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Removing Incentives for Technology Transfer: Medimmune v. Genentech

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NOTE

REMOVING INCENTIVES FOR TECHNOLOGY TRANSFER: MEDIMMUNE V. GENENTECH

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I.
INTRODUCTION

MedImmune v. Genentech changed the landscape for licensors and licensees of patented technology.[2] The decision places an emphasis on coercion in patent licensing negotiations, while attempting to realign the balance of power between licensors and licensees. The realignment, however, shifts the power far back to licensees, leaving licensors with fewer options in the realm of licensing. The realignment also creates barriers to effective and efficient technology transfer. The likely result will be a chilling of licensing practices.

This paper proceeds in three parts: Part I summarizes the *MedImmune* decision; Part II inspects the subsequent decisions by the Court of Appeals for the Federal Circuit ("CAFC") interpreting *MedImmune*; and Part III examines the impact of these decisions on patent practice.

II.
THE SUPREME COURT'S DECISION IN MEDIMMUNE V. GENENTECH

MedImmune, a biotechnology company, manufactures the drug Synagis, which treats certain respiratory tract diseases in infants and children.[3] Revenue for MedImmune largely depends on sales of Synagis for which profits reached 942.3 million dollars in 2004.[4] MedImmune's total revenue in 2004 was only 1.2 billion dollars.[5] So, the majority of MedImmune's revenue was derived from Synagis alone, and the patents protecting Synagis were extremely valuable to the company.

In 1997, MedImmune licensed a patent related to chimeric antibodies and a then-pending application relating to the coexpression of immunoglobulin chains in recombinant cells from Genentech (and co-assignee City of Hope.)[6] The application matured into a patent and Genentech requested that MedImmune pay additional royalties as described in the licensing agreement.[7] MedImmune felt that Genentech's patent in question was invalid and unenforceable, and that Synagis did not infringe the patent's claims or owe royalties under the licensing agreement.[8]

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2 MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (U.S. 2007).

3 *Id.*, at 768 (U.S. 2007); *See also*, MedImmune, Inc. v. Genentech, Inc., 2004 U.S. Dist. LEXIS 28680 (C.D. Cal. Aril 23, 2004) [hereinafter MedImmune I].

4 MedImmune, Inc., Annual Report 2005, http://www.medimmune.com/ar/2005/financials/mda4.html (last visited Dec. 27 2007).

5 *Id.*

6 MedImmune, *supra* note 2, at 768.

7 *Id.*

8 *Id.*

MedImmune, however, did not want to risk treble damages, attorney's fees, and enjoinment by refusing to pay royalties and willfully infringing the recently granted patent.[9] Therefore, MedImmune paid the royalties under protest and sought a declaratory judgment of invalidity, unenforceability, non-infringement and lack of royalty obligation.[10]

The lower court dismissed the action for lack of subject matter jurisdiction stating that "the license agreement 'obliterated any reasonable apprehension' that the licensee will be sued for infringement.' "[11] In other words, a licensee in good standing could never bring a declaratory judgment action. According to the district court, MedImmune and other patent licensees could either submit to the licensor's demands or they would have to break the licensing agreement, risk treble damages by continuing to practice the discovery, or even halt production altogether until the dispute was resolved.[12] All of the available options had potentially devastating economic consequences for MedImmune. The CAFC later agreed with and affirmed the district courts decision to apply CAFC precedent instead of ninth circuit precedent.[13]

The Supreme Court reversed by holding that MedImmune could not bring a declaratory judgment to challenge the patent's validity.[14] Justice Scalia delivered the opinion of the court which refocused declaratory judgment jurisdiction on earlier precedent and Article III justiciability under the Declaratory Judgment Act.[15] The Declaratory Judgment Act refers to the type of cases or controversies justiciable under Article III of the United States Constitution[16] Prior precedent dictated that declaratory judgments can be a case or controversy under Article III.[17] The question then becomes "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

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9 *Id.*

10 *Id.*

11 *Id.*, at 768 (citing Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004)); *See also*, MedImmune I, *supra* note 3.

12 MedImmune I, *supra* note 3, at *9 (MedImmune asserted that Ninth Circuit precedent should control in the case instead of CAFC precedent because they felt that subject matter jurisdiction is a procedural matter unrelated to patent law. The district court disagreed stating that "[t]his decision clearly implicates patent law, and is well within the purview of the Federal Circuit.").

