

MEDIMMUNE: THE FEDERAL CIRCUIT FILLS IN THE BLANKS*

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I. OVERVIEW

MedImmune! This has been the rallying cry for patent and licensing executives for more than a year seeking to turn back the clock on the nearly forty year old *Lear*¹ that opened the door to a patent licensee challenge of the validity of a patent and which – in the case presented to the Court – sought to further widen the door to permit a licensee to *retain* its license by paying royalties while simultaneously challenging the patent. Yet, the Supreme Court in its landmark opinion in *MedImmune*² left the merits and policy-based *Lear* issues largely untouched. Instead, the Court chose *MedImmune* as a vehicle to return Federal Circuit declaratory judgment jurisdiction back to the judicial mainstream; it overruled the lower court’s precedent that had denied *standing* to bring a declaratory judgment action in cases that lacked a “reasonable apprehension” of a near term infringement suit. Reversing this line of case law solely on the issue of

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¹ *Lear, Inc. v. Adkins*, 395 U.S. 653, 673 (1969).

² *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ___, 127 S.Ct. 764 (2007)(Scalia, J.).

standing, many issues remain open for clarification either by the Federal Circuit or by statutory reform.

Within the first three months after *MedImmune* – and all within the month of March – the Federal Circuit has taken decisive action to start to fill in the blanks in the law and practice created by the Supreme Court: The Federal Circuit has remanded the *MedImmune* case itself to the trial court, so no new law should be created from this particular case.³ It has also issued three opinions that consider *MedImmune*: The lead case is *SanDisk*,⁴ which was followed four days later by *Teva v. Novartis*;⁵ and, one week before *SanDisk*, the court expressed *dictum* in the nonprecedential opinion in *Cellco*.⁶ The factual issues in *MedImmune* remain before the Federal Circuit in the companion *MedImmune II*⁷ that remains before

³ *MedImmune, Inc. v. Centocor, Inc.*, 127 S.Ct. 1118 (2007)(per curiam)(GVR)(“On petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit. Petition for writ of certiorari granted. Judgment vacated, and case remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ___, 127 S.Ct. 764 (2007).”).

⁴ *SanDisk Corp. v. STMicroelectronics, Inc.*, ___ F.3d ___, 2007 WL 881008 (Fed. Cir. March 26, 2007)(Bryson, Linn, Dyk, JJ.)(with concurring opinion by Bryson, J.).

⁵ *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, ___ F.3d ___, 2007 WL 942201 (Fed. Cir. March 30, 2007)(Mayer, Friedman, Gajarsa, JJ.)(with concurring opinion by Friedman, J.).

⁶ *Cellco Partnership v. Broadcom Corp.*, ___ Fed. Appx. ___, 2007 WL 841615 (Fed. Cir. March 19, 2007)(Mayer, Plager, Prost, JJ.)(*per curiam*)(nonprecedential).

⁷ *MedImmune, Inc. v. Centocor, Inc.*, 127 S.Ct. 1118 (2007)(per curiam)(GVR)(“On petition for writ of certiorari to the United States Court of Appeals for the Federal Circuit. Petition for writ of certiorari granted. Judgment vacated, and case remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ___, 127 S.Ct. 764 (2007).”).

that court and – so far – has not been returned to the trial court.⁸ *SanDisk* is particularly important as the first precedential opinion to interpret *MedImmune*.⁹

MedImmune arose as the product of controversy over the denial of declaratory judgment actions in several areas; the Court had before it in 2006 two very different petitions for *certiorari*. The *MedImmune* petition opened the door to reconsideration of cases such as *Gen-Probe* where standing was denied because of a lack of a “reasonable apprehension” of a near term infringement suit.¹⁰ Whether a generic manufacturer could sue for invalidity of a pioneer drug holder’s patent was raised in *Apotex*, where – under existing practice – the pioneer manufacturer would often refrain from suit on *all* of its patents until the generic entered the market.¹¹ See § II, *The “Questions Presented” in MedImmune and Apotex*.

⁸ *Medimmune, Inc. v. Centocor, Inc.*, ___ F.3d ___, 2007 WL 779342 (Fed. Cir. February 27, 2007)(per curiam)(Schall, Bryson, Gajarsa, JJ.)(Order setting briefing schedule for issues on remand from the Court).

⁹ *Teva v. Novartis*, slip op. at p. 4 (quoting *Tex. Am. Oil Co. v. U.S. Dep’t of Energy*, 44 F.3d 1557, 1561 (Fed.Cir.1995) (en banc)) (“This court respects the principle of stare decisis and follows its own precedential decisions unless the decisions are ‘overruled by the court en banc, or by other controlling authority such as an intervening ... Supreme Court decision.’” *Tex. Am. Oil Co. v. U.S. Dep’t of Energy*, 44 F.3d 1557, 1561 (Fed.Cir.1995) (en banc).”). The court acknowledged the prior decision in *SanDisk*, see *Teva v. Novartis*, slip op. at p. 5 (“[B]ecause the Supreme Court in *MedImmune* cautioned that our declaratory judgment ‘reasonable apprehension-of-suit’ test ‘contradict[s]’ and ‘conflicts’ with its precedent, these Federal Circuit tests have been ‘overruled by ... an intervening ... Supreme Court decision.’ *Tex. Am. Oil Co.*, 44 F.3d at 1561; see also, *SanDisk v. STMicroelectronics*, ___F.3d___, 2007 WL 881008 (Fed.Cir. Mar. 26, 2007).”)

¹⁰ *MedImmune*, 127 S.Ct. at 768 (“*Gen-Probe [Inc. v. Vysis, Inc.]*, 359 F.3d 1376, 1381 (Fed. Cir. 2004),] had held that a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement ‘obliterate[s] any reasonable apprehension’ that the licensee will be sued for infringement.”).

¹¹ *Apotex Inc. v. Pfizer, Inc.*, Supreme Court No. 05-1006.

The *MedImmune* petition was widely heralded in initial press reports as opening the door to declaratory judgment actions to challenge patent validity by paying patent licensees. On the *merits* the decision did nothing of the sort; rather, *MedImmune* addressed the more fundamental issue of whether the licensee has an actual controversy and has *standing* to bring the suit: Whether the suit will continue to reach the merits is subject to a variety of factors, including the discretionary power of the trial court to entertain such an action. See § III, *Standing, the Limited MedImmune Holding*.

Following the lead of *Apotex*, the Court made its biggest mark in “footnote 11”¹² that will long be remembered as the most important part of the opinion. Footnote 11 repudiates the Federal Circuit’s standard for a justiciable controversy. See § IV, *The Now Overruled “Imminent Suit” Test*. Repudiating *Teva v. Pfizer*, the Court in *dicta* in footnote 11 clearly sent the message that the Court would not countenance continuation of the Federal Circuit requirement for a “reasonable apprehension of imminent suit” as a condition precedent for standing for a declaratory judgment action.¹³ See § IV-A, *Blunt Repudiation of Teva v. Pfizer*. While footnote 11 *is dictum*, this hardly detracts from the stern and unequivocal message sent by the Court – as recognized by the most experienced Supreme Court expert on the Federal Circuit, former Acting Solicitor General Friedman who was involved in more than 100 Supreme Court cases on behalf of the Department of Justice. See § IV-A-1, *Judge Friedman’s Concurrence in Teva v. Novartis*. Yet a second Acting Solicitor General added his concurrence as well. See § IV-A-2, *Judge Bryson’s Concurrence in SanDisk*. Indeed, there are four Supreme Court experts on the Federal Circuit including two who clerked at the Court, three former Acting Solicitors General and the head of a major Supreme Court appellate practice group; *all* were on panels that approved the broad

¹² *MedImmune*, 127 S.Ct. at 774 n. 11.

