TOO COSTLY TO DEFEND: WHO IS BENEFITED FROM THE U.S. SUPREME COURT'S RECENT HOLDINGS CONCERNING BIOTECHNOLOGY PATENT DISPUTES?

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I. INTRODUCTION

Justice Scalia's recent holdings on behalf of the Supreme Court in *Merck KGaA v. Integra Lifesciences I, Ltd*. and *MedImmune Inc. v. Genentech, Inc*. have had a grave impact on biotechnology research.[1] These cases represent the two sides of the same coin and, therefore, should be examined together rather than separately.

On one hand, when there is a biotechnology patent[2] dispute

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[1] MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007); Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); Brief of American Intellectual Property Law Association as Amicus Curiae Supporting Respondents at 2–3, *MedImmune, Inc.*, 127 S. Ct. 764 (No. 05-608), 2006 WL 2190747.

[2] *See* NIH, Definitions Related to Technology Transfer and Research Tools, http://www.nih.gov/news/researchtools/appendb.htm (last visited Apr. 13, 2008).

without involving a license agreement, the Court will determine whether the use of the patented invention falls under the infringement exemption pursuant to 35 U.S.C. § 271(e)(1).[3] The situation will be controlled by *Merck KGaA v. Integra Lifesciences I, Ltd*.[4] On the other hand, when the biotechnology patent dispute involves license agreements, the court will determine whether the user of the patented invention is coerced, either by the patent holder or the fear of losing business, to pay royalties under the agreement.[5] If coercion is found, the licensee, who is a user of the patented invention, will be allowed to challenge the patent's validity in court without being required to breach the agreement first.[6] In such situations, *MedImmune Inc. v. Genentech, Inc*. dictates the outcome.[7]

In *Merck*, Justice Scalia's holding was a decision in favor of the users of a patented invention. The patented invention in this case was a tri-peptide.[8] The defendants used the tri-peptide to test its tumor suppressing function[9] without the patent holder's approval or first entering into a license agreement with the patent holder.[10] The patent holder sued defendants for patent infringement.[11] The Court held that:

> A patent contains a narrative description of the subject matter covered by the patent called the *specification*. It also contains one or more *claims* that describe the subject matter covered by the patent in highly technical and specific terms, much as the metes and bounds of a survey might exactly describe and identify the land conveyed by a deed.

Id.

[3] *Merck KGaA*, 545 U.S. at 195.

[4] *Id.* at 206–07 (holding that 35 U.S.C. § 271(e)(1) exempts patented compounds used in preclinical studies from infringement when the results of the research are not ultimately included in submission to the Food and Drug Administration).

[5] *See* Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 165 (2004). A license agreement can be defined as a waiver of the licensor's rights under the patent to exclude the licensee from practicing the claimed invention. *Id.*

[6] *MedImmune, Inc.*, 127 S. Ct. at 777.

[7] *See* Rite Aid Corp. v. Purdue Pharma, L.P., 2007 U.S. Dist. LEXIS 61583, at *9, 2007 WL 2388912, at *3 (S.D.N.Y. Aug. 21, 2007) (noting that the holding in *MedImmune, Inc.*, 127 S. Ct. 764, now controls because *MedImmune* rejected the previous standard).

[8] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 197 (2005).

[9] *Id.*

[10] Integra Lifesciences I, Ltd. v. Merck KGaA, 2004 U.S. Dist. LEXIS 20725, at *10, 2004 WL 2284001, at *3 (S.D.Cal. Sept. 7, 2004) (noting that Merck terminated negotiations before concluding a licensing agreement).

[11] *Merck KGaA*, 545 U.S. at 200.

> [T]he use of patented compounds in preclinical studies is protected under [35 U.S.C.] § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that is relevant to an IND [(Investigational New Drug Application)] or NDA [(New Drug Application) under Federal Drug Administration (FDA) regulations].[12]

In *MedImmune*, Justice Scalia also held in favor of the user of the patented invention. The patented invention in that case was an experimental process called "coexpression technology" to produce immunoglobulin chains in a recombinant host cell.[13] The user was assigned the right to use the "coexpression technology"[14] to manufacture a drug under a license agreement with the patent holder.[15] The user paid the demanded royalties under protest, but sought declaratory relief claiming that the patent at issue was invalid and unenforceable.[16] The Court held that the user was "not required to break or terminate its . . . license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed."[17]

A New York Times article comments that the holding in *MedImmune* "shift[s] power in the courtroom from bigger patent-owning companies to smaller start-up companies."[18] It is expected that similar lawsuits will significantly increase since the hurdle for a user of a patented invention claiming patent invalidity has been removed.[19] Biotechnology patent holders may have to defend their patents in numerous lawsuits that they

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[12] *Id.* at 208.

> Under the FDCA [(Food, Drug, and Cosmetic Act)], a drugmaker must submit research data to the FDA at two general stages of new-drug development. First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND). . . . Second, to obtain authorization to market a new drug, a drugmaker must submit a new drug application (NDA), containing "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use.

Id. at 196 (citations omitted).

[13] Brief of Respondent Genentech, Inc. at *2, MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007) (No. 05–608), 2006 WL 2190748.

[14] *MedImmune, Inc.*, 127 S. Ct. 764, 767–68.

[15] *Id.* at 768.