13 MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958 (Fed. Cir. 2005).

14 MedImmune, *supra* note2, at 769; MedImmune, 427 F.3d 958, 965 (Fed. Cir. 2005) ("The district court did not err in holding that MedImmune, since under no threat or apprehension of suit, did not have standing to bring a declaratory challenge to the Cabilly II patent.").

15 *Id.*, at 771; *See generally*, Altvater v. Freeman, 319 U.S. 359 (1943).

16 *Id.*; *See also*, 28 U.S.C. § 2201(a) (2007).

17 *Id.* (citing Nashville, C. & St. L. R. Co. v. Wallace, 288 U.S. 249 (1933)).

judgment."[18]

As a result of the Supreme Court's decision, the CAFC's test for declaratory judgment jurisdiction had been abrogated.[19] The earlier CAFC precedent had focused on a "reasonable apprehension of suit test."[20] The reasonable apprehension of suit test asked the question if there was "(1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity."[21] A licensee in good standing could never fulfill the "reasonable apprehension" part of the test because a license in good standing removed any reasonable apprehension that an infringement suit would be instituted. After all, patent licenses are often considered a license to infringe.

Justice Scalia warned that patents can be used coercively to garner high royalty payments and inflate the value of a technology. Coercion, he felt, was present in common business situations where serious economic injury is threatened. The court analogized to a situation where government action is threatened.[22] A person threatened with the government action does not have to subject himself to liability before challenging the law or regulation. In *Steffel* v. *Thompson*, 415 U.S. 452 (1974), the court allowed a plaintiff to seek a declaratory judgment on the constitutionality of a state statute prohibiting the distribution of handbills instead of risking prosecution.[23] Additionally, In *Terrace v. Thompson*, 263 U.S. 197 (1923), a farmer faced forfeiture of his property if he entered into a lease in violation of the state's anti-alien act.[24] The threat of enforcement of the act vested subject matter jurisdiction in the court. A patent licensee would similarly have to "bet the farm" by breaking the license in order to bring an action challenging the validity of the patent.[25]

Justice Scalia felt that "[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

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18 *Id.* (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270 (1941)).

19 *Id.*; *See also*, SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380 (Fed. Cir. 2007) ("The Supreme Court's opinion in MedImmune represents a rejection of our reasonable apprehension of suit test.").

20 *Id.*; *See generally* Gen-Probe, 359 F.3d 1376 (2004).

21 BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed.Cir.1993).

22 MedImmune, *supra* note 2, at 772; *See also*, Steffel v. Thompson, 415 U.S. 452 (1974).

23 *Id.*, at 769 (citing Steffel v. Thompson, 415 U.S. 452 (1974)).

24 Terrace v. Thompson, 263 U.S. 197 (1923).

25 MedImmune, *supra* note 2.

injunction fatal to his business[,]"[26] whereas the Federal Circuit felt that prior precedent was distinguishable because it dealt with injunctive relief. So, a licensor cannot coerce a licensee into paying royalties without conferring that licensee with standing. In the past, injunctive relief and fear of willful infringement would become bargaining chips instead of coercive entitlements. After *MedImmune*, the role of these elements changes and shifts power back into the hands of the potential licensee. The line where standing is conferred, however, is not brightly drawn.

Justice Thomas, the lone dissenter, felt that licensees should have to break their license in order to challenge the validity of the underlying patent.[27] To hear declaratory judgments when a license has not been broken would be to hear a hypothetical case in violation of Article III of the Constitution.[28] Particularly, he felt that the court should not expand the concept of coercion from *Steffel* to parties that voluntarily accept contractual obligations.[29] Patent licensees voluntarily accept licenses, albeit often under threat of an infringement suit, but the license are nonetheless voluntarily. *Steffel* applies to the coercive power of governmental conduct where parties do not voluntarily enter into an agreement.[30] By applying *Steffel* to voluntary contractual obligations, the court was going beyond what *Steffel* actually stood for.[31] Instead, MedImmune could have avoided the situation by never agreeing to the license in the first place. Justice Thomas warns that the opinion contains no limiting principal and "has given every patent licensee . . . a free pass around Article III's requirements for challenging the validity of licensed patents."[32]

III.
THE FEDERAL CIRCUIT'S REACTION TO MEDIMMUNE V. GENENTECH

The CAFC has faced a variety of situations that present novel questions regarding declaratory judgment jurisdiction in the wake of the *MedImmune* decision. These decisions greatly affect licensing practices because they drastically lower the bar that was previously required to challenge the validity of a patent in licensing negotiations. As a result,

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26 *Id.*

27 *Id.* (Thomas, J., dissenting).