¹³ *Id.* (quoting *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)).

construction of the now famous footnote 11. See § IV-A-3, *Concurrence of all Four Supreme Court Experts*.

Judge Bryson fully concurs in the new standard announced by the Federal Circuit as he views the court as being *compelled* to do by *MedImmune*; he nevertheless notes the extreme breadth of the new law of the Federal Circuit: “[U]nder the [Federal Circuit]’s standard virtually any invitation to take a paid license relating to the prospective licensee’s activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent.” See § IV-B, *The Bryson Open-Ended Slippery Slope*. Indeed, a possibly not so extreme ruling of the case law is that the Federal Circuit standard would appear to provide that a justiciable controversy to open the door to a declaratory judgment action is triggered by any affirmative action by the patentee that suggests the possibility of patent infringement. See § IV-C, *The Patentee’s Affirmative Action Trigger*.

A variety of questions remain for resolution. See § V, *Post-MedImmune Open Questions*. The most significant open area is the question of discretion to entertain a declaratory judgment action. Will bright line rules be announced by the Federal Circuit? Will a case by case determination be made at the trial level that will then percolate up to the Federal Circuit. See § V-A, *The Discretion of the Trial Judge*.

A nuanced approach that can only be gained through case by case determinations at the trial level that percolate up to the Federal Circuit is undoubtedly the best approach that can be taken. As a paradigm for why this is important, a detailed consideration is given to the “vacatur-on-demand” case law that had evolved at the Federal Circuit in the early 1990’s. See § VI, *The Vacatur-on-Demand Paradigm: Nuances*. The Federal Circuit had a brief history of vacatur practice that isolated it from the mainstream that was finally, seemingly put

to an end in *Cardinal Chemical*¹⁴ and *Bancor*.¹⁵ Yet, before that time the Federal Circuit granted vacatur-on-demand in the notorious *Tamoxifen Citrate I*,¹⁶ which has now made its way to the Supreme Court in the *Tamoxifen Citrate II* “reverse payment” patent antitrust dispute.¹⁷ See § VI-A, *Genesis of Federal Circuit Vacatur-on-Demand*. The *MedImmune* case involves a settlement that invokes *Tamoxifen Citrate I*, a voluntary settlement of parties to an interference which includes a determination by the parties to have the decision of the administrative body vacated with the result that a patent is granted to the party determined below as the *losing* party. The switch in who would win the patent resulted in the parties gaining an additional period of years of patent exclusivity. See § VI-B, *The MedImmune Settlement: Whither Bancorp?*

The grant of *certiorari* this past year in *MedImmune* generated a renaissance in policy debates over *Lear*, which have gone unanswered by the procedural

¹⁴*Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993), *overruling Vieau v. Japax, Inc.*, 823 F.2d 1510 (Fed.Cir.1987).

¹⁵ *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994)(Scalia, J.)

¹⁶ *Tamoxifen Citrate I* is a brief procedural opinion styled as *Imperial Chemical Industries, PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931, slip op. at *1 (Table) (Fed. Cir. 1993)(order)(Michel, J.) (“Imperial Chemical Industries PLC (ICI) and Barr Laboratories, Inc. (Barr) jointly move to vacate the July 21, 1992 judgment of the United States District Court for the Southern District of New York and to remand with instructions to the district court to dismiss without prejudice pursuant to Fed.R.Civ. P. 41(a).”)

Certiorari was granted in *Izumi* on February 22, 1993; the *Heumann Pharma* order was entered March 19, 1993, just 25 days later.

¹⁷*Joblove v. Barr Labs.*, Supreme Court No. 06-830, *proceedings below, In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2nd Cir. 2006). Presently, there is an outstanding order from the Court asking the Solicitor General for the *certiorari* views of the government (“CVSG”). Vacatur is an integral factual issue in the *Tamoxifen Citrate* case, but is not directly part of the *Question Presented* (“Under what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic's agreement not to market its product, a violation of the antitrust laws?”).

holding of the case. *See* § VII, *The Untouched Policy Considerations of Lear*. The country remains with the unfortunate situation that the United States lacks an administrative patent revocation system that can provide the basis for patent invalidity challenges that would make it possible to meet the policy objectives of *Lear* without “licensee estoppels”. *Amici* seeking to turn the clock back on *Lear* have been naïve in thinking that the Court would do so *even if it were to address the merits*. In the nearly forty years since *Lear* there has been no successful effort to provide a method for culling out clearly invalid patents. If anything, the negative image of the patent system has been amplified by business interests seeking a weakening of the rights of the patentee, a voice that has been heard by the Court in its pronouncements over the past year. *Lear* has not disappeared as an anachronistic old case; rather, *Lear* continues to be cited by the Court as bedrock principle. *See* § VII-A, *Public Policy, Blonder-Tongue and Beyond*.

More than twenty years ago, Professor Rochelle Cooper Dreyfuss had suggested that *Lear* should be overturned, particularly because of the then-new reexamination system that offered the expectation – at the time – that an alternative to litigation had been found to cull out invalid patents. Post-grant patent reform of a meaningful nature *could* provide the alternative that is called for by *Lear*. To the extent that meaningful legislation can be crafted to provide post-grant review, then an essential element of such legislation could provide a *statutory* override of *Lear*. *See* § VI-B, “*Dethroning Lear*” *through Patent Reform*. Indeed, the United States is far behind the United Kingdom, Germany and Japan in terms of providing a cheap, effective and prompt judicial or administrative vehicle to cull out invalid patents. *See* § VI-C, *A Comparative View: A Different Approach Abroad*.

The United States would do well to take a page from the British system where declaratory relief has fared better and has been found manageable as manifested in the *Nokia* case.¹⁸ *See* § VII, *The Future: Lessons from London*.

¹⁸ *Nokia v. InterDigital*, *supra*, at ¶ 30 (Carnwath, L.J.) (quoting *Messier Dowty Ltd v Sabena SA* [2001] 1 All ER 275, 285).

II. THE “QUESTIONS PRESENTED” IN *MEDIMMUNE* AND *APOTEX*

Two petitions for review were filed concerning the scope of the right of a patent challenger to bring a declaratory judgment action for a determination of patent invalidity, *MedImmune* and *Apotex*.

The *Question Presented* to the Court in *MedImmune* did not directly deal with *Lear*,¹⁹ but rather with the more fundamental issue as to whether there exists a justiciable controversy where a patent licensee *operating under his license and therefore not under a threat of an infringement suit* presents a justiciable controversy when he sues for a declaratory judgment of invalidity.²⁰

Following on the heels of *MedImmune*, *Apotex* asked the Court to consider whether a generic manufacturer seeking to go onto the market has a right to a declaratory judgment action,²¹ frontally assaulting the Federal Circuit’s “immediacy” test as of *Gen-Probe*²² as amplified in the context of generic drug litigation in *Teva v. Pfizer*,²³ cases which the Court later tied together in

¹⁹ *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

²⁰The *Question Presented* in *MedImmune*: “Does Article III’s grant of jurisdiction of ‘all Cases ... arising under ... the Laws of the United States,’ implemented in the ‘actual controversy’ requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?”

²¹The *Question Presented* in *Apotex* “is whether ... a suit [brought by a generic drug manufacturer seeking a declaratory judgment that a generic equivalent will not infringe a patent held by the brand-name manufacturer] states a justiciable controversy when ... the failure to secure a court judgment prohibits the federal government from approving the generic equivalent and the prospect of massive patent liability deters the generic manufacturer from entering the marketplace.”

²² *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004)(Rader, J.).