[16] *Id.*

[17] *Id.* at 777.

[18] Linda Greenhouse, *Ruling Seen as Giving an Edge to Challengers of Patents*, N.Y. TIMES, Jan. 10, 2007, at C3.

[19] *See id.*

could not have expected before.

However, not all users of patented inventions are small start-up companies. In fact, it has been shown that most small start-up companies choose to license their technology to large pharmaceutical companies because they "do not have the expertise or funds necessary to bring a product to market."[20] Also, a policy favoring the users of a patented invention is not necessarily in favor of the general public. If both the *Merck* and *MedImmune* decisions are broadly interpreted and applied to future cases, they may discourage biotechnology research tool inventors from seeking patent protection because of the high cost arising from defending their patents in court. Subsequently, they will discourage information disclosure and impede scientific progress.[21]

This Article argues: (i) Justice Scalia's holding in *Merck* should be broadly construed to mean that the § 271(e)(1) exemption includes the use of research tools under National Institute of Health (NIH) definition; and, (ii) Justice Scalia's holding in *MedImmune* should be narrowly construed to mean that the threat faced by the licensee, a user of patented inventions, needs be fatal or at least losing eighty percent of its business to justify a claim of patent invalidity without first breaching the license agreement at issue. As a result, a broad interpretation of *Merck* and a narrow interpretation of *MedImmune* will retain the balance of interests among patent holders, users of patented inventions, and the general public.

Part II of this Article will explore how the distinction between drugs and research tools has confused the courts, and why it is impractical to restrict the application of the § 271(e)(1) exemption only to chemical compounds. Part III will examine how the *MedImmune* decision has placed patent holders at a disadvantage and why its application should be limited. Part IV

[20] Mireles, *supra* note 5, at 163–64.

[21] *See* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 41 (2001). As Janice M. Mueller has noted, "[t]he most commonly stated objection to broadening the experimental use exemption is the possibility that it would significantly reduce the incentives for invention of new research tools." *Id.* However, "[t]he extent of any potential reduction in innovation, and the optimal balance between a desired level of innovation in research tools versus innovation in new commercial products developed through the unrestricted use of those tools, are probably impossible to determine." *Id.* Therefore, this Article will not rely on and repeat Mueller's arguments.

will examine the interests of each party involved in a biotechnology patent dispute and conduct a balancing test in the aftermath of *Merck* and *MedImmune* decisions.

II. SCOPE OF EXEMPTION

One of the questions raised by *Merck KGaA v. Integra Lifesciences I, Ltd.* is how to define the scope of "patented invention" to fall under the biotechnology patent infringement exemption pursuant to 35 U.S.C. § 271(e)(1). A broad interpretation of "patented invention" would include biotechnology research tools, such as methods and processes, as well as drugs.[22] A narrow interpretation would include drugs only.[23] This section examines why a broad interpretation should be adopted.

Both traditional and modern definitions of biotechnology suggest that sharing techniques and experiment processes are essential to the development of biotechnology. Biotechnology has been generally defined as "the use of biology or biological process to develop helpful products and services."[24] A modern definition of biotechnology is "the set of biological techniques originally resulting from basic research, specifically molecular biology and genetic engineering, and now used for research and product development."[25] Popular examples of biotechnology techniques and processes include recombinant DNA, polymerase chain reaction (PCR) technology, DNA sequencing instruments, and expressed sequence tags.[26] These technologies and processes are all research tools which have greatly enhanced the progress of biotechnology.[27]

The patent law has been perceived within the scientific research community as conflicting with the traditional norms of

[22] *See* Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005).

[23] Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 865–67 (Fed. Cir. 2003), *vacated by* 545 U.S. 193 (2005). The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, enacted § 271(e)(1) originally aimed at facilitating FDA approval of a generic version of a drug already on the market.

[24] Dep't of Agric., Biotechnology & Genomics, http://www.csrees.usda.gov/nea/biotech/biotech_all.html (last visited Apr. 13, 2008).

[25] *Id.*

[26] Tanuja V. Garde, *Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-Funded Research Tools*, 11 MICH. TELECOMM. & TECH. L. REV. 249, 273 (2005).

[27] *Id.*

sharing.[28] A non-consensual use of another party's patented biotechnology invention during the term of the patent will constitute infringement unless the use falls under the so called "FDA exemption."[29] 35 U.S.C. § 271(e)(1) provides 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)) . . . 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.[30]

To satisfy the FDA exemption, two elements must be met: (1) the subject matter is a patented invention;[31] and (2) the use is "reasonably related to the development and submission of information under a Federal law."[32] The Federal law in the second element refers to FDA regulations under the Food, Drug, and Cosmetic Act that apply when the subject matter is a patented biotechnology invention. This Article will focus on the discussion of the first element, specifically the scope of patented inventions under the exemption.

The disagreement between Judge Newman and the Federal Circuit panel majority in *Integra Lifesciences I, Ltd. v. Merck KGaA* raised the question of whether the FDA exemption should cover research tools.[33] Judge Newman's dissenting opinion identified the RGD-containing peptides[34] of the Integra patents as "new compositions having certain biological properties" rather than research tools.[35] On the other hand, the panel majority viewed the Integra patents as a "research tool."[36] Though the

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[28] Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 184–85 (1987).

[29] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 195 (2005).

