

DECLARATORY RELIEF AFTER *MEDIMMUNE*

by
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In MedImmune, Inc. v. Genentech, Inc., the Supreme Court of the United States rejected the Federal Circuit’s “reasonable apprehension of imminent suit” test for determining the existence of a justiciable controversy in actions for declaratory relief involving alleged or potential patent infringement. The Supreme Court substituted the totality-of-circumstances test, which has long been used trans-substantively in actions for declaratory relief. Justice Clarence Thomas, the lone dissenter, contended that the majority’s holding would allow parties to seek improper advisory opinions. This Article evaluates MedImmune’s impact on declaratory judgment actions in patent litigation and considers whether Justice Thomas’s prediction was accurate. To do so, this Article compares how the Federal Circuit and other federal courts addressed justiciability in patent cases in the three years before and after the Supreme Court announced its MedImmune decision in January 2007. The Article also examines how lower courts have (and have not) utilized their discretion to decline to hear actions for declaratory relief in patent litigation. In sum, MedImmune appears to have had the results desired by the Court majority: (1) Parties can more easily demonstrate the existence of a controversy in order to question arguably coercive measures by patentees in court; and (2) The lower courts have adhered to a reasonable notion of when a sufficiently concrete controversy exists, even though they have not utilized the discretion to decline actions for declaratory relief as often as they might. Justice Thomas’s concern that MedImmune would unleash a torrent of hypothetical actions in and out of the realm of patent litigation does not appear to be coming to fruition.

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I. INTRODUCTION

Every law student learns that the United States Constitution permits federal courts to hear only “cases . . . [or] controversies.”¹ Thus, it has long been understood that parties cannot obtain opinions on hypothetical questions from federal courts.² Operating on the edge of this requirement, actions for declaratory relief nevertheless enable courts to determine the duties, rights, obligations, and status of parties before any harm has occurred and without making an award of damages to any party.³ Because a declaratory judgment clarifies the relationship between litigants, it is a useful tool for parties who want to determine the nature

¹ U.S. CONST. art. III, § 2, cl. 1.

² See, e.g., *Pelham v. Rose*, 76 U.S. (9 Wall.) 103, 107 (1870).

³ See, e.g., DAVID I. LEVINE ET AL., *REMEDIES: PUBLIC AND PRIVATE* 415–40 (5th ed. 2009).

of any obligations they may have to one another. More contentious litigation (and higher stakes, such as punitive damages or criminal prosecution) may be avoided, abandoned, or settled if the court renders a declaratory judgment that enables the parties to proceed accordingly.

Actions for declaratory relief are particularly common in patent litigation because of the large costs involved and the potential for substantial damages. For instance, if a patent owner is aware of a potential infringer, the patent owner can wait to bring a suit of infringement while the monetary damages increase, but the (increasingly liable) potential infringer would have no recourse to rectify the situation. In this instance, declaratory relief would allow a potential infringer to determine quickly whether it was in fact infringing on the patent and to mitigate potential damages. Another common situation is a manufacturer who would hesitate to make a major investment if it risked a ruinous infringement suit later. As a result, both licensees and non-licensees find it useful to seek declaratory relief to protect against potential suits of infringement by patentees.⁴

The Supreme Court has returned from time to time to the question of when parties may seek declaratory relief, while meeting the case or controversy requirement, ever since it upheld the constitutionality of the Declaratory Judgment Act in 1937.⁵ *MedImmune, Inc. v. Genentech, Inc.*⁶ is one of the latest examples. *MedImmune*, which was a closely followed case,⁷ addressed whether a justiciable controversy existed when the party

⁴ Chief Judge Howard Markey more colorfully described the situation as: “[T]he sad and saddening scenario that led to enactment of the Declaratory Judgment Act. In the patent version of that scenario, a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword. Guerrilla-like, the patent owner attempts extra-judicial patent enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity. Before the Act, competitors victimized by that tactic were rendered helpless and immobile so long as the patent owner refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an *in terrorem* choice between the incurrance of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests.” *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734–35 (Fed. Cir. 1988) (citations omitted).

⁵ Federal Declaratory Judgment Act of 1934, Pub. L. No. 73-343 (current version at 28 U.S.C. § 2201 (2006)); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239–40 (1937); *Am. Life Ins. Co. v. Stewart*, 300 U.S. 203, 212 (1937).

⁶ 127 S. Ct. 764 (2007).

⁷ *MedImmune* generated substantial attention from court observers, particularly in the patent law field. Examples of websites and blogs that detailed the Court’s decision and traced its effects in the lower courts ranged from personal blog websites, e.g., Posting of Joseph Scott to The Fire of Genius, <http://www.thefireofgenius.com/declaratory-judgment/> (Jan. 10, 2007), to websites more dedicated to patent law, e.g., Posting of Aaron Barkoff to Orange Book Blog, http://www.orangebookblog.com/2007/01/supreme_court_r.html (Jan. 9, 2007); Posting of Dennis Crouch to Patently-O Blog, http://patentlaw.typepad.com/patent/2006/02/supreme_court_t.html (Feb. 22, 2006); Posting of Kevin Noonan to Patent Docs, http://patentdocs.typepad.com/patent_docs/2007/01/medimmune_inc_v.html (Jan. 9, 2007). *See also*

seeking declaratory relief was a *non-repudiating* licensee. The Supreme Court, in an eight-to-one decision written by Justice Antonin Scalia, held that such a licensee could demonstrate the existence of a controversy⁸ without repudiating the agreement.⁹ In doing so, the Court rejected the Federal Circuit's "reasonable apprehension of imminent suit" test.¹⁰ In its place, the Court substituted an older, and broader, totality-of-circumstances test,¹¹ which has been used commonly in actions for declaratory relief to determine whether a controversy exists.¹² Justice Clarence Thomas, the lone dissenter, contended that the majority's holding opened the door for parties to seek advisory opinions¹³ even beyond patent litigation because it "contain[ed] no limiting principle whatsoever."¹⁴

This Article evaluates *MedImmune's* impact on declaratory judgment actions in patent litigation, and considers whether Justice Thomas's prediction of near-disaster was prescient.¹⁵ To do so, the Article traces the impact of *MedImmune* in conventional patent litigation and in the regulated procedures under the federal Food and Drug Administration.

Transcript of Oral Argument, *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007) (No. 05-608), *reprinted in* 26 BIOTECH L. REP. 155 (2007).

⁸ An action for declaratory relief is, technically speaking, a "controversy," rather than a "case." *Aetna Life Ins. Co.*, 300 U.S. at 239–40.

⁹ *MedImmune*, 127 S. Ct. at 767–77.

¹⁰ *Id.* at 768, 774 n.11. The Federal Circuit originally used the phrase "reasonable apprehension," but it evolved into the "reasonable apprehension of imminent suit" test. *Compare, e.g.,* *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1398 (Fed. Cir. 1984), *with* *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007).

¹¹ *MedImmune*, 127 S. Ct. at 771.

¹² *See id.* at 773 (citing cases).

¹³ *Id.* at 777 (Thomas, J., dissenting).

¹⁴ *Id.* at 782.

¹⁵ Justice Thomas did not remain alone in this view once the decision was released. For a collection of comments predicting that *MedImmune* "would 'open the floodgates' to increased filings of declaratory judgment actions in patent cases," see Ronald A. Bleeker & Michael V. O'Shaughnessy, *One Year After MedImmune—The Impact on Patent Licensing & Negotiation*, 17 FED. CIR. B.J. 401, 401 & n.2 (2008). *See also* Katherine A. Helm & Gene W. Lee, *Call It a Comeback: A Sweeping Change in the Law on Declaratory Judgment Actions Against Patent Owners*, 64 N.Y.U. ANN. SURV. AM. L. 231, 245 (2008) (*MedImmune* "kicked open the courthouse door for both licensees and prospective licensees"); Richard Weil Goldstucker, Note, *Stop the Bleeding: MedImmune Ends the Unjustified Erosion of Patent Holders' Rights in Patent Licensing Agreements*, 16 J. INTELL. PROP. L. 137, 139 (2008) ("The *MedImmune* decision, on its face, has left patent holders defenseless. Licensees can negotiate a patent license and face no risk in challenging the validity of the patent."); Peter Jay, Note, *Removing Incentives for Technology Transfer: MedImmune v. Genentech*, 5 BUFF. INTELL. PROP. L.J. 69, 70 (2007) (*MedImmune's* "likely result will be a chilling of licensing practices"); Jonathan S. Pope, Comment, *Declaratory Judgment Jurisdiction in Patent Disputes: A Rock and a Hard Place*, 9 J. MARSHALL REV. INTELL. PROP. L. 583, 599 (2010) (*MedImmune* "reduces the value of the patent," which "discourages inventors from applying for patents and potentially decreases the pool of knowledge that the patent system discloses").

The analysis addresses whether, under *MedImmune*: (1) the Federal Circuit and district courts have begun to grant declaratory relief in cases stretching the controversy requirement to include far-fetched circumstances; and (2) whether there has been a rapid increase in declaratory relief actions.¹⁶

This analysis concludes that Justice Thomas's critique was accurate in part. The Court's loosening (or, as he contends, its lack) of limiting principles¹⁷ certainly lowers the burden placed upon the party seeking declaratory relief—and consequently increases the burden on the declaratory relief defendant to demonstrate there is no actual controversy. Before *MedImmune*, a declaratory relief plaintiff was required to demonstrate the *probability* of suit, which was a fairly high hurdle to overcome. But *MedImmune* lowered the hurdle, such that the declaratory relief plaintiff need only demonstrate the *potential* for suit. As a result, there is an increased chance that a court may render an opinion which proves to be hypothetical. This critique aside, the courts applying *MedImmune* so far appear to have managed to adhere to the separation they must keep between real and hypothetical controversies. Furthermore, while *MedImmune* has spread to areas of law outside of patent litigation, this outgrowth has been limited. Thus, Justice Thomas's broader critique, that *MedImmune* would unleash a torrent of hypothetical actions, does not seem to be coming to fruition.

The Article contains the following parts: Part II reviews the facts surrounding *MedImmune* and the Federal Circuit's application of the reasonable apprehension of imminent suit test. Part III summarizes the majority and dissenting opinions in *MedImmune* and examines the Court's rejection of the Federal Circuit's reasonable apprehension of imminent suit test in favor of the trans-substantive totality-of-circumstances test. Part IV assesses "Life after *MedImmune*." It addresses how the Federal Circuit and other federal courts have applied the new test the Supreme Court announced in January 2007 in *MedImmune* while deciding whether to grant declaratory relief both within and beyond patent litigation. It includes discussion of how lower courts have utilized the discretion to decline to hear actions for declaratory relief in patent litigation. Finally, Part V concludes the Article by addressing to what degree Justice Thomas's critique of Justice Scalia's majority opinion has proven to be true. It raises suggestions of how the courts might establish some limiting principles under the *MedImmune* regime to maintain an appropriate burden on the party seeking declaratory relief, in order to be sure that only true controversies are brought into the judicial arena.

¹⁶ Also relevant is whether the district courts have appropriately exercised the discretion available to choose not to proceed in an action seeking declaratory relief. The action for declaratory relief is unusual because, even where an actual controversy exists and there is jurisdiction over the claim and the parties, the trial court may decline to hear a declaratory judgment action. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995). See *infra* text accompanying notes 245–51.

¹⁷ *MedImmune*, 127 S. Ct. at 782 (Thomas, J., dissenting).

II. *MEDIMMUNE* AND THE REASONABLE APPREHENSION OF IMMINENT SUIT TEST

The business relationship between MedImmune and Genentech began harmoniously. The two biotech companies signed a licensing agreement in 1997 that covered an existing patent and a then-pending patent application.¹⁸ Genentech's existing patent covered the production of chimeric antibodies¹⁹ and its pending patent related to the co-expression of immunoglobulin chains²⁰ in recombinant host cells.²¹ In 2001, Genentech's pending patent (the co-expression application "covered by the 1997 license agreement"), "matured into" its Cabilly II patent.²² Soon after, Genentech informed MedImmune of its belief that MedImmune's drug Synagis²³ "was covered by the Cabilly II patent and its expectation that [MedImmune] would pay royalties beginning March 1, 2002."²⁴

Disputing Genentech's claim, MedImmune filed a declaratory judgment action that challenged the validity of the Cabilly II patent.²⁵ Although it continued to pay all the royalties Genentech claimed under the license agreement, MedImmune contended that the Cabilly II patent was invalid and that the portion of the agreement referring to "the coexpression of immunoglobulin chains in recombinant host cells" was

¹⁸ *Id.* at 767–68 (majority opinion).

¹⁹ A basic medical text explains: "*Antibodies* are complex glycoproteins (also called *immunoglobulins*) that are produced by mature B lymphocytes, circulate in body fluids, and are secreted on mucosal surfaces. Antibodies specifically recognize and bind to foreign antigens." HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 750 (Anthony S. Fauci et al. eds., 17th ed. 2008). A Genentech website defines chimeric antibodies as "A genetically engineered fusion of parts of a mouse antibody with parts of a human antibody. Generally, chimeric antibodies contain approximately 33% mouse protein and 67% human protein. Developed to reduce the HAMA [Human Anti-Mouse Antibodies] response elicited by murine antibodies, they combine the specificity of the murine antibody with the efficient human immune system interaction of a human antibody. However, chimeric antibodies can exhibit a HACA response (Human Anti-Chimeric Antibodies; similar to HAMA response) and thereby may show reduced efficacy as a therapeutic." GENENTECH, ANTIBODY TECHNOLOGY: GLOSSARY OF TERMS (2003), <http://www.gene.com/gene/news/kits/science/pdf/antibodyglossary.pdf>.

²⁰ HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, *supra* note 19, at 2035 ("Immunoglobulins are the products of differentiated B cells and mediate the humoral arm of the immune response. . . . All immunoglobulins have the basic structure of two heavy and two light chains." (paragraph break and citation omitted)).

²¹ *MedImmune*, 127 S. Ct. at 768.

²² *Id.*

²³ Synagis is a medication injected for the prevention of respiratory syncytial virus disease in high risk infants and children. See RxList, Synagis: Drug Description, <http://www.rxlist.com/synagis-drug.htm> ("Indications & Dosage").

²⁴ *MedImmune*, 127 S. Ct. at 768.

²⁵ *Id.*

unenforceable.²⁶ Further, MedImmune contended that, in any event, Synagis did not infringe on the claims covered in the Cabilly II patent.²⁷

In support of its contention that a controversy between the parties had arisen, MedImmune asserted that Genentech's letter was "a clear threat to enforce the Cabilly II patent, terminate the 1997 license agreement, and sue for patent infringement if [MedImmune] did not make royalty payments as demanded."²⁸ MedImmune also contended that any potential lawsuit launched by Genentech was a substantial threat. If Genentech succeeded in demonstrating that Synagis infringed on the Cabilly II patent, MedImmune could be ordered "to pay treble damages and attorney's fees, and could be enjoined from selling Synagis, a product that [accounts] for more than 80 percent of its revenue from sales since 1999."²⁹ Judge Mariana Pfalzer of the Central District of California dismissed the action for declaratory relief for lack of subject matter jurisdiction because MedImmune did not have a reasonable apprehension of an imminent suit.³⁰

The Federal Circuit affirmed the district court on appeal.³¹ In evaluating the circumstances surrounding MedImmune's declaratory relief action, Judge Pauline Newman, writing for the Federal Circuit panel, applied the court's reasonable apprehension of imminent suit test.³² The Federal Circuit first articulated the reasonable apprehension of imminent suit test in *BP Chemicals Ltd. v. Union Carbide Corp.*,³³ where it explained that:

[a party seeking jurisdiction must show that there is] both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with intent to conduct such activity.³⁴

This test divides the assessment of the litigants' conduct into two parts.³⁵ The first part is an objective analysis of the conduct of the

²⁶ *Id.*

²⁷ *Id.* at 769.

²⁸ *Id.* at 768.

²⁹ *Id.*

³⁰ *Id.*; see also *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567 MRP (CTX), 2004 WL 3770589, at *6 (C.D. Cal. Apr. 26, 2004), *aff'd*, 427 F.3d 958 (Fed. Cir. 2005), *rev'd*, 127 S. Ct. 764. The district court relied upon *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004).

³¹ *MedImmune*, 427 F.3d at 965.

³² *Id.* at 961, 965.

³³ 4 F.3d 975 (Fed. Cir. 1993).

³⁴ *Id.* at 978 (citation omitted).