28 U.S. Const. art. III, § 2, cl. 1.

29 MedImmune, *supra* note 2 (Thomas, J., dissenting).

30 *Id.*, at 781-782 (Thomas, J., dissenting).

31 *Id.*, at 781 (Thomas, J., dissenting) ("By holding that the voluntary choice to enter an agreement to avoid some other coerced choice is itself coerced, the Court goes far beyond *Steffel*.").

32 *Id.*, at 782 (Thomas, J., dissenting).

parties entering into licensing negotiations must be aware of the potential consequences and conflicts that may arise. The following section will summarize several of the CAFC's decision regarding the *MedImmune* decision.

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

SanDisk, as owner of several patents related to flash memory storage, was approached by STMicroelectronics seeking to discuss a potential cross-licensing agreement.[33] In a letter initiating these discussions, STMicroelectronics stated that eight patents "may be of interest" to SanDisk, and later in another letter listed four additional patents that "may also be of interest."[34] In a series of meetings, STMicroelectronics's attorneys presented to SanDisk an infringement analysis of several SanDisk products.[35] After business and licensing negotiations broken down, SanDisk filed a law suit alleging infringement of one of its patents and seeking a declaratory judgment of noninfringement and invalidity of the patents discussed during the failed negotiations.[36] The district court dismissed SanDisk's declaratory judgment action declaring that SanDisk did not have a reasonable apprehension of suit.[37] Therefore, the court was divested of subject matter jurisdiction.

The CAFC vacated and remanded stating that the *MedImmune* decision represented a rejection of the reasonable apprehension of suit test that the district court applied.[38] Applying *MedImmune*, the court found that STMicroelectronics's activities created "a substantial controversy, between parties having adverse legal interest, of significant immediacy and reality to warrant the issuance of a declaratory judgment."[39] The infringement analysis and asserted right to royalties was sufficient to give rise to subject matter jurisdiction, even though STMicroelectronics had promised not to sue.[40] A promise not to sue is insufficient if the asserting party "shows a

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

34 *Id.*

35 These meetings were treated as "settlement discussions" which were to be kept confidential under Federal Rules of Evidence Rule 408. However, the court points out that since there was no active litigation the Federal Rules of Evidence simply do not apply because there was not and could not be a claim in dispute. A much simpler solution would have been to simply sign confidentiality agreements before presenting the infringement analysis.

36 SanDisk, *supra* note 33.

37 *Id.*

38 *Id.*, at 1380.

39 *Id.* (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 272 (U.S. 1941)).

40 *Id.*

preparedness and willingness to enforce its patent rights."[41]

B. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330 (Fed. Cir. 2007)

Novartis listed several patents in the Food and Drug Administration's Orange Book which covered the active ingredient in its drug Famvir and the associated method of therapeutic use.[42] Teva filed an Abbreviated New Drug Application ("ANDA") for a generic version of Famvir, and in its paragraph IV certification stated that it did not infringe any of the Novartis patents, or alternatively that the patents were invalid.[43] Since paragraph IV certifications constitute an act of infringement, Novartis filed suit against Teva, but only on the patent covering the active ingredient in Famvir.[44] Teva then sought a declaratory judgment establishing "patent certainty" that the remaining method patents were "invalid or will not be infringed."[45]

The district court dismissed the declaratory judgment action by applying the reasonable apprehension of suit test.[46] The CAFC reversed

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41 *Id.*, at 1383.

42 Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330 (Fed. Cir. 2007).

43 *Id.*, at 1330 (Paragraph IV certification refers to 21 U.S.C. § 355(j)(2)(A)(vii) which states

. . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and . . .

Novartis, within 45 days, could file a suit for patent infringement which invokes an automatic 30-month stay to delay FDA approval of the ANDA according to 21 U.S.C. § 355(j)(5)(B)(iii) which states:

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that— . . .).

44 *Id.*

45 *Id.*, at 1335.