[30] 35 U.S.C. § 271(e)(1) (2007).

[31] *Id.*

[32] *Id.*

[33] Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part).

[34] *Id.* at 873 (RGD-containing peptides are "certain peptide components of fibronectin, containing a chain of the three amino acids arginine (R), glycine (G), and aspartic acid (D)").

[35] *Id.* at 878 (defining a research tool as "a product or method whose purpose is use in the conduct of research, whether the tool is an analytical balance, an assay kit, a laser device . . . or a biochemical method such as the PCR (polymerase chain reaction)") (Newman, J., dissenting).

[36] *Id.* at 871; *see also id.* at 878 (describing the majority's view of the patents

Federal Circuit held that Merck's infringing activities were not "solely for uses reasonably related" to the provision of information to the FDA under 35 U.S.C. § 271(e)(1) and did not touch the question of whether research tools fall under the exemption,[37] Judge Newman stressed that the question "was fundamental to [the] resolution of [the] case, and it [could not] be ignored."[38]

The Supreme Court was dissatisfied with the Federal Circuit's narrow interpretation of the § 271(e)(1) exemption. The Federal Circuit's judgment was vacated by the Supreme Court in a unanimous decision written by Justice Scalia.[39] Though Justice Scalia was reluctant to express "a view about whether, or to what extent, § 271(e)(1) [sic] exempts from infringement the use of 'research tools' in the development of information for the regulatory process,"[40] he extended the exemption to "all uses of patented inventions that are reasonably related to the development and submission of *any* information under the [Food, Drug, and Cosmetic Act]."[41] It is clear from this opinion that the exemption was not created only applicable to the research relevant to FDA submission for approval of a generic drug.[42]

The panel majority of the Federal Circuit characterized the Integra patents as research tools by adopting the definition of research tools developed by the National Institute of Health (hereinafter NIH).[43] The NIH has defined the term "research tools" as including "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR),

as a research tool) (Newman, J., dissenting).

[37] *Id.* at 872.

[38] *Id.* at 878 (Newman, J., dissenting).

[39] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 208 (2005).

[40] *Id.* at 205 n.7.

[41] *Id.* at 202 (emphasis supplied).

[42] *Id.* at 206; *see also* Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 875 (Fed. Cir. 2003).

> [T]he Drug Price Competition and Patent Term Restoration Act of 1984 . . . sought to restore patent term to pharmaceutical inventions to compensate for the often-lengthy period of pre-market testing pending regulatory approval to sell a new drug. These regulatory delays can deprive a patentee of many years of its patent's term. The second reason for the 1984 Act . . . sought to ensure that a patentee's rights did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval.

Integra Lifesciences I, Ltd., 331 F.3d at 865.

[43] *Integra Lifesciences I, Ltd.*, 331 F.3d at 872 & n.4.

methods, laboratory equipment and machines, databases and computer software."[44] Under the NIH definition, drugs are included as research tools.

By advancing such definition, the NIH acknowledged that it has used the term "research tools" in its broadest sense.[45] The NIH has intended to "embrace the full range of resources that scientists use in the laboratory, while recognizing that from other perspectives the same resources may be viewed as 'end products.'"[46]

A broad definition of "research tools" is consistent with NIH policy and the traditional norms in science research on sharing materials.[47] The rapid progress of research on many model organisms for biomedical research has been shown to be the result of "sharing biomaterials, reagents, and data in a timely manner."[48]

On the other hand, some have suggested that a narrow definition of research tools should be adopted to help restrict the scope of FDA exemption.[49] Janice M. Mueller developed one of the definitions; she stated that research tools are limited to "those patented tools used in development of new biotechnological or pharmaceutical products that do not themselves physically incorporate the tool."[50] However, a biotechnology patented invention may contain more than one feature;[51] specifically, chemical composition and process.[52]

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[44] NIH, Report of the National Institutes of Health (NIH) Working Group on Research Tools (1998), http://www.nih.gov/news/researchtools/index.htm (last visited Apr. 13, 2008); *see also* Principles and Guidelines for Recipients of NIH Research Grants on Obtaining and Disseminating Biomedical Research, 64 Fed. Reg. 72,090, 79,092 n.1 (Dec. 23, 1999).

[45] NIH, Working Group on Research Tools, *supra* note 44; *see also* Principles and Guidelines for Recipients of NIH Research Grants on Obtaining and Disseminating Biomedical Research, 64 Fed. Reg. at 72,092.

[46] NIH, Working Group on Research Tools, *supra* note 44.

[47] *See* Eisenberg, *supra* note 28, at 197; NIH, NIH Policy on Sharing of Model Organisms for Biomedical Research (2004), http://www.nih.gov/science/models/sharingpolicy.html (last visited Apr. 13, 2008).

[48] NIH Policy on Sharing, *supra* note 47.

[49] *See* Michael R. Mischnick, Note, *Evaluating the* Integra*ty of Biotechnology Research Tools:* Merck v. Integra *and the Scope of 35 U.S.C. § 271(e)(1)*, 91 MINN. L. REV. 484, 487 (2006) (arguing that a research tool should not be part of the end product resulting from the research. As a result, the patented invention in *Merck* should be a drug because the tri-peptide itself constituted the end product of the research.).

[50] Mueller, *supra* note 21, at 14.