³⁵ See, e.g., *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, No. Civ. 05-2881 JLL, 2005 WL 3619389, at *2 (D.N.J. Dec. 12, 2005), *rev'd*, 482 F.3d 1330 (Fed. Cir. 2007) (citing *BP Chems. Ltd.*, 4 F.3d at 978).

patentee.³⁶ The second part focuses on the conduct of the accused infringing party.³⁷

Applying this test as used in *B.P. Chemicals Ltd.* and subsequent cases such as *Gen-Probe Inc. v. Vysis, Inc.*,³⁸ the Federal Circuit found MedImmune failed to demonstrate a reasonable apprehension of suit because it continued to pay the royalties.³⁹ Genentech had not threatened to sue MedImmune, and there had been no “change in circumstances which affected performance of the contract”⁴⁰ In concluding, the Federal Circuit stated, “[l]icensors and licensee always have ‘adverse legal interests,’ but that relationship alone does not create a justiciable controversy. The Declaratory Judgment Act requires a ‘definite and concrete controversy.’”⁴¹ MedImmune, it concluded, had not met this requirement.

After the Federal Circuit’s ruling, MedImmune sought further review. The Supreme Court granted certiorari “to decide whether . . . the ‘actual controversy’ requirement of the Declaratory Judgment Act . . . requires a patent licensee to terminate or be in breach of this license agreement before it can seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed.”⁴²

III. THE SUPREME COURT’S ANALYSIS IN *MEDIMMUNE*

The Supreme Court overturned the Federal Circuit in an eight-to-one ruling with Justice Scalia writing the majority opinion.⁴³ In its opinion, the majority established what it saw as the correct framework for analyzing declaratory judgment actions in patent litigation. First, the Court rejected the Federal Circuit’s reliance on *Gen-Probe Inc. v. Vysis, Inc.*,⁴⁴ in favor of the Court’s own opinion in *Altwater v. Freeman*.⁴⁵ In so

³⁶ *MedImmune* reflected a common issue between licensees and patentees. Generally, in patent litigation commenced as an action for declaratory judgment, the patentee is the defendant because the declaratory relief sought by the plaintiff is invalidation of a patent in response to alleged patent infringement.

³⁷ As the Federal Circuit put it, “[t]he element of threat or reasonable apprehension of suit turns on the conduct of the patentee, while the infringement element depends on the conduct of the asserted infringer.” *BP Chems.*, 4 F.3d at 978 (citation omitted).

³⁸ *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004).

³⁹ *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964 (Fed. Cir. 2005), *rev’d*, 127 S. Ct. 764 (2007).

⁴⁰ *Id.*

⁴¹ *Id.* (citations omitted).

⁴² *MedImmune*, 127 S. Ct. at 767.

⁴³ *Id.*

⁴⁴ *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004).

⁴⁵ In *Altwater v. Freeman*, 319 U.S. 359 (1943), several patentees sued their licensees to enforce territorial restrictions in the license. The licensees filed a counterclaim that the underlying patents were invalid but continued to pay royalties “under protest.” The royalties were required by an injunction that the patentees had obtained in a prior action. *Id.* at 360, 365. The Court held “that a licensee’s failure to

doing, the Court expanded the notion of coercion in patent litigation outside of government actions to private party contracts.⁴⁶ Second, the Court did away with the Federal Circuit's reasonable apprehension of imminent suit test. Justice Scalia's majority opinion found that the reasonable apprehension of imminent suit test conflicted with the Court's precedent defining coercion.⁴⁷

A. *The Majority Opinion*

Because a declaratory judgment requires a ripe controversy, *MedImmune* presented an interesting claim: Does a controversy exist if the claimant is continuing to pay the agreed-upon royalties, thereby insuring itself against a suit of (in this case) patent infringement by the defendant? Thus, a controversy existed only if *MedImmune's* continued payments were the result of coercion, or of a threat of retaliation by Genentech for failure to pay. Justice Scalia's opinion found coercion could exist because a license agreement does not preclude the existence of a controversy.⁴⁸

1. *Coercion Between Private Parties: Altwater v. Freeman*

The Court's analysis in *MedImmune* began by examining coercion in the context of threatened action by the government. Where threatened action by the government exists, a plaintiff is not required "to expose himself to liability before bringing suit to challenge the basis for the threat."⁴⁹ Justice Scalia cited Justice Rehnquist's concurrence in *Steffel v. Thompson*,⁵⁰ stating, "the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity."⁵¹ Thus, where a plaintiff "eliminated the imminent threat of harm by simply not doing what he claimed the right to do . . . [t]hat did not preclude subject-matter jurisdiction because the threat-eliminating behavior was effectively coerced."⁵²

Consequently, declaratory relief is rare in situations where the "plaintiff's self-avoidance of imminent injury is coerced by threatened

cease its payment of royalties did not render nonjusticiable a dispute over the validity of the patent." *MedImmune*, 127 S. Ct. at 773 (citing *Altwater*, 319 U.S. at 364).

⁴⁶ See *MedImmune*, 127 S. Ct. at 772–73; and *id.* at 781–82 (Thomas, J., dissenting).

⁴⁷ *Id.* at 774 n.11 (majority opinion).

⁴⁸ *Id.* at 776.

⁴⁹ *Id.* at 772.

⁵⁰ 415 U.S. 452, 478 (1974) (Rehnquist, J., concurring). In *Steffel*, the local police threatened to arrest the plaintiff, who sought to distribute handbills against U.S. involvement in Vietnam on an exterior sidewalk of a shopping mall. The Court held that the plaintiff had pleaded an actual controversy because the threats of prosecution were real, and it was unnecessary for the plaintiff to expose himself to actual arrest in order to make a constitutional challenge. *Id.* at 459 (majority opinion).

⁵¹ *MedImmune*, 127 S. Ct. at 772 (quoting *Steffel*, 415 U.S. at 480 (Rehnquist, J., concurring)).

⁵² *Id.* (citations omitted).

enforcement action of a *private party* rather than the government.”⁵³ In such situations, the plaintiff’s actions to prevent injury may remove the ability to demonstrate a controversy; for example, by ceasing to engage in the disputed behavior. This is not to say, however, that jurisdiction in such circumstances was non-existent. Lower courts “have long accepted jurisdiction in such cases,”⁵⁴ and the best applicable instance in Supreme Court precedent, *Altwater v. Freeman*, was “fortuitously, close on its facts” to *MedImmune’s*.⁵⁵ Justice Scalia’s conclusion contrasted sharply with Judge Newman’s opinion for the Federal Circuit, which distinguished *Altwater* from *MedImmune* because *Altwater* “involved the compulsion of an injunction.”⁵⁶

Rejecting the Federal Circuit’s analysis, the Supreme Court found *Altwater* could not be distinguished as precedent merely because it involved the compulsion of an injunction.⁵⁷ First, the injunction in *Altwater* was “privately obtained” and thus within the “control of the patentees.”⁵⁸ As a result, the patentees “could permit its modification.”⁵⁹ Second, *Altwater* “did not say that the coercion dispositive of the case was governmental, but suggested just the opposite.”⁶⁰ Although “licensees had the option [to cease payments] . . . the consequence of doing so would be to risk” treble damages.⁶¹ And third, the Court in *Altwater* approvingly cited a 1913 treatise for the proposition “that an ‘actual or threatened serious injury to business or employment’ by a private party can be as coercive as other forms of coercion.”⁶² Therefore, Justice Scalia concluded, coercion can exist where initiatives by a private party threaten the existence of, or extensive damage to, a business.⁶³

2. License Agreements Do Not Preclude a Case or Controversy

In completing its opinion, the Court dismissed three arguments raised by Genentech. First, the Court rejected the contention that a license agreement provides immunity from suits of infringement.⁶⁴ Moreover, the Court noted the lack of an explicit prohibition against a licensee’s challenging the validity of patents where “pay[ing] royalties on

⁵³ *Id.* at 773.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Compare *id.* at 774 with *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 961 (Fed. Cir. 2005).

⁵⁷ *MedImmune*, 127 S. Ct. at 774.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* (emphasis omitted).

⁶² *Id.* (citing FREDERICK CAMPBELL WOODWARD, THE LAW OF QUASI CONTRACTS § 218 (5) (1913)).

⁶³ *Id.* at 775.

⁶⁴ *Id.* at 775–76.

patents that have not been held invalid does not amount to a promise not to seek a holding of their invalidity.”⁶⁵

Next, the Court dismissed the contention that a license agreement precludes a challenge to a patent’s validity. Justice Scalia agreed with MedImmune that, “the contract, properly interpreted, does not prevent it from challenging the patents.”⁶⁶ Moreover, the Court noted that, even if common law or the license agreement did preclude the suit, Genentech would “win this case *on the merits*—not that the very genuine contract dispute disappears, so that Article III jurisdiction is somehow defeated.”⁶⁷

Finally, the Court declined to simply dismiss the case on discretionary grounds.⁶⁸ Instead, the Court remanded to the district court for further proceedings “because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within [its] grasp.”⁶⁹ In concluding, the Court reversed the Federal Circuit and remanded for further proceedings because MedImmune was not required to breach the license agreement before seeking declaratory relief.⁷⁰

B. Justice Thomas’s Dissent

Justice Thomas critiqued the Court’s ruling as conceptually incorrect and against the force of precedent. He presented three arguments: (1) MedImmune lacked standing because its claim was for a hypothetical ruling; (2) the Court’s rationale improperly extended principles of coercion to voluntarily entered private contracts; and (3) the lack of an actual controversy precluded a declaratory judgment.⁷¹

1. *MedImmune Lacked Standing to Bring Suit*

Justice Thomas began his criticism by asserting that MedImmune’s action was “not a justiciable case or controversy under Article III.”⁷² MedImmune, Justice Thomas argued, was not under a threat of suit by Genentech because the license agreement had not been breached. Further, MedImmune had no cause of action against Genentech because a claim of patent invalidity is merely an affirmative defense to a patent

⁶⁵ *Id.* at 776 (emphasis omitted).

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ “The Declaratory Judgment Act . . . has long been understood ‘to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants.’” *Id.* (quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995)).

⁶⁹ *Id.* (quoting *Wilton*, 515 U.S. at 289).

⁷⁰ *MedImmune*, 127 S. Ct. at 777. On remand, the district court held that under the Supreme Court’s test, it did have jurisdiction over MedImmune’s cause of action for declaratory relief regarding the status of Synagis and the Cabilly II patent. *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000 (C.D. Cal. 2008).

⁷¹ *MedImmune*, 127 S. Ct. at 777 (Thomas, J., dissenting).

⁷² *Id.* at 779.

infringement suit.⁷³ Thus, in finding the requisite controversy, the Court had to import an underlying contract claim that MedImmune had failed to put forth in its briefs or at oral argument, but had been raised by an amicus.⁷⁴

Justice Scalia responded that Justice Thomas's interpretation of MedImmune's complaint missed the underlying contract claim.⁷⁵ But Justice Thomas's critique is arguably more narrowly focused on the failure of MedImmune to state *why* "sale[s] of its Synagis® product d[o] not infringe any valid claim of the [Cabilly II] patent."⁷⁶ Justice Thomas isolated the problem as the "lack of specificity in the complaint."⁷⁷ MedImmune's contract claim was reducible to a simple argument: "the patent is invalid and unenforceable . . . [therefore] MedImmune is not bound by its contractual obligations."⁷⁸ Thus, MedImmune's claim was "independent of any contractual question."⁷⁹ Justice Thomas's conclusion was simply that the Court should not permit the district court to hear the action if the contract claim likely would have a minimal effect on the outcome. In the view of Justice Thomas, the Court's willingness to import the contract claim to fabricate an actual controversy was indicative of the "broad scope" of the ruling.⁸⁰

2. *The Majority Redefined Coercion*

Justice Thomas next criticized the Court's expanded application of coercion to "voluntarily accepted contractual obligations between private parties."⁸¹ He found the Court's reliance on *Altwater* to be misplaced and an erroneous extension of the protection against coercion to contracts between private parties.⁸² Specifically, he noted what he thought were three pivotal differences between the parties in *Altwater* and *MedImmune*.

First, the petitioner in *Altwater* raised the "affirmative defense of patent invalidity . . . in a declaratory judgment motion filed as a counterclaim to a patent infringement suit."⁸³ In contrast, MedImmune

⁷³ *Id.* at 778.

⁷⁴ *Id.* at 779.

⁷⁵ *Id.* at 770 n.6 (majority opinion).

⁷⁶ *Id.* at 779 (Thomas, J., dissenting) (alterations in original; citation omitted).

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 780.

⁸² *Id.* at 781.

⁸³ *Id.* Addressing *Altwater*'s unique facts, Justice Thomas noted that, in *Altwater*, the patent infringement defendant raised the affirmative defense of invalidity as a counterclaim and had the burden of demonstrating a case or controversy for a declaratory judgment. Justice Thomas stated: "We specifically held that a finding of noninfringement on appeal did not moot a counterclaim alleging invalidity. But we stressed: '[T]he issue before us, therefore[,] concern[s] the jurisdiction of an intermediate appellate court—not the jurisdiction of a trial . . . court. . . . In the trial court, of course, a party seeking a declaratory judgment has the burden of

raised the issue of validity on its own accord.⁸⁴ Unlike in *Altwater*, MedImmune had not suffered any actual suit, let alone damages. Second, both the district court and court of appeals in *Altwater* held “the underlying license had been terminated prior to the filing of the case.”⁸⁵ MedImmune, however, desired a judgment as to whether the patent itself was invalid. And third, the royalty payments made by the licensee in *Altwater* were made under “compulsion of an injunction that had been entered in a prior case.”⁸⁶ Here, Genentech was barred from seeking an injunction because MedImmune was a non-repudiating licensee.

Justice Scalia replied that Justice Thomas “incorrectly asserts that *Altwater* required actual infringement.”⁸⁷ He faulted Justice Thomas’s reliance on a “wildly out of context” quotation concerning “*Altwater*’s statement that ‘[t]o hold a patent valid if it is not infringed is to decide a hypothetical case.’”⁸⁸ Justice Scalia contended that the quotation was simply a means for the Court to distinguish *Altwater* from another case “which involved an affirmative defense of patent invalidity that had become moot in light of a finding of no infringement.”⁸⁹

Justice Thomas, however, did not rely on the quotation from *Altwater* to assert a standard. Rather, he contended that MedImmune could not bring suit because “a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy.”⁹⁰ Thus, he thought that the facts in *MedImmune* were distinguishable from *Altwater*. In *Altwater*, the Court allowed “a ‘licensee’ . . . to bring a declaratory judgment counterclaim asserting the affirmative defense of patent invalidity in response to a patent infringement suit.”⁹¹ By contrast, Justice Thomas contended that MedImmune’s claim was hypothetical because of MedImmune’s failure to allege “why” the Cabilly II patent claims were *not* infringed.⁹² By failing to properly place the burden on MedImmune, Justice Thomas contended that the Court transgressed the very concern raised in *Altwater*: the burden to demonstrate a controversy would shift away from the party seeking the declaratory relief.⁹³

Justice Scalia also disagreed with Justice Thomas that *Altwater*’s unique facts limited the rationale “that payment of royalties under ‘coercive’ circumstances does not eliminate jurisdiction.”⁹⁴ Thus, where

establishing the existence of an actual case or controversy.” *Id.* (alterations in original) (quoting *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95 (1993)).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.* at 773 n.10 (majority opinion).

⁸⁸ *Id.* (quoting *Altwater v. Freeman*, 319 U.S. 359, 363 (1943)).

⁸⁹ *Id.* at 774 n.10.

⁹⁰ *Id.* at 781 (Thomas, J., dissenting) (quoting *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95 (1993)).

⁹¹ *Id.* at 778.

⁹² *Id.* at 779.

⁹³ *Id.* at 778–79.

⁹⁴ *Id.* at 774 n.10 (majority opinion).

