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THE IMPACT OF *MEDIMMUNE, INC. V. GENENTECH, INC.* AND ITS PROGENY ON TECHNOLOGY LICENSING

MICHAEL DONOVAN*

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I. INTRODUCTION

Patent law has long been used as an incentive-based monopoly system for encouraging the development of science and technology. The government's power to grant a legal monopoly in the form of a patent was originally expressed in the Constitution.² Congress may grant exclusive rights "[t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited [t]imes to . . . [i]nventors the exclusive [r]ight to their . . . [d]iscoveries."³

Since its Constitutional foundation, United States patent law has evolved to the system we know today. Claims, currently the metes and bounds of the property right granted in the patent, were originally considered unnecessary; the specification was the vital part of the patent.⁴ Similarly, patent prosecution and examination procedures were originally viewed as cumbersome to the government and thus were not rigorously applied.⁵ Not until the nineteenth century were examination procedures, similar to the burdensome ones employed today by the United States Patent and Trademark Office ("USPTO"), made part of the Patent Act.⁶

One of the more drastic changes to patent law has arisen from a series of cases, originating with the U.S. Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*⁷ In *MedImmune*, the Court allowed a licensee to bring a declaratory judgment action against a licensor without first repudiating the license.⁸ Additionally, in dicta, the Court obliterated the standard for bringing a declaratory judgment action in patent law cases.⁹ Subsequent cases have interpreted the *MedImmune* decision broadly, effectively altering the negotiating stances for both sides of a licensing arrangement, and making it easier for a prospective licensee/accused infringer to bring a declaratory judgment action seeking a statement of noninfringement, invalidity, or unenforceability.¹⁰ This line of cases has left patent law and subsequently patent valuation in flux.

Part I of this paper will address relevant background information, including a brief discussion of the statutory requirements of patent law and the declaratory judgment act. Part II will discuss the *MedImmune* decision in detail. Part III will discuss the progeny of the *MedImmune* decision, highlighting six cases. Part IV will discuss how potential licensing relationships have been altered in light of *MedImmune* and its progeny. Finally, Part V is a brief conclusion.

² U.S. CONST. art. I, § 8, cl. 8.

³ *Id.*

⁴ JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 54 (2d ed. 2006).

⁵ See F. SCOTT KIEFF ET AL., PRINCIPLES OF PATENT LAW 19-20 (4th ed. 2008).

⁶ *Id.* at 19-21; see also 35 U.S.C. §§ 131-35 (2006).

⁷ 549 U.S. 118 (2007).

⁸ *Id.*

⁹ *Id.* at 132 n.11 (Scalia, J., dictum).

¹⁰ See *infra* Part III.

II. BACKGROUND

A. Patent Law Background

Outside of the difficult prosecution and examination procedures, there are four distinct statutory “hurdles” an inventor must overcome to be awarded a patent by the USPTO.¹¹ This section will detail each of the following four requirements: patentable subject matter, utility, novelty/loss of right, and obviousness.

Section 101 of the Patent Act incorporates both the patentable subject matter and the utility requirements.¹² It states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor.”¹³ The patentable subject matter requirement is embodied in the words “process, machine, manufacture, or composition of matter.”¹⁴ While these words are highly ambiguous in their statutory state, case law attempts to define them, with mixed results. In *Diamond v. Chakrabarty*,¹⁵ the Supreme Court held that any item that was manmade and not naturally occurring was a composition of matter.¹⁶ The *Diamond* decision has greatly expanded patentable subject matter, as anything manmade is now arguably a composition of matter, and thus patentable subject matter.¹⁷ What is certain about patentable subject matter is that “laws of nature, physical phenomena, and abstract ideas” are not patentable subject matter.¹⁸ Thus, potentially anything *man-made* is patentable subject matter; however, laws of nature and similar natural phenomena are not.¹⁹

Similar to the broad standard of patentable subject matter, the utility hurdle is easy to surpass. The utility requirement is also found in section 101 in the statements “useful process,” “manufacture,” and “useful improvement.”²⁰ The burden to prove that an invention is *not* useful rests with the USPTO.²¹ The USPTO, to bar an applicant under the utility provision, must show by clear and convincing evidence that a person having ordinary skill in the art would have *reasonably* doubted the invention’s utility.²² Additionally, a patent applicant need only show that his or her invention “is capable of providing some identifiable benefit” to meet the utility requirement.²³ Thus, overcoming both the patentable subject matter and utility requirements is relatively straightforward and easily

¹¹ See 35 U.S.C. § 101(2006).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ 447 U.S. 303, 309 (1980).

¹⁶ *Id.* at 309.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ 35 U.S.C. § 101 (2000).

²¹ *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

²² *Id.*

²³ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

achievable for an inventor.

The novelty provisions of the Patent Act are codified in section 102, subsections (a), (e), and (g).²⁴ The novelty provision is part of the driving force behind the incentive for encouraging advancement in technology and the sciences.²⁵ The legal monopoly given with a patent is not handed out for inventions that are not “new.”²⁶ Any information that predates the inventor’s own date of invention (known as “prior art”) that would enable a person having ordinary skill in the art to use the invention, will “anticipate” the invention, making it not novel.²⁷ Prior art can be found in another patent or printed publication that has been publically issued in any country in the world.²⁸ Also, prior art, as long it was publically known or used in the United States, regardless if it is in written form, will serve as novelty-barring prior art.²⁹

Next, the loss of right (known as “statutory bars”) provision is found in section 102(b).³⁰ This provision works to bar an inventor from getting a patent which introduces the invention to the public too far in advance of seeking a patent.³¹ The policy behind this provision is that the public will come to rely on an invention, and, if not given notice that the invention is patented, the public will consider the invention as part of the public domain.³² The loss of right bar depends on the invention’s “critical date.”³³ This is the date that is exactly one year prior to the date of application to the USPTO.³⁴ If the inventor has previously patented or described the invention in a printed publication in the United States or a foreign country, or places the invention in public use or on sale, earlier than the critical date, the inventor may no longer patent his or her invention.³⁵

A further hurdle to obtaining a patent is the obviousness requirement found in section 103.³⁶ This provision is employed to prevent inventions that meet the technical requirements of section 102, but do not truly advance technology and the sciences.³⁷ The obviousness provision is judged by whether a person having ordinary skill in the art would have found the invention obvious at the time of conception.³⁸ The actual application of the obviousness requirement has been performed according to the factors set forth in *Graham v. John Deere Co.*,³⁹ a

²⁴ § 102 (a), (e), (g).

²⁵ 1 DONALD S. CHISUM, CHISUM ON PATENTS § 3.01 (2006).

²⁶ *Id.*

²⁷ § 102(a).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* § 102(b).

³¹ *Id.*

³² CHISUM, *supra* note 25, at § 3.01.

³³ *Id.*

³⁴ *Id.* § 102(b).