[51] "[A patent] application may properly be required to be restricted to one of

Assuming that the patented invention can treat certain ailments and is used in developing a new product, the chemical composition feature of the patented invention can be properly termed as a drug and will physically incorporate into the products, while the process feature of the same invention will fall under the definition, both narrow and broad, of research tools. It is unlikely to separate the chemical composition from the process or method that is used in an analysis. In fact, Janice M. Mueller has proposed a broadened rule of "experimental use" exemption rather than a restricted one.[53]

It is impractical, if not impossible, to ask courts to analyze which patented invention is a research tool and which is not on a case-by-case basis since they can be both.[54] As explained, drugs can be research tools, and vice versa. Sometimes it also depends on how the researchers design their experiments. The patented invention in *Merck* is a typical example to show that the narrow definition of research tools is not workable in similar situations.

In *Merck*, the tri-peptide was both a drug and a research tool. For instance, "[c]laim 8 of U.S. Patent No. 4,792,525 . . . claims the composition of non-naturally occurring RGD-containing peptides that have cell attachment activity."[55] A patent claiming chemical composition can be drugs or research tools, depending on how the alleged infringer uses or designs the experiment.[56]

two or more claimed inventions only if they are able to support separate patents and they are either independent . . . or distinct." Manual of Patent Examining Procedure, section 803 (Dep't of Commerce 1998) [hereinafter MPEP].

[52] *Id.* at section 802.01 (listing "composition and the process in which the composition is used [and the] process and the product made by such process" as examples of dependent features).

[53] Mueller, *supra* note 21, at 9–10 (proposing "an expanded model of the experimental use doctrine that would permit the non-consensual 'development use' of research tools, coupled with an ex post royalty payment based on the marketplace-determined value of the new products that result from that use" while "prohibiting the patent owner from enjoining the non-consensual use of the research tool . . . .").

[54] *See* Mischnick, *supra* note 49, at 499 ("Unless Congress explicitly authorizes such a blanket exemption, courts would more effectively meet the patent system's beneficial goals by analyzing each research tool use on a case-by-case basis.").

[55] Respondents' Brief on the Merits at 11, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, (2005) (No. 03-1237) 2005 WL 682089; *See also Merck KGaA*, 545 U.S. at 197.

[56] *See Merck KGaA*, 545 U.S. at 207 (noting that uncertainties often arise, depending on the experiment, with respect to what research to include when submitting information to the FDA and that use of a patented compound without mention in such submission was not necessarily infringement).

Additionally, claims 15 through 18 of U.S. Patent No. 5,695,997 claim various "methods" for blocking cell surface receptors.[57] A method patent is equivalent to a process,[58] which is clearly a research tool in the biotechnology context. Even if a narrow definition of research tools is adopted, the patented invention in *Merck* still contains the features of research tools, specifically the patent claiming methods for blocking cell surface receptors, as well as drugs.

By vacating the Federal Circuit's decision, the Supreme Court has expanded the FDA exemption to cover research tools because the patented invention in *Merck*, at least in part, was a research tool.[59] Therefore, suggesting that research tools should not be covered under the FDA exemption essentially conflicts with the Supreme Court's decision.[60]

The tri-peptide in *Merck* is a typical example of the blurred distinction between drugs and research tools. As pharmacogenomics booms, the pharmaceutical industry shifts its focus to develop pharmaceuticals that are target specific.[61]

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[57] U.S. Patent No. 5,695,997 col.2. l.25, 30, 32, 38 (filed June 2, 1995) (issued Dec. 9, 1997).

[58] 35 U.S.C. § 100(b)(2000) ("The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

[59] Tetrapeptide, U.S. Patent No. 5,695,997 col.2. l.25, 30, 32, 38 (filed June 2, 1995) (issued Dec.9, 1997).

[60] *See* Mischnick, *supra* note 49, at 486.

> While research tool use is often reasonably related to the submission of information to the FDA, research tools do not fall under the intended definition of 'patented invention' used in § 271(e)(1), and courts should not expand the provision to include them.

Id.

[61] *See* Garde, *supra* note 26, at 250–51.

> [T]he Human Genome Project which served to redefine medical research by fusing biological systems with advances in information technology. Pharmacogenomics . . . describes the science behind targeted pharmaceuticals, which serves as a novel business model for the pharmaceutical industry.
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> . . . .
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> Targeted treatments . . . shift the focus from traditional blockbuster one-for-all medications to more selective products. However, much of the success of these drugs depends on the discovery and validation of new targets using existing and developing research tools. . . . As a result, the clinical diagnostics business will play an important role in developing targeted treatments.

Id.

Consequently, the specific methods or processes leading the pharmaceuticals to certain targets are inseparable from, and are at least as important as, the chemical composition of the pharmaceuticals. Adopting a narrow interpretation distinguishing research tools from drugs will likely cause a significant number of cases like *Merck* to flood the courts.