²³*Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2005)(Schall, J.); cf. *Teva*, 395 F.3d at 1339 (Mayer, J., dissenting). As pointed out in the petition, “*Teva [Pharmaceuticals USA, Inc. v. Pfizer, Inc.]*, 395 F.3d 1324 (Fed. Cir. 2005)(Schall, J.),] concerned the justiciability of another manufacturer’s declaratory judgment action against Pfizer regarding this same drug product - a

MedImmune.²⁴ The extreme holding in *Teva v. Pfizer* is far more difficult to defend than the far more reasonable merits denial of an invalidity challenge by a paying licensee, a point that is forcefully brought out in the dissent in the *Teva v. Pfizer* proceedings at the Federal Circuit.²⁵

generic competitor....A divided panel of the Federal Circuit [(Mayer, J., dissenting, 395 F.3d at 1339)]The petition frontally assaulted “*Teva* [which] concerned the justiciability of another manufacturer's declaratory judgment action against Pfizer regarding this same drug product - a generic competitor....A divided panel of the Federal Circuit [(Mayer, J., dissenting, 395 F.3d at 1339)], tightening its already rigorous requirement for finding a justiciable case or controversy, held that a court may adjudicate a declaratory judgment action only if the generic competitor faces an ‘*imminent*’ suit by a brand-name manufacturer. *Teva*, 395 F.3d at 1333 . Like the district court in this case, the Federal Circuit in *Teva* did not doubt that a generic manufacturer is directly and immediately injured by this state of affairs. Rather it was dispositive that ‘*Teva* virtually concedes that Pfizer will not bring immediate suit’ because it ‘does not wish to expose the patent to the possibility of a noninfringement or invalidity determination.’ *Id.* at 1333-34.” (record citations omitted).

²⁴ *MedImmune*, 127 S.Ct. at 768 (“The District Court [in the proceedings below in *MedImmune*] granted respondents' motion to dismiss the declaratory-judgment claims for lack of subject-matter jurisdiction, relying on ... *Gen-Probe*.... *Gen-Probe* had held that a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement ‘obliterate[s] any reasonable apprehension” that the licensee will be sued for infringement.’ [359 F.3d] at 1381. The Federal Circuit affirmed the District Court, also relying on *Gen-Probe*. 427 F.3d 958 (2005).”)

²⁵ The dissent takes an “economics and common sense” approach to permitting a declaratory judgment suit to proceed. *Teva*, 395 F.3d at 1339 (Mayer, J., dissenting.) (“[The patentee] Pfizer ... has a history of asserting its patent rights against infringers of other patents. Considering [its] patent [covering] the brand name drug Zolofit [that] produced nearly 3 billion dollars in profit in 2002, economics and common sense dictate that Pfizer may well bring suit.”).

The dissent furthermore explains a public policy rationale that is not effectively rebutted in the majority ruling: “Allowing *Teva*'s declaratory judgment action is consistent with the ‘case or controversy’ requirement of Article III of the Constitution because the suit will achieve a final determination that resolves the entire controversy between *Teva* and Pfizer. Subsequent ANDA applicants suffer a real and defined harm when uncertainty exists as to their rights to manufacture and sell a generic drug product free from infringement allegations. By permitting generic companies to bring declaratory judgment claims, Congress has not sought to create a hypothetical injury-in-fact; it has simply recognized the harm that exists absent such relief. Consequently, under the Hatch-Waxman regime, *Teva*'s injuries are traceable to Pfizer's conduct and those injuries could be redressed by a favorable decision. Therefore, *Teva* maintains a reasonable apprehension of suit sufficient to confer jurisdiction under the Declaratory Judgment Act.” *Id.*

B. Apotex Handwriting on the Wall

The handwriting was on the wall for the death of *Teva v. Pfizer* when the Court in *Apotex* issued an order asking the Solicitor General to opine on whether to grant review,²⁶ whereupon the patentee surrendered for that case by giving in to Apotex to moot the controversy,²⁷ which was then followed by denial of *certiorari*.²⁸

III. STANDING, THE LIMITED *MEDIMMUNE* HOLDING

A. The Controversy in *MedImmune*

While the *MedImmune* case generated considerable attention in the patent and licensing communities over the continued viability of the *Lear* doctrine, it is important to note that the Court gave no answer to the question as to whether a paying – or “nonrepudiating”²⁹ – licensee has a right to challenge the validity of a patent through a declaratory judgment action.

Justice Scalia summarizes the controversy in *MedImmune*:

“The District Court granted [the patentee’s] motion to dismiss the declaratory-judgment claims for lack of subject-matter jurisdiction, relying on the decision of the United States Court of Appeals for the Federal Circuit in *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). *Gen-Probe* had held that a patent licensee in good standing cannot establish an Article III case or

²⁶ *Apotex v. Pfizer*, 126 S.Ct. 2057 (2006)(order asking for the views of the Solicitor General (“CVSG”).

²⁷ *Supplemental Brief for Respondent*, 2006 WL 2569797 (“Pfizer sent to counsel for Apotex an unconditional covenant not to sue Apotex with respect to th[e] patent.... This covenant ensures that Apotex will never face any risk of a lawsuit by Pfizer under the subject patent.”).

²⁸ *Apotex v. Pfizer*, 126 S.Ct. 2057 (2006)(order asking for the views of the Solicitor General (“CVSG”)), 127 S.Ct. 379 (2006)(denying *certiorari*).

²⁹ 127 S.Ct. at 769.

controversy with regard to validity, enforceability, or scope of the patent because the license agreement ‘obliterate[s] any reasonable apprehension’ that the licensee will be sued for infringement. *Id.*, at 1381. The Federal Circuit affirmed the District Court, also relying on *Gen-Probe*. [*MedImmune*,] 427 F.3d 958 (2005).”³⁰

The *holding* of the Court in *MedImmune* is that the petitioner-licensee *MedImmune* “has raised a contractual dispute... It has done so” and has brought forth a justiciable controversy.³¹

B. The *MedImmune* Holding

The court in *SanDisk* acknowledged that the Supreme Court in *MedImmune* has overruled the Federal Circuit test: “[I]n *MedImmune*, [the Court] addressed the ‘reasonable apprehension of suit’ aspect of this court’s two-part test and concluded that it conflicts with *Aetna Life Insurance* and *Maryland Casualty*, and is in tension with *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 98 (1993).”³² The court in *SanDisk* explained the fundamental conflict with the now overruled Federal Circuit test:

“In *Aetna Life Insurance*, an insurer sought a declaratory judgment that the insured was not relieved of his duty to continue to pay insurance premiums and that, since the insured had stopped making the payments, the insurance policy had lapsed. In that case, the Supreme Court first upheld the constitutionality of the federal Declaratory Judgment Act. 300 U.S. at 240-41. The Supreme Court then held that, although the insured party gave no indication that he would file suit, *id.* at 239, the case nevertheless presented a controversy under Article III because the parties had taken adverse positions with regard to their obligations, each side presenting a concrete claim of a specific right—the insured claiming that he had become disabled and therefore was relieved of making insurance premium payments and the insurer claiming that the insured was not disabled and that the

³⁰ 127 S.Ct. at 768.

³¹ 127 S.Ct. at 770.