Justice Thomas relied upon facts he found to be unique to *Altwater*, such as the counterclaim against a license agreement already found invalid, Justice Scalia argued that “none of *Altwater*’s ‘unique facts,’ suggests that a different test applies to the royalty payments here.”⁹⁵ Indeed, Justice Scalia faulted Justice Thomas for “never explain[ing] why the threat of treble damages and the loss of 80 percent of petitioner’s business does not fall within *Altwater*’s coercion rationale.”⁹⁶

Justice Thomas did not address the threat of treble damages directly, perhaps because he focused on the actual imposition of a monetary cost in *Altwater*. Unlike in *MedImmune*, the licensee in *Altwater* was bound by an injunction issued in a prior case to pay patent royalties it claimed it did not owe.⁹⁷ Furthermore, in *Altwater*, there were multiple cases in litigation and damages accruing against a licensee who could not break out of the contract because of the injunction. In *MedImmune*, there was no such threat; the damages suffered in *Altwater* were real and persistent, not conjectured as in *MedImmune*. Justice Thomas feared that *MedImmune* raised the specter that in the future, cases of an increasingly far-fetched nature would be granted declaratory relief.⁹⁸

3. *The Majority Improperly Expanded the Concept of Coercion*

Finally, Justice Thomas contended that the Court improperly extended the “concept of coercion . . . to . . . voluntarily accepted contractual obligations between private parties.”⁹⁹ He criticized the Court for its misapplication of *Steffel v. Thompson*, which in turn served to expand the concept of coercion.¹⁰⁰ Although *Steffel* was based on the coercive nature of governmental power, *MedImmune* involved two parties who voluntarily entered contractual obligations. Justice Thomas contended that the concept of coercion in *Steffel* “would apply only if Genentech had threatened MedImmune with a patent infringement suit *in the absence of a license agreement*.”¹⁰¹ Yet *MedImmune* was under no threat of suit. Consequently, Justice Thomas charged that the Court’s ruling went “far beyond *Steffel*”¹⁰² and removed any “limiting principle whatsoever” from the definition of a case or controversy.¹⁰³

Justice Scalia countered by claiming the coercion principle he relied on for the Court did not originate with *Steffel*, but with *Altwater*. He further argued that the threat of treble damages was “every bit as coercive

⁹⁵ *Id.* (citation omitted).

⁹⁶ *Id.*

⁹⁷ *Id.* at 781 (Thomas, J., dissenting).

⁹⁸ *See id.* at 782 (“[T]he majority has given every patent licensee a cause of action and a free pass around Article III’s requirements for challenging the validity of licensed patents.”).

⁹⁹ *Id.* at 780.

¹⁰⁰ *Id.* at 782 (citing *Steffel v. Thompson*, 415 U.S. 452 (1974)).

¹⁰¹ *Id.* at 782.

¹⁰² *Id.*

¹⁰³ *Id.*

as the modest penalties for misdemeanor trespass threatened in *Steffel*.¹⁰⁴ But as Justice Thomas noted, *Altwater* is factually different: there was an injunction in place from a prior judgment imposing damages. Thus, absent *Altwater*, *Steffel* provides the only basis from which to derive a concept of coercion. Further, *Steffel* can be distinguished because the coercion stemmed from the government and not from private parties. The state government's action imposed criminal penalties for actions protected by the Constitution.¹⁰⁵ By contrast, Genentech did not have a judicially imposed injunction against MedImmune.

C. The Court Rejects the Reasonable Apprehension Test

Aside from holding that *MedImmune*'s circumstances supported a finding that a controversy existed, the Court also abrogated the Federal Circuit's reasonable apprehension of imminent suit test. In a footnote, the Court expressly rejected the Federal Circuit's test because it conflicted with a proper understanding of *Altwater*. Indeed, the Court found that even if *Altwater* could be distinguished because of the government's injunction, the earlier opinion "still contradict[ed] the Federal Circuit's 'reasonable apprehension of [imminent] suit' test."¹⁰⁶ In addition, the Court found the Federal Circuit's test in conflict with several other leading cases in determining subject matter jurisdiction for declaratory relief.¹⁰⁷

Justice Thomas did not directly address the footnote. Rather, he argued that the cases cited by the Court (including *Aetna Life, Maryland Casualty*, and *Cardinal Chemical*) provided "a uniform [constitutional] framework for assessing whether an Article III case or controversy exists."¹⁰⁸ Consequently, the Court's efforts to apply those cases to *MedImmune*'s circumstances were inapt.¹⁰⁹

Nevertheless, the demise of the reasonable apprehension of imminent suit test is probably the most significant holding in *MedImmune*. It necessitated the substitution of a different framework of analysis for

¹⁰⁴ *Id.* at 775 n.12 (majority opinion).

¹⁰⁵ *Steffel*, 415 U.S. at 459.

¹⁰⁶ *MedImmune*, 127 S. Ct. at 774 n.11 (citation omitted).

¹⁰⁷ *Id.* at 774–75 & n.11 (citing *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270 (1941)) (finding "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"); *id.* at 774 n.11 (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937)) (finding "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"); *and id.* at 774 n.11 (citing *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993)) (finding "appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity").

¹⁰⁸ *MedImmune*, 127 S. Ct. at 777 (Thomas, J., dissenting).

¹⁰⁹ *Id.* at 781 ("*Cardinal Chemical* . . . is similarly inapt here. In that case, as in *Altwater*, the defendant raised the affirmative defense of patent invalidity in a counterclaim to a patent infringement suit.").

declaratory judgment claims in patent litigation. The Supreme Court did not create one out of whole cloth. Instead, it held that the totality-of-circumstances test, long used in other declaratory relief actions, should be applied.¹¹⁰ In doing so, it bolstered the uniform application of the Declaratory Relief Act by bringing patent litigation back into the trans-substantive fold.¹¹¹

IV. LIFE AFTER *MEDIMMUNE*

MedImmune eradicated the hurdles the Federal Circuit had erected to limit when a controversy existed in an action for declaratory relief. The Court provided a recycled framework for parties seeking declaratory relief in patent litigation. The totality-of-circumstances test certainly broadened the scope of coercive conduct that would suffice as the predicate for a declaratory relief action. The question remaining was how much this would open the door to federal court, particularly to would-be patent challengers who had been unable to enter previously.

Justice Thomas contended that the majority in *MedImmune* went too far and opened the door completely, which worked to the unfair detriment of patentees.¹¹² He charged that because the Court's totality-of-circumstances standard lacked any limiting principles, it allowed parties to seek hypothetical opinions. As a result, plaintiffs who previously would have been unable to enter federal court would now be able to successfully commence declaratory judgment actions. Furthermore, Justice Thomas's concerns extend beyond patent litigation. If he is correct that *MedImmune* lacks any limiting factors, that breadth should make itself felt outside of patent litigation. Therefore, the goal of the analysis presented in this Part of the Article is to determine whether the Federal Circuit and district courts have: (1) begun to expand their reasoning to apply *MedImmune* to any situation, absent any limiting factors; and/or (2) significantly increased the granting of declaratory relief.

To evaluate Justice Thomas's critique, the analysis is broken into several sections examining how the Federal Circuit and lower courts have applied *MedImmune*. The first Part examines post-*MedImmune* cases

¹¹⁰ "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 771 (majority opinion) (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

¹¹¹ Compare Lorelei Ritchie, *Reconciling Contract Doctrine with Intellectual Property Law: An Interdisciplinary Solution*, 25 SANTA CLARA COMPUTER & HIGH TECH. L.J. 105, 149 (2008) (calling for courts to not treat intellectual property as a discipline kept separate from other bodies of law), with Helm & Lee, *supra* note 15, at 232 (observing that the Court's "significant efforts to realign the patent laws with other non-patent law jurisprudence . . . has tipped the balance of power away from patent owners and toward patent challengers").

¹¹² *MedImmune*, 127 S. Ct. at 777-82 (Thomas, J., dissenting).

involving “classic patent litigation.”¹¹³ The second examines litigation within the Abbreviated New Drug Application (ANDA) regime.¹¹⁴ These disputes are framed by federal statutes and regulations. Because the ANDA regime imposes different procedures and obligations on the litigants, these decisions can be based on more than the narrow confines of the parties’ conduct. Rather, the judicial opinions are often guided by procedural obligations imposed by the statutory regime, a distinction recognized in the opinions.

The analysis then makes a preliminary effort at comparing decisional outcomes before and after the Supreme Court released *MedImmune* on January 9, 2007. Three years of judicial opinions following *MedImmune*¹¹⁵ are compared with a baseline of three years of opinions preceding it.¹¹⁶ The goal is to see whether *MedImmune* has affected how often actions for declaratory relief are being permitted and when the relief is granted.¹¹⁷

A review of cases following *MedImmune* demonstrates that Justice Thomas may well be correct in part. Courts have seemingly shifted the burden to declaratory relief defendants to try to preclude declaratory relief. Before *MedImmune*, the *probability* of a future suit determined whether a controversy existed. *MedImmune* introduced a lower threshold, the *potential* for suit. Yet, even with this shift, the lower courts have constrained their reasoning and findings in the cases examined. Foreshadowing the conclusion, Justice Thomas’s worst fears do not appear to have been warranted.

¹¹³ Classic patent litigation is defined here as a dispute based on patent rights between parties outside of the Federal Drug Administration’s regulatory scheme.

¹¹⁴ “An Abbreviated New Drug Application (ANDA) contains data which when submitted to FDA’s Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.” FDA, U.S. DEP’T OF HEALTH & HUMAN SERVS., ABBREVIATED NEW DRUG APPLICATION (ANDA): GENERICS (2009), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm>. See LAWRENCE M. SUNG & JEFF E. SCHWARTZ, PATENT LAW HANDBOOK § 5.12, at 435–40 (2008–09 ed. 2008); Ankur N. Patel, Comment, *Delayed Access to Generic Medicine: A Comment on the Hatch-Waxman Act and the “Approval Bottleneck,”* 78 FORDHAM L. REV. 1075 (2009).

¹¹⁵ January 9, 2007 to January 8, 2010.

¹¹⁶ January 9, 2004 to January 8, 2007.

¹¹⁷ The *MedImmune* opinion has been cited by courts over 300 times. Most of these citations are not relevant for present purposes. Therefore, the cases examined for this section of the Article consist of the cases decided in the three-year periods before and after *MedImmune*, which addressed declaratory relief in patent cases and which were classified as “Examined” or “Discussed” in the Westlaw KeyCite References for all federal cases. Cases which were classified as “Cited” or “Mentioned” were excluded from this sample. The KeyCite Reference list was also cross-checked with search terms that included various combinations of “reasonable apprehension,” “declaratory judgment,” and the main KeyCite, “118A,” within the selected timeframe.

A. *The Challenges of MedImmune*

After *MedImmune*, the Federal Circuit (and the district courts) faced twin challenges. On one hand, the Supreme Court rejected the Federal Circuit's reasonable apprehension of imminent suit test because it conflicted with the Court's view of precedent.¹¹⁸ However, the Supreme Court did not provide a detailed framework in *MedImmune* to guide lower courts in their application of the totality-of-circumstances test. The Federal Circuit addressed this gap almost immediately in two cases: *SanDisk Corp. v. STMicroelectronics, Inc.* and *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*¹¹⁹ *SanDisk* provided a framework for courts to examine the totality of circumstances in the context of classic patent litigation, while *Teva* has served as the defining case in the context of the federal drug application regime.

1. *MedImmune in Classic Patent Litigation: SanDisk Corp. v. STMicroelectronics, Inc.*

In *SanDisk Corp. v. STMicroelectronics, Inc.*, the Federal Circuit had to decide when a controversy existed given *MedImmune's* elimination of the former test's first prong: "whether conduct by the patentee creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit."¹²⁰ Because *SanDisk* arose from a common scenario in patent litigation—negotiations over possible patent infringement in advance of a lawsuit—the Federal Circuit's opinion provided guidance to assess whether a party's conduct was sufficiently coercive to justify the other party's seeking declaratory relief under *MedImmune*.

Both *SanDisk* and *ST* are manufacturers of flash memory.¹²¹ After a review of its patent portfolio, *ST* believed *SanDisk* was infringing fourteen of its patents. *ST* contacted *SanDisk* to discuss a cross-licensing agreement.¹²² The two manufacturers held a meeting where each party

¹¹⁸ *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 774–75 n.11 (2007) (finding that *Altwater* contradicted the Federal Circuit's "reasonable apprehension of imminent suit test" as does *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270 (1941); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937); and *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993)). See also *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 (Fed. Cir. 2007) ("[T]he Court specifically addressed and rejected our reasonable apprehension test.").

¹¹⁹ *SanDisk*, 480 F.3d at 1372; *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.* (*Teva 2007*), 482 F.3d 1330 (Fed. Cir. 2007).

¹²⁰ *SanDisk*, 480 F.3d at 1379; see also *Cat Tech, LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879–80 (Fed. Cir. 2008) (The Federal Circuit addressed the second prong in *Cat Tech*, holding that, "although *MedImmune* articulated a 'more lenient legal standard' for the availability of declaratory judgment relief in patent cases," the second prong of the reasonable apprehension test—the plaintiff must take "concrete steps to conduct infringing activity"—is still a necessary consideration in a court's assessment of the totality of the circumstances").

¹²¹ *SanDisk*, 480 F.3d at 1374.

¹²² *Id.*

presented an analysis of alleged infringement by the other party on their respective patents.¹²³ While providing ST's information, its vice president of intellectual property and licensing allegedly stated, "I know that this is material that would allow SanDisk to DJ [ST] on . . . [b]ut I have decided that I will go ahead and give you these materials."¹²⁴ In addition, the ST vice-president informed the SanDisk representative, "ST has absolutely no plan whatsoever to sue SanDisk."¹²⁵ The licensing talks between the two parties, however, failed to lead to an agreement. SanDisk filed a lawsuit in the Northern District of California alleging infringement of one of its patents and seeking declaratory judgment of non-infringement and invalidity of the fourteen patents ST had initially contacted SanDisk to discuss about cross-licensing.¹²⁶

Because this case initially arose before the Supreme Court's decision in *MedImmune*, the Federal Circuit's reasonable apprehension of imminent suit test applied. Judge Jeremy Fogel of the Northern District of California granted ST's motion to dismiss on the basis that there was no actual controversy. "SanDisk did not have an objectively reasonable apprehension of suit, even though it may have subjectively believed that ST would bring an infringement suit."¹²⁷ The district court also found that SanDisk had not provided sufficient evidence to indicate ST threatened litigation or any other conduct to demonstrate intent "to initiate an infringement action."¹²⁸

On appeal, the Federal Circuit reversed on the basis of the Supreme Court's intervening ruling in *MedImmune*. Writing for the Circuit panel, Judge Richard Linn first found that *MedImmune* "represent[ed] a rejection of [the] reasonable apprehension of suit test."¹²⁹ Then, applying *MedImmune*, the circuit court found that a controversy might exist where conduct by the patentee places the "declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do."¹³⁰ The court stated that to evaluate whether the conduct has forced the plaintiff to seek a declaratory judgment "depend[s] on . . . the facts and circumstances of each case."¹³¹

The Federal Circuit found that a controversy existed because: (1) ST sought a right under its patents based on specific activity by SanDisk; and (2) ST asserted a right to royalties, which SanDisk disputed.¹³² Finally, ST's statement that it did not intend to sue did not obviate a controversy

¹²³ *Id.* at 1375.

¹²⁴ *Id.* (first alteration in original).

¹²⁵ *Id.* at 1376.

¹²⁶ *Id.* at 1374, 1376.

¹²⁷ *Id.* (citing *SanDisk Corp. v. STMicroelectronics, Inc.*, No. C 04-04379 JF, 2005 WL 5801276 (N.D. Cal. Jan. 20, 2005), *vacated*, 480 F.3d 1372).

¹²⁸ *Id.* at 1376-77.

¹²⁹ *Id.* at 1380.

¹³⁰ *Id.* at 1381.

¹³¹ *Id.*

¹³² *Id.* at 1382.

“because ST ha[d] engaged in a course of conduct that show[ed] a preparedness and willingness to enforce its patent rights despite [the] statement.”¹³³

a. Understanding SanDisk

Although it is consistent with *MedImmune*, *SanDisk* nevertheless confirms Justice Thomas’s point that the Supreme Court did not provide any limiting factors for when parties could seek declaratory relief. As Judge William Bryson noted in a concurrence, *MedImmune* compelled the circuit court’s holding. However, he also “[saw] no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the patentee.”¹³⁴ In effect, Judge Bryson reiterated Justice Thomas’s concern that the lack of limiting principles would allow for hypothetical opinions in other cases in the future.

In addition, *SanDisk* illustrates the Federal Circuit’s compelled abandonment of the principles underlying the reasonable apprehension of imminent suit test. Although ST sought to alleviate the threat of suit, the Federal Circuit found its actions occurred too late, after a threat had been established.¹³⁵ In so doing, the court focused on the timing of ST’s conduct (i.e., whether the patentee made any claim of infringement); and, who was involved in the negotiations (e.g., lawyers or engineers). This analysis contrasts starkly with the Federal Circuit’s reasonable apprehension of imminent suit test, which took into account ST’s conduct in exposing itself to a declaratory judgment action (and thereby decreasing its own ability to succeed in an infringement suit).