46 *Id.*

finding five circumstances that supported Teva's assertion of a justiciable controversy, which were:

1. Novartis listing of Famvir in the Orange Book;[47]

2. Teva submitting an ANDA, which is an act of infringement;[48]

3. the unfair judicial gaming under the Hatch-Waxman Act by Novartis;[49]

4. the pending infringement litigation involving the same technology and same parties;[50] and

5. the possibility of future litigation over the related method patents.[51]

Under the totality of the circumstances, these five factors established Teva's standing and an actual controversy sufficient to confer subject matter jurisdiction on the court.[52]

C. Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982 (Fed. Cir. 2007)

Honeywell alleged patent infringement of five patents related to a virtual look ahead system used to give terrain or obstacle warnings in aviation electronics.[53] At the district court, Honeywell withdrew all previously asserted claims, except for eight specific claims in two of the patents, some of which were dependent claims.[54] The district court felt that since Honeywell refused to withdraw all claims Universal Avionics had a reasonable apprehension of suit.[55] Subsequently, the court maintained subject matter jurisdiction and several of the withdrawn claims were found to be invalid based on anticipation.[56]

The CAFC affirmed the lower court's decision, and distinguished *Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902 (Fed. Cir. 1988) in the process. When "infringement of a dependent claim also entails infringement of its associated independent claim," the entire subject matter of the technology will still be at issue.[57] The claims that Honeywell withdrew were both independent and dependent claims, but the claims that

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47 *Id.*, at 1341.

48 *Id.*, at 1342.

49 *Id.*, at 1342 (According to the court, judicial gaming refers to the practice of exploiting aspects of the Hatch-Waxman Act to delay generic competition in the pharmaceutical industry.).

50 *Id.*, at 1344.

51 *Id.*, at 1345.

52 *Id.*, at 1346.

53 Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982 (Fed. Cir. 2007).

54 *Id.*

55 *Id.*

56 *Id.*

57 *Id.*

it maintained in its action were all dependent.[58] *Grain Processing* presented a different situation where a group of process claims were withdrawn from consideration, but a group of product claims remained.[59] The Court felt that only such a blanket withdrawal, like a withdrawal of a group of process claims, would divest the court of subject matter jurisdiction.[60]

Unlike *Grain Processing*, Honeywell left the entire subject matter at issue because it withdrew independent claims while remaining to assert some dependent claims. Additionally, Honeywell charged co-defendant Sandel with infringement of the withdrawn patents in another lawsuit.[61] Therefore, the court felt that it properly maintained jurisdiction.[62]

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

Sony, Mitsubishi, JVC, and Matsushita all brought declaratory judgment actions against Guardian Media, which attempted to assert patent rights by initiating licensing negotiations relating to methods and apparatuses for blocking television programs.[63] The district court consolidated the actions, and then dismissed for lack of subject matter jurisdiction because Guardian Media had not expressly threatened to sue any of the plaintiffs for patent infringement.[64] The CAFC reexamined the licensing attempts in light of *MedImmune*, recognizing that "[t]he Supreme Court has not articulated a bright-line rule for distinguishing those cases that satisfy the actual controversy requirement from those that do not."[65]

Despite Guardian Media's statement that "it had 'absolutely no plan whatsoever to sue' ", the declaratory judgment plaintiffs were not required to put themselves "at further risk by continuing to engage in the allegedly infringing activity before seeking a declaration of its rights."[66] The court also suggested that the Declaratory Judgment Act should be used to prevent patent holders from engaging in "extra-judicial patent enforcement tactics [that] rendered its competitors helpless and immobile so long as the patent owner refused to grasp the nettle and sue."[67] Guardian's tactics included:

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58 *Id.*

59 *Id.* (citing Grain Processing Corp. v. American Maize-Prods. Co., 840 F.2d 902 (Fed. Cir. 1988)).

60 *Id.*

61 *Id.*, at 996.

62 *Id.*

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

64 *Id.*

65 *Id.*, at 1283.

66 *Id.*, at 1284.

67 *Id.* (citing Arrowhead Industrial Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 734

1) alleging specific products infringed its patents; 2) providing detailed infringement analysis; 3) disputing invalidity assertions; and, 4) requesting royalties.[68] The CAFC determined that these actions gave rise to an actual controversy, but cautioned that the district court still has discretionary dismissal and staying power. Thus, the case was remanded to the lower court.