³² *SanDisk*, slip op. at p.6, citing *MedImmune*, 127 S.Ct. at 774 n. 11.

failure to make payments caused the policy to lapse, *id.* at 244. Similarly, in *Maryland Casualty*, the declaratory judgment plaintiff, an insurance company which had agreed to indemnify and defend the insured against actions brought by third parties against the insured, sought a declaration that it had no duty to defend or to indemnify the insured. 312 U.S. at 272. In that case, the insured could not have sued the declaratory judgment plaintiff without first obtaining a judgment against the third party and the underlying action against the third party “[a]pparently ... ha[d] not proceeded to judgment.” *Id.* at 271. Nevertheless, the Supreme Court held that “[i]t is clear that there is an actual controversy between petitioner and the insured” since the insured was in the process of seeking a judgment and had a statutory right to proceed against the declaratory judgment plaintiff if such judgment were obtained and not satisfied. *Id.* at 274. Finally, in *Cardinal Chemical*, the Supreme Court held that this court's affirmance of a judgment of noninfringement does not necessarily moot a declaratory judgment counterclaim of patent invalidity. 508 U.S. at 98. The Supreme Court's rationale for holding that the declaratory judgment action can proceed consistent with Article III was that a contrary result would create the potential for relitigation or uncertainty with regard to the validity of patents and would be contrary to *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971).”³³

The court expressly acknowledged that “[t]he Supreme Court's opinion in *MedImmune* represents a rejection of our reasonable apprehension of suit test.”³⁴ It is explained in *SanDisk* that “[t]he Court first noted that ‘the continuation of royalty payments makes what would otherwise be an imminent threat at least remote, if not nonexistent.... Petitioner's own acts, in other words, eliminate the imminent threat of harm.’ *MedImmune*, 127 S.Ct. at 772. The Court nonetheless concluded that declaratory judgment jurisdiction existed relying in particular on its earlier decision in *Altwater v. Freeman*, 319 U.S. 359 (1943). There, the patentee brought suit to enjoin patent infringement, and the accused infringer filed declaratory judgment counterclaims of invalidity. The district court found that

³³*SanDisk*, slip op. at p. 6.

³⁴*SanDisk*, slip op. at p. 7.

there was no infringement and that the patent was invalid. *Id.* at 362. The appellate court affirmed the finding of noninfringement but vacated the finding of invalidity as moot. *Id.* The Supreme Court held that the declaratory judgment counterclaims were not mooted by the finding of noninfringement. *Id.* at 365-66.”³⁵

C. Leaving *Lear* Untouched

The Court noted the similarity of the case to *Lear* where, as here, the licensee was required to pay royalties until the end of the patent term.³⁶ But, here, the licensee was seeking to have a holding that as a paying – or “nonrepudiating” – licensee it could bring suit for invalidity. This, the Court refused to decide.³⁷ The holding explicitly leaves open whether the *MedImmune* or other cases should be able to proceed, leaving the door open to various equitable, prudential and policy arguments as well as merits-based defenses.³⁸

IV. THE NOW OVERRULED “IMMINENT SUIT” TEST

A. Blunt Repudiation of *Teva v. Pfizer*

³⁵*Id.*

³⁶ 127 S.Ct. at 769 (“But the license at issue in *Lear, Inc. v. Adkins*, 395 U.S. 653, 673 (1969), similarly provided that ‘royalties are to be paid until such time as the ‘patent ... is held invalid,’ and we rejected the argument that a repudiating licensee must comply with its contract and pay royalties until its claim is vindicated in court.”)

³⁷ 127 S.Ct. at 769-70 (“We express no opinion on whether a *nonrepudiating licensee* is similarly relieved of its contract obligation during a successful challenge to a patent's validity—that is, on the applicability of licensee estoppel under these circumstances. Cf. *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997) (‘[A] licensee ... cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid’).”)

³⁸ *MedImmune*, 127 S.Ct. at 777.

Perhaps the most significant part of *MedImmune* in terms of the broad sweep of its reach is found in the discussion in “footnote 11”, a repudiation of the Federal Circuit’s test of a “reasonable apprehension of imminent suit”: The *Sandisk* court stated that “the Court specifically addressed and rejected our reasonable apprehension test [of *Teva v. Pfizer*]:

“[e]ven if *Altwater* could be distinguished..., it would still contradict the Federal Circuit's ‘reasonable apprehension of suit’ test (or, in its evolved form, the ‘reasonable apprehension of imminent suit’ test, *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (2005)). A licensee who pays royalties under compulsion of an injunction has no more apprehension of imminent harm than a licensee who pays royalties for fear of treble damages and an injunction fatal to his business. The reasonable-apprehension-of-suit test also conflicts with our decisions in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941), where 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; and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937), where 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. It is also in tension with *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 98 (1993), which held that appellate affirmance of a judgment of noninfringement, eliminating any apprehension of suit, does not moot a declaratory judgment counterclaim of patent invalidity.”³⁹

³⁹ *Sandisk*, slip op. at p. 7, quoting *MedImmune*, 127 S.Ct. at 774 n. 11.

B. Controlling, Powerful Dicta

1. Judge Friedman's Concurrence in *Teva v. Novartis*

To be sure, the repudiation of *Teva v. Pfizer* is found in *dicta* unnecessary to the Question Presented in the petition. Yet, the blunt wording of “footnote 11” simply cannot be ignored.

In *Teva v. Novartis*, the Friedman concurrence acknowledged that the statements of footnote 11 (quoted in *SanDisk*) represent “dicta,”⁴⁰ yet “the Court apparently was telling us that it rejected our ‘reasonable apprehension of *imminent* suit’ test [of *Teva v. Pfizer*] for determining declaratory judgment jurisdiction in patent cases, and that the broader general rules governing declaratory judgment jurisdiction also govern patent cases.”⁴¹ Thus, even though *dicta*, “in [such] unusual circumstances, where the Supreme Court went out of its way to state its disagreement with our “reasonable apprehension of *imminent* suit” test, which was not an issue in the case before it, it appears incumbent on us to stop using that test and hereafter to apply the general declaratory judgment standards that the Supreme Court applied in *Medimmune*.”⁴²

⁴⁰ *Teva v. Novartis*, Friedman Concurrence at p. 12.

⁴¹*Id.*, original emphasis. Prior to this blunt statement, the Friedman concurrence had quoted from the strong language in “footnote 11.”

⁴²*Id.*, original emphasis.

2. Judge Bryson's Concurrence in *SanDisk*

Judge Bryson, too, implicitly recognized that “footnote 11” represented dicta, yet he, too, saw the need to follow this directly stated guidance from the Supreme Court:

“Footnote 11 of the *MedImmune* opinion, however, went further and... criticized this court's ‘reasonable apprehension of suit’ test for declaratory judgment jurisdiction. I agree with the court that the footnote calls our case law into question and would appear to make declaratory judgments more readily available to parties who are approached by patentees seeking to license their patents. In particular, the reasoning of the *MedImmune* footnote seems to require us to hold that the district court in this case had jurisdiction to entertain SanDisk's declaratory judgment action. For that reason I concur in the judgment of the court in this case reversing the jurisdictional dismissal of the complaint.”⁴³

3. Concurrence of all Four Supreme Court Experts

The Friedman and Bryson Concurrences represent the opinions of two of four of the most experienced members of the Federal Circuit in terms of a pre-existing Supreme Court background and practice,⁴⁴ while a third expert was a member of the *Sandisk* panel and the fourth was part of the *per curiam* panel in *Cellco*. Thus, all four of the current members of the Federal Circuit with an extensive Supreme Court background were thus involved in a post-*MedImmune* opinion.⁴⁵

⁴³*SanDisk*, slip op. at p. 11, Bryson, J., concurring.

⁴⁴Judge Friedman argued countless cases before the Supreme Court; his name as counsel in Westlaw on the SCT database shows 172 hits, including numerous cases where he argued before the Court.

⁴⁵ Three members of the Federal Circuit have served as the Acting Solicitor General (Judges Friedman and Bryson and the late Oscar Hirsch Davis). Judge Dyk headed an appellate practice for a

B. The Bryson Open-Ended Slippery Slope

The broad sweep of *MedImmune* is emphasized in the concurrence by Judge Bryson in *SanDisk*:

“[I]t is important... to point out the implications of ... footnote [11] in *MedImmune* as applied here, because the implications are broader than one might suppose from reading the court's opinion in this case. While noting that it is not necessary to define the outer boundaries of declaratory judgment jurisdiction, the court holds that ‘where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license,’ the party may bring a declaratory judgment action. ...