Finally, besides altering the framework for determining an imminent threat, *SanDisk* also illustrates the lowered threshold a declaratory relief plaintiff needs to meet to demonstrate a controversy.¹³⁶ Almost any conduct might now be considered “threatening” given the totality of the circumstances. The court’s reasoning in *SanDisk*, however, raised three additional questions. One, by merely asserting a claim of infringement, is a patentee necessarily exposed to a declaratory judgment action? Two, can a patentee take actions to insulate its claim of infringement from a

¹³³ *Id.* at 1383.

¹³⁴ *Id.* at 1385 (Bryson, J., concurring in result).

¹³⁵ Factors cited by the court include: ST approaching SanDisk after having made a determination of infringement; ST’s communication of its determination to SanDisk of infringement; and, only then stating, “it does not intend to sue.” *Id.* at 1383 (panel opinion). *SanDisk* is discussed in Patrick R. Colsher, Comment, *SanDisk Corp. v. STMicroelectronics, Inc.*, 53 N.Y.L. SCH. L. REV. 351 (2008); Greg Halsey, Comment, *There is a Pink Elephant at Our Patent Negotiation, and His Name is Declaratory Judgment*, 46 SAN DIEGO L. REV. 247 (2009).

¹³⁶ See *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) (“Whether intended or not, the now more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases.” (citations omitted)).

declaratory judgment action? And three, when is the proper time for a patentee to communicate that it does not plan on filing an action on its own behalf? Subsequent cases provide some insight into the path the Federal Circuit has taken to answer these questions.

b. Subsequent Cases—Conduct After SanDisk

The Federal Circuit explored the bounds of unacceptable conduct in *Sony Electronics, Inc. v. Guardian Media Technologies, Inc.*¹³⁷ *Sony Electronics*, represents a “returning” case, i.e., one that had been decided previously under the reasonable apprehension of suit test, but was reviewed after the decision in *MedImmune*.¹³⁸ The district court had dismissed the declaratory relief action before *MedImmune* was decided because the patentee had not expressly threatened to sue the plaintiff for patent infringement and none of the patentee’s actions “amounted to an implicit threat of *immediate litigation*.”¹³⁹ The Federal Circuit reversed on the basis of the intervening *MedImmune* decision.¹⁴⁰

In *Sony Electronics*, Guardian claimed that Sony’s use, among other firms, of the V-Chip technology in its television and DVD products infringed on Guardian’s patents.¹⁴¹ After negotiations between the two companies failed, Sony filed an action for declaratory relief, challenging the validity of Guardian’s patents.¹⁴²

Judge Sharon Prost, writing for the circuit panel, focused on the patentee’s conduct to determine whether there was a controversy. Drawing on *SanDisk*, the circuit court rested its finding of subject matter jurisdiction in *Sony Electronics* on two points. One, prior to Sony filing its complaint, the parties adopted adverse positions. Judge Prost cited Guardian’s detailed infringement analyses and “position . . . [that the patents] were valid and infringed by Sony and that Guardian was therefore entitled to past and future royalties based on that infringement.”¹⁴³ And two, Sony’s claim was not a request for a merely hypothetical opinion because Guardian had “explicitly identified the patents” in question.¹⁴⁴

Like *SanDisk*, *Sony Electronics* demonstrates what the Federal Circuit later observed as the “ease of achieving declaratory judgment jurisdiction in patent cases” as a result of *MedImmune*’s holding.¹⁴⁵ While failing under

¹³⁷ *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007).

¹³⁸ *Id.* at 1283.

¹³⁹ *Id.* at 1281 (citation and internal quotation marks omitted).

¹⁴⁰ *Id.* at 1283, 1285.

¹⁴¹ *Id.* at 1273–74.

¹⁴² *Id.* at 1276.

¹⁴³ *Id.* at 1285.

¹⁴⁴ *Id.*

¹⁴⁵ *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008). See also Jennifer R. Saionz, Note, *Declaratory Judgment Actions in Patent Cases: The Federal Circuit’s Response to MedImmune v. Genentech*, 23 BERKELEY TECH. L.J. 161 (2008).

the reasonable apprehension of imminent suit test,¹⁴⁶ Guardian's conduct easily surpassed the "controversy" threshold under *MedImmune*. Guardian sent letters with the option for parties to pay a lump sum payment to acquire a "paid up license;" it asserted patent infringement against several companies all for the exact same patent; it made public assertions of its intent to enforce its patents through litigation; and it sent Sony a letter stating its failure to respond was "unacceptable."¹⁴⁷

District court decisions have reflected *SanDisk*'s lowered threshold for establishing a controversy. The courts' recognition of the lower threshold, however, was evident even before *SanDisk* was decided. For instance, in two cases published on the same day, two district courts applied reasoning mirroring what became the Federal Circuit's interpretation of *MedImmune*'s lowered threshold just a few weeks later in *SanDisk*. In *Rite-Hite Corp. v. Delta T Corp.*,¹⁴⁸ a magistrate judge in the Eastern District of Wisconsin found that a licensee's acts constituted the basis for a controversy because the acts gave notice of the licensee's intent to terminate a license agreement (pursuant to the contract).¹⁴⁹ The licensee believed the patent was invalid and intended to launch a competing product.¹⁵⁰ Similarly, in *Highway Equipment Co., Inc. v. Cives Corp.*, Chief Judge Linda Reade of the Northern District of Iowa found that the patentee's conduct was indicative of a controversy under *MedImmune* because the patentee failed to promise that it would not sue.¹⁵¹

The district courts applying *SanDisk* as direct precedent have, not surprisingly, continued to apply a lowered threshold for declaratory relief plaintiffs to demonstrate the existence of a controversy. Two examples highlight the courts' willingness to interpret a threat broadly, including indirect actions taken by a patentee. A third example illustrates the outer limits of the new test.

In *WS Packaging Group, Inc. v. Global Commerce Group, LLC*,¹⁵² no specific threat was made, yet the district court found that a declaratory judgment action was justified. The patentee's "bragg[ing] in a trade magazine of its habit of threatening to sue . . . the customers of allegedly infringing vendors or manufacturers" was a means of pressuring parties.¹⁵³ Similarly, in *EchoStar Satellite LLC v. Finisar Corp.*, the district court found the *SanDisk* "standard allows a finding of an actual controversy in circumstances where the party seeking declaratory judgment has reason to believe that further negotiations will be

¹⁴⁶ *Sony Elecs., Inc.*, 497 F.3d at 1288 (district court finding "even if some of Guardian's language can be construed as implied threats, the overall tone . . . was one of discussion and negotiation" (citation omitted)).

¹⁴⁷ *Id.* at 1275.

¹⁴⁸ No. 06-C-1187, 2007 WL 725327 (E.D.Wis. Mar. 7, 2007).

¹⁴⁹ *Id.* at *7.

¹⁵⁰ *Id.* at *8.

¹⁵¹ 476 F. Supp. 2d 1079, 1082, 1086 (N.D. Iowa 2007).

¹⁵² 505 F. Supp. 2d 561 (E.D. Wis. 2007).

¹⁵³ *Id.* at 565-66.

fruitless.”¹⁵⁴ Therefore, the court concluded, a patentee’s successful infringement suit against a third party and a press statement stating “its *intention* to continue ongoing licensing discussions with other companies” was sufficient to demonstrate a threat.¹⁵⁵

Where a district court has not found a controversy under the standard announced in *SanDisk*, the link claimed between the patentee and the declaratory relief defendant was deemed to be too tenuous. For example, in *segOne, Inc. v. Fox Broadcasting Co.*,¹⁵⁶ segOne brought an action for declaratory relief based on Fox’s alleged coercion. The action contended that Fox’s successful copyright infringement suit filed against one of segOne’s customers,¹⁵⁷ who used segOne’s technology while violating copyright laws, was coercive.¹⁵⁸ The court dismissed the suit, however, because Fox’s suit did not coerce segOne customers into “complying with Fox’s demands,” but only to stop infringing on Fox’s copyrighted material.¹⁵⁹

The *segOne* case, however, can be distinguished from *WS Packaging* and *EchoStar*. Fox was not contesting the validity of segOne’s patent, merely a customer’s allegedly improper use of the patented device. Unlike in *MedImmune*, there was no real potential for a suit about alleged infringement or validity of the patent or the patented product.¹⁶⁰ By contrast, in *WS Packaging* and *EchoStar*, the courts found the mere potential for a future lawsuit alleging infringement to be sufficient to establish the basis for a controversy.

c. Covenant Not to Sue

Despite the new lower threshold, the Federal Circuit has recognized that a covenant not to sue can insulate a party from a declaratory relief suit. In *Benitec Australia, Ltd. v. Nucleonics, Inc.*,¹⁶¹ the district court dismissed Nucleonics’ suit for declaratory relief because Benitec offered Nucleonics a covenant not to sue after commencement of the

¹⁵⁴ *EchoStar Satellite LLC v. Finisar Corp.*, 515 F. Supp. 2d 447, 451 (D. Del. 2007).

¹⁵⁵ *Id.* at 451–52 (emphasis added).

¹⁵⁶ No. 3:07-CV-342, 2007 WL 2965064 (E.D. Va. Oct. 9, 2007).

¹⁵⁷ *Id.* at *1. SegOne produced a device that enabled specific content to be delivered through the television to targeted groups of consumers by piggybacking on the signals of television broadcasters. *Id.* Fox Broadcasting successfully sued one of segOne’s customers, Flying J, for copyright infringement stemming from the public performance of copyrighted material without authorization. Although segOne was not a party to the suit, “the parties settled the [dispute] using money provided by segOne’s insurer.” *Id.* Moreover, Flying J was required to “stop using segOne’s device.” *Id.* As a result, segOne ceased to distribute the device in the U.S.

¹⁵⁸ *Id.* at *3.

¹⁵⁹ *Id.* at *2.

¹⁶⁰ *Compare with* *Cordance Corp. v. Amazon.com, Inc.*, 521 F. Supp. 2d 340, 345 (D. Del. 2007) (finding controversy where the party provided technical assistance and developed “the architecture by which other companies are able to allegedly infringe Amazon’s patent”).

¹⁶¹ 495 F.3d 1340 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2055 (2008).

litigation.¹⁶² Nucleonics appealed, but the Federal Circuit affirmed the lower court's dismissal on the basis of the intervening *MedImmune* decision.¹⁶³

The Federal Circuit panel majority distinguished *Benitec* from *SanDisk* because Benitec offered a covenant not to sue after determining it did not have a case for infringement against Nucleonics.¹⁶⁴ The *Benitec* court noted that ST's statements that it would not sue in *SanDisk* had come in the course of negotiations in which ST had never disavowed any intent to sue SanDisk in the future. In contrast, Benitec's actions effectively made a covenant not to sue, and it "sought dismissal of its infringement claim after it concluded that [federal regulatory rules] precluded an infringement claim based upon the activities of Nucleonics."¹⁶⁵ Consequently, Benitec's offer did not place Nucleonics in a forced position to accept or face legal action. The regulatory statutes precluded an infringement claim even without the covenant not to sue.¹⁶⁶

The *Benitec* case illustrates how a party, without a prior agreement, might insulate its patents from any action for declaratory relief: simply offer a covenant not to sue. *Benitec*, however, raises an additional question: Would an action for declaratory relief have been granted absent the overriding context of the federal regulations?¹⁶⁷

Benitec's particular circumstances aside, district courts have adhered to the Federal Circuit's preclusion of declaratory relief because of an offer of a covenant not to sue. But the district courts have read *Benitec* narrowly. For instance, in *Furminator, Inc. v. Ontel Products Corp.*, the district court followed *Benitec* explicitly while dismissing a counterclaim for declaratory relief after the patent holder dismissed its infringement claims and granted a covenant not to sue.¹⁶⁸ By contrast, in *FieldTurf USA, Inc. v. Sports Construction Group, LLC*, the district court, invoking *Benitec*, found a controversy existed because the patentee's covenant not to sue

¹⁶² *Id.* at 1347–48.

¹⁶³ *Id.* at 1349.

¹⁶⁴ *Id.* at 1347. Judge Timothy Dyk dissented because he believed that the court should analyze the jurisdictional question a little differently when the infringement claim was withdrawn after the commencement of litigation. But he also said that he would have agreed with the majority if the covenant not to sue had been offered before the action for declaratory relief had been filed. *Id.* at 1350 (Dyk, J., dissenting).

¹⁶⁵ *Id.* at 1347 (panel opinion).

¹⁶⁶ *Id.* at 1346–47.

¹⁶⁷ *See, e.g.,* *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1298, 1300 (Fed. Cir. 2009) (reversing denial of declaratory relief action and distinguishing *Benitec* because of differences in scope of covenant not to sue); Edo Royker, Note, *Covenants Not to Sue Provide Less Immunity in a Post-MedImmune World*, 61 *HASTINGS L.J.* 473 (2009) (reviewing different situations involving covenants not to sue under the Federal Circuit precedents).

¹⁶⁸ *Furminator, Inc. v. Ontel Products Corp.*, 246 F.R.D. 579, 590 (E.D. Mo. 2007).

was not unconditional.¹⁶⁹ In *FieldTurf*, the court found the “narrow promise not to sue and the resulting estoppel do not preclude plaintiffs from re-filing suit with respect to defendant’s offers for sale, . . . and [installation of its product at other] locations.”¹⁷⁰

d. Summary

MedImmune changed how lower courts evaluate the threat of suit from whether there is a *probability* of suit to whether a *potential* for suit exists. Under the now-discarded reasonable apprehension of imminent suit test, the lower courts looked for whether any express threats to sue were made. By contrast, courts now examine whether a potential suit might arise in the future. Thus, a controversy might be found in indirect threats made through third parties (e.g., *WS Packaging*) or even subjective feelings of threatening circumstances (e.g., *EchoStar*). The courts do impose some limitations; for example, in *Benitec*, the patentee offered a covenant not to sue, which eliminated any potential for suit. These limitations appear to arise out of the context of statutory regulations. In fact, statutory regulations in the ANDA regime serve as a limiting framework, which is explored in the next Part.

2. *MedImmune and the Abbreviated New Drug Application (ANDA)*

Following on the heels of *SanDisk*, the Federal Circuit released *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp. (Teva 2007)*.¹⁷¹ Unlike in *SanDisk*, however, the disputants in *Teva 2007* were operating within the Federal Drug Administration’s ANDA regime.¹⁷² Accordingly, federal regulatory powers imposed a framework on the Federal Circuit’s analysis of coercive conduct and the potential for suit.

a. Teva Pharmaceuticals v. Novartis Pharmaceuticals

In 2005, Teva Pharmaceuticals, a generic drug manufacturer, filed an ANDA based on five patents protecting Novartis’ drug Famiciclovir.¹⁷³ Novartis responded by filing a patent infringement suit, a standard procedure by a patent holder under the ANDA regime. Novartis, however, claimed infringement on only one of the five threatened patents.¹⁷⁴ In so doing, Novartis left open the possibility of a lawsuit under

¹⁶⁹ *FieldTurf USA, Inc. v. Sports Construction Group, LLC*, 507 F. Supp. 2d 801, 808 (N.D. Ohio 2007).

¹⁷⁰ *Id.*

¹⁷¹ *Teva 2007*, 482 F.3d 1330 (Fed. Cir. 2007).

¹⁷² *Id.* at 1334. See *supra* note 114. Firms file ANDAs with the Federal Drug Administration for the review and ultimate approval of generic drugs. The Drug Price Competition and Patent Term Restoration Act of 1984 provides that a filing of a Paragraph IV certification with respect to a drug claimed by an existing patent, which may be included in an ANDA, constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2) (2006).

¹⁷³ *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp. (Teva 2005)*, No. Civ. 05-2881 JLL, 2005 WL 3619389, at *1 (D.N.J. Dec. 12, 2005); *rev’d*, 482 F.3d 1330 (Fed. Cir. 2007).