³⁵ *Id.*

³⁶ *Id.* § 103

³⁷ *Id.* § 103(a)

³⁸ *Id.*

³⁹ 383 U.S. 1 (1966).

highly fact-based analysis involving the prior art, the ordinary skill in the art, and secondary considerations.⁴⁰ Interestingly, the Supreme Court recently sent the obviousness analysis into flux in the landmark case, *KSR International Co. v. Teleflex Inc.*⁴¹ In *KSR*, the Court held that everyday common sense and information found implicitly within the prior art could be applied in the obviousness analysis.⁴² Thus, the current state of obviousness analysis is uncertain, but the analysis is at least less favorable to patent holders and applicants than it was prior to *KSR*.

In conclusion, if an inventor is able to surpass all of the above hurdles, he or she may be entitled to a patent. There are also requirements related to the manner in which the patent application is written,⁴³ but they are beyond the scope of this paper. Once an inventor is awarded a patent, he or she is given a legal monopoly to exclude all others from making, using, selling, or importing that invention in the United States.⁴⁴ After the patent issues, during litigation, the patent itself is still susceptible to being invalidated or held unenforceable. One manner in which a potential infringer, be it a licensee or another party, can attempt to invalidate a patent is through declaratory judgment.

B. Declaratory Judgment Background

Declaratory judgment is a procedural mechanism where a party, who is uncertain of his or her legal position, can have that position adjudicated in a federal court.⁴⁵ In terms of patent cases, the litigants' roles in a declaratory judgment action are generally reversed.⁴⁶ Usually, the patent owner is the defendant, and the accused infringer is the plaintiff.⁴⁷ Interestingly, an empirical study done by Judge Kimberly Moore revealed that there is a statistically significant difference between a patent owner's success rate in litigation when he or she is a plaintiff compared to when he or she is a declaratory judgment defendant.⁴⁸ The data shows that when a patent owner asserts a claim in an infringement suit, he or she is victorious fifty-eight percent of the time.⁴⁹ When one is the declaratory judgment defendant, however, he or she is victorious only forty-four percent of the time.⁵⁰ The exact reason for this discrepancy is unknown, but Judge Moore hypothesizes that the difference is in part due to the accused infringer's benefit of choosing when and

⁴⁰ *Id.* at 17-18.

⁴¹ 550 U.S. 398 (2007).

⁴² *Id.* at 420.

⁴³ *See* § 112.

⁴⁴ *Id.* § 154(a).

⁴⁵ Declaratory Judgment Act of 1934, 28 U.S.C. § 2201 (2006).

⁴⁶ Kimberly Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 920 (2001).

⁴⁷ *Id.*

⁴⁸ *Id.* at 920-21.

⁴⁹ *Id.* at 921.

⁵⁰ *Id.*

where the declaratory judgment suit will commence.⁵¹

Prior to the enactment of the Declaratory Judgment Act (“DJA”) in 1934,⁵² potential targets of patent infringement suits were in a difficult position, with almost no bargaining leverage. Therefore, prior to 1934, a party informed of his or her likely-infringing status had three options: (1) sign a license agreement at whatever price the licensor commanded; (2) wait for a high-priced lawsuit to be filed in the local federal district court; or (3) completely abandon the industry, never knowing if he or she was actually infringing. To alleviate some of the problems with this situation, Congress enacted the DJA.⁵³

The DJA was enacted in 1934, and with amendments currently reads: “[i]n a case of actual controversy within its jurisdiction . . . any court of the United States. . . may declare the rights and other legal relations of any interested party seeking such declaration.”⁵⁴ Shortly after the enactment of the original DJA, the Supreme Court decided *Aetna Life Insurance Co. v. Haworth*.⁵⁵ The Court held that the DJA was constitutional and that the use of the phrase “actual controversy” refers only to the “case or controversy” requirement found in Article III of the Constitution.⁵⁶ The Court reasoned that as long as the parties possessed adverse legal interests and their dispute was not a hypothetical one, a federal court may exercise jurisdiction.⁵⁷—The Court later elaborated on the test for an “actual controversy” stating the question 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.”⁵⁸ However, the Court warned that the question of whether a set of circumstances was within a federal court’s declaratory judgment jurisdiction is one of factual degree, and that fashioning a precise test would be difficult.⁵⁹

In spite of the Court’s warning that it would be difficult to articulate a precise test to determine whether a declaratory judgment jurisdiction exists, the Court of Appeals for the Federal Circuit (“CAFC”) did just that.⁶⁰ Shortly after the CAFC’s inception, they articulated a two-part test for determining the actual controversy aspect of patent declaratory judgment jurisdiction, which stood until the *MedImmune* decision.⁶¹ First, the declaratory judgment defendant/patent owner must have engaged in conduct that created a “reasonable apprehension” of suit on the part of the declaratory judgment plaintiff.⁶² Second, the declaratory

⁵¹ *Id.* at 921-22.

⁵² Declaratory Judgment Act of 1934, 28 U.S.C. § 2201 (2006).

⁵³ § 2201.

⁵⁴ *Id.*

⁵⁵ 300 U.S. 227 (1937).

⁵⁶ *Id.* at 239-40.

⁵⁷ *Id.* at 240-41.

⁵⁸ *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

⁵⁹ *Id.*

⁶⁰ *See Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388 (Fed. Cir. 1984).

⁶¹ *Id.*

⁶² *Id.* at 1398-99 (Fed. Cir. 1984); *see C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 880-81 (Fed. Cir.

judgment plaintiff must be either involved in, or prepared to be involved in, an activity that could be construed as infringement.⁶³ If these two requirements are met, declaratory judgment jurisdiction *may* be present.

Additionally, a discretionary component exists for declaratory judgment jurisdiction determination. The DJA states that where there is an actual controversy, courts of the United States *may* declare the rights of the parties.⁶⁴ Prior to *MedImmune*, if a court found, based on an objective standard, a declaratory judgment plaintiff possessed a “reasonable apprehension” that a patent infringement suit was to be commenced against him or her, and he or she was undertaking an activity that could be construed as infringement, the court would likely decide the discretionary component.

The DJA does not provide unlimited discretion to turn away declaratory judgment actions. The CAFC does have the power to reverse a lower court’s decision to dismiss a declaratory judgment action on discretionary grounds based on different findings.⁶⁵ The Supreme Court, however, has left some power with the district courts to make decisions on discretionary grounds by creating a deferential standard of review. The standard of review in discretionary declaratory judgment dismissals is an abuse of discretion, rather than a *de novo* review.⁶⁶ Thus, the power to dismiss a declaratory judgment action on discretionary grounds is highly fact specific and can be overturned, but there is deference to a district court’s decision to dismiss.⁶⁷

Declaratory judgment actions, in the context of licensing, have evolved over time. Prior to *Lear, Inc. v. Adkins*,⁶⁸ a licensee was estopped from asserting patent invalidity or unenforceability in a suit for royalties under a license agreement.⁶⁹ This legal theory, licensee estoppel, was abolished in *Lear* in favor of the public policy of testing the validity of a patent and determining what inventions are truly parts of the public domain.⁷⁰

The CAFC’s interpretation of *Lear* has changed over time. Initially, the CAFC took the approach that a declaratory judgment proceeding is not barred simply because the license agreement is still in effect.⁷¹ The court reasoned that a contrary position would violate the policy set forth in *Lear* that patents should be contested, and often licensees are the only parties who can bring suit.⁷² Between 1983 and 2004, the CAFC continued to reign in the *Lear* policy and made it more difficult for a licensee to bring a declaratory judgment action against a licensor

1983) (articulating the reasonable apprehension factor).