“In practical application, the new test will not be confined to cases with facts similar to this one. If a patentee offers a license for a fee, the offer typically will be accompanied by a suggestion that the other party's conduct is within the scope of the patentee's patent rights, or it will be apparent that the patentee believes that to be the case. Offers to license a patent are not requests for gratuitous contributions to the patentee; the rationale underlying a license offer is the patentee's express or implied suggestion that the other party's current or planned conduct falls within the scope of the patent. Therefore, it would appear that under the court's standard virtually any invitation to take a paid license relating to the prospective licensee's activities would give rise to an Article III case or controversy if the prospective licensee elects to assert that its conduct does not fall within the scope of the patent. Indeed, as the court makes clear, even a representation by the patentee that it does not propose to file suit against the prospective licensee will not suffice to avoid the risk that the patentee will face a declaratory judgment action. And if there is any

major law firm and argued about ten cases before the Court; both he and Judge Bryson are the only former Supreme Court Law Clerks on the Federal Circuit, while, for several years, Judge Mayer was Special Assistant to the Chief Justice. Judges Bryson and Dyk were members of the *SanDisk* panel while Judge Mayer was a member of the *Cellco* panel.

uncertainty on that score, all the prospective licensee has to do in order to dispel any doubt is to inquire of the patentee whether the patentee believes its activities are within the scope of the patent. If the patentee says ‘no,’ it will have made a damaging admission that will make it very hard ever to litigate the issue, and thus will effectively end its licensing efforts. If it says ‘yes’ or equivocates, it will have satisfied the court’s test and will have set itself up for a declaratory judgment lawsuit.”⁴⁶

C. The Patentee’s Affirmative Action Trigger

The *SanDisk* court also noted that there must be some affirmative act by the patentee to raise a justiciable controversy under *MedImmune*:

“[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned ...or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principles of declaratory judgment jurisdiction to the facts and circumstances of each case. We hold only that *where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.*”⁴⁷

⁴⁶*SanDisk*, slip op. at p. 11, Bryson, J., concurring.

V. POST-MEDIMMUNE OPEN QUESTIONS

While the door is wide open for a declaratory judgment plaintiff to seek an invalidity ruling as a matter of *standing*, it is yet another matter whether the trial court will exercise its jurisdiction to hear the action.

The Court was very careful to note that the patentee is free to present arguments on the merits against continuation of the lawsuit. As to the discretion of the trial court to entertain the declaratory judgment action, the Court expressly “leave[s] the equitable, prudential, and policy arguments in favor of ... a discretionary dismissal for the lower courts' consideration on remand.”⁴⁸

There also may be arguments on the merits perhaps based upon contractual provisions that may be basis for a defense to a declaratory judgment action. Thus, “[s]imilarly available for consideration [beyond equitable, prudential and policy arguments]... are any merits-based arguments for denial of declaratory relief.”⁴⁹

A. The Discretion of the Trial Judge

The Court expressly “leave[s] the equitable... arguments in favor of ... a discretionary dismissal for the lower courts' consideration....”⁵⁰ Thus, beyond

⁴⁷ *SanDisk* majority, slip op. at p. 7 (emphasis supplied). The court immediately after this quotation acknowledges a case as being contra, *Contra Cygnus Therapeutics Sys. v. ALZA Corp.*, 92 F.3d 1153 (Fed.Cir.1996), characterized by the court as “holding that declaratory judgment jurisdiction was not supported where the ‘patentee does nothing more than exercise its lawful commercial prerogatives and, in so doing, puts a competitor in the position of having to choose between abandoning a particular business venture or bringing matters to a head by engaging in arguably infringing activity’”. *Id.*

⁴⁸ *MedImmune*, 127 S.Ct. at 777.

⁴⁹ *Id.*

any contractual or other legal arguments against letting a declaratory judgment action proceed, it should above all be up to the District Court to make a case by case determination whether to invoke the discretion of the court to entertain the declaratory judgment action.⁵¹

Merely because there *is* a justiciable controversy between licensor and licensee, this does not mean that a trial court should or must entertain a declaratory judgement action by the licensee against the patentee. As explained by the Court, “[t]he Declaratory Judgment Act provides that a court ‘*may* declare the rights and other legal relations of any interested party,’ ... not that it *must* do so.”⁵² This provision “has long been understood ‘to confer on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants.’”⁵³

B. Federal Circuit Guidance in *SanDisk* and Beyond

In the post-*MedImmune* era and with specific citation to that case, the Federal Circuit has provided guidance on the equitable discretion of the trial court in two different cases and mentioned the topic in three:

⁵⁰ *Id.*

⁵¹ *MedImmune*, 127 S.Ct. at 776 (quoting *Wilton v. Seven Falls Co.*, 515 U.S. at 289) (“We have found it ‘more consistent with the statute’ however, ‘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.”)

⁵² *MedImmune*, 127 S.Ct. at 776 (quoting 28 U.S.C. § 2201(a)); emphasis added by the Court.

⁵³ *Id.*, quoting *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995); also citing *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95, n. 17 (1993); *Brillhart v. Excess Ins. Co. of America*, 316 U.S. 491, 494-96 (1942).

1. *SanDisk* Guidance on Discretion

In *SanDisk*, the Federal Circuit has quite correctly emphasized the issue of a trial court's discretion: Thus, "[a]lthough the district court is given the discretion, in declaratory judgment actions, to dismiss the case, there are boundaries to that discretion."⁵⁴ Thus, "[w]hen there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal."⁵⁵ The court also points to *Electronics for Imaging*⁵⁶ and *Capo v. Dioptics*⁵⁷ as providing guidance for the proposition that "the exercise of discretion must be supported by a sound basis for refusing to adjudicate an actual controversy."⁵⁸ The court has made it clear that "[w]hen there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity, in the usual circumstance the declaratory judgment is not subject to dismissal."⁵⁹

⁵⁴ *SanDisk*, ___ F.3d at ___, slip op. at 10 (citing *Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995)).

⁵⁵ *SanDisk*, ___ F.3d at ___, slip op. at 10 (quoting *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed.Cir.1993)).

⁵⁶ *Electronics for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1345 (Fed.Cir.2005)(Gajarsa, J.)

⁵⁷ *Capo, Inc. v. Dioptics Med. Prod., Inc.*, 387 F.3d 1352, 1357 (Fed.Cir.2004)(Newman, J.)

⁵⁸ *SanDisk*, ___ F.3d at ___, slip op. at 10.

⁵⁹ *Electronics for Imaging*, 394 F.3d at 1345 (quoting *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed.Cir.1993)).

2. *Cellco* Discretionary Dismissal of a DJ Action

Cellco represents the first post-*MedImmune* decision of the Federal Circuit to confirm the standing of the declaratory judgment plaintiff but to affirm a trial court dismissal, finding “no abuse of discretion [by the trial judge] in dismissing the case.”⁶⁰

But, there were circumstances unique to the *Cellco* case which clearly warranted the dismissal: “In light of [various] other [pending] proceedings..., the trial court determined that entertaining *Cellco*'s declaratory judgment action would be ‘an inappropriate use of multiple judicial districts.’ Because of potential judicial efficiency, and because *Cellco* has not shown sufficient harm to require immediate resolution of its case prior to the conclusion of these other proceedings[.]”⁶¹

3. *Teva v. Novartis*, The Special ANDA Case

Teva v. Novartis does not deal with the issue of discretionary dismissal of a declaratory judgment action. There is, however, a footnote acknowledgment of the

⁶⁰ *Cellco*, ___ F.3d at ___, slip op. at 1.