¹⁷⁴ *Id.*

the four remaining patents.¹⁷⁵ In turn, Teva filed an action for declaratory relief concerning those four patents.¹⁷⁶

The district court in New Jersey dismissed Teva's declaratory judgment action for lack of a controversy.¹⁷⁷ In rejecting Teva's action against Novartis in *Teva 2005*, the district court relied on the Federal Circuit's holding in yet another case involving Teva.¹⁷⁸ In *Teva/Pfizer*, the Federal Circuit had dismissed an action for declaratory judgment relief that Teva had filed against Pfizer because Teva could not demonstrate a reasonable apprehension of imminent suit.¹⁷⁹

Following the Supreme Court's holding in *MedImmune*, however, Teva sought to revive its action against Novartis in *Teva 2007*. Resubmitting its appeal to the Federal Circuit, Teva requested a declaratory judgment with respect to the four therapeutic patents held by Novartis.¹⁸⁰ The Federal Circuit, now applying *MedImmune*, discarded its reasonable apprehension of imminent suit test. Examining the totality of the circumstances, the circuit court found Novartis had in fact created a controversy by threatening Teva's approval of Teva's ANDA.¹⁸¹ Novartis, by claiming even a single act of infringement, "plac[ed] into actual dispute the soundness of Teva's ANDA and Teva's ability to secure approval of the ANDA."¹⁸² Although Novartis had not expressly threatened to sue Teva for infringement of the other four patents, the court found the "threat of litigation is a present injury creating a justiciable controversy [because the] statutory window does not preclude Novartis from pursuing additional infringement suits under 35 U.S.C. § 271 (e) (2) (A)."¹⁸³ Put simply, a controversy exists because of the potential that a lawsuit could be initiated in the future based on Novartis's four therapeutic patents, which Teva listed in its federally required ANDA.

b. Comparing Teva 2005 and Teva 2007

The circuit court's analysis in *Teva 2007* sharply diverged from the district court's in *Teva 2005*. In *Teva 2005*, the district court applied the Federal Circuit's reasonable apprehension of imminent suit test and dismissed Teva's action for declaratory relief.¹⁸⁴ By contrast, in *Teva 2007*, the Federal Circuit found that even though "several of Teva's grounds alleging an 'actual controversy' when standing alone might not be sufficient, if taken as a whole these circumstances establish a justiciable

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at *4.

¹⁷⁸ *Id.* at *2 (citing *Teva Pharm. USA, Inc. v. Pfizer, Inc. (Teva/Pfizer)*, 395 F.3d 1324 (Fed. Cir. 2005)). *Teva/Pfizer* concluded several months before *Teva 2005* was decided.

¹⁷⁹ *Id.*

¹⁸⁰ *Teva 2007*, 482 F.3d at 1330, 1334.

¹⁸¹ *Id.* at 1340.

¹⁸² *Id.*

¹⁸³ *Id.* at 1341.

¹⁸⁴ *Teva 2005*, 2005 WL 3619389, at *4.

controversy.”¹⁸⁵ Two key differences between *Teva 2005* and *Teva 2007* illustrate the changes that *MedImmune* made in the analytical framework.

First, the circuit court changed the threshold of analysis. In *Teva 2005*, the district court focused on the probability of future litigation, or lack thereof, under the compulsion of the Federal Circuit’s reasonable apprehension of imminent suit test.¹⁸⁶ In contrast, the Federal Circuit in *Teva 2007* shifted the emphasis to the *potential* for future litigation in the wake of *MedImmune*. A controversy existed in 2007 because Novartis had insulated its patents from suit by withholding some potential suits of its own, but still held the potential of suing later.¹⁸⁷

Second, the circuit court changed its framework for analysis with respect to federal regulations. Although neither the facts nor the applicable regulations had changed between *Teva 2005* and *Teva 2007*, the courts employed the regulations differently. In *Teva 2005*, patent filing was a statutory requirement; an objective standard was used to assess the patentee’s intentions.¹⁸⁸ Applying *MedImmune* in *Teva 2007*, however, the Federal Circuit cited the ability of Novartis to sue Teva under 35 U.S.C. § 271 (e) (2) (A) as evidence of a threat and therefore the existence of a controversy.¹⁸⁹ Thus, the statutory regulations—previously used to make an objective assessment—now became instrumental in identifying an implicit threat without any additional facts or circumstances surrounding a patentee’s intentions.

c. Later Cases and the Lower Courts

Other examples illustrate how ANDA regulations have constrained the courts’ interpretation of *MedImmune* in that context. For instance, in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*,¹⁹⁰ the patentee, Forest Laboratories, filed a motion to dismiss Caraco’s declaratory judgment action for patent invalidity because Forest Laboratories offered a covenant not to sue after being served.¹⁹¹ The Federal Circuit, however, held that a controversy existed, despite the covenant.¹⁹² The panel majority, Judges Arthur Gajarsa and Sharon Prost, dismissed the covenant because their court’s “singular approach to the

¹⁸⁵ *Teva 2007*, 482 F.3d at 1341.

¹⁸⁶ *Id.* at 1335.

¹⁸⁷ *Id.* at 1345.

¹⁸⁸ *Teva Pharm. USA, Inc. v. Pfizer, Inc. (Teva/Pfizer)*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (citing *Capo, Inc. v. Dioptics Med. Prods.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004) (“The standard is objective, and focuses on whether the patentee manifested the intention to enforce the patent, and would be reasonably expected to enforce the patent against the declaratory plaintiff.”)).

¹⁸⁹ *Teva 2007*, 482 F.3d at 1340. “While it is true that the suit on the ‘937 patent is a different ‘case’ than Teva’s declaratory judgment action, Novartis created a present and actual ‘controversy’ by choosing to sue under 35 U.S.C. § 271 (e) (2) (A) on Teva’s single act of infringement, thereby placing into actual dispute the soundness of Teva’s ANDA and Teva’s ability to secure approval of the ANDA.” *Id.*

¹⁹⁰ 527 F.3d 1278 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 1316 (2009).

¹⁹¹ *Id.* at 1282.

¹⁹² *Id.* at 1297.

justiciability of declaratory judgment actions was struck down by the Supreme Court in *MedImmune*.¹⁹³ The circuit court noted that a covenant not to sue would have precluded a declaratory judgment action under the reasonable apprehension of suit test “because [Caraco] would no longer have a reasonable apprehension of [imminent] suit by the patentee.”¹⁹⁴ Consistent with *Benitec*, the Federal Circuit recognized in *Caraco* that the existence of a covenant not to sue was no longer determinative; rather, the totality of the circumstances, per *MedImmune*, had to be evaluated.¹⁹⁵

Several other lower court decisions have followed *Teva 2007*'s operative constraints within the ANDA regime. For example, in *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co.*,¹⁹⁶ the district court faced the question of whether a case or controversy existed when the ANDA procedures were not properly followed. In this case, Mutual Pharmaceutical sought declaratory judgment following its submission of an ANDA.¹⁹⁷ SB Pharmco, the patentee, however, challenged the action for declaratory relief, contending that no controversy existed because Mutual sent its notice letter prematurely pursuant to the FDA's regulations for ANDA. Citing *Teva 2007*, the court examined whether “an injury-in-fact . . . can be redressed by the court.”¹⁹⁸ Finding for the patentee, the court dismissed the declaratory judgment action, holding that there was no controversy at the time the plaintiffs filed their complaint, because the ANDA “could not have been approved by the FDA” and the “Defendants’ ANDA could not cause an injury-in-fact to Plaintiffs.”¹⁹⁹

3. Conclusion

SanDisk well illustrates an expansive notion of controversy. Where the reasonable apprehension of imminent suit test would have precluded a controversy, *MedImmune* lowers the bar. This lowered threshold allows parties to engage in conduct that might be an attenuated controversy, but is still sufficient to initiate an action challenging the validity of a patent.

The expanded notion of controversy, however, is held somewhat in check through two mechanisms. First, it does not appear that either the Federal Circuit or the district courts have granted declaratory relief in far-fetched circumstances in the wake of *MedImmune*. In fact, they seem to have adhered to a narrow focus on the circumstances of each case. One example is *FieldTurf USA*, where the district court found a sufficient

¹⁹³ *Id.* at 1294 n.13.

¹⁹⁴ *Id.*

¹⁹⁵ Judge Daniel Friedman thought that the basis for the claim was too speculative and dissented on that basis. *Id.* at 1297–98 (Friedman, J., dissenting).

¹⁹⁶ 552 F. Supp. 2d 500 (E.D. Pa. 2008).

¹⁹⁷ *Id.* at 504–05.

¹⁹⁸ *Id.* at 512.

¹⁹⁹ *Id.*

controversy because the covenant not to sue was not unconditional.²⁰⁰ Where the courts have begun to develop some habits of potential concern is the seeming shift in burden from the declaratory relief plaintiff to the defendant.

Second, the ANDA regime imposes procedural elements where it applies, which establish a minimum threshold to demonstrate controversy outside of the totality of circumstances. Consequently, a party's failure to follow ANDA procedures would likely preclude a declaratory judgment action under either the reasonable apprehension of imminent suit test or *MedImmune's* totality-of-circumstances test. A good example of this is SB Pharmco's failure to submit its ANDA materials by the deadline.²⁰¹ As the court noted in *SB Pharmco*, ANDA filings impose a host of procedural mechanisms, which are designed in part to mitigate unnecessary patent litigation.²⁰²

Therefore, based on the cases discussed so far, it appears that Justice Thomas was partially correct, but probably overly concerned, about the potentially widespread effects of *MedImmune*. Although *MedImmune* removed the firm limiting principles that the Federal Circuit had previously applied when determining the existence of a controversy in patent litigation, even this shift has been mitigated somewhat, such as when those disputes fall under federal regulations via the ANDA regime.

B. Outcome Assessment of *MedImmune* in the Lower Courts

In addition to seeking to determine how *MedImmune* might affect the availability of declaratory relief, this Article also tries to determine whether there were any major changes in the rate of decisional outcomes. This Part shows the results of comparing declaratory relief actions decided in the three years preceding *MedImmune* with the three years immediately following. There are forty and fifty-two cases, respectively, in these two categories.²⁰³ Also, after separating the decisions into those decided by the Federal Circuit and those decided by district courts, the cases were further categorized by: (1) the type of party seeking the declaratory judgment, e.g., patentee, non-licensee, or licensee; and (2) the outcome, i.e., whether a declaratory judgment was granted or not.

²⁰⁰ *FieldTurf USA, Inc. v. Sports Constr. Group, LLC*, 507 F. Supp. 2d 801, 808 (N.D. Ohio 2007).

²⁰¹ *SB Pharmco Puerto Rico Inc.*, 552 F. Supp. 2d at 512.

²⁰² *Id.* at 508.

²⁰³ Some cases were excluded because they were not rulings by the Federal Circuit, but by other circuits. *E.g.*, *Wis. Ctr., Ltd. v. Shannon*, 539 F.3d 751 (7th Cir. 2008); *Metrologic Instruments, Inc. v. Symbol Tech., Inc.*, 254 F. App'x 128 (3d Cir. 2007). Other cases were not included because other factors necessitated their exclusion. *E.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 535 F. Supp. 2d 1000 (C.D. Cal. 2008) (on remand); *Dow Chem. Co. v. Reinhard*, No. 07-12012-BC, 2007 WL 5361218 (E.D. Mich. Sept. 20, 2007) (not patent litigation).

Overall, it appears that the lower courts have implicitly heeded Justice Thomas's concern about the lack of limiting factors in *MedImmune*.²⁰⁴ The post-*MedImmune* decisions appear fairly consistent with the pre-*MedImmune* outcomes. The totality-of-circumstances test has not actually gone unchecked. Even before *MedImmune*, the Federal Circuit generally found subject matter jurisdiction to exist because it thought that there was a sufficient controversy under the reasonable apprehension of imminent suit test. It does not appear that the rate of finding subject matter jurisdiction has gone up greatly after *MedImmune* lowered the threshold. This implies a certain consistency in the Federal Circuit's reasoning because, even with *MedImmune*'s lowered threshold, the circuit court has not dramatically changed in its rate of determination of when a controversy exists.

MedImmune did create a category of litigants bringing "returning cases." These parties sought to use *MedImmune* to reassert previously unsuccessful claims for declaratory relief. These returning cases, however, are small in number and a temporary phenomenon by their nature. They do not seem to presage a large upswelling of actions for declaratory relief.

1. Federal Circuit

Despite the fact that its former test was rejected as being too hard to meet, the Federal Circuit's post-*MedImmune* decisions are generally consistent with its pre-*MedImmune* decisions. Where a party has sought declaratory relief, the Federal Circuit has not dismissed for lack of subject matter jurisdiction when it has found that a controversy actually existed. A comparison of court decisions before and after *MedImmune*, however, does illustrate some slight changes in the type of party seeking declaratory relief.

For instance, the Federal Circuit has ruled fairly consistently (but not totally) in favor of non-licensees seeking declaratory relief. In the three years prior to *MedImmune*, the Federal Circuit granted declaratory relief in three out of the four instances in which it was sought.²⁰⁵ In the three years after *MedImmune*, although the Federal Circuit had a few more cases per year, it granted declaratory relief in five out of the seven cases in which it was sought.²⁰⁶ The differences may simply reflect some non-

²⁰⁴ These conclusions are necessarily tentative because the different categories are not statistically significant from one another.

²⁰⁵ Subject matter jurisdiction found in: *Elects. for Imaging, Inc. v. Coyle*, 394 F.3d 1341 (Fed. Cir. 2005); *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361 (Fed. Cir. 2004); *Capo, Inc. v. Dioptics Med. Prods., Inc.*, 387 F.3d 1352 (Fed. Cir. 2004). Subject matter jurisdiction denied in: *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005).

²⁰⁶ Subject matter jurisdiction found in: *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294 (Fed. Cir. 2009); *Cat Tech, LLC v. TubeMaster, Inc.*, 528 F.3d 871 (Fed. Cir. 2008); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271

licensees seeking to push the new and uncertain looser limits on actions for declaratory judgment relief. However, due to the limited number of cases, no firm conclusions can be drawn. Moreover, the Federal Circuit's willingness to deny declaratory relief in some cases, despite the rebuke it received in *MedImmune*, indicates that some limiting principles do exist in the totality-of-circumstances formula.

One small difference is that, since *MedImmune*, the number of licensees versus patentees initiating the action for declaratory relief has reversed. Before *MedImmune*, there were two instances of licensees seeking a declaratory judgment, and one suit by a patentee. Where licensees did seek declaratory relief, the circuit court split, finding a sufficient controversy and therefore subject matter jurisdiction in one instance but not the other.²⁰⁷

By contrast, after *MedImmune*, licensees have not appealed any declaratory relief actions to the Federal Circuit, but one patentee has sought declaratory relief.²⁰⁸ In that instance, however, the patentee was operating within the ANDA regime. Because there are so few cases, it is not possible to draw conclusions with any confidence. The paucity of cases, however, may reflect a change in negotiation strategy by licensors because licensees clearly have more ability to challenge the validity of patents. Finally, where the ANDA regime was invoked, the Federal Circuit's post-*MedImmune* decisions overturned the district courts and found subject matter jurisdiction in both instances.²⁰⁹

2. District Courts

District courts generated more holdings than the Federal Circuit. Many regional circuits have had at least one district court case, both before and after *MedImmune*'s decision during the evaluated time period. Of these cases, the type of parties seeking declaratory relief, i.e., mostly non-licensees, has remained constant.

Broadly speaking, a comparison of district court decisions before and after *MedImmune* was decided demonstrates the lower courts' consistency. Subject matter jurisdiction was found at a somewhat higher rate after *MedImmune*. In the three years before *MedImmune*, district courts found subject matter jurisdiction in 5 of 26 contested cases

(Fed. Cir. 2007). Subject matter jurisdiction denied in: *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2055 (2008); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329 (Fed. Cir. 2008).

²⁰⁷ *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376 (Fed. Cir. 2005) (no jurisdiction); *Pactiv Corp. v. Dow Chem. Co.*, 449 F.3d 1227 (Fed. Cir. 2006) (jurisdiction).

²⁰⁸ *Caraco Pharm. Labs., Ltd v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008). *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897 (Fed. Cir. 2008), presents a similar but distinguishable case because in *Micron*, the patentee sought to preclude the non-licensee's suit for declaratory relief of noninfringement.

²⁰⁹ *Teva Pharm. USA, Inc.*, 482 F.3d 1330 (non-licensee); *Caraco Pharm. Labs., Ltd.*, 527 F.3d 1278 (patentee).