⁶³ *Jervis B. Webb*, 742 F.2d at 1399.

⁶⁴ Declaratory Judgment Act of 1934, 28 U.S.C. § 2201 (2004).

⁶⁵ *Minn. Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 673 (Fed. Cir. 1991).

⁶⁶ *Wilton v. Seven Falls, Co.*, 515 U.S. 277, 289-90 (1995).

⁶⁷ *See id.*

⁶⁸ 395 U.S. 653, 656 (1969).

⁶⁹ *Id.* at 656.

⁷⁰ *Id.* at 670.

⁷¹ *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 880 (Fed. Cir. 1983).

⁷² *Id.*

without first repudiating the license.⁷³ Finally, in *Gen-Probe Inc. v. Vysis, Inc.*,⁷⁴ the CAFC held that a licensee, in good standing, who has not repudiated the license agreement, does not have standing to bring a declaratory judgment action.⁷⁵ The court reasoned that no sufficient “actual controversy” existed between Gen-Probe and Vysis until the license agreement had been repudiated by a material breach.⁷⁶ Thus, prior to *MedImmune*, a licensee wishing to bring a declaratory judgment action seeking to have a patent invalidated or found unenforceable, first must repudiate the license.⁷⁷ All of this, however, was changed by the Supreme Court’s decision in *MedImmune* and its progeny.⁷⁸

III. THE *MEDIMMUNE* DECISION

A. *Facts and Procedural History*

The dispute in *MedImmune* arose as a result of a license agreement signed in 1997.⁷⁹ MedImmune, the licensee, signed an agreement with Genentech, the licensor/patent assignee, to license the Cabilly I patent and the then-pending Cabilly II patent application.⁸⁰ MedImmune was entitled to make, use, and sell the subject matter of the Cabilly I patent, a chimeric antibody, which it used in its drug, Synagis.⁸¹ Synagis accounted for eighty percent of MedImmune’s revenue in 1999.⁸² For use of the Cabilly I patent in the manufacture of Synagis and the application covered in the Cabilly II patent application, MedImmune paid Genentech royalties.⁸³

In December 2001, however, upon the maturation of the Cabilly II application into an issued patent, Genentech decided that more royalties were owed.⁸⁴ Soon after the Cabilly II patent issued, Genentech informed MedImmune that it desired further royalty payments beginning March 1, 2002.⁸⁵ This was a signal to MedImmune that Genentech would enforce the Cabilly II patent, perhaps terminate the original license agreement, and sue MedImmune for willful patent infringement.⁸⁶ Although MedImmune believed the Cabilly II patent to be both unenforceable and invalid, it did not wish to risk losing a potential willful patent infringement suit, the results of which could be an order to pay treble damages and

⁷³ See e.g., *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1567-68 (Fed. Cir. 1997); *Diamond Scientific Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224-26 (Fed. Cir. 1988).

⁷⁴ 359 F.3d 1376 (Fed. Cir. 2004).

⁷⁵ *Id.* at 1381-82.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

⁷⁹ *Id.*

⁸⁰ *Id.* at 122.

⁸¹ *Id.* at 121.

⁸² *Id.* at 122.

⁸³ *MedImmune*, 549 U.S. at 122.

⁸⁴ *Id.* at 121.

⁸⁵ *Id.*

⁸⁶ *Id.* at 122.

attorney's fees, in addition to losing a product that produced so much revenue.⁸⁷ MedImmune, therefore, continued to pay royalties "under protest."⁸⁸

Although MedImmune continued to pay Genentech its royalties, it filed a declaratory judgment action in the United States District Court for the Central District of California.⁸⁹ MedImmune sought a declaratory judgment that Synagis did not infringe any claim of the Cabilly II patent (valid or not) and that the Cabilly II patent was both unenforceable and invalid.⁹⁰ The district court, relying on the CAFC's decision in *Gen-Probe*, dismissed the declaratory judgment action because MedImmune was still in paying royalties and had not repudiated the license agreement, thus there was no "reasonable apprehension" of suit brought against them.⁹¹ The CAFC affirmed the district court's decision.⁹² MedImmune sought and received certiorari.⁹³

B. *The Issue*⁹⁴

The issue before the Court was whether a licensee, who is threatened with a potential infringement suit and loss of a majority of their revenue, without ceasing royalty payments and repudiating the license agreement, can bring an action for declaratory relief and meet the requirement of the case or controversy standard of Article III.⁹⁵

C. *The Rationale*⁹⁶

The Court began its analysis by looking at whether a plaintiff is required to expose him or herself to potential liability before bringing a declaratory judgment suit against the government; for example, in alleging that a statute is unconstitutional.⁹⁷ The Court stated that by not violating a potentially unconstitutional law, the threat of imminent suit (prosecution in this case) was eliminated; *however*, Article III jurisdiction remained.⁹⁸ The Court reasoned that jurisdiction was present because the fear of prosecution effectively *coerced* the plaintiff to not violate the law, and that "the declaratory judgment procedure [was] an alternative to pursuit of the arguable illegal activity."⁹⁹

⁸⁷ *Id.*

⁸⁸ *Id.* at 122.

⁸⁹ See *MedImmune*, 549 U.S. at 122; *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567 MPR (CTX), 2004 U.S. Dist. LEXIS 28680 (C.D. Cal. Apr. 26, 2004).

⁹⁰ *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 961-63 (Fed. Cir. 2005).

⁹¹ See *id.* at 961; see also *Jervis B. Webb Co. v. S. Sys. Inc.*, 742 F.2d 1388, 1398-99 (Fed. Cir. 1984); *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 881 (Fed. Cir. 1983).

⁹² *C.R. Bard*, 716 F.2d at 881.

⁹³ *MedImmune*, 549 U.S. at 122.

⁹⁴ *Id.* at 125.

⁹⁵ *Id.*

⁹⁶ *Id.* at 126-37.

⁹⁷ *Id.*

⁹⁸ *Id.* at 128.