E. Adenta GmbH v. OrthoArm, Inc., 2007 U.S. App. LEXIS 22315 (Fed. Cir. September 19, 2007)

American Orthodontics Corporation ("American") manufactures orthodontic brackets for Adenta GmbH ("Adenta").[69] OrthoArm sued American for infringement of a patent relating to the brackets American manufactured for Adenta.[70] OrthoArm and American entered into a settlement agreement where American would pay a four percent royalty in exchange for an assignment of the OrthoArm patent.[71] Adenta and American also agreed to a royalty sharing agreement where each party would pay half of the royalty obligation to OrthoArm. Adenta later believed that the patent was invalid and advised that it would stop paying royalties, and American countered that it would "pursue its available legal remedies to protect its rights."[72] Adenta then filed a complaint seeking a declaratory judgment that the patent in question was invalid and unenforceable.[73] In the resulting trial, the district court denied without prejudice OrthoArm's motion to dismiss for lack of subject matter jurisdiction stating that the matter could not be resolved without proper documentation.[74]

The CAFC's *de novo* review once again determined that the party's actions gave rise to a justiciable Article III case or controversy under *MedImmune*.[75] American clearly intended to assert its rights under the terms of the license agreement with Adenta.[76] The statement that American would "pursue its available legal remedies" indicated this intent and created

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(Fed. Cir. 1988)).

68 *Id.*

69 Adenta GmbH v. OrthoArm, Inc., 2007 U.S. App. LEXIS 22315 (Fed. Cir. September 19, 2007).

70 *Id.*

71 *Id.*

72 *Id.*

73 *Id.*

74 Adenta GmbH v. Orthoarm Inc., 2006 U.S. Dist. LEXIS 3020 (E.D. Wis. Jan. 20, 2006).

75 Adenta, *supra* note 69.

76 Particularly, that it would "pursue all legal remedies."

a substantial controversy.[77] The court also notes that American's failure to file an infringement counterclaim was insufficient to divest the court of subject matter jurisdiction.[78] Therefore, the court affirmed the lower court decision accepting subject matter jurisdiction.

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

Benitec brought an infringement action against Nucleonics concerning RNA-based disease therapy.[79] Nucleonics counterclaimed that the patent in question was invalid and that the accused actions were subject to the pharmaceutical research exception of 35 U.S.C. § 271 (e).[80] During discovery, evidence was exposed that suggested that additional inventors contributed to the subject matter of the patent but were not named as inventors.[81] Benitec, therefore, moved to dismiss its complaint without prejudice because the Supreme Court had expanded the pharmaceutical research exception and Benitec no longer felt that they had a colorable claim of infringement.[82] Nucleonics, on the other hand, felt that Benitec's motion to dismiss was to prevent the patent from being declared invalid.

The district court granted Benitec's motion to dismiss its own claims, and also dismissed Nucleonic's counterclaim for lack of declaratory judgment jurisdiction. On review, the CAFC affirmed the dismissal of Nucleonics' counterclaim because the burden of demonstrating declaratory judgment jurisdiction rests on party claiming such jurisdiction, and remains with that party throughout litigation.[83] In dissent, Circuit Judge Dyk felt that the burden should shift to Benitec because Benitec failed to show that there will be no future controversy.[84] Under the majority rule, the continuing burden rests with Nucleonics to establish declaratory judgment jurisdiction because it was the party to invoke declaratory judgment jurisdiction.[85] Additionally, the court reasoned that subsequent events to

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77 *Id.*

78 *Id.*

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

80 35 U.S.C. §271(e) states that "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

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

82 *Id.*

83 *Id.*, at 1345.

84 *Id.*

85 *Id.*

the filing of the lawsuit could also divest the court of jurisdiction such as the expanded pharmaceutical research exception.[86]

Nucleonics, however, had future plans to extend its research to animal applications which may not be covered under the section 271(e) (1) exception.[87] Therefore, Nucleonics felt that a hearing on the validity of the patent should be granted. The future plans were subject to a confidentiality agreement preventing Nucleonics from specifically discussing the plans with the court. The vagueness of these future plans did not give rise to a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

IV.
THE FUTURE OF TECHNOLOGY LICENSING PRACTICES: IMPACT OF MEDIMMUNE

MedImmune represents a changing tide in the practice of technology transfer and valuation of patents. In the wake of its holding, standing is conferred to a wide array of licensees and potential licensees.[88] Subsequent CAFC decisions further expanded these concepts to licensing negotiations, withdrawing claims at trial, and Orange Book practice. Patent valuation will also be affected because the ability to challenge the validity of a patent before or after accepting a license changes the licensing risk calculus. *MedImmune* and the CAFC decisions maintain a pro-technology transfer stance, but the eventual result will be entirely the opposite. The standing conferred to licensees is likely to chill the practice of technology transfer because it drastically increases the transaction costs of licensing. Increased transaction costs remove economic incentives and create barriers to efficient technology transfer, all while diminishing patents' economic value.