(19%);²¹⁰ in the three years after *MedImmune*, subject matter jurisdiction was found in 19 out of 49 contested cases (39%).²¹¹

The increase in the finding of subject matter jurisdiction has largely occurred in cases brought by non-licensees.²¹² Pre-*MedImmune*, non-licensees were granted subject matter jurisdiction only once out of nine attempts (11%).²¹³ Not unexpectedly, post-*MedImmune*, non-licensees were more successful; subject matter jurisdiction was found in 7 out of 19 attempts (37%).²¹⁴

By contrast, patentees have seen almost the same success rate in precluding subject matter jurisdiction for lack of a controversy. Pre-*MedImmune*, patentees sought to preclude declaratory relief for lack of controversy 8 times out of 8 (100%),²¹⁵ with the courts finding the existence of a controversy only 2 times out of the 8 (25%).²¹⁶ After *MedImmune* there was an increase in the number of patentees seeking to preclude a declaratory judgment in 19 instances out of 21 (90%);²¹⁷

²¹⁰ *Infra* notes 216, 220, 222.

²¹¹ *Infra* notes 212, 213, 217.

²¹² There is one case brought by a licensee, *Linzer Products Corp. v. Sekar*, 499 F. Supp. 2d 540 (S.D.N.Y. 2007). In that case, the licensee sought and was granted subject matter jurisdiction in part and denied in part.

²¹³ *Teva Pharm. USA, Inc. v. FDA*, 398 F. Supp. 2d 176 (D.D.C. 2005).

²¹⁴ *Document Generation Corp. v. AllMeds, Inc.*, No. 07-841-GPM, 2009 WL 2848997 (S.D. Ill. Sept. 1, 2009); *Tesco Corp. v. Weatherford Int'l, Inc.*, No. H-08-2531, 2009 WL 497134 (S.D. Tex. Feb. 26, 2009); *Alpharma, Inc. v. Purdue Pharm. L.P.*, 634 F. Supp. 2d 626 (W.D. Va. 2009); *Astec Am., Inc. v. Power-One, Inc.*, No. 6:07-cv-464, 2008 WL 1734833 (E.D. Tex. April 11, 2008); *Highway Equip. Co., Inc. v. Cives Corp.*, 476 F. Supp. 2d 1079 (N.D. Iowa 2007); *WS Packaging Group, Inc. v. Global Commerce Group, LLC*, 505 F. Supp. 2d 561 (E.D. Wis. 2007); *Judkins v. HT Window Fashions Corp.*, 514 F. Supp. 2d 753 (W.D. Pa. 2007). Subject matter jurisdiction was found in two instances where non-licensees sought to preclude: *PharmaNet, Inc. v. DataSci Ltd. Liability Co.*, No. 08-2965 (GEB), 2009 WL 396180 (D.N.J. Feb. 17, 2009); *EchoStar Satellite LLC v. Finisar Corp.*, 515 F. Supp. 2d 447 (D. Del. 2007).

In one case initiated by a patentee against a non-licensee, the district court found no subject matter jurisdiction. *Hewlett-Packard Co. v. Acceleron LLC*, 601 F. Supp. 2d 581 (D. Del. 2009). The Federal Circuit, however, reversed because it found subject matter jurisdiction. *Hewlett-Packard Co. v. Acceleron LLC*, 587 F.3d 1358 (Fed. Cir. 2009). The numbers reported above reflect the district court's holding for the sake of simplicity.

²¹⁵ *Fairplay Elec. Cars LLC v. Textron Innovations, Inc.*, 431 F. Supp. 2d 491 (D. Del. 2006); *Nutrasweet Co. v. Ajinomoto Co.*, 423 F. Supp. 2d 450 (D. Del. 2006); *Black & Decker Inc. v. Bosch Tool Corp.*, 371 F. Supp. 2d 965 (N.D. Ill. 2005); *Neil Bros. Ltd. v. World Wide Lines, Inc.*, 396 F. Supp. 2d 340 (E.D.N.Y. 2005); *Teva Pharm. USA, Inc. v. Abbott Lab.*, 301 F. Supp. 2d 819 (N.D. Ill. 2004); *Mutual Pharm. Co. v. Pfizer, Inc.*, 307 F. Supp. 2d 88 (D.D.C. 2004); *Institut Pasteur v. Simon*, 332 F. Supp. 2d 755 (E.D. Pa. 2004); *DePalma v. Nike, Inc.*, 341 F. Supp. 2d 178 (N.D.N.Y. 2004).

²¹⁶ The district courts found subject matter jurisdiction in: *Teva Pharm. USA, Inc.*, 301 F. Supp. 2d 819; *Neil Bros. Ltd.*, 396 F. Supp. 2d 340.

²¹⁷ *BridgeLux, Inc. v. Cree, Inc.*, No. C 06-6495 PJH, 2007 WL 2022024 (N.D. Cal. July 9, 2007) (In *BridgeLux*, the court split, finding subject matter jurisdiction for some causes of action and denying it for others); *Nat'l Presort, Inc. v. Bowe Bell &*

subject matter jurisdiction was found in 9 of the 19 cases (47%).²¹⁸ Although patentees were less successful after *MedImmune*, given the greater number of cases (8 versus 19), no final conclusions can be drawn, nor is the increase, from 37.5% to 50% necessarily significant.

Conversely, where patentees have sought declaratory relief, the numbers are so small it is impossible to draw any definitive conclusions.²¹⁹ Before *MedImmune*, patentees sought, and were granted, subject matter jurisdiction once.²²⁰ Similarly, after *MedImmune*, patentees sought subject matter jurisdiction only once, which the court denied.²²¹ But this case was in the context of the ANDA regime, raising a final point.

In the context of the ANDA regime, the parties had mixed success seeking declaratory relief before *MedImmune*. Before *MedImmune*, non-licensees sought declaratory relief once within the ANDA regime and it was granted; in two other instances, non-licensees were able to preclude

Howell Co., 663 F. Supp. 2d 505, 514 (N.D. Tex. 2009); Int'l Development Corp. v. Richmond, No. 09-4595 (GEB), 2009 WL 3818141 (D.N.J. 2009); Hoffman-La Roche Inc. v. Mylan Inc., No. 2:09-01692, 2009 WL 4796736 (D.N.J. Dec. 9, 2009); Argonide Corp. v. In-Tec Water Prods., LLC, No. 6:09-cv0852-Orl-28DAB, 2009 WL 4667398 (M.D. Fla. Dec. 3, 2009); D2L Ltd. v. Blackboard, Inc., No. WDQ-09-1763, 2009 WL 4348806 (D. Md. Dec. 2, 2009); Cobra N. Am., LLC v. Cold Cut Sys. Svenska AB, No. 08-cv-00873-DME-CBS, 2009 WL 4506404 (D. Colo. Nov. 30, 2009); Ass'n for Molecular Pathology v. USPTO, No. 09 Civ. 4515, 2009 WL 3614434 (S.D.N.Y. Nov. 2, 2009); Microsoft Corp. v. WebXchange Inc., C.A. No. 09-484-JJF, 2009 WL 3534845 (D. Del. Oct. 30, 2009); Teva Pharm. USA, Inc. v. Eisai Co., No. 08-2344 (GEB), 2009 WL 2905534 (D.N.J. Sept. 9, 2009); Barnhardt Mfg. Co. v. Illinois Tool Works, Inc., No. 3:08-cr-00617-W, 2009 WL 2498036 (W.D.N.C. Aug. 13, 2009); Vantage Trailers, Inc. v. Beall Corp., No. H-06-3008, 2008 WL 304747 (S.D. Tex. Jan. 31, 2008), *aff'd*, 567 F.3d 745 (5th Cir. 2009); Diamonds.net, LLC, v. Idex Online, Ltd., 590 F. Supp. 2d 593 (S.D.N.Y. 2008); Rite-Hite Corp. v. Delta T. Corp., No. 06-C-1187, 2007 WL 725327 (E.D. Wis. March 7, 2007); FieldTurf USA, Inc. v. Sports Constr. Group, LLC, 507 F. Supp. 2d. 801 (N.D. Ohio 2007); Janssen Pharmaceutica., N.V. v. Apotex, Inc., No. 06-cv-1020 (DMC), 2007 WL 3014702 (D.N.J. Oct. 11, 2007), *aff'd*, 540 F.3d 1353 (Fed. Cir. 2008); Pfizer, Inc. v. Ranbaxy Lab. Ltd., 525 F. Supp. 2d 680 (D. Del. 2007); Cordance Corp. v. Amazon.com, Inc., 521 F. Supp. 2d 340 (D. Del. 2007).

²¹⁸ *BridgeLux, Inc.*, 2007 WL 2022024 (In *BridgeLux*, the court split, finding subject matter jurisdiction for some causes of action and denying it for others; for simplicity, this case is not included in the results); *Ass'n for Molecular Pathology*, 2009 WL 3614434; *Int'l Dev. Corp.*, 2009 WL 3818141; *Cobra N. Am., LLC*, 2009 WL 4506404; *D2L Ltd.*, 2009 WL 4348806; *Argonide Corp.*, 2009 WL 4667398; *Diamonds.net, LLC*, 590 F. Supp. 2d 593; *Rite-Hite Corp.*, 2007 WL 725327; *FieldTurf USA, Inc.*, 507 F. Supp. 2d. 801; *Cordance Corp.*, 521 F. Supp. 2d 340.

²¹⁹ The small numbers preclude any meaningful assessment of how the changes in preliminary injunction standards—making it more difficult for patentees to use that remedy—have affected the strategy of patentees and licensees with respect to the wisdom of seeking declaratory relief as an alternative remedy. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006); David W. Opderbeck, *Patent Damages Reform and the Shape of Patent Law*, 89 B.U. L. REV. 127, 131 (2009) (assessing impact of recent patent cases, including *eBay* and *MedImmune*).

²²⁰ *Takeda Chem. Indust., Ltd. v. Watson Pharm., Inc.*, 329 F. Supp. 2d 394 (S.D.N.Y. 2004).

²²¹ *SB Pharmco P.R., Inc. v. Mut. Pharm. Co.*, 552 F. Supp. 2d 500 (E.D. Pa. 2008) (ANDA case).

subject matter jurisdiction.²²² But a non-licensee has yet to seek declaratory relief under the ANDA regime since *MedImmune*. In fact, for the time period evaluated, there have been only four cases brought to the district courts under the ANDA regime.²²³ In one case, subject matter jurisdiction was sought, but the court declined to hear the action; in the other three the patentee successfully sought to preclude subject matter jurisdiction.

3. Conclusion

Both the Federal Circuit and the district courts appear to have largely adhered to their previous patterns despite *MedImmune*. Perhaps most notable is the fact that licensees, although never heavily involved in declaratory judgment actions, have not yet appeared before the Federal Circuit.²²⁴ Given that *MedImmune's* facts surrounded the conduct of a licensee, licensors may have simply avoided litigation through negotiation or strategic decision-making. Nevertheless, it is intriguing that of the cases following *MedImmune* (including cases returning to court because of the *MedImmune* decision) the Federal Circuit has not addressed even one action for declaratory relief brought by a licensee.

C. *MedImmune: An Assessment in Patent Litigation*

Both *SanDisk* and *Teva 2007* demonstrate a focus on the *potential* for suit in the future, which constitutes a change from the previous focus on the *probability* of a suit. In addition, courts appear to have begun with the presumption of a controversy, as opposed to placing the burden on the party seeking declaratory relief to make that showing. This shift in the burden is consistent with one of the concerns Justice Thomas raised.²²⁵ This effect is not surprising, however, since the rationale employed in *MedImmune* lends itself to expansion: a non-repudiating party can demonstrate a controversy absent any direct threat of litigation. Thus, parties not in an agreement presumptively can be understood to have adverse interests and controversy unless someone demonstrates otherwise.

The potentially expansive effects of *MedImmune* have been constrained, however, within the ambit of government regulated ANDA

²²² Subject matter jurisdiction sought and granted: *Teva Pharm., USA, Inc. v. FDA*, 398 F. Supp. 2d 176 (D.D.C. 2005). Subject matter jurisdiction precluded: *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187 (S.D.N.Y. 2005); *Glaxo Group Ltd. v. Dr. Reddy's Lab., Ltd.*, 325 F. Supp. 2d 502 (D.N.J. 2004).

²²³ *Hoffman-La Roche Inc. v. Mylan Inc.*, No. 2:09-01692, 2009 WL 4796736 (D.N.J. Dec. 9, 2009); *Teva Pharm. USA, Inc. v. Eisai Co.*, No. 08-2344 (GEB), 2009 WL 2905534 (D.N.J. Sept. 9, 2009); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, No. 06-cv-1020 (DMC), 2007 WL 3014702 (D.N.J. Oct. 11, 2007), *aff'd*, 504 F.3d 1353 (Fed. Cir. 2008); *SB Pharmco P.R., Inc.*, 552 F. Supp. 2d 500 (subject matter jurisdiction sought and declined).

²²⁴ For the time period evaluated.

²²⁵ *See supra* notes 71–98.

cases.²²⁶ The ANDA creates clear procedural obligations that constrain a patentee's conduct and options. Because of these constraints, courts may feel more secure in establishing hurdles on a non-patentee seeking declaratory relief. In effect, the ANDA provides the scope through which to evaluate the relevant facts and circumstances.

In sum, the lower courts have recognized the lack of limiting factors in the totality-of-circumstances test, but do not appear to have overly stretched their reasoning to determine whether a controversy exists. Further, the consistency in the outcomes of the Federal Circuit and district courts underscores a constrained framework the courts have adopted to prevent unrestrained growth.

D. *MedImmune's Impact Outside of Patent Litigation*

MedImmune has begun to seep into areas of the law outside of patent litigation, which is appropriate given that the major effect of the Court's ruling was to return declaratory relief in patent cases to the trans-substantive standard. Circuits that had relied on versions of the Federal Circuit's reasonable apprehension of suit test in other contexts have recognized that such precedent is now superseded. These courts have interpreted *MedImmune* as the Federal Circuit has. They agree that the Supreme Court rejected the reasonable apprehension of imminent suit test and lowered the bar for determining the existence of a controversy.²²⁷

For instance, the Tenth Circuit Court of Appeals applied *MedImmune* in a trademark case and overturned precedent that it had built upon the Federal Circuit's reasonable apprehension of imminent suit test. In *Surefoot LC v. Sure Foot Corp.*, both parties were manufacturers of footwear.²²⁸ Sure Foot Corp. had "repeatedly accused Surefoot LC[] of infringing on its trademark, [and] occasionally threatened litigation . . . and filed five administrative petitions opposing Surefoot LC's attempts to obtain trademark registrations."²²⁹ In turn, Surefoot LC brought a declaratory judgment action to ascertain "whether it was infringing on Sure Foot Corp.'s [trademark] rights."²³⁰

The district court held there was no controversy because Surefoot LC lacked a reasonable apprehension of an imminent suit for trademark infringement from Sure Foot Corp. The Tenth Circuit, however, overturned the district court. The precedent relied upon by the district court, the Circuit's own opinion in *Cardtoons, L.C. v. Major League Baseball*

²²⁶ See, e.g., *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 421 (D. Del. 2007) (Parties submitting an ANDA initiate a paragraph IV certification process because "[a] paragraph IV certification begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent").

²²⁷ See, e.g., *Revell v. Port Auth. of N.Y. & N.J.*, No. 06-402 (KSH), 2007 WL 2318390 (D.N.J. Aug. 10, 2007).

²²⁸ 531 F.3d 1236, 1238 (10th Cir. 2008).

²²⁹ *Id.* at 1238.

²³⁰ *Id.*

Players Ass'n,²³¹ was no longer good law because of *MedImmune*.²³² *Cardtoons* had been developed in reliance “on an extensive body of case law—developed primarily by the Federal Circuit[’s]” reasonable apprehension of suit test.²³³ But “[i]n light of *MedImmune*’s direction . . . *Cardtoons* [was] no longer good law.”²³⁴ The court went on to apply *MedImmune*’s broader, new standard of totality of circumstances to find a controversy.²³⁵

As the Tenth Circuit noted in *Surefoot LC*, *MedImmune* was not limited to patent or even to intellectual property cases.²³⁶ The Supreme Court’s analysis in *MedImmune* took a trans-substantive approach by relying on two opinions where the underlying dispute lay in contracts of insurance.²³⁷ Furthermore, the Court in *MedImmune* never sought to limit the holding to patent litigants. As the majority opinion stated, the “petitioner has raised and preserved a contract claim.”²³⁸

The Tenth Circuit’s trans-substantive interpretation of *MedImmune* is hardly unique. District courts based in other circuits have also applied *MedImmune* broadly, finding it applicable beyond the scope of patent litigation. For example, in *Geisha, LLC v. Tuccillo*, *Geisha*, which alleged that it held a trademark in a restaurant name and a stylized rendering of the name, brought a declaratory judgment action against Tuccillo, who also claimed a trademark in the name and a very similar rendering.²³⁹ As had the Tenth Circuit Court of Appeals in *Surefoot LC*, Judge Rebecca Pallmeyer of the Northern District of Illinois applied *MedImmune* and precedent interpreting *MedImmune*.²⁴⁰

MedImmune has also been applied outside of intellectual property disputes. For example, in *Dow Chemical Co. v. Reinhard*, Dow Chemical

²³¹ 95 F.3d 959 (10th Cir. 1996).