⁹⁹ *MedImmune*, 549 U.S. at 129 (citing *Steffel v. Thompson*, 415 U.S. 452, 480 (1974) (Rehnquist,

The Court then analyzed its application of the DJA to a plaintiff who is coerced, not by the government, but by a private party, to self-avoid an imminent injury.¹⁰⁰ Surprisingly, the only Supreme Court precedent on point was *Altvater v. Freeman*,¹⁰¹ a patent licensing case.¹⁰² In *Altvater*, the Court held that a declaratory judgment suit involving the validity of a patent was not non-justiciable simply because of the licensee's failure to cease royalty payments.¹⁰³ Similar to *MedImmune*, royalties were being paid under protest, with the licensee paying simply to avoid an infringement suit.¹⁰⁴ The CAFC, in *Gen-Probe*, distinguished *Altvater* because it involved an injunction; however, the Court disagreed with that rationale.¹⁰⁵ Although the injunction was issued by the judiciary, the Court stated that even more pressing than a potential government sanction for violation of the injunction, was the threat of serious injury to the licensee's business.¹⁰⁶ The Court reasoned that a looming injury to a licensee's business can be just as coercive as government action.¹⁰⁷ Thus, the idea of coercion, either by governmental prosecution or by the potential of a patent infringement suit, potentially leading to damages and loss of revenue, is enough to satisfy the Article III requirements to bring a declaratory judgment action.¹⁰⁸ Therefore, with the specific facts present in this case, the threat of paying treble damages, attorney's fees, in addition to potentially losing eighty percent of their revenue; MedImmune was effectively coerced into continuing to pay royalties, albeit "under protest."¹⁰⁹

Interestingly, in its analysis, the Court effectively destroyed the CAFC's "reasonable apprehension" test.¹¹⁰ In footnote eleven, the Court stated that the test was incompatible with its precedent; reasoning that no apprehension of suit was necessary to bring a declaratory judgment action.¹¹¹

Finally, Genentech argued that the MedImmune's suit should be dismissed on discretionary grounds.¹¹² The Court stated that due to the district court's outright dismissal of the declaratory judgment suit, they could not decide this issue and it would have to be decided on remand.¹¹³

J., concurring)).

¹⁰⁰ *Id.* at 129-32.

¹⁰¹ 319 U.S. 359 (1943).

¹⁰² *Id.*

¹⁰³ *Id.* at 364-65.

¹⁰⁴ *See id.*

¹⁰⁵ *MedImmune*, 549 U.S. at 132.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 132-34.

¹⁰⁹ *Id.* at 130-31, 134-36.

¹¹⁰ *Id.* at 132.

¹¹¹ *MedImmune*, 549 U.S. at 132.

¹¹² *Id.* at 136-37.

¹¹³ *Id.*

*D. The Holding and Potential Impact on Licensing*¹¹⁴

In the end, the Court held that MedImmune was not required, as far as Article III jurisdiction is concerned, to cease royalty payments or to repudiate its license agreement, in order to bring a declaratory judgment action in federal court.¹¹⁵ Thus, MedImmune was free to continue its declaratory action seeking a judgment stating that the Cabilly II patent was not infringed, invalid, and unenforceable.

The potential impact on licensing is seen in several ways. First, one traditional way in which two parties could avoid the extreme costs of a patent infringement suit would be to agree to a license. In light of *MedImmune*, a putative infringer can agree to a license, claim they were coerced into signing through fear of suit, and then bring a declaratory judgment action, putting the patent owner/licensor on the defensive. Second, some commentators say that *MedImmune* may drastically affect the transaction costs of licensing.¹¹⁶ Licensors may be forced to both alter the manner in which the license agreement is drafted (including clauses regarding validity challenges) and calculating costs, by building in the costs of the potential declaratory judgment litigation into the royalties and other fees associated with the license; thus, making the entire transaction more expensive.¹¹⁷ Finally, as far as existing license agreements are concerned, licensors will have to be very careful not to suggest anything remotely concerning litigation or anything that could be construed as a threat.¹¹⁸ Although these concerns are just a few, many more concerns began cropping up after the progeny of *MedImmune* began to be decided.

IV. THE PROGENY OF *MEDIMMUNE*

Since the Supreme Court decided *MedImmune*, the CAFC has handed down several cases interpreting *MedImmune*'s holding. Four cases¹¹⁹ have interpreted *MedImmune* broadly; finding declaratory judgment jurisdiction in factual situations that would not have existed pre-*MedImmune*. However, one other CAFC¹²⁰ case and a recent case from the district court in Delaware¹²¹ have shown that declaratory judgment does still have its limits.

¹¹⁴ *Id.* at 137.

¹¹⁵ *Id.*

¹¹⁶ Bryan C. Diner & Ali Ahmed, *United States: In the Aftermath of MedImmune v. Genentech, Is It All Doom and Gloom for Licensors or Are There Rays of Hope in the Future?*, BNA INT'L IP & TECH. PROGRAMME, April 2007, available at <http://www.thefreelibrary.com/In+The+Aftermath+Of+MedImmune+v.+Genentech,+Is+It+All+Doom+And+Gloom...-a0166210098>.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Tech., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007);

SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372 (Fed. Cir. 2007).

¹²⁰ *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007).

¹²¹ *Edmunds Holding Co. v. Autobyte, Inc.*, Civ. No. 08-149-SLR, 2009 WL 424250 (D. Del. 2009).

A. *SanDisk v. STMicroelectronics*

SanDisk was the first post-*MedImmune* declaratory judgment case to come out of the CAFC, and thus, was the first to interpret *MedImmune*.¹²² The facts of *SanDisk* differed from *MedImmune* in that there was no existing licensing relationship; the plaintiff and defendant were merely in negotiations for a license.¹²³ STMicroelectronics (“ST”) owned several patents relating to flash memory storage and wished to license them to SanDisk when it discovered that products SanDisk was selling were possibly infringing.¹²⁴ ST presented claim charts to SanDisk and noted that SanDisk’s products were likely infringing, but also mentioned that “ST has absolutely no plan whatsoever to sue SanDisk.”¹²⁵ SanDisk claimed its products were not infringing and eventually license negotiations broke down.¹²⁶ Later, SanDisk filed a declaratory judgment action alleging ST’s patents were not infringing and were invalid.¹²⁷

At the district court level, the action was dismissed because no “reasonable apprehension” of imminent suit was present, but by the time the case made it to the CAFC, *MedImmune* had already been decided, which drastically changed the CAFC’s analysis.¹²⁸ The issue that faced the CAFC was whether the “actual controversy” requirement of the DJA was met by the specific facts of this case and thus, whether the case could proceed.¹²⁹

To address the main issue, the CAFC first focused on the Supreme Court’s rejection of the “reasonable apprehension” test in footnote eleven in *MedImmune*; recognizing the fact that the test was effectively obliterated.¹³⁰ From the rejection of the CAFC’s prior declaratory judgment test, the court went on to *greatly* expand declaratory judgment jurisdiction.¹³¹ The CAFC stated that jurisdiction will not be present when a potential licensee learns of a patent and that their product or process *might* infringe; however, when a potential licensor makes an affirmative move, in addition to the above, jurisdiction could be present.¹³² The CAFC broadly held:

[T]hat 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

¹²² *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007).