A categorical exemption covering drugs and research tools is preferable to relieve the difficulty and confusion faced by the courts struggling to distinguish between drugs and research tools. In *Merck*, both the Federal Circuit panel majority and the dissent have correctly identified one of the Integra patents' features respectively, but failed to identify other features. Justice Scalia may have relied on Federal Circuit Judge Newman's characterization of the Integra patents,[62] and described the patents in his opinion as "patented compounds."[63] However, this is a misstatement serving no function of clarification, and only creating more confusion.[64]

In fact, since the *Merck* decision, several lower courts have adopted a broad interpretation of FDA exemption as covering research tools. For instance, in *Classen Immunotherapies, Inc. v. Biogen Idec*, the patented invention at issue involved a "mechanism for evaluating the safety of vaccine administration schedules by comparing or identifying the adverse events associated with various vaccine schedules."[65] The "mechanism" did not "physically incorporate" itself into the end product under Mueller's definition.[66] Therefore, the "mechanism" was clearly a research tool. However, the district court held that the use of the "mechanism" in collecting vaccine data fell within the § 271(e)(1) exemption.[67]

Similarly, in *Genentech, Inc. v. Insmed Inc.*, one of the patents at issue was directed to the "use" of binding protein, which was a

[62] Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205 n.7 (2005).

[63] *Id.* at 206–07.

[64] *See* MPEP, *supra* note 51 at § 803 (suggesting the inseparable dual nature of drugs as research tools and medicine); *see also* Mueller, *supra* note 21, at 17 (discussing the need for a broader experimental use rule).

[65] Classen Immunotherapies, Inc. v. Biogen Idec, 381 F. Supp. 2d 452, 454 (D. Md. 2005).

[66] *See* Mueller, *supra* note 21, at 14; *see also Classen*, 381 F. Supp. 2d at 455 (describing the mechanism used through Classen's claim that "the Defendants 'collectively [] publish, encourage, recommend and administer the vaccines according to a protocol which is believed to minimize the risk of incidence in chronic immune mediated disorders.'" (citation omitted)).

[67] *Classen*, 381 F. Supp. 2d at 456.

research tool, with insulin-like growth factor (IGF-I) as an anabolic growth promoting agent.[68] Though the district court was reluctant to adjudicate whether the defendants' use of the patented invention constituted infringement, the court granted the defendants summary judgment and held that the research conducted by defendants was protected under the § 271(e)(1) safe harbor doctrine.[69] In *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.*, the patented invention involved "methods for identifying and commercializing new uses of existing drugs,"[70] that was a research tool under both the narrow and the broad definition. Nevertheless, the court held that the defendant's "use of the patented process was reasonably related to the submission of information under the [Food, Drug, and Cosmetic Act] and . . . protected under § 271(e)(1)."[71]

Though restricted availability of research tools, upon which further studies are dependent, can impede the progress of research,[72] NIH policy in favor of sharing research tools is not without limit. For example, the NIH has declined to expand the definition of research tools to include diagnostic genetic tests.[73] "[T]he NIH [also] recognizes that databases and software present unique questions" that require special consideration.[74]

Most importantly, the FDA exemption is still limited to the restriction of "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."[75] However, the *Merck* court by stating that "the use of a patented [invention] in experiments that are not themselves included in a 'submission of information' to the FDA does not, standing alone, render the use infringing,"[76] has broadened the application of this element as well.

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[68] Genentech, Inc. v. Insmed Inc., 436 F. Supp. 2d 1080, 1082 (N.D. Cal. 2006).

[69] *Id.* at 1094–95.

[70] Classen Immunotherapies, Inc. v. King Pharms., Inc., 466 F. Supp. 2d 621, 623 (D. Md. 2006).

[71] *Id.* at 625.

[72] *See supra* note 44. *But see* Mueller, *supra* note 21, at 41.

[73] NIH, Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 246, 72090 (Dec. 23, 1999), http://ott.od.nih.gov/pdfs/64FR72090.pdf (last visited Feb. 19, 2008).

[74] *Id.*

[75] 35 U.S.C. § 271(e)(1).

[76] *Merck KGaA*, 545 U.S. at 207.

Merck exemplified a biotechnology patent dispute without involving a license agreement between the patent holder and the users of the patented inventions. On the other hand, when a biotechnology patent dispute involves a license agreement between the parties and the licensee seeks to challenge the patent's invalidity, *MedImmune Inc. v. Genentech, Inc*. will kick in.

III. EXTENT OF THREAT

Justice Scalia's holding on behalf of the Court in *MedImmune Inc. v. Genentech, Inc*. vested the users of patented inventions with standing under the Article III "cases and controversy" requirement to challenge the patent's validity in court, while the licensee was allowed to continue using the patented invention without terminating its license agreement with the patent holder.[77] This Part examines why a narrow interpretation of *MedImmune* is preferable.

The Declaratory Judgment Act provides that, "[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, whether or not further relief is or could be sought."[78] The Supreme Court has explained "that the phrase 'case of actual controversy' in the Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III" of the Constitution.[79] To meet the requirement, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[80]

There is no dispute that refusing to pay royalties will satisfy the "cases and controversy" requirement if a licensee has taken this final step of refusal under a license agreement with the patent holder.[81] However, the licensee in *MedImmune* "allege[d] [] a threat by [the licensor] to enjoin sales if royalties [were] not forthcoming."[82] The licensee asserted that no royalties were

[77] *MedImmune*, 127 S.Ct. at 777.
[78] 28 U.S.C. § 2201(a).
[79] *MedImmune*, 127 S.Ct. at 771.
[80] *Id.*
[81] *Id.* at 771–72.
[82] *Id.* at 772.