A. MedImmune Increases Transaction Costs

Technology transfer refers to the process of licensing patents and related technology.[89] In a perfect market, patent holders who lack the ability to enforce and exploit patents would license the patent to the firm

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86 *See generally*, Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054 (Fed. Cir. 1995).

87 Benitec, *supra* note 79.

88 MedImmune, *supra* note 2.

89 Sean B. Seymore, *The "Printed Publication" Bar After Klopfenstein: Has the Federal Circuit Changed the Way Professors Should Talk About Science?*, 40 Akron L. Rev. 493, 497 (2007) ("technology transfer offices (TTOs) which strive to "transfer" faculty-generated inventions from the laboratory to the world of commerce.").

that could best use it.[90] Transaction costs, however, create an imperfect market where individuals and entities face barriers to effectively transferring technology to the best user. The holding in *MedImmune* represents an additional barrier to efficient technology transfer, and thus, furthers an already imperfect market.

In *The Economics of Improvement in Intellectual Property Law*, Mark Lemley identifies several of the innumerable transaction costs in the licensing of patents.[91] These include: lawyer's fees; monitoring the relationship created by the license; identification of the scope and proper parties of the license; and valuation of the patent in question.[92] The true cost of these expenses is uncertain and may vary depending on the subject matter of the technology and complexity of the transaction. It is clear, however, that the cost is not trivial; Lemley estimates that the cost represents "as much as twenty percent of the total value of the underlying technology license, or in excess of $ 100,000 per transaction."[93] By giving standing to licensees and potential licensees, the *MedImmune* decision makes these transaction costs even greater and more imposing.

For instance, a lawyer drafting patent licenses will now have to consider alternative contract provisions avoiding declaratory judgments.[94] The monetary cost of actually drafting the provisions may be minimal, but the transaction costs will greatly increase. Transaction costs cannot be measured simply in dollars and cents, but must also consider lost opportunities and other consequences not easily quantifiable. Licensors faced with the decision to license a patent under an agreement that limits the availability of a declaratory judgment, or creates hurdles to declaratory judgments, may be apprehensive to consider and agree to the license. As the court indicated in *SanDisk*, licensors and licensees may have to agree to confidentiality agreements before even discussing the possibility of a license.[95] Both additional contract provisions and confidentiality agreements add expenditures and risk to the licensing process.

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[90] John R. Allison, et al., *Frontiers of Intellectual Property: Software Patents, Incumbents, and Entry*, 85 Tex. L. Rev. 1579 (2007).

[91] *Id.*, at 1614.

[92] Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 Tex. L. Rev. 989, 1053 (1997) ("This list is non-exclusive, but indicates some of the potential problems that parties may face in a licensing negotiation.").

[93] *Id.* (citations omitted).

[94] Stephanie Chu, *Operation Restoration: How Can Patent Holder Protect Themselves from MedImmune*, 2007 Duke L. & Tech. Rev. 8 (2007).

[95] SanDisk, *supra* note 33, at n. 1 ("To avoid the risk of a declaratory judgment action, ST could have sought SanDisk's agreement to the terms of a suitable confidentiality agreement. The record before us reflects that the parties did not enter into such an agreement. Rather, ST sought to condition its open licensing discussions and the infringement study on adherence to Federal Rule of Evidence 408.").

Beyond the increase in fees for drafting and negotiating a license, the possibility of litigation greatly increases as well. It may become the standard procedure to challenge a patent on its validity before accepting a license.[96] Additional legal fees represent another barrier to licensing that may prevent some patent holders from entering the market at all. Small businesses and independent inventors may view the risk of litigation as insurmountable when considering licensing practices, when previously these groups would have transferred the patent rights to the best user.