¹²³ *Id.* at 1374-75.

¹²⁴ *Id.* at 1375-76.

¹²⁵ *Id.* at 1376.

¹²⁶ *Id.*

¹²⁷ *Id.* at 1376.

¹²⁸ *SanDisk*, 480 F.3d at 1376-77.

¹²⁹ *Id.* at 1377-78.

¹³⁰ *Id.* at 1379-83.

¹³¹ *Id.* at 1385 (Bryson, J. concurring).

¹³² *Id.* at 1381.

its legal rights.¹³³

This holding effectively set down a rule so broad that as soon as a potential licensor is informed by a patent owner that a product or process they are making, using, or selling, *may* potentially read onto another's patent, declaratory judgment jurisdiction will be present.

Under the facts of this case, the CAFC found an actual controversy to exist, even though there was an explicit promise not to file an infringement suit on the part of ST.¹³⁴ ST's preparation of claim charts and other studies of SanDisk's products,¹³⁵ together with their interest in meeting about a potential license, was enough to create an "actual controversy."¹³⁶ In fact, the CAFC referred to this strategy as the kind of "extra-judicial patent enforcement with scare-the-customer-and-run tactics that the [DJA] was intended to obviate."¹³⁷ This was truly a sweeping change from the old CAFC test.

Of note is Judge Bryson's concurring opinion.¹³⁸ This concurrence pointed out the different result that would have occurred under the "reasonable apprehension" test,¹³⁹ as well as notes that the CAFC's holding in this case is broad-sweeping and will not be remotely limited to the facts of this case.¹⁴⁰

In conclusion, *SanDisk* effectively alters any proposal for a license agreement; save for a set of facts involving a potential licensee not currently manufacturing a potentially infringing product. Any patent owner wishing to avoid the costs of litigation and enter a license agreement through well-balanced negotiation must now be wary of a declaratory judgment action. This is further seen in the next case, one decided only a few days after *SanDisk*.

B. Teva Pharmaceuticals, USA, Inc. v. Novartis Pharmaceuticals Corp.

Although *Teva* does not involve a licensing relationship, it does further illustrate the CAFC's declaratory judgment jurisprudence.¹⁴¹ Novartis owned five patents relating to the drug, Famvir; one relating to the active ingredient itself, and the other four relating to methods associated with the drug.¹⁴² All five of these patents were listed in the FDA's Orange Book.¹⁴³ Teva, attempting to get approval for a generic version of Famvir, filed an Abbreviated New Drug Application ("ANDA"), per the Hatch-Waxman Act, including a statement that each of the five

¹³³ *Id.* at 1381.

¹³⁴ *SanDisk*, 480 F.3d at 1383.

¹³⁵ *Id.* at 1375.

¹³⁶ *Id.* at 1383.

¹³⁷ *Id.* at 1383 (citing in part *Arrowhead Indus. Chem., Inc. v. Ecolchem, Inc.* 846 F.2d 731, 735 (Fed. Cir. 1988)).

¹³⁸ *Id.* at 1383-85.

¹³⁹ *Id.* at 1383-85.

¹⁴⁰ *SanDisk*, 480 F.3d at 1384.

¹⁴¹ *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007).

¹⁴² *Id.* at 1334.

¹⁴³ *Id.*

patents was either invalid or noninfringed by Teva's generic drug.¹⁴⁴ Novartis filed a patent infringement suit based solely on the active ingredient patent, not suing on the other four patents.¹⁴⁵ Teva then filed a declaratory judgment action based on the other four patents, claiming that they were not infringed and invalid.¹⁴⁶ Similar to *MedImmune* and *SanDisk*, the district court dismissed the action based on a lack of an objective-based "reasonable apprehension" of suit because Novartis had never threatened suit on any of the four remaining patents.¹⁴⁷ The CAFC took the case and would reverse.¹⁴⁸

Once again, the CAFC pronounced the death of the "reasonable apprehension" test, reiterating the amorphous standard originally espoused in *Maryland Casualty*.¹⁴⁹ That standard being *under all of the circumstances*, whether there is a controversy between parties having adverse legal interests that warrants an immediate issuance of declaratory judgment.¹⁵⁰ In this case, the CAFC focused on five different circumstances, leading to the conclusion that this test is now a one of "totality of the circumstances."¹⁵¹ The five were: (1) Novartis' listing of all the patents in the Orange Book – this provided notice alone, but was not an affirmative act; (2) Teva's ANDA certification stating its generic did not infringe Novartis' patents/the patents were invalid; (3) statutory provisions in the Hatch-Waxman on achieving "patent certainty"; (4) Novartis actually bringing suit on its active ingredient patent; and (5) the potential of Novartis' strategy leading to multiple infringement suits against Teva.¹⁵²

All together, these factors illustrate that after *SanDisk* and *Teva*, the "reasonable apprehension" test is dead and the current standard is amorphous, highly fact-based, and judged by on a totality of the circumstances approach.

C. Sony Electronics, Inc. v. Guardian Media Technologies., Ltd.

Sony is very similar to *SanDisk*, in that it involved pre-licensing negotiations.¹⁵³ Guardian, owner of two different patents on V-Chip technology, noted that several electronics manufacturers, including Sony, were producing products that potentially infringed their patents.¹⁵⁴ Initially, Guardian informed these manufacturers of their potentially infringing status and provided claim charts comparing the specific claims of Guardian's patents to the accused devices.¹⁵⁵ In

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* at 1334-35.

¹⁴⁶ *Id.* at 1335.

¹⁴⁷ *Teva*, 482 F.3d at 1335.

¹⁴⁸ *Id.* at 1346.

¹⁴⁹ *Id.* at 1339.

¹⁵⁰ *Id.* at 1339 n.2.

¹⁵¹ *Id.* at 1340.

¹⁵² *Id.* at 1340-41.

¹⁵³ *Sony Elecs, Inc. v. Guardian Media Tech., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007).

¹⁵⁴ *Id.* at 1281.