⁶¹ The Federal Circuit noted that “[t]he same patents at issue here are also the subject of a pending International Trade Commission (“ITC”) proceeding, which was instituted by Broadcom ... against Qualcomm.... Qualcomm manufactures the chips used by *Cellco*.... That proceeding raised many of the same issues as *Cellco*'s declaratory judgment action, including the validity of the patents. Although the ITC's findings lack preclusive effect and cannot conclusively resolve the controversy between *Cellco* and Broadcom, they can be considered by federal courts for their persuasive value. *Texas Instruments v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1568-69 (Fed.Cir.1996). In addition, a separate district court proceeding raising similar issues was pending between Qualcomm and Broadcom in the Central District of California. As required by statute, that case was stayed at Qualcomm's request until the ITC's determination becomes final. 28 U.S.C. § 1659(a); see *In re Princo Corp.*, ___ F.3d ___, 2007 WL 610732 (Fed.Cir.2007) (order). When that suit resumes, it will have the benefit of the ITC's determinations, and *Cellco* can seek to intervene.” *Id.*

issue of discretion.⁶² Yet, there is perhaps little room for discretion in the context of this case:

Thus, *Teva v. Novartis* involves the special factual pattern of an Abbreviated New Drug Application (ANDA) and involves a specific statutory provision that was amended in 2003. The 2003 amendment law would appear to make the holding in *Teva v. Pfizer* wrong even without a consideration of *MedImmune*, as emphasized by the dissent in the opinion in that case.⁶³ While the majority opinion in *Teva v. Novartis* acknowledges the 2003 amendment,⁶⁴ the majority does not go so far as to indicate that the 2003 amendment gives a right, by itself, to

⁶² *Teva v. Novartis*, Gajarsa Majority, slip op. at 4 n.3 (“However, unlike non-declaratory judgment actions, even if there is an actual controversy, the district court is not required to exercise jurisdiction to address the merits of the action, as it retains discretion under the Act to decline declaratory judgment jurisdiction. *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 241 (1952); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed.Cir.1991) (“When there is no actual controversy, the court has no [jurisdiction and no] discretion to decide the case. When there is an actual controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary.”).

⁶³ *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1339 (Fed. Cir. 2005)(Mayer, J., dissenting)(“Regardless of whether the [Federal Circuit test] is a constitutional necessity or not, the legislative history voices Congress' intent to apply the ‘reasonable apprehension’ portion of the test in determining whether a court may determine the rights of an ANDA filer seeking relief. See H.R. Conf. Rep. No. 108-391, at 836 (2003) (“Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a ‘reasonable apprehension’ of suit to establish jurisdiction.”).

⁶⁴ *Teva v. Novartis*, ___ F.3d at ___, slip op. at 7 (Gajarsa majority opinion)(“Novartis listed its [] patents in the Orange Book. By so doing, Novartis represents that ‘a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale’ of generic [drug] covered by the claims of its listed [] patents. 21 U.S.C. § 355(b)(1); see *Pfizer*, 395 F.3d at 1341 (Mayer, J., dissenting).”).

a declaratory judgment action.⁶⁵ Yet, much of the lengthy majority opinion must be regarded as *dicta*; it remains to be seen whether the Congressional intention as manifested in the language quoted in the dissent will be followed by a future panel of the Federal Circuit to give the broad scope of relief that is stated in the legislative history.

VI. THE VACATUR-ON-DEMAND PARADIGM: NUANCES

So far, the Federal Circuit has refrained from issuing any bright line rules as to when a trial court may abuse its discretion by entertaining a declaratory judgment action. Absent such guidance, the trial courts will have a certain degree of freedom to entertain policy and other arguments for the dismissal of a declaratory judgment action for invalidity, as has already been affirmed in the *Cellco* case.

Whether the post-*MedImmune* practice will evolve with a nuanced case by case approach keyed to the discretion of individual trial court judges or whether the court will now issue bright line one-size-fits-all rules remains to be seen. However, as a cautionary note as an example straight from the underlying facts of *MedImmune* itself, the paradigm of the Federal Circuit vacatur practice should be considered.

⁶⁵*Id.* (“While this conduct on its own may not be sufficient to establish an Article III controversy, it is a circumstance to be considered in determining whether a justiciable controversy exists under the totality of the circumstances.”).

A. Genesis of Federal Circuit Vacatur-on-Demand

If ever there were a case with facts to demonstrate the need for a nuanced, case by case approach, it is *MedImmune* itself, which brings together conflicting policy issues that were considered by the Court more than ten years ago in *Izumi*⁶⁶ and *Bancorp* – both on the heels of the overruling of the notorious *Vieau* practice in *Cardinal Chemical*.⁶⁷ Before *Izumi* was dismissed by the Court and the appeal was still pending, the vacatur practice overruled in *Bancorp* was basis for vacatur-on-demand in *Tamoxifen Citrate I*.⁶⁸ Conceivably, the vacatur practice of *Tamoxifen Citrate I* could provide underlying grist for consideration of antitrust issues keyed to that vacatur as early as the next term of the Court in the *Tamoxifen Citrate II* case.⁶⁹

⁶⁶ *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27 (1993).

⁶⁷ *Cardinal Chemical Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993), overruling *Vieau v. Japax, Inc.*, 823 F.2d 1510 (Fed.Cir.1987).

⁶⁸ *Tamoxifen Citrate I* is a brief procedural opinion styled as *Imperial Chemical Industries, PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811, 1993 WL 118931, slip op. at *1 (Table) (Fed. Cir. 1993)(order)(Michel, J.)("Imperial Chemical Industries PLC (ICI) and Barr Laboratories, Inc. (Barr) jointly move to vacate the July 21, 1992 judgment of the United States District Court for the Southern District of New York and to remand with instructions to the district court to dismiss without prejudice pursuant to Fed.R.Civ. P. 41(a).")

Certiorari was granted in *Izumi* on February 22, 1993; the *Heumann Pharma* order was entered March 19, 1993, just 25 days later.

⁶⁹ Presently, there is an outstanding order from the Court asking the Solicitor General for the *certiorari* views of the government ("CVSG"). Vacatur is an integral factual issue in the *Tamoxifen Citrate* case, but is not directly part of the *Question Presented* ("Under what circumstances is an agreement by a brand pharmaceutical manufacturer (and patent holder) to share a portion of its future profits with a generic market entrant (and alleged patent infringer), in exchange for the generic's agreement not to market its product, a violation of the antitrust laws?").

Two different vacatur policies were in operation at the Federal Circuit of the early 1990's:

First, there was the the *Vieau* practice overruled in *Cardinal Chemical* where the court sought to preserve the validity of patents that had been lost on *both* noninfringement and invalidity at the trial level and where the trial level decision was affirmed on the basis of noninfringement: Here, to save the patentee to be able to sue again, the court ordered vacatur of the “moot” invalidity issue, a result that was introduced in the *Cardinal Chemical* case at the Federal Circuit *sua sponte* without briefing by the parties.⁷⁰

The *Bancorp* decision overruled the practice of *Tamoxifen Citrate I* where the court vacated a trial court ruling of invalidity⁷¹ of an important anticancer drug patent based upon the “reverse payment” of more than \$ 20 million by the patentee to the successful generic litigant so that the patent would remain in force and could be used against the industry and so that – as part of the settlement – even the successful generic litigant would honor the exclusive marketing position of the patentee: Critical to the success of the settlement was the participation of the court in *Tamoxifen Citrate I* in granting vacatur.

⁷⁰ *Morton Intern., Inc. v. Cardinal Chemical Co.*, 967 F.2d 1571, 1571-72 (Fed. Cir. 1992)(Nies, J., dissenting from denial of reh'g en banc)(“[Patentee] Cardinal ... sought and obtained a declaratory judgment that [the patents] owned by Morton ... were invalid. On appeal, a majority of the panel reasoned that because it affirmed the district court's finding on Morton's infringement claim that Cardinal did not infringe the subject patents, it ‘need not address the question of validity.’ Citing *Vieau v. Japax, Inc.*, 823 F.2d 1510 (Fed.Cir.1987) as authority, the majority, *sua sponte*, vacated the judgment of invalidity entered on Cardinal's declaratory counterclaim.”).