owed "because the [] patent [was] invalid and not infringed" while continuing to pay royalty payments under the license agreement.[83]

In *MedImmune*, the user of the patented invention entered into a patent license agreement with the patent holder in 1997 "cover[ing] an existing patent relating to the production of 'chimeric antibodies' and a then-pending patent application relating to . . .' coexpression'" technology.[84] The licensee "agreed to pay royalties on sales of 'Licensed Products,' and the [licensor] granted [the licensee] the right to make, use, and sell them."[85] Additionally, "[t]he license agreement gave [the licensee] the right to terminate [the agreement] upon six months' written notice."[86] Then, "[i]n December 2001, the 'coexpression' application covered by the 1997 license agreement matured into. . .[a] patent."[87] The licensor delivered a letter expressing that the licensee's product was covered by the new patent, and it expected the licensee to pay royalties.[88] The licensee "considered the letter to be a clear threat to enforce the . . . patent" and believed that the licensor would "terminate the 1997 license agreement, and sue for patent infringement if [it] did not make royalty payments."[89] The licensee "paid the demanded royalties under protest" and sought declaratory relief, claiming that the patent was "invalid, unenforceable, or not infringed."[90]

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[83] *Id.*

[84] *Id.* at 768. Coexpression technology "relates to processes for the production of antibodies by 'coexpression' of immunoglobulin chains in a recombinant host cell. Genentech uses this technology in a number of its own products, including treatments for breast and colorectal cancer. It also licenses the technology to other companies." Brief of Respondent Genentech*, supra* note 13, at 2 (citations omitted).

[85] *MedImmune*, 127 S.Ct. at 768.

[86] *Id.*

[87] *Id.*

[88] *Id.*

[89] *Id.*; *see also* Brief for Petitioner at *7, MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007) (No. 05-608), 2006 WL 1355600.

> Based on the communications from Genentech asserting that [MedImmune's product infringed the "coexpression patent"] and demanding royalties, and also on Genentech's 'public statements about the breadth and importance of the . . . patent,' MedImmune concluded that 'Genentech would terminate the . . . [l]icense [a]greement and sue MedImmune for patent infringement . . . if MedImmune did not make the royalty payments as demanded.

Brief for Petitioner at *7, *MedImmune, Inc.*, 127 S. Ct. 764 (No. 05-608), 2006 WL 1355600 (citations omitted).

[90] *MedImmune*, 127 S. Ct. at 767, 768; *See also* Brief for Petitioner at *7,

As the American Intellectual Property Law Association has noted in its *amici* brief, the patent holder in *MedImmune* did not even threaten to sue the licensee.[91] The Association enumerated two situations where the licensee does not have to breach the license agreement to support jurisdiction.[92] Both situations require the licensor to make it clear that it will promptly sue or threaten to sue the licensee.[93]

Before *MedImmune*, the Federal Circuit had adopted an approach established in *Gen-Probe Inc. v. Vysis, Inc*, [94]stating "a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement [has] 'obliterate[d] any reasonable apprehension' that the licensee will be sued for infringement."[95]

The Federal Circuit's *MedImmune* decision, relying on *Gen-Probe*, was reversed and remanded by the Supreme Court.[96] In an opinion by Justice Scalia, the Supreme Court held that a licensee is "not required, insofar as Article III is concerned, to break or terminate its . . . license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed."[97] In this opinion, Justice Scalia likened the threat against MedImmune to the situation where "a plaintiff must destroy a large building, [or] bet the farm" to avoid an even larger loss.[98] Consequently, Justice Scalia advanced a "coercion principle" to distinguish this case from situations where the licensee "voluntarily accepted contractual obligations between private parties."[99]

However, it is questionable whether attempting to make more

MedImmune, 127 S. Ct. 764 (No. 05-608), 2006 WL 1355600 ("MedImmune decided to pay royalties under protest . . . and subsequently challenge in court whether the Cabilly II patent was valid, enforceable and/or infringed by MedImmune's Synagis(R) product.").

[91] *See* Brief of American Intellectual Property Law Association as Amicus Curiae Supporting Respondents, *supra* note 1, at *2–3 (discussing that the threat of suit by the licensor to the licensee never occurred).

[92] *Id.*

[93] *Id.*

[94] Gen-Probe Inc. v. Vysis, Inc., 359 F.3d 1376 (Fed. Cir. 2004), *abrogated by*, MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007).

[95] *MedImmune, Inc.*, 127 S. Ct. at 768 (citation omitted).

[96] *Id.* at 777.

[97] *Id.*

[98] *Id.* at 775.

[99] *Id.* at 775 n.12 (citations omitted).

profit, at least in part, can be properly termed as a "threat."[100] In *MedImmune*, the licensee sought an exemption from paying royalties under the license agreement to increase its revenue.[101] For a threat to be justified, a threshold of loss needs to be erected.[102] For instance, if the licensor is a small start-up company owning a biotechnology research tool patent and the licensee is a large company, then the profit derived from the license agreement accounts for fifty percent of the licensor's revenue. On the other hand, the licensee will risk the loss of ten percent of its revenue if it breaches or terminates the agreement. The ten percent loss of business will be deemed grave enough to justify a threat to meet the coercion principle.