¹⁵⁵ *Id.* at 1273-74.

response, the manufacturers noted potentially patent-invalidating prior art.¹⁵⁶ Eventually, Guardian offered the manufacturers a discounted license and the parties later met to negotiate.¹⁵⁷ Negotiations failed and the electronics manufacturers filed a declaratory judgment action seeking a statement that Guardian's patents were not infringed, invalid, and unenforceable.¹⁵⁸ Similar to the previous cases, the district court dismissed, relying on the CAFC's old "reasonable apprehension" test because Guardian never threatened suit and the action was commenced while the parties were still negotiating.¹⁵⁹ The CAFC accepted the case on appeal.¹⁶⁰

Using the rationale from *SanDisk*, the CAFC found that there was jurisdiction for the declaratory judgment action.¹⁶¹ The CAFC stated that even though a potential licensee is willing to partake in negotiations, this does not destroy their right to bring a declaratory judgment action.¹⁶² The CAFC reasoned that there is no requirement that a potential licensee should put themselves at risk of an infringement suit by continuing to engage in the putatively infringing activity without first seeking a declaration of its rights via declaratory judgment.¹⁶³ The manufacturers had no requirement to continue licensing negotiations; they could terminate them at will.¹⁶⁴ In fact, the CAFC held that as soon as Guardian stated it was due royalties for specific past and ongoing activities and the manufacturers disagreed with that assertion, declaratory judgment jurisdiction was present.¹⁶⁵

Sony further illustrates how little a potential licensor must do to create jurisdiction for a declaratory action. Once again, simply approaching a potential licensee to avoid the costs of pricey patent litigation could put the validity and enforceability of a potential licensor's at stake in a declaratory judgment action.

D. Adenta GmbH v. OrthoArm, Inc.

Similar to both *MedImmune* and *SanDisk*, the CAFC also held in *Adenta* that declaratory judgment jurisdiction was present.¹⁶⁶ *Adenta* is similar to *Medimmune* in that there is a dispute over language used by a patent owner when communicating with a licensee regarding possible litigation threats, and the fact that there is already an existing licensing relationship.¹⁶⁷ This case is different than both *MedImmune* and *SanDisk* in that the district court did not dismiss this

¹⁵⁶ *Id.* at 1274.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 1275.

¹⁵⁹ *Sony*, 497 F.3d at 1276.

¹⁶⁰ *Id.* at 1281.

¹⁶¹ *Id.* at 1281-82.

¹⁶² *Id.* at 1284.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Sony*, 497 F.3d at 1284.

¹⁶⁶ *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007).

¹⁶⁷ *Id.* at 1366.

case for lack of declaratory judgment jurisdiction.¹⁶⁸ Here, the district court found that the language used by OrthoArm's patent assignee ("[assignee] would pursue its available legal remedies to protect its rights")¹⁶⁹ was sufficient to create a "reasonable apprehension" of imminent suit, in response to the licensee, Adenta, threatening to stop payment of royalties because of some potentially patent-invalidating information it discovered.¹⁷⁰ In fact, the district court allowed this case to reach a jury verdict, and the appeal to the CAFC was regarding the issue of whether or not the district court erred in *not* dismissing the case for lack of jurisdiction.¹⁷¹

Although Adenta did eventually cease some royalty payments, which itself created declaratory judgment jurisdiction, that was not necessary to bring this action.¹⁷² The CAFC stated that as soon as OrthoArm's assignee announced it would pursue its legal remedies to protect its rights in response to Adenta's statement that it would cease royalty payments, the two parties were at adverse legal positions.¹⁷³ Thus, when parties are at adverse legal positions and the matter warrants an immediate judicial declaration, jurisdiction is present.¹⁷⁴

E. Benitec v. Nucleonics and Edmonds Holding Co. v. Autobytel

The previous four cases indicate how the CAFC has broadly interpreted the Supreme Court's *MedImmune* decision. As it currently stands, *almost* every potential licensor who contacts a party that may be infringing would be remiss to not worry about a declaratory judgment action being filed soon thereafter, alleging invalidity and non-infringement. In spite of the ease with which a licensee could bring a declaratory judgment action, there have been some cases attempting to rein in declaratory judgment jurisdiction.

F. Benitec Australia, Ltd. v. Nucleonics, Inc.

Benitec demonstrates that there are still some limits on declaratory judgment jurisdiction.¹⁷⁵ *Benitec* originally sued *Nucleonics* over an RNAi technology patent, alleging infringement for *Nucleonics*' use of the technology in human medical applications.¹⁷⁶ *Nucleonics* counterclaimed, seeking a declaratory judgment that *Benitec*'s patent was invalid and that it was protected based on 35 U.S.C. § 271(e).¹⁷⁷ Section 271(e) states that use of certain biotechnology patents for human medical applications is not infringement until a New Drug Application

¹⁶⁸ *Id.* at 1367.

¹⁶⁹ *Id.* at 1370.

¹⁷⁰ *Id.* at 1370.

¹⁷¹ *Id.* at 1366.

¹⁷² *Adenta*, 501 F.3d at 1370.

¹⁷³ *Id.*

¹⁷⁴ *Id.* at 1370.

¹⁷⁵ *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340 (Fed. Cir. 2007).

¹⁷⁶ *Id.* at 1342.

¹⁷⁷ *Id.*

is filed with the FDA;¹⁷⁸ this provision also was given an expansive reading by the Supreme Court while *Benitec* was pending in the district court.¹⁷⁹ In light of the Supreme Court's reading of Section 271(e), *Benitec* moved to dismiss its own claims because Nucleonics' activities were covered under the exception and there was no longer a colorable claim of infringement.¹⁸⁰ Nucleonics wished to proceed on its declaratory judgment action, but the district court dismissed the action for lack of jurisdiction because the parties were no longer adverse.¹⁸¹ The CAFC took the case to determine whether there was still jurisdiction in light of the recent *MedImmune/SanDisk* rationale.¹⁸²

The CAFC affirmed the district court's decision to dismiss for lack of jurisdiction.¹⁸³ The court found that Nucleonics had failed to show there was an "actual controversy" of sufficient and immediate reality to support jurisdiction.¹⁸⁴ The CAFC reasoned that the burden of proof is on the party *seeking* declaratory judgment jurisdiction to establish that jurisdiction exists at the time the claim is filed and continues to exist.¹⁸⁵ Here, jurisdiction plainly existed at the time the declaratory action was filed;¹⁸⁶ however, upon *Benitec*'s voluntary dismissal of its claim recognizing that Nucleonics' current actions are immune from an infringement suit, jurisdiction ceased to exist.¹⁸⁷ There was no longer jurisdiction because the parties were no longer legally adverse in a manner that warranted immediate declaratory relief.¹⁸⁸ Jurisdiction could be regained if the situation changed. If, as Nucleonics argues, it files a New Drug Application based on its RNAi work, or if it changed fields in which it was using the technology, from human medical applications to animal husbandry ones, jurisdiction would be present.¹⁸⁹ The CAFC agreed with those statements, but stated that those events were too far in the future to be certain enough to satisfy the jurisdictional requirements.¹⁹⁰

Finally, a holding of no declaratory judgment jurisdiction was supported by *Benitec*'s promise not to sue.¹⁹¹ The CAFC rationalized that *Benitec*'s statement that it would not file suit was different than ST's assertion that it did not *intend* to sue.¹⁹² While this may merely be semantics, the CAFC compounded this with *Benitec*'s withdrawal of its infringement suit and the lack of Nucleonics' concrete

¹⁷⁸ *Id.* at 1346.

¹⁷⁹ *Id.* at 1342.

¹⁸⁰ *Id.* at 1343.