The transaction costs of monitoring the relationship created by a licensing agreement will also increase in difficulty and uncertainty after *MedImmune*.[97] Patent licensors will have to monitor the activities of licensees closely and analyze the risk of facing a declaratory judgment. Current patent licensees will certainly be reassessing the validity of the patents in their outstanding licenses. As the *Adenta* court indicated, the mere existence of a license and the intent to enforce it will confer subject matter jurisdiction on the court.[98] So, the transaction costs of monitoring a relationship will increase because both parties will be seeking judicial review whenever a conflict arises instead of negotiating.

Determining the proper parties and scope of the license also presents problems. Markets are imperfect, so the best user of a patent is not always clear. Entities cannot seek to license to a broad group of potential licensees like in *Sony* or *SanDisk* without being subject to multiple validity challenges.[99] Instead, licensors will have to carefully consider each individual licensee, and determine whether the risk associated with seeking a license outweighs the risk of a validity challenge. As presented, the situation indicates that patents will not be transferred to the best user, but will actually be given to the least risky user. So, the costs in determining the proper party increases along with the risk that any party may jointly or individually seek to invalidate the patent in question.

While the exact costs of *MedImmune* are uncertain, it is clear that licensors and licensee will face an increase in costs associated with licensing. Increased transaction costs remove economic incentives to license patents and technology. The risk calculus changes by placing additional burdens on the patent holder. Burdens represent a barrier to patent licensing by decreasing economic incentives, and furthering an already imperfect market.

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96 Although, if the patent was strong enough to withstand a challenge to the validity then the patent holder would have a stronger position to negotiate. The patent holder also would not have to license the patent to the challenger. Thus, the risk of lost opportunity remains in the background of these challenges.

97 Lemley, *supra* note 92.

98 Adenta, *supra* note 69.

99 *See*, Sony, *supra* note 63; SanDisk, *supra* note 33.

B. MedImmune Adds Difficulty in Determining Patent Value

Perhaps most importantly, *MedImmune* represents an added difficultly in determining the value of patents. Value is essentially a function of risk where firms balance the risk of being found liable for infringement with the cost of securing a license.[100] A finding of infringement can be extremely costly because the damages are trebled upon a finding of willfulness. The litigation expenses may be prohibitive too.[101] So, a firm may negotiate a license instead of going to going to court just to save time and money. Even when a firm is virtually certain to win an infringement suit, it may be cheaper to simply accept a license rather than go to court. *MedImmune*, however, adds another factor in licensing or litigation analysis: the risk of the patent in question being declared invalid before licensing or litigation ever occurs.

The result is a shift in the balance of power in licensing negotiations. Licensors lose power to threaten an infringement suit, and licensees gain the power to threaten to bring a declaratory judgment against the licensors. Therefore, the risk partially shifts away from the licensee to the patent holder. Since value is a function of risk, the value of the patent will certainly be affected.

The valuation problem is only compounded by *eBay v. MercExchange*, where the Supreme Court eliminated the presumption that an injunction is granted as a matter of course upon a finding of infringement.[102] In addition to facing a validity challenge of their licensees, after *eBay* patent licensors, particularly non-practicing entities, may not be able to secure injunctive relief. Instead, the court may grant an ongoing royalty rate in lieu of an injunction if a balancing of the traditional four factor injunction test favors the plaintiff.[103] *eBay* will lower patent value because of the lost certainty of an injunction. Again, the risk is lowered for the licensee because even though they may face damages, an injunction will not be granted as a matter of course. The diminished value of patents represents another barrier to the already difficult process of technology transfer.

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100 John R. Allison, et al., *Valuable Patents*, 92 Geo. L.J. 435, 440 (Mar. 2004) ("Parties arguing over a patent worth $ 1 million in damages may have little incentive to litigate their claim, because the cost of litigation will eat up much of the surplus.").

101 *Id.*, at 440 ("Total direct litigation costs for the median patent case with between $ 1 million and $ 25 million at stake were $ 2 million per side in 2003 and those figures do not take into account either the higher mean (some cases cost much more) or other costs in lost employee productivity and uncertainty.").

102 eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (U.S. 2006).

103 *Id.*, at 391 ("According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief.").

V.
CONCLUSION

While attempting to cure an imbalance in the negotiation power of licensors and licensees, the Supreme Court has simply shifted the power from licensors to licensees. The power shift is problematic for patent holders who face increased transaction costs in licensing. Patent holders may now be reluctant to seek licenses altogether because of the additional barriers in licensing negotiations. The shift in power diminishes economic incentives to license by increasing transaction costs and lowering the value of patents. The likely result is a chilling of technology transfer.