In fact, "most start-up [small] biotechnology companies seek to license their technology to large pharmaceutical companies"—rather than vice-versa.[103] Small biotechnology start-up companies generally do not plan to use the technology that they developed because they do not have the expertise or funds to bring a product to the market.[104]

Furthermore, without a safeguard to shield patent holders from frivolous claims of patent invalidity, patent holders may be forced to defend their patents against numerous parties even if their patents are properly examined and granted by the Patent and Trademark Office. The high cost expected to arise from

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[100] *See* MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376, 1378 (Fed. Cir. 2005), *vacated by*, 127 S. Ct. 1118 (2007) (mem.). It is a later case involving MedImmune's same product. MedImmune negotiated with Centocor, the exclusive licensee of the patent, for several months. *Id.* MedImmune claimed that it could design around the patent at issue without infringing the patent during the negotiation. *Id.* However, MedImmune concluded a sublicense agreement with Centocor as a consequence. *Id.* Similarly, MedImmune filed a declaratory judgment suit seeking a declaration that it owed no royalties under the license agreement with Centocor and that the patent was invalid and/or unenforceable. *Id.*

[101] *See id.* at 1378 (stating that MedImmune sought a declaration stating that it owed no royalties). The likelihood of eliminating expenses and increasing revenue may motivate a licensee to seek to invalidate a licensor's patent.

[102] *See* MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 775 (2007). Here, in failing to seek to invalidate the licensor's patent, the licensee "risk[ed] treble damages and the loss of 80 percent of its business." *Id.* This risk and threat of loss have persuaded the Court that the licensee was actually threatened. *See id.* at 775 n.12 ("We find the threat of treble damages and loss of 80 percent of petitioner's business every bit as coercive as the modest penalties for misdemeanor trespass threatened in *Steffel*.") (citation omitted).

[103] Mireles, *supra* note 5, at 163–64.

[104] *Id.* at 163.

defending their patents in court may deter inventors from seeking patent protection and retain the techniques or research tools for the inventors' own use as trade secrets.[105] Also, it may give a licensee weapons with which to harass the patent holder in order to force the patent holder to waive certain rights under the patent, or to bargain for lower royalty rates.[106]

In *MedImmune*, Justice Scalia cited a series of cases in support of his "coercion principle."[107] None of these cases have delineated a clear outline as to what extent a threat can be justified under the principle. Among them, two cases arose from patent disputes. In *Altvater v. Freeman*,[108] a case that Justice Scalia has heavily relied on in his reasoning,[109] the licensees continued to pay royalties under protest because the patent holders had been granted an injunction decree against other licensees in a prior related case.[110] The Court reasoned that, "[u]nless the injunction decree were modified, the only other course [for the licensees] was to defy the [injunction], and to risk . . . actual but treble damages in infringement suits."[111] In *American Machine & Metals, Inc. v. De Bothezat Impeller Co.*, the threat was that the licensor had expressly asserted in several occasions that upon termination of the license agreement, the licensee would no longer have the right to continue the manufacture and sell the fans.[112]

The other three cases cited by Justice Scalia in support of the coercion principle arose from disputes concerning other contractual obligations.[113] These cases appear to suggest that a

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105 *See* Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 377, 407, 408 (2002).

106 *See* Lewis R. Clayton, *Strengthening the Hand of Accused Patent Infringer*, N.Y.L.J. Jan 17, 2007, at 3 ("allowing a paid-up licensee to sue would raise licensing costs [because] licensors presumably would build expected litigation costs into royalty rates. . . . [It would also] encourage technology users to negotiate sham licenses, merely meant to shield them during expected litigation.")

107 MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 773 (2007).

108 Altvater v. Freeman, 319 U.S. 359 (1943).

109 *See MedImmune*, 127 S. Ct. at 773 ("The only Supreme Court decision in point is . . . *Altvater v. Freeman*, 319 U.S. 359").

110 *Altvater*, 319 U.S. at 362.

111 *Id.* at 365 (citation omitted).

112 Am. Mach. & Metals, Inc. v. De Bothezat Impeller Co., 166 F.2d 535, 536 (2d Cir. 1948).

113 *MedImmune*, 127 S.Ct. at 773 (listing Keener Oil & Gas Co. v. Consol. Gas Utils. Corp., 190 F.2d 985 (10th Cir. 1951); Hess v. Country Club Park, 2

threat exists when it is impracticable for the party to perform or the performance may frustrate the purpose of the contract. In *Keener Oil & Gas Co. v. Consolidated Gas Utilities Corp*., the threat was the plaintiff's inability to contract with new gas suppliers, despite exhausted supplies, due to restrictions in its contract with defendant, even if the plaintiff's business with defendant was doomed.[114] In *Hess v. Country Club Park*, the plaintiff was unable to use the land for business purposes because of the restrictive covenants, and the opposition of the original grantor and the other lot owners, even though the character of the neighborhood had changed and was no longer suitable for residence.[115] In *Washington-Detroit Theater Co. v. Moore*, the threat was that the plaintiff could not demolish or operate a building for purposes other than a theater under the ninety-nine year lease with defendant because the defendant was opposed to the plaintiff's idea and threatened to forfeit the building if the plaintiff did so.[116] The plaintiff alleged that it could not operate the building for theater purposes without great loss and had already lost an opportunity for a profitable sublease because of the defendant's opposition.[117]

Unlike those cases cited in his *MedImmune* decision, Justice Scalia went a step further by stressing several times in his opinion that the licensee was facing the threat of losing eighty percent of his business in addition to an infringement suit and treble damages.[118] He did not mention in his opinion whether a threat of losing less than eighty percent of business was grave enough to justify the licensee's challenge of patent invalidity

P.2d 782 (Cal. 1931); and Wash.-Detroit Theater Co. v. Moore, 229 N.W. 618 (Mich. 1930).