¹⁸¹ *Benitec*, 495 F.3d at 1343.

¹⁸² *Id.*

¹⁸³ *Id.* at 1349.

¹⁸⁴ *Id.*

¹⁸⁵ *Id.* at 1344-45.

¹⁸⁶ *Id.* at 1345.

¹⁸⁷ *Benitec*, 495 F.3d at 1347-48.

¹⁸⁸ *Id.* at 1346.

¹⁸⁹ *Id.* at 1346-47.

¹⁹⁰ *Id.* at 1346.

¹⁹¹ *Id.* at 1347-48.

¹⁹² *Id.*

plans to infringe Benitec's patent in a totality of the circumstances analysis to affirm the dismissal of Nucelonics' declaratory judgment action.

Benitec does have an impact on declaratory judgment. Prior to this case, it was unclear how certain the controversy must be between the two parties before the matter was ripe enough to be heard. After *Benitec* it is clear that a future controversy that is not reasonably certain to exist, is not enough to obtain declaratory judgment jurisdiction. From the rationale, it seems possible that declaratory judgment jurisdiction can be destroyed after an action commences by a dismissing a patent infringement suit (if one exists) and promising not to sue over existing products.

G. Edmunds Holding Co. v. Autobytel, Inc.

In early 2009, a district court in Delaware decided a case that further attempted to control the *MedImmune* line of rationale.¹⁹³ Edmunds Holding Company and Autobytel were both companies involved in an industry where businesses sell sales leads on potential automobile buyers to retailers.¹⁹⁴ Autobytel owns a method patent directed toward distribution of these sales leads.¹⁹⁵ Prior to the initiation of this declaratory action, Autobytel had vigorously asserted their patent rights.¹⁹⁶ Autobytel previously commented in a business magazine that it would assert its rights through litigation,¹⁹⁷ as well as instituted patent infringement suits against several competitors, three of which were customers of Edmunds.¹⁹⁸ Significantly, Autobytel never communicated with Edmunds, never asking Edmunds to enter into a license agreement with them.¹⁹⁹ After initiation of the declaratory judgment action, Autobytel sought to have the action dismissed for lack of jurisdiction, claiming that there was no "case or actual controversy," as is required by the DJA and the *MedImmune* line of cases.²⁰⁰

In deciding that no declaratory judgment jurisdiction is present, the court differentiated the facts in this case from those of *MedImmune* and its progeny.²⁰¹ In all of the previously described cases, the patent owner had communicated in some fashion with the declaratory judgment plaintiff.²⁰² Here, Autobytel never communicated with Edmunds, although they did have a reputation for being litigious and stated that they would protect their intellectual property.²⁰³ The court reasoned that although an overt act toward a declaratory judgment plaintiff was never explicitly required by the *MedImmune* line of cases, the absence of an overt

¹⁹³ *Edmunds Holding Co. v. Autobytel, Inc.*, 598 F. Supp. 2d 606(D. Del. 2009).

¹⁹⁴ *Id.* at 607-08.

¹⁹⁵ *Id.* at 608.

¹⁹⁶ *Id.* at 607-08.

¹⁹⁷ *Id.* at 608 n.4.

¹⁹⁸ *Id.* at 608.

¹⁹⁹ *Edmunds Holding*, 598 F. Supp. 2d at 610.

²⁰⁰ *Id.* at 607.

²⁰¹ *Id.* at 609.

²⁰² *Id.* at 610.

²⁰³ *Id.*

act is a significant hurdle to finding jurisdiction present.²⁰⁴ The court stated that Autobyte's litigation history combined with its statements about protecting its intellectual property was not enough to create an "actual controversy."²⁰⁵ The court also stated that there was no imminent fear of suit and that with none of these factors present, the controversy here was at best "speculative" and "one-sided."²⁰⁶ Thus, this case leaves declaratory judgment jurisprudence in a state that does not explicitly require an overt act toward a plaintiff by a defendant, but a lack of that act is difficult to overcome.

In conclusion, these cases, starting with *MedImmune v. Genentech*, have truly reshaped declaratory judgment jurisdiction jurisprudence, but not necessarily in the best way possible. The CAFC's objective "reasonable apprehension" test was nearly completely abrogated by *MedImmune*'s footnote eleven, and was fully abandoned by the CAFC in *SanDisk*. As of now, it is difficult to imagine a situation where a patent owner, wishing to avoid litigation, could contact a potential licensee, and not have to fear being served with a declaratory judgment complaint. This line of cases has already impacted technology licensing, and will continue to do so as long as the current standards remain.

V. IMPACTS ON LICENSING AND VALUATION

At the very least, the *MedImmune* line of cases has re-shaped the licensing relationship. *MedImmune* and *Adenta* affect existing license relationships, whereas *SanDisk* and *Sony* affect pre-license negotiations, thus, all phases of licensing are in new territory.

A. Existing License Relationships

Prior to *MedImmune*, a licensor in an existing license relationship had little to worry about, until the licensee ceased royalty payments, or otherwise repudiated the license agreement, potentially risking a willful infringement suit. Then, to confer declaratory judgment jurisdiction on a licensee, the licensor would have to threaten the licensee with the infringement suit. This was the rule of *Gen-Probe*; a licensee in good standing had no grounds to bring a declaratory judgment action.²⁰⁷ Now, in light of *MedImmune*, a licensor must worry about the *vastly* increased likelihood of litigation. Currently, a licensor who communicates with a licensee about perhaps changing either the royalty rate or some other provision in the license has created an adverse legal relationship, effectively conferring declaratory action jurisdiction.²⁰⁸

This shift in the existing license landscape has decidedly slanted the playing field toward the licensee.²⁰⁹ When already involved in a licensing relationship and

²⁰⁴ *Id.*

²⁰⁵ *Edmunds Holding*, 598 F. Supp. 2d at 610-11.

²⁰⁶ *Id.* at 610.

²⁰⁷ *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1382 (Fed. Cir. 2004).

²⁰⁸ Jason Stolworthy & Ida Shum, *You Can Bet the Farm*, 50 *ADVOC.* 13, 13 (2007).

²⁰⁹ Toshihiro Kuwahara, *Drafting Strategies for Licensing Agreements after MedImmune Decision*,

the licensor wishes to alter the contract, the licensor must now consider *MedImmune* in their negotiating tactics.²¹⁰ If a licensor wishes not to worry about litigation that may lead to their patent being found invalid or unenforceable, the licensor may now have to sacrifice license alterations it feels are owed in light of changes in the conditions or context of the license. Unfortunately for the licensor, there is little that can be done if there is already an existing license agreement.²¹¹ Licensors should take *great* care in drafting all communications to the licensee, making sure that no language could be construed as a threat.²¹² Perhaps a licensor could attempt to renegotiate a license, incorporating provisions that may be beneficial in minimizing the impact of *MedImmune*. However, with the current broad jurisdiction standard, that letter itself may be enough to confer the licensee with jurisdiction.²¹³

B. Future License Agreements

Prior to *SanDisk* and *Sony*, a patent owner who learned of a potential infringer could ask an infringer to enter into a license agreement. This was a simple, relatively non-adversarial manner in which to conduct business that was beneficial to both parties. Each party received what they wanted; the accused infringer could continue on in its business, legitimized by the license agreement, and the patent owner would be satisfied by being compensated for the use of its patent rights. Most importantly, neither would face the prospect of a costly patent infringement suit.

