.S. at 112, and therefore constitutes an abuse of discretion.

The District Court's discretionary dismissal of ITI's declaratory judgment patent counts also clearly conflicts with the objectives of the Declaratory Judgment Act. On the eve of the commercial launch of its first product, ITI was faced with the choice of accruing potential damages or abandoning its activities. Indeed, one of KCI's Executive Committee members handicapped the odds of suit at "100%" if ITI launched its foam-based NPWT product, and KCI had already sued every competitor that dared to enter the market with such a product. *Supra* at 15-16. This Court explained that such an *in terrorem* choice is precisely what the Declaratory Judgment Act was designed to prevent. *MedImmune*, 549 U.S. at 134 (recognizing that "[a] plaintiff need not 'bet the farm, or ... risk treble damages" before seeking a declaration of its actively contested legal rights). A declaratory judgment plaintiff, such as ITI, should not be blocked from removing a litigious patentee's Damoclean threat

of suit by a district court's whimsical exercise of discretionary dismissal.

The Federal Circuit erred by effectively failing to review the discretionary dismissal. As an initial matter, the Federal Circuit merely restated the District Court's rationale for the discretionary dismissal—ITI's pre-suit conduct somehow did not comport with the objectives of the Declaratory Judgment Act—and concluded that the rationale was not an abuse of discretion. 12a-13a. The Federal Circuit also failed to review the District Court's discretionary dismissal under its own controlling precedent.

The Federal Circuit previously ruled that in deciding whether to exercise its discretion, a district court must determine "whether hearing the case would serve the objectives for which the Declaratory Judgment Act was created." *Micron*, 518 F.3d at 902 (internal quotation omitted). Indeed, the Federal Circuit explained that if the objectives of the Act are served, dismissal is "rarely" appropriate. *Id.* But the District Court and the Federal Circuit erroneously focused on ITI's pre-suit conduct, which has no bearing on whether the declaratory judgment action was consistent with the purposes of the Act. Had the Federal Circuit applied the correct standard, it should have reversed the District Court's discretionary dismissal.

Judge Friendly famously announced that "[j]udicial and academic statements with respect to the discretion of the trial court under the Federal Declaratory Judgment Act can be described as 'curiouser and curiouser.'" Henry J. Friendly, *Indiscretion About*

Discretion, 31 Emory L.J. 747, 778 (1982). More than two decades later, the legal standard for discretionary dismissals of declaratory judgment actions involving patent disputes remains just as murky. As noted above, the Court has not spoken directly on this issue. Therefore, the Court should grant this petition to clarify the correct legal standard for analyzing discretionary dismissals of declaratory judgment complaints involving patent disputes.

VII.
CONCLUSION

For the foregoing reasons, this Court should grant ITI's petition for writ of certiorari.

Respectfully submitted,

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