²³² *Surefoot LC*, 531 F.3d at 1241–42.

²³³ *Id.*

²³⁴ *Id.* at 1242.

²³⁵ *Id.* at 1244.

²³⁶ *Id.* at 1243.

²³⁷ *Id.* (“[T]wo of the cases the *MedImmune* Court cited in the process of rejecting the reasonable-apprehension-of-suit test were insurance cases—themselves well outside the intellectual property, much less patent, context. See *MedImmune*, 127 S. Ct. at 744 n.11 (citing *Maryland Cas.*, 312 U.S. at 273 . . . (insurance case), and *Aetna*, 300 U.S. at 239 . . . (same)).”).

²³⁸ *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 770 (2007).

²³⁹ *Geisha, LLC v. Tuccillo*, 525 F. Supp. 2d 1002, 1004 (N.D. Ill. 2007). The court noted the circumstances in *Geisha* were converse to the typical declaratory judgment action, but that “[i]n *Lang [v. Pac. Marine & Supply Co.*, 895 F.2d 761 (Fed. Cir. 1990)], . . . the Federal Circuit addressed this type of situation and modified the reasonable-apprehension-of-suit test to fit the reversed circumstances.” *Geisha, LLC*, 525 F. Supp. 2d at 1012.

²⁴⁰ Despite applying *MedImmune*, the court held that there was no subject matter jurisdiction because the declaratory relief defendant’s plans to open a restaurant with the same name were not concrete enough to constitute a controversy. *Geisha, LLC*, 525 F. Supp. 2d at 1013. See also *Young v. Vannerson*, 612 F. Supp. 2d 829, 846 (S.D. Tex. 2009); *AARP v. 200 Kelsey Assocs., LLC*, No. 06 Civ. 81 (SCR), 2009 WL 47499 (S.D.N.Y. Jan. 8, 2009) (applying *MedImmune* and *Geisha* in trademark infringement disputes).

filed for declaratory relief along with other claims to determine the company's "obligation to Reinhard . . . under ERISA to . . . provide notice of coverage under COBRA."²⁴¹ Citing *MedImmune*, the district court denied the request for declaratory judgment because "Dow Chemical [had] not here identified any basis on which it face[d] a coercive dilemma."²⁴² Returning to the roots of declaratory relief precedent, a district court in Colorado has applied *MedImmune* to an insurance coverage dispute.²⁴³ Further affirming the trans-substantive impact of *MedImmune*, judges of the Sixth Circuit have twice applied the case in matters having nothing to do with intellectual property.²⁴⁴

E. *MedImmune and the Discretion to Decline Actions for Declaratory Relief*

At the end of his *MedImmune* opinion, Justice Scalia went to some length to remind lower courts that, even if there was subject matter jurisdiction over the controversy, they retained "unique and substantial" discretion to decide whether to declare the rights of the parties.²⁴⁵ If courts wanted to continue to make it relatively difficult for declaratory relief plaintiffs to initiate actions, i.e., to keep the discredited reasonable apprehension of imminent suit test in another guise, one would expect that they would seize the opportunity afforded by the discretionary alternative.

However, courts do not seem to be clutching this option as often as they could. Only twenty patent cases decided in the lower courts from January 2007 to January 2010 have even cited the Supreme Court opinions in both *MedImmune* and *Wilton v. Seven Falls Co.*,²⁴⁶ the lead precedent on the discretion to decline an action for declaratory relief.²⁴⁷

²⁴¹ Dow Chem. Co. v. Reinhard, No. 07-12012-BC, 2007 WL 5361218, at *9 (E.D. Mich. Sept. 20, 2007). Dow Chemical fired an executive vice-president (and another employee) for engaging "in activity harmful to the interests of Dow Chemical" and was engaged in protracted litigation with the defendants. *Id.* at *2.

²⁴² *Id.* at *9.

²⁴³ Am. Auto. Ins. Co. v. Marlow, 666 F. Supp. 2d 1209 (D. Colo. 2009).

²⁴⁴ Sch. Dist. of Pontiac v. Sec'y of the U.S. Dep't of Educ., 584 F.3d 253, 278 (6th Cir. 2009) (en banc) (opinion of Sutton, J., for eight judges in equally divided court) (applying *MedImmune* to case involving No Child Left Behind Act); Fieger v. Mich. Sup. Ct., 553 F.3d 955 (6th Cir. 2009) (applying *MedImmune* to an action filed by Dr. Kevorkian's former attorney who was contesting censure for ethical violations for comments he made about a judicial panel).

²⁴⁵ *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 776–77 (2007). See *supra* text accompanying notes 68–70.

²⁴⁶ *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995) (holding that court had discretion to determine whether or not to stay a declaratory judgment action during parallel state court proceedings).

²⁴⁷ See, e.g., *AllMeds v. Document Generation Corp.* (*AllMeds II*), No. 07-841-GPM, 2009 WL 3461896 (S.D. Ill. Oct. 23, 2009). *AllMeds II* is related to *Document Generation v. AllMeds, Inc.*, No. 07-841-GPM, 2009 WL 2848997 (S.D. Ill. Sept. 1, 2009). In *AllMeds II*, however, the court addressed whether it should abstain. In its decision, the court mentioned *Wilton*, just as it did in *Document Generation v. AllMeds, Inc.*, but it

In the three cases in the Federal Circuit, the court has used *Wilton* one time to decline to exercise the discretion to proceed in a declaratory relief case and one time to explain why it was appropriate to proceed.²⁴⁸ Of the seventeen cases²⁴⁹ in the district courts, *Wilton* was the basis of declining jurisdiction three times, and was used three times to buttress the decision to exercise jurisdiction.²⁵⁰

It is hard to know why courts have not used *Wilton* more often in patent cases. Any time a court concluded that there was a controversy under *MedImmune*, it would make sense to go on to explain why it would not decline to exercise its power, especially if the declaratory relief defendant raised the issue as an alternative ground for dismissal. In cases where the district court concluded that it did not have jurisdiction, it would seem smart to avoid being reversed on appeal by discussing *Wilton* as an alternative basis for the dismissal. The district court could easily explain why, even if its analysis of the existence of a controversy under *MedImmune* proved to be incorrect, it would nevertheless exercise its discretion to dismiss under *Wilton*. The simple expedient of discussing *Wilton* would discourage an appeal or make the chance of being affirmed much greater because of the deference owed to the district court under the abuse of discretion standard.²⁵¹

relied more substantively on *Brillhart v. Excess Ins. Co. of America*, 316 U.S. 491 (1942), as the major precedent.

²⁴⁸ *Micron Tech., Inc. v. MOSAID Techs., Inc.*, 518 F.3d 897 (Fed. Cir. 2008); *Cellco P'ship v. Broadcom Corp.*, 227 F. App'x 889 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007).

²⁴⁹ *Google, Inc. v. EMSAT Adv. Geo-Location Tech., LLC*, No. 4:09CV1243, 2010 WL 55685 (N.D. Ohio Jan. 4, 2010); *Microsoft Corp. v. WebXchange Inc.*, No. 09-484-JJF, 2009 WL 3534845 (D. Del. Oct. 30, 2009); *Document Generation Corp.*, 2009 WL 2848997; *Teva Pharm. USA, Inc. v. Eisai Co.*, No. 08-2344 (GEB), 2009 WL 2905534, (D.N.J. Sept. 9, 2009); *Warrior Sports, Inc. v. STX, LLC*, 596 F. Supp. 2d 1070 (E.D. Mich. 2009); *Duhn Oil Tool, Inc. v. Cooper Cameron Corp.*, 609 F. Supp. 2d 1090 (E.D. Cal. 2009); *Photothera v. Oron*, No. 07cv490-MMA(AJB), 2009 WL 734282 (S.D. Cal. Mar. 19, 2009); *Dish Network Corp. v. TiVo, Inc.*, 604 F. Supp. 2d 719 (D. Del. 2009); *Ours Tech, Inc. v. Data Drive Thru, Inc.*, 645 F. Supp. 2d 830 (N.D. Cal. 2009); *Berry Floor USA, Inc. v. Faus Group, Inc.*, No. 08-CV-0044, 2008 WL 4610313 (E.D. Wis. Oct. 15, 2008); *Idaho Energy v. Harris Contracting Co.*, No. CV07-423-N-EJL, 2008 WL 4498809 (D. Idaho Sept. 30, 2008); *Delphi Corp. v. Automotive Tech. Int'l, Inc.*, No. 08-CV-11048, 2008 WL 2941116, (E.D. Mich. July 25, 2008); *3D Systems, Inc. v. Envisiontec, Inc.*, 575 F. Supp. 2d 799 (E.D. Mich. 2008); *Priority Healthcare Corp. v. AETNA*, 590 F. Supp. 2d 663 (D. Del. 2008); *Diamonds.net, LLC v. Idex Online Ltd.*, 590 F. Supp. 2d 593 (S.D.N.Y. 2008); *Highway Equip. Co., Inc. v. Cives Corp.*, 476 F. Supp. 2d 1079 (N.D. Iowa 2007); *Crossbow Tech., Inc. v. YH Tech.*, 531 F. Supp. 2d 1117 (N.D. Cal 2007).

²⁵⁰ In the remaining eleven cases, *Wilton* was cited, but was not used as a major precedent.

²⁵¹ *See, e.g., Micron Tech., Inc.*, 518 F.3d at 905 (reversing district court because it had applied the now-moribund Federal Circuit test, and because the lower court neglected to evaluate the "convenience factors" of 28 U.S.C. § 1404(a) before declining subject matter jurisdiction and thereby "effectively transferring the case to another jurisdiction" where the parties were involved in related litigation).

A good example of a missed opportunity to apply *Wilton* is *Hewlett-Packard Co. v. Acceleron, LLC*.²⁵² In *Hewlett-Packard*, District Judge Sue Robinson applied *MedImmune* and post-*MedImmune* precedent from the Federal Circuit and other district courts to a motion to dismiss an action for declaratory relief in a classic patent case. After carefully reviewing the relevant precedent, Judge Robinson granted the dismissal requested by the patentee, Acceleron. The trial judge concluded that she did not have subject matter jurisdiction over the action for declaratory relief involving possible infringement by HP's Blade Server products.²⁵³ The case was a close one under the totality-of-circumstances test, and the court went out of its way to underscore the facts leading to its conclusion. For example, the district court cautioned that its "holding should not be interpreted as foreclosing jurisdiction in every case involving a carefully crafted letter."²⁵⁴ In dismissing for lack of subject matter jurisdiction, the court did not mention either *Wilton* or the discretion to decline to exercise jurisdiction.

Chief Judge Paul Michel, writing for the circuit panel on appeal, reversed. After looking "objectively and in totality,"²⁵⁵ the panel saw the facts adding up a little differently. In the circuit court's view, once Acceleron had taken affirmative steps constituting an implied assertion of its rights against HP's Blade Server products, and HP disagreed, there was subject matter jurisdiction arising from a "definite and concrete" dispute.²⁵⁶ The circuit court observed that it agreed with Judge Robinson's "careful opinion analyzing declaratory judgment jurisdiction [that] there is no bright-line rule for distinguishing those cases that satisfy the actual case-or-controversy requirement from those that do not."²⁵⁷ Nevertheless, due to *MedImmune*, "[o]ur jurisprudence must consequently also evolve, and in this case the facts demonstrate adverse legal interests that warrant judicial resolution."²⁵⁸

For present purposes, it is not necessary to resolve whether Judge Robinson or Chief Judge Michel's panel opinion placed the facts of this close case on the correct side of a non-existent bright line. Nor is it important to analyze whether the appellate court gave appropriate deference to the considered findings of the trial court. Nevertheless, it seems reasonable to presume that the Federal Circuit would have had a much harder time reversing "objectively and in totality" if the district court spent a bit of time buttressing its conclusion with a careful analysis under *Wilton* as to why it would not exercise its discretion to hear HP's action even if it had subject matter jurisdiction under *MedImmune*.

²⁵² *Hewlett-Packard Co. v. Acceleron, LLC*, 601 F. Supp. 2d 581 (D. Del. 2009), *rev'd*, 587 F.3d 1358 (Fed. Cir. 2009).

²⁵³ *Id.* at 583, 589.

²⁵⁴ *Id.* at 589.

²⁵⁵ *Hewlett-Packard Co. v. Acceleron, LLC*, 587 F.3d at 1364.

²⁵⁶ *Id.*

²⁵⁷ *Id.*

²⁵⁸ *Id.*

In contrast to the missed opportunity represented by *Hewlett-Packard*, one of the few examples of what should be the ordinary way to apply *Wilton* is *Warrior Sports, Inc. v. STX, LLC*.²⁵⁹ In a classic patent case, Warrior Sports alleged that a competitor, STX, sold a model of lacrosse gloves that infringed on the plaintiff's patents for hockey gloves.²⁶⁰ As part of its defense, STX filed a counterclaim seeking a declaration of noninfringement and of the invalidity of Warrior Sports' patents.²⁶¹ The parties came to a partial settlement, in which Warrior Sports agreed not to seek damages for any sales by STX prior to July 31, 2009.²⁶²

Warrior Sports sought dismissal of the entire action without prejudice because of the partial settlement and because no one knew what STX might choose to sell in the future.²⁶³ Despite the partial settlement, STX contended that the district court still had jurisdiction over its counterclaim regarding infringement and invalidity because of its intent to sell gloves with similar or identical features after July 31, 2009. Writing in January 2009, Judge David Lawson of the Eastern District of Michigan dismissed the action without prejudice. The district court explained that the present controversy was mooted by the settlement.²⁶⁴ Unlike in *MedImmune*, STX was under no compulsion to choose to pay disputed royalties or face the risk of suit (at least through July 31, 2009). The court concluded that the possibility that a suit might arise because of the marketing choices STX might make after July 31, 2009, did not render the potential controversy sufficiently ripe to support jurisdiction under Article III of the U.S. Constitution or under the Declaratory Judgment Act.²⁶⁵

The court went on to discuss *Wilton*, even though the parties had not raised the matter. Given the settlement agreement, STX faced no risk of litigation for its present conduct and did not have to give up any rights. Any risk of suit STX faced "in the distant future rests within its immediate control."²⁶⁶ Even if the controversy in its present state was of sufficient immediacy to support jurisdiction, the court concluded that it would not exercise its discretion to hear the action for declaratory relief at that time.²⁶⁷

²⁵⁹ *Warrior Sports, Inc. v. STX, LLC*, 596 F. Supp. 2d 1070 (E.D. Mich. 2009).

²⁶⁰ *Id.* at 1072.

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.* at 1072-73.

²⁶⁴ *Id.* at 1072.

²⁶⁵ The court pointed out that STX had not shown evidence of what its product line would be after July 31, 2009, so there was no way to judge how similar the products might be to Warrior Sports' patents. STX offered only ambiguous statements of intent to sell products after the expiration of the time period. *Id.* at 1076-77.

²⁶⁶ *Id.* at 1077.

²⁶⁷ *Id.* For a similar example in the ANDA context, see, e.g., *Teva Pharm. USA, Inc. v. Eisai Co.*, No. 08-2344 (GEB), 2009 WL 2905534 (D.N.J. Sept. 9, 2009). In this case, the district court wrote a lengthy opinion explaining why Teva had not

Although consideration of *Wilton* can help to insulate a case from reversal on appeal,²⁶⁸ it is not complete protection. The Federal Circuit has been appropriately skeptical when the “discussion” of *Wilton* consisted of merely a rote recital that the district court would decline to exercise discretion.²⁶⁹ The Federal Circuit has occasionally second-guessed the exercise of discretion, but with a remand for further consideration by the district court.²⁷⁰

A good example of the Federal Circuit’s thinking is presented in *Micron Technology, Inc. v. MOSAID Technologies, Inc.*²⁷¹ Micron Technology filed an action for declaratory relief against MOSAID in the Northern District of California. MOSAID had pursued an aggressive litigation and licensing strategy to enforce its circuit technology patents, including suits filed against three of the four major competitors in the manufacture of dynamic random access memory chips (DRAMs).²⁷² Given that it was one of the four largest manufacturers, Micron assumed that it would be the next company in the cross-hairs. It accordingly sought a declaration that it had not infringed on fourteen patents held by MOSAID. The very next day, MOSAID filed a patent infringement action against Micron and some smaller manufacturers in the Eastern District of Texas.²⁷³ Despite this record, Judge Fogel of the Northern District dismissed Micron’s action under the reasonable apprehension of suit test. He indicated that he would exercise the discretion to dismiss even if there was subject matter jurisdiction, which he thought was “tenuous at best.”²⁷⁴

presented a justiciable controversy under Article III. For good measure, the court added a brief paragraph explaining why, even if there were subject matter jurisdiction, it would choose not to hear the case under *Wilton*. *Id.* at *12–13.