⁷¹ *Imperial Chemical Industries, PLC v. Barr Laboratories*, 795 F.Supp. 619, 629, Conclusion of Law no. 3(S.D.N.Y. 1992)(“U.S. Patent 4,536,516... covering tamoxifen is invalid and is unenforceable by the plaintiff ICI because ICI deliberately, knowingly and fraudulently with purpose to deceive and mislead with respect to material matters[.]”). The decision more properly should be characterized as a holding of *unenforceability* based upon such patent fraud.

Under *Bancorp*, it is clear that “mootness attributable to a voluntary act of a nonprevailing party ordinarily does not justify vacatur of a judgment under review[.]”⁷² The topic had generated much controversy in the period leading up to *Bancorp*.⁷³ But, the settlement in *Tamoxifen Citrate I* took place just before

⁷² *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 195 n.6 (2000)(citing *Bancorp*). Furthermore, “it is far from clear that vacatur of the District Court’s judgment would be the appropriate response to a finding of mootness on appeal brought about by the voluntary conduct of the party that lost in the District Court. See *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18 (1994) (mootness attributable to a voluntary act of a nonprevailing party ordinarily does not justify vacatur of a judgment under review); see also *Walling v. James V. Reuter, Inc.*, 321 U.S. 671 (1944).” *Id.* See also *Arizonans for Official English v. Arizona*, 520 U.S. 43, 71-72 (1997)(Ginsburg, J.) (“When a civil case becomes moot pending appellate adjudication, ‘[t]he established practice ... in the federal system ... is to reverse or vacate the judgment below and remand with a direction to dismiss.’ *United States v. Munsingwear, Inc.*, 340 U.S. 36, 39 (1950). Vacatur ‘clears the path for future relitigation’ by eliminating a judgment the loser was stopped from opposing on direct review. *Id.*, at 40. Vacatur is in order when mootness occurs through happenstance – circumstances not attributable to the parties – or ... the ‘unilateral action of the party who prevailed in the lower court.’ *U.S. Bancorp Mortgage Co.*, 513 U.S. at 23; cf. *id.*, at 29 (‘mootness by reason of settlement [ordinarily] does not justify vacatur of a judgment under review’).”)

⁷³ See William P. Atkins, *The History And Subsequent Demise Of Vacatur Upon Settlement By The Federal Circuit*, 78 J. Pat. & Trademark Off. Soc’y 295, 296 n.6 (1996) (“Kendrew H. Colton and Michael W. Haas, *Patent Law Developments in the United States Court of Appeals for the Federal Circuit During 1992*, 42 Am. U. L. Rev. 909, 924-28 (1993); Marcia Coyle, *Corporate Giants Lock Horns Over Granting of Vacatur*, Nat’l L.J., Oct. 25, 1993, at 21; Elizabeth Bowen, *Routine Vacatur: The Supreme Court Strikes the Balance in Favor of Finality*, 3 Fed. Cir. Bar J. 259 (1993); Stephen R. Barnett, *Making Decisions Disappear: Depublication and Stipulated Reversal in the California Supreme Court*, 26 Loyola L. Rev. 1033, 1073 (1993); Michael W. Loudenslager, *Erasing The Law: The Implications of Settlements Conditioned Upon Vacatur Or Reversal of Judgments*, 3 Wash. & Lee L. Rev. 1229 (1993); Harold C. Wegner, “Vitiat[ing] ... Blonder-Tongue”; *Nestle Vacatur-on-Demand*, 75 JPTOS 671 (Sept. 1993); Stephen McG. Bundy, *The Policy in Favor of Settlement in an Adversary System*, 44 Hasting L.J. 1 (1992); Kipp D. Snider, *Vacatur: The Vacatur Remedy For Cases Becoming Moot Upon Appeal: In Search of A Workable Solution For the Federal Courts*, 60 Geo. Wash. L. Rev. 1642 (1992); Jill E. Fisch, *Rewriting History: The Propriety of Eradicating Prior Decisional Law through Settlement and Vacatur*, 76 Cornell L. Rev. 589 (1991); Henry E. Klingeman, *Settlement Pending Appeal: An Argument for Vacatur*, 58 Fordham L. Rev. 233 (1989); William D. Zeller, *Avoiding Issue Preclusion by Settlement Conditioned upon the Vacatur of Entered Judgments*, 96 Yale L.J. 860 (1987); Stuart N.

Bancorp, at a time when the Second and Federal Circuits permitted vacatur in situations like that of the tamoxifen case.⁷⁴

B. The *MedImmune* Settlement: Whither *Bancorp*?

Contrary to the policy of *Bancorp*, a review of the facts of *MedImmune* show that the Cabilly patent that is the subject of the underlying patent validity issue was granted *after* there had been a ruling by the administrative patent judges that had determined that a patent should be awarded to the first inventor – the opposing party – and not Cabilly. But, if a Cabilly patent were granted instead, then the patent term would extend far longer and permit a longer flow of royalties. As a result of a settlement agreement where the parties *privately* determined that the decision by the administrative patent judges was wrong, the parties were able to obtain a settlement that permitted Cabilly to gain the patent.

Rappaport, *Collateral Estoppel Effects of Judgments Vacated Pursuant to Settlement*, 1987 U. Ill. L. Rev. 731 (1987).”)

⁷⁴ *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 30 n.2 (1993)(dismissing *certiorari* as improvidently granted)(“Like the Federal Circuit, the Second Circuit will generally grant motions to vacate when parties settle on appeal. See *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 282-284 (2nd Cir. 1985). The Third, District of Columbia, and Seventh Circuits will generally deny such motions. See *Clarendon Ltd. v. Nu-West Industries, Inc.*, 936 F.2d 127 (3rd Cir. 1991); *In re United States*, 927 F.2d 626 (D.C.Cir. 1991); *In re Memorial Hospital of Iowa County, Inc.*, 862 F.2d 1299 (7th Cir. 1988). The Ninth Circuit requires district courts to balance ‘the competing values of finality of judgment and right to relitigation of unreviewed disputes.’ *Ringsby Truck Lines, Inc. v. Western Conference of Teamsters*, 686 F.2d 720, 722 (1982).”)

VII. THE UNTOUCHED POLICY CONSIDERATIONS OF *LEAR*

A. Public Policy, *Blonder-Tongue* and Beyond

Lear provides that despite a contractual proscription on a licensee challenging patent validity, such a “licensee estoppel” contractual provision is unenforceable in substantial part because of the dearth of a simple *inter partes* mechanism for the public to challenge patent validity:

“Surely the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain. Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification. We think it plain that the technical requirements of contract doctrine must give way before the demands of the public interest in the typical situation involving the negotiation of a license after a patent has issued.”⁷⁵

Yet, *Lear* cannot be simply dismissed as an old precedent. *Lear* represents one of the major Supreme Court patent precedents of the past forty years, one that is not forgotten and which has uniformly been cited with approval by the Supreme Court in later decisions. It must be remembered that the *Blonder-Tongue* rule on collateral estoppel is today one of the leading cases in general jurisprudence, yet the case arose in a patent context.⁷⁶ A root cause for the Court changing its law on collateral estoppel in the dramatic fashion of *Blonder-Tongue* may be traced to *Lear*:

⁷⁵ *Lear, Inc. v. Adkins*, 395 U.S. 653, 670-71 (1969).

⁷⁶ *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 349-50 (1971).