After *SanDisk* and *Sony*, things have changed, favoring the accused infringer/potential licensee.²¹⁴ No longer can a patent owner send a letter to a potential infringer informing them that their product may be infringing and that a license may be in order; this could be enough to confer declaratory action jurisdiction. One possible solution would be to send a *very* general letter to a potential licensee informing them that licenses are available for the *general* products they manufacture, making sure to never specify exactly which products and *never* mentioning infringement. However, no licensee would enter a license agreement without having more specifics, and once those specifics are revealed, based on *Sony* and *SanDisk*, a declaratory action could be instituted. Important to note is that even the statement that there is no intention to file an infringement could not save ST in *SanDisk*, so a unilateral promise on the part of the patent owner might not be enough to stop a declaratory judgment action.

Outside of changes in licensing agreement drafting, there are two other possible means a patent owner might be able to use that stem the effects of *SanDisk* and *Sony*. First, the patent owner can threaten a suit, with a complaint in

PRACTISING LAW INSTITUTE: PATENTS, COPYRIGHTS, TRADEMARKS, AND LITERARY PROPERTY COURSE HANDBOOK SERIES, at 156 (2008), available at WL 927 PLI/PAT 141.

²¹⁰ *Id.* at 153.

²¹¹ *Id.* at 156.

²¹² *Id.*

²¹³ *Id.*

²¹⁴ Stolworthy & Shum, *supra* note 208, at 14.

hand, inform the potential infringer of this fact, and that unless a contract stating that neither party will file suit (a “stand still agreement”), the infringement action will commence.²¹⁵ This could be difficult to implement for two reasons. First, the patent owner must be willing to spend the resources to prosecute the infringement suit. If not, they have given the accused infringer the ability to file a declaratory action judgment. Second, this creates a more hostile environment for the licensing relationship. It might be difficult to create an amicable business relationship when it begins in such a conflicted manner.

The second option to get around *SanDisk* is for a patent owner to file suit in district court, but to not serve the complaint immediately.²¹⁶ This provides the patent owner with their choice of forum and gives them considerable leverage for negotiations. The Federal Rules of Civil Procedure state that service must be made within 120 days, thus allowing the patent owner and the accused infringer approximately four months to negotiate.²¹⁷ Once again, this may be a difficult manner in which to start a licensing relationship, but with *SanDisk* and *Sony* out there, any chance a patent owner has to equal the playing field must be used.

MedImmune and its progeny’s effects will be seen for many years to come. One thing is for sure, these cases will drastically affect the mind set of the potential licensor. Not only will the licensor always have to bear in mind the possibility of litigation, but will have to alter their negotiation stance. These cases will force licensors to either expect higher licensing fees to offset the greater potential for litigation or will lead to less technology licensing and transfer. This latter option can have dire consequences for the growing global technology age; the less technology in the public domain, the more the technology age will slow down.

C. Impact on Patent Valuation

Intellectual property valuation is important for both legal and business reasons. Legally, during and after litigation and in transactional matters such as bankruptcy, company reorganization, or a company transfer, the value of a patent may have to be determined for damages and other matters.²¹⁸ Patent valuations in the business context may be necessary during mergers, acquisitions, spin-offs, and especially in licensing.²¹⁹

Patent valuation is based on several elements, including a patent’s uniqueness, breadth, competing technologies, time to commercialize, the market for the technology, and economic and legal influences on the future of the patent and the technology.²²⁰ One factor commonly associated with valuation in any context, is the amount of risk associated with that commodity.²²¹ Part of the value

²¹⁵ Ronald A. Bleeker & Michael V. O’Shaughnessy, *One Year After MedImmune – The Impact on Patent Licensing & Negotiation*, 17 FED. CIR. B.J. 401, 431-32 (2008).

²¹⁶ *Id.* at 431.

²¹⁷ See FED. R. CIV. P. 4(m).

²¹⁸ WESTON ANSON, FUNDAMENTALS OF INTELLECTUAL PROPERTY VALUATION 77 (2005).

²¹⁹ *Id.*

²²⁰ *Id.* at 76.

²²¹ John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 440 (2004).

of a patent has been described as a function of the risk associated with being able to enforce the patent's rights and win a patent infringement suit, perhaps being awarded treble damages and attorney's fees.²²² Prior to *MedImmune*, factors associated with the decision to bring an infringement suit compared entering license negotiations against the potential cost of the litigation, including how sure a party was that their patent was valid and enforceable. However, during that calculus, they knew that as long as no threat was made to a putative infringer, their patent was safe from litigation, if they chose not to file suit; the risk to the patent itself was non-existent.

After *MedImmune*, things have changed.²²³ The risk associated with enforcing a patent's rights has gone up. Previously, a patent owner could decide to enter into a license as a way of enforcing their rights, knowing that the patent was never at risk as long as there was no litigation. Now, simply approaching another party about a potentially infringing product could put a patent's validity and enforceability in jeopardy.²²⁴ The risk associated with asserting patent rights has gone up, and the value has likely gone down.²²⁵ There is no point to having a legal monopoly when there is no way to safely assert rights under that privilege. With no point to having the monopoly, correspondingly, the value will likely drop across the board on patents if there is no safe way to assert patent rights. Thus, *MedImmune* impacts more than just negotiating licenses; it will likely affect the very core of patents and the business associated with them.²²⁶

VI. CONCLUSION

MedImmune and its progeny have re-shaped the face of licensing. It destroyed the CAFC's objective standard for bringing a declaratory judgment action and made the standard for bringing an action much more lax than it was previously. This line of cases has effectively redistributed the power in license negotiations and existing license agreements. As things currently stand, any licensor/patent owner with any doubts about the validity of their patent or a strong urge to avoid litigation, must walk on eggshells around licensees for fear that they could be involved in litigation at a moment's notice. In addition, the *MedImmune* cases have potentially permanently dropped the value of all patents due to the increased inability of a patent owner to enforce their rights and the risks associated with that enforcement. These are just some of the impacts that have been noted in the two years since the Supreme Court decided *MedImmune*, more serious side effects may be still to come.

²²² *Id.*

²²³ Peter Jay, Note, *Removing Incentives for Technology Transfer: MedImmune v. Genentech*, 5 BUFF. INTELL. PROP. L.J. 69, 80 (2007).

²²⁴ *Id.* at 82.

²²⁵ *Id.*

²²⁶ *Id.* at 84.