²⁶⁸ For example, in *Cellco P’ship v. Broadcom Corp.*, 227 F. App’x 889 (Fed. Cir. 2007) (per curiam), the Federal Circuit concluded “that the district court [had] erred as a matter of law in holding that no actual controversy existed between the parties” under the intervening *MedImmune* test. *Id.* at 889. However, the Federal Circuit affirmed the dismissal despite the application of the discarded standard. *Id.* at 890. The dismissal was warranted as an exercise of discretion because the district court had also explained how maintaining the declaratory relief action would be an inefficient use of judicial resources. Other proceedings were pending which raised the same issues. *Id.*

²⁶⁹ *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007). In *SanDisk*, the district court provided no explanation as to why it said that it would exercise its discretion not to hear the claims even if it had jurisdiction. When the Federal Circuit had to reverse because of the intervening *MedImmune* decision, it acidly stated, “we discern little basis for the district court’s refusal to hear the case and expect that in the absence of additional facts, the case will be entertained on the merits on remand.” *Id.*

²⁷⁰ *E.g.*, *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271, 1289 (Fed. Cir. 2007).

²⁷¹ 518 F.3d 897 (Fed. Cir. 2008).

²⁷² *Id.* at 899.

²⁷³ The Texas action concerned some of the patents in the California action as well as some additional ones. *Id.* at 900.

²⁷⁴ *Id.* at 903.

The Federal Circuit reversed. Judge Randall Rader's opinion for the panel discussed how the intervention of *MedImmune* had changed the jurisdictional analysis. Under the new totality-of-circumstances test, the panel thought that MOSAID's saber-rattling gave Micron ample reason to file for declaratory relief.²⁷⁵ Judge Rader spent a considerable part of the opinion on the question of discretion. The panel observed that the new jurisdictional standard had eased the bar to filing actions for declaratory relief. This enabled the patentees and would-be infringers to make a "forum-seeking race to the courthouse,"²⁷⁶ as had happened in this case.

The circuit rejected the reasons Judge Fogel had relied upon in dismissing Micron's action. First, the court noted that Judge Fogel's belief that the case was "tenuous at best"²⁷⁷ was based on the obsolete reasonable apprehension of suit test. Second, the circuit rejected the "broader" scope of the Texas action because that was easily manipulated by simply adding another defendant or another claim.²⁷⁸ Finally, the circuit rejected the district court's reliance on the fact that neither forum had invested much effort in their respective actions.²⁷⁹

The circuit court observed that in cases "with competing forum interests, the trial court" was obliged to apply the "convenience factors' found in a transfer analysis under 28 U.S.C. § 1404(a)."²⁸⁰ By focusing on these factors,²⁸¹ rather than any rule of thumb such as first to file, the circuit hoped that the parties would be deterred from racing to forum shop. Applying the convenience factors to the case at hand, the circuit panel thought that the Northern District of California was a more convenient forum than the "well-known patent forum" of the Eastern District of Texas.²⁸² Since it would be an abuse of discretion to transfer the case to Texas under § 1404(a), a dismissal which effectively transferred the case to that forum was equally an abuse of discretion.²⁸³

²⁷⁵ *Id.* at 901.

²⁷⁶ *Id.* at 902.

²⁷⁷ *Id.* at 903.

²⁷⁸ The court noted that the action in Texas was actually narrower in some respects than the California action. *Id.*

²⁷⁹ *Id.* at 903–04.

²⁸⁰ *Id.* at 902–03.

²⁸¹ "The convenience and availability of witnesses, absence of jurisdiction over all necessary or desirable parties, possibility of consolidation with related litigation, or considerations relating to the interest of justice must be evaluated to ensure the case receives attention in the most appropriate forum." *Id.* at 904–05.

²⁸² The strongest factor favoring the forum was the fact that MOSAID, a Canadian company, based its U.S. operations in the Northern District of California. *Id.* at 905.

²⁸³ "A district court's discretion to decline jurisdiction is reviewed for an abuse of that discretion An abuse of discretion occurs when: '(1) the court's decision was clearly unreasonable, arbitrary, or fanciful; (2) the decision was based on an erroneous conclusion of law; (3) the court's findings were clearly erroneous; or (4) the record contains no evidence upon which the court rationally could base its decision.'" *Id.* (citing *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991)).

The *Micron* opinion provides fairly clear guidance for district courts in the race to the courthouse scenario.²⁸⁴ Parties in the declaratory relief action can use this opinion as a template for how to provide reasoned arguments to the district courts in support of a decision to accept or decline to hear the action.²⁸⁵ It is not difficult to do, and will provide more protection from reversal on abuse of discretion.²⁸⁶

V. CONCLUSION

MedImmune removed nearly any formal limiting factors or constraints to find the existence of a controversy in actions for declaratory relief.²⁸⁷ In those instances where the courts have found limits, only the ANDA regime appears to be a formal constraining force.²⁸⁸ Furthermore, absent the framework imposed by federal regulations, there may be a small trend toward a finding of controversy in sometimes attenuated circumstances.²⁸⁹

But the courts have not demonstrated a willingness to completely abandon all boundaries when identifying a controversy. Absent any firm limiting principles, courts have instead maintained a narrow focus on the totality-of-circumstances test. Thus, *MedImmune* has been interpreted to remove only a rigid definition of what must occur to demonstrate a

²⁸⁴ Judge Fogel later applied *Micron* to deny a request to exercise the discretion to dismiss a declaratory relief action in favor of pending litigation in the Eastern District of Texas. Judge Fogel applied the convenience factors as *Micron* instructed. *Acer, Inc. v. Tech. Props. Ltd.*, No. C 08-877 JF (HRL), 2008 WL 4661603 (N.D. Cal. Oct. 21, 2008).

²⁸⁵ Another very good example of the careful exercise of discretion under *Wilton* is contained in *Google, Inc. v. EMSAT Advanced Geo-Location Tech., LLC*, No. 4:09CV1243, 2010 WL 55685 (N.D. Ohio Jan. 4, 2010). After finding that it had subject matter jurisdiction to hear a patent dispute concerning Google Maps, the district court nevertheless declined to hear the matter after analyzing the case under the Sixth Circuit's five-factor test. *Id.* at *3–6.

²⁸⁶ See, e.g., Lorelei Ritchie de Larena, *Re-evaluating Declaratory Judgment Jurisdiction in Intellectual Property Disputes*, 83 IND. L.J. 957 (2008); Paul J. LaVanway, Jr., Note, *Patent Licensing and Discretion: Reevaluating the Discretionary Prong of Declaratory Judgment Jurisdiction After MedImmune*, 92 MINN. L. REV. 1966 (2008) (discussing factors courts should consider in exercising discretion in declaratory judgment actions). For discussion of the courts' use of that discretion in other declaratory relief contexts, see *Sherwin-Williams Co. v. Holmes County*, 343 F.3d 383, 390 (5th Cir. 2003) (quoting formulations from five other circuits). See also *Gemini Ins. Co. v. Clever Const., Inc.*, No. 09-00290 DAE-BMK, 2009 WL 3378593, at *3 (D. Haw. Oct. 21, 2009) (applying discretionary factors in context of absent necessary party); Grace M. Geisel, *The Expanded Discretion of Lower Courts to Regulate Access to the Federal Courts After Wilton v. Seven Falls Co.: Declaratory Judgment Actions and Implications Far Beyond*, 33 HOUS. L. REV. 393 (1996).

²⁸⁷ See *supra* notes 43–47.

²⁸⁸ See, e.g., *SB Pharmco P.R., Inc. v. Mut. Pharm. Co.*, 552 F. Supp. 2d 500 (E.D. Pa. 2008).

²⁸⁹ See, e.g., *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007).

controversy, i.e., the looming presence of imminent suit. In effect, the courts have interpreted *MedImmune* as removing constraints on *how* a controversy may arise, not the prerequisite that a controversy must exist. As a result, there has been no torrent of declaratory relief actions, far-fetched or otherwise.

The analysis presented here cannot entirely refute the concern Justice Thomas expressed, that the lower courts were given too much discretion to render declaratory opinions in situations which were actually too hypothetical. As Justice Thomas noted, another issue still exists in the shift of burden of showing a case or controversy from declaratory relief plaintiffs to defendants. Consequently, managing the application of *MedImmune* rests not in the imposition of new limiting factors per se, but in assuring that declaratory relief plaintiffs shoulder the burden to demonstrate the existence of a controversy in their cases.²⁹⁰

Preserving the burden on the declaratory relief plaintiff may require the courts to reintroduce some objective measurements. For example, the Federal Circuit might be able to resurrect one part of the reasonable apprehension test, in a revised form of the notion of imminence. Although *MedImmune* rejected the reasonable apprehension of imminent suit test, the Federal Circuit still might be able to limit actions for declaratory judgments where time is not of the essence.²⁹¹

For instance, in *Teva 2007*, the Federal Circuit found that the four therapeutic patents at-large might still be sued on. Implicit to the court's findings, however, were the time limits imposed by the ANDA regulatory process in which a claim must be filed. By applying a narrow reading of *Teva 2007*—a declaratory relief action would be precluded if a plaintiff were unable to provide an exact point in time at which a patent might be

²⁹⁰ Another important means of managing the potential effect of *MedImmune* is to draft licensing agreements in light of the case. One list of possible techniques includes: “contractually prohibiting the licensee from challenging patent validity, terminating if the licensee files a challenge, increasing royalties if the licensee files a challenge, requiring that the licensee pay the licensor’s costs in the event of a challenge, imposing venue limitations, or requiring pre-filing mediation or arbitration.” Lawrence K. Nodine, et al., *Declaratory Judgment Jurisdiction and Injunctions in Patent Cases After MedImmune and eBay*, 948 P.L.I./PAT 599, 605 (2008). For further discussion, see Toshihiro Kuwahara, *Drafting Strategies for Licensing Agreements After MedImmune Decision*, 927 P.L.I./PAT 141 (2008); Liza Vertinsky, *Reconsidering Patent Licensing in the Aftermath of MedImmune*, 45 HOUS. L. REV. 1609 (2009); M. Natalie Alfaro, Comment, *Barring Validity Challenges Through No-Challenge Clauses and Consent Judgments: MedImmune’s Revival of the Lear Progeny*, 45 HOUS. L. REV. 1277 (2008); Stephanie Chu, Note, *Operation Restoration: How Can Patent Holders Protect Themselves from MedImmune?*, 2007 DUKE L. & TECH. REV. 008 (2007), <http://www.law.duke.edu/journals/dltr/articles/pdf/2007DLTR0008.pdf>.

²⁹¹ For example, the Supreme Court has reaffirmed the imminence requirement as part of the standing doctrine in another context: “Such ‘some day’ intentions—without any description of concrete plans, or indeed any specification of *when* the some day will be—do not support a finding of the ‘actual or imminent’ injury that our cases require.” *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1151 (2009) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 (1992)).

challenged—the court might assure that a plaintiff’s litigation strategy focuses on objective actions by the defendant that exerted a coercive force. Further, the court might be able to extend this reasoning beyond the ANDA regime under *SanDisk*, by focusing on the means through which companies such as STMicroelectronics initiated contact, e.g., the point in time that in-house counsel assumed the negotiating lead in lieu of the engineering department. This requirement of specificity would: (1) assist in constraining attenuated third-party threats; (2) allow the lower courts to build on the proposition that at least one limiting factor does in fact exist in the totality-of-circumstances test; and (3) provide practitioners with a more predictable process through which to advise clients on the best procedures to follow to prevent suit. These changes would be consistent with the totality-of-circumstances test and still allow licensees to sue for declaratory relief in appropriate circumstances.²⁹²

A more powerful tool, however, may rest in the courts’ ability to dismiss actions for declaratory relief on discretionary grounds. Yet, it is curious that the lower courts have not placed greater reliance on the wide discretion they enjoy under *Wilton*²⁹³ to dismiss an action at the initial stage even if there is controversy, or to choose to deny declaratory relief at a later point.²⁹⁴ The Supreme Court has consistently struck a very deferential stance on the ability of the lower courts to exercise their discretion. As Justice Scalia noted in remanding *MedImmune*, “[w]e have found it ‘more consistent with the statute . . . to vest district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp.’”²⁹⁵ Declaratory relief defendants, such as patentees, can make it easier for lower courts to

²⁹² Declaratory relief defendants might find support for this approach in the Supreme Court’s new directive to district courts to demand more detail from all plaintiffs if their complaints are challenged under Rule 12(b)(6) of the Federal Rules of Civil Procedure. District courts have been informed that they have the power to ensure that the facts pleaded are sufficient in detail and constitute *plausible* claims for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949–50 (2009). *See, e.g.*, *Ass’n for Molecular Pathology v. USPTO*, No. 09 Civ. 4515, 2009 WL 3614434, at *28 (S.D.N.Y. Nov. 2, 2009); *Capitol Specialty Ins. Corp. v. Whitaker*, No. 09-cv-92-JPG, 2009 WL 2488275, at *1–2 (S.D. Ill. Aug. 13, 2009) (both assessing actions for declaratory relief under *Iqbal*); Kevin M. Clermont, *Litigation Realities Redux*, 84 NOTRE DAME L. REV. 1919, 1930–35 (2009) (discussing potential impact of the new pleading requirement); *see also* Symposium, *Pondering Iqbal*, 14 LEWIS & CLARK L. REV. 1 (2010).

²⁹³ *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995).

²⁹⁴ *See MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 777 (2007) (“We leave the equitable, prudential, and policy arguments in favor of such a discretionary dismissal for the lower courts’ consideration on remand. Similarly available for consideration on remand are any merits-based arguments for denial of declaratory relief.”).

²⁹⁵ *Id.* at 776 (quoting *Wilton*, 515 U.S. at 289).

exercise that discretion by presenting well-reasoned arguments for them to do so.²⁹⁶

Although the Supreme Court may not have stated any formal limiting principles in *MedImmune*, the decision demonstrates a similar faith in the ability of the lower courts to continue to work through the totality of the circumstances and to arrive at just conclusions in often complicated matters. So long as the lower courts (especially the district courts) show that the Supreme Court was correct to place faith in their abilities, all should be well.

In sum, Justice Thomas's fear of unbridled use of the totality-of-circumstances test has not come to pass, at least not yet. Unless and until the lower courts begin to demonstrate a greater willingness to grant declaratory relief in attenuated circumstances than they have shown to date, *MedImmune's* lack of limiting factors is of theoretical interest but is not deeply problematic. Still, the shadow of Justice Thomas's critique has not been eliminated in full. The shift in burden to show a case or controversy away from the party seeking declaratory relief is more of a real concern. The Court should monitor whether the lower courts continue to properly determine the existence of a controversy under the totality-of-circumstances test and whether they apply the power of discretion appropriately despite laboring without any express structural guidelines in the patent context on either issue. But, for now, *MedImmune* appears to have had the results desired by the Court majority. Parties can more easily demonstrate the existence of a controversy in order to question arguably coercive measures by patentees in court, and the lower courts have adhered to a reasonable notion of when a sufficiently concrete controversy does and does not exist. Justice Thomas can rest easier—for now.

²⁹⁶ It may be that some declaratory relief defendants are not providing the district courts much basis to exercise that discretion. *See, e.g.*, *EchoStar Satellite LLC v. Finisar Corp.*, 515 F. Supp. 2d 447, 452 (D. Del. 2007) (rejecting defendant's argument that the court should exercise its discretion to dismiss because of the "strong public policy considerations in favor of resolving disputes without the need for litigation"). Some defendants are not raising the contention at all, leaving it to happenstance whether the court decides to raise the issue *sua sponte*. *See, e.g.*, *Warrior Sports, Inc. v. STX, LLC*, 596 F. Supp. 2d 1070, 1077 (E.D. Mich. 2009).