“When the[] judicial developments are considered in the light of our consistent view – last presented in *Lear, Inc. v. Adkins* – that the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted, it is apparent that the uncritical acceptance of the principle of mutuality of estoppel expressed in *Triplett v. Lowell* is today out of place. Thus, we conclude that *Triplett* should be overruled to the extent it forecloses a plea of estoppel by one facing a charge of infringement of a patent that has once been declared invalid.”⁷⁷

Lear continues to be cited by the court as a cornerstone for patent policy in the United States. As stated in *Bonito Boats*, “all ideas in general circulation [should] be dedicated to the common good unless they are protected by a valid patent.”⁷⁸

Quoting *Lear* in *Devex*, “[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.”⁷⁹ Citing a nineteenth century precedent, “a patent challenge in the courts permits a more informed decision regarding the merits of a particular patent. And, as we have long recognized, ‘It is as important to the public that

⁷⁷ *Blonder-Tongue*, 402 U.S. at 349-50.

⁷⁸ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 159-60 (1989)(quoting *Lear*, 395 U.S. at 668).

⁷⁹ *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 658 (1983)(Stevens, J., concurring)(quoting *Lear* 395 U.S. at 670).

competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly; ...”⁸⁰

The court in *Quick Point Pencil* summarizes *Lear*, where the Court “held that a person licensed to use a patent may challenge the validity of the patent, and that a licensee who establishes that the patent is invalid need not pay the royalties accrued under the licensing agreement subsequent to the issuance of the patent. Both holdings relied on the desirability of encouraging licensees to challenge the validity of patents, to further the strong federal policy that only inventions which meet the rigorous requirements of patentability shall be withdrawn from the public domain.”⁸¹

In *Kewanee Oil*, it was pointed out that “the Court [in *Lear*] thought that an invalid patent was so serious a threat to the free use of ideas already in the public domain that the Court permitted licensees of the patent holder to challenge the validity of the patent. Better had the invalid patent never issued.”⁸²

The Court noted in *Glaxo Group* that “[because of the public interest in free competition, [the Court] had repeatedly held that the private licensee-plaintiff in an antitrust suit may attack the validity of the patent under which he is licensed even though he has agreed not to do so in his license. The authorities for this proposition were *Sola Electric Co. v. Jefferson Electric Co.*, 317 U.S. 173 (1942); *Edward Katzinger Co. v. Chicago Metallic Mfg Co.*, 329 U.S. 394 (1947); and *MacGregor v. Westinghouse Electric & Mfg. Co.*, 329 U.S. 402 (1947). The essence of those cases is best revealed in *Katzinger* where the Court held that,

⁸⁰ *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 658 (1983)(Stevens, J., concurring)(quoting *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

⁸¹ *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 264 (1979)(citing *Lear*, 395 U.S. at 670-71).

⁸² *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 488-89 (1974).

although a patent licensee (under the then-controlling law) was normally foreclosed from questioning the validity of a patent he is privileged to use, the bar is removed when he alleges conduct by the patentee that would be illegal under the antitrust laws, absent the patent. The licensee was free to challenge the patent in these circumstances because the ‘federal courts must, in the public interest, keep the way open for the challenge of patents which are utilized for price-fixing . . .’ 329 U.S., at 399. *Katzinger* and *Gypsum* were much in the tradition of *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234, 12 S.Ct. 632, 636, 36 L.Ed. 414 (1892): ‘It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly . . .,’ a view most recently echoed in *Lear, Inc. v. Adkins*, 395 U.S. 653, 663 (1969).”⁸³

B. “Dethroning Lear” through Patent Reform

Less than a decade after *Lear*, the most respected senior scholar knowledgeable about patents and procedures advocated “dethroning Lear” in large measure because the problem identified in *Lear* had been dealt with through enactment of patent reexamination legislation.⁸⁴ Yet, while that view may *prospectively* have been realistic, the failure of the current reexamination system manifests the continued need to address the policy concerns of the Court in *Lear*. Yet, reexamination remains a viable option to meet the challenge of *Lear* if there were appropriate legislation.⁸⁵ Indeed, if there were a meaningful post-grant patent

⁸³ *U. S. v. Glaxo Group Ltd.*, 410 U.S. 52, 57-58 (1973).

⁸⁴ Rochelle Cooper Dreyfuss, *Dethroning Lear: Licensee Estoppel and the Incentive to Innovate*, 72 Va. L. Rev. 677 (1986).

⁸⁵ Kimberly A. Moore, *Jury Demands: Who’s Asking*, 17 Berkeley Tech. L.J. 847, 849 n.8 (2002) (citing Dreyfuss, 72 Va. L. Rev. at 754 n.277)(“ Of course, reexamination procedures exist as a present alternative to litigation, but they are infrequently chosen because of their estoppel effects on litigating

review system instituted as part of patent reform efforts, thereby eliminating a root cause for *Lear*, then it would be logical to legislatively overrule *Lear* at such a time.

C. A Comparative View: A Different Approach Abroad

When contrasted with the patent regimes of Germany, the United Kingdom and Japan, the critical failing mentioned in *Lear* is missing: Each of these systems has a highly reliable and efficient method for weeding out invalid patents in a far shorter time and with greater predictability and less expense than in the costly patent litigation system of the United States. The High Court in the United Kingdom is able to swiftly and with great judicial expertise sort through patent validity challenges. The German *Bundespatentgericht* in Munich is able to provide an expertise and speed of purely invalidity determinations in its *Nichtigkeitsklagen*. Japan has totally revamped its administrative post-grant review system at the Japan Patent Office to provide a roughly one *inter partes* proceeding at its Board of Appeals. Swift appellate review is possible at the Court of Appeal, the *Bundesgerichtshof* and the Intellectual Property High Court, each manned by a patent-experienced group of jurists.

validity issues. Opposition proceedings prior to patent issuance presently do not exist. However, if enacted, they could help reduce subsequent litigation by minimizing the issuance of invalid patents.”) Professor Moore also cites several other authorities: “Gregory Gelfand, *Expanding the Role of the Patent Office in Determining Patent Validity: A Proposal*, 65 Cornell L. Rev. 75, 98-102 (1979); Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 Harv. J.L. & Tech. 1 (1997) (suggesting further examination of foreign nullity, opposition, and revocation proceedings as potentially advantageous over the present scheme of resolving validity disputes via litigation); Mark A. Lemley, *Rationale Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1525 (2001) (discussing the costs and benefits of an opposition proceeding for patents); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 Berkeley Tech. L.J. 577, 610-12 (1999); Craig Allen Nard, *Legitimacy and the Useful Arts*, 10 Harv. J.L. & Tech. 515, 557 (1997) (suggesting that the PTO is better suited to resolve patent validity issues than a judge or lay jury); Joel M. Freed & Thomas C. Reynolds, *The New Patent Landscape*, 18 Computer & Internet Law., Dec. 2001, at 1, 2-4 (reporting on a Congressional bill which would establish opposition proceedings for business method patents).” *Id.*

VII. THE FUTURE: LESSONS FROM LONDON

Keeping the door open to the discretion of the trial court to entertain declaratory judgment actions should be followed to the exclusion of bright line rules established from an appellate tribunal. It would be useful to follow the wisdom from the recent British *Nokia* case: “The development of the use of declaratory relief in relation to commercial disputes should not be constrained by artificial limits wrongly related to jurisdiction. It should instead be kept within proper bounds by the exercise of the courts of discretion.”⁸⁶ Against the argument that the “floodgates” of more litigation would be opened by broadening the scope of declaratory relief,⁸⁷ “there has not been a flood of applications.... Moreover, if cases involving too many patents at one time were brought the Court has ample machinery for cutting the cases down to size or splitting them into manageable portions. And if in the end the whole thing became unmanageable that might [at that time] be a reason to decline jurisdiction.....”⁸⁸

⁸⁶ *Nokia v. InterDigital*, *supra*, at ¶ 30 (Carnwath, L.J.) (quoting *Messier Dowty Ltd v Sabena SA* [2001] 1 All ER 275, 285).

⁸⁷ *Id.* at ¶ 21 (Jacob, L.J.).

⁸⁸ *Id.* at ¶ 22.