114 *Keener Oil & Gas Co.*, 190 F.2d at 990.

115 *Hess*, 2 P.2d at 783.

116 Wash.-Detroit Theater Co., 229 N.W. at 618.

117 *Id.* at 618–19.

118 *See, e.g.*, *MedImmune*, 127 S.Ct. at 768 ("If respondents were to prevail in a patent infringement action, petitioner could be ordered to pay treble damages and attorney's fees, and could be enjoined from selling Synagis, a product that has accounted for more than 80 percent of its revenue from sales since 1999."), 773 n.10 ("the dissent never explains why the threat of treble damages and the loss of 80 percent of petitioner's business does not fall within *Altvater's* coercion rationale."), 775 ("The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III."), 775 n.12 ("We find the threat of treble damages and loss of 80 percent of petitioner's business every bit as coercive as the modest penalties for misdemeanor trespass threatened in *Steffel*.").

without breaching the license agreement first. Rather, in analogizing to a "reasonable apprehension of imminent suit" context, Justice Scalia characterized MedImmune's situation as a licensee who pays royalties for fear of treble damages and an injunction "fatal to his business."[119] It appears that Justice Scalia intended to draw a line that would be easier for future courts to follow by suggesting that "losing 80 percent revenue" and "fatal to the licensee's business" are critical in assessing a threat under the coercion principle.

A threshold requiring at least eighty percent loss of business can also guarantee that small start-up companies are protected under the policy. Small start-up companies usually rely on a small number of products. Being enjoined from selling the product can easily amount to a fatal consequence. On the contrary, large companies, which possess numerous product lines independent from each other, do not need this protection. Being enjoined from selling a single product is unlikely to be deemed a threat fatal to the business of a large company.

Accordingly, it is proposed here that the threat of losing eighty percent of the licensee's business should be the threshold to justify a licensee's challenge of biotechnology patent invalidity in court without breaching the license agreement first.[120] Only a licensee risking eighty percent loss or more of its revenue can be said to be under a threat that is fatal to its business and thus satisfy the coercion principle.

The Supreme Court's decisions in *Merck KGaA v. Integra Lifesciences I, LTD*. and *MedImmune Inc. v. Genentech, Inc*. both favor the users of patented inventions to disregard the existence of license agreements between parties.[121] The stacking effect of both decisions essentially place patent holders at a disadvantage. The interests of each party need to be reassessed in the aftermath of these decisions.

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[119] *Id.* at 774 n.11.

[120] *See* Clayton, *supra* note 106. Alternatively, Lewis R. Clayton suggested that licensers should consider adding provisions to license agreements in order to discourage licensee challenge. Examples of provisions include "filing litigation is grounds for termination, or grounds to increase royalty rates or trigger liquidated damages." However, he acknowledged that the court did not rule on whether any such clause would be enforceable. *Id.*

[121] Merck KGaA v. Integra Lifesciences I, LTD., 545 U.S. 193, 208 (2005); MedImmune, Inc. v.Genentech, Inc., 127 S.Ct. 764, 777 (2007).

IV. BALANCING OF INTEREST

Whenever there is a biotechnology patent dispute, it inevitably involves the interests of three parties: the patent holders, the users of patented inventions, and the general public. Since every step of biotechnology progress may lead to a breakthrough for treating currently untreatable diseases, each party's interests must be weighed, identified, and balanced in every situation. Part IV examines the interests of each party and argues that a broad interpretation of the *Merck* decision coupled with a narrow interpretation of the *MedImmune* decision will achieve an outcome most likely to balance each party's interests.

The best interest for the users of patented inventions is to minimize the burden of using that patented invention to develop their own products, such as royalty payments or infringement suits. The interests of the users of patented inventions will be maximized when the inventors' patent rights are under-protected. A patent holder's best interest is to maximize the royalties and other profits derived from that patent, such as gathering royalties from as many licensees as possible. Patent holders' interests will be maximized when their patent rights are over-expanded. However, both parties' interests must be compromised, because the public interest can be maximized only if their interests are balanced.

Both over-expansion and under-protection of patent rights will lead to the detriment of public interest. The development of biotechnology requires a large investment of funds because of the complexity, collaborative nature, and uncertainty faced by the investors.[122] Without strong and stable patent rights to ensure a return on their investment, investors will withhold their funds.[123] The general public will suffer from the impediment because the development of biotechnology flows directly to life-saving inventions or better medical care. However, the proliferation and expansion of patent rights may also stifle life-saving inventions further downstream in the course of research and product development because people who are unable to afford royalties will be denied access to the patented inventions to further develop new products or services.[124] Therefore, the interests between the patent holders and the users of patented inventions

[122] *See* Mireles, *supra* note 5, at 146.
[123] *See id.*
[124] *Id.* at 172.

need to be balanced in order to maximize public interest. The accumulated effect of the Supreme Court's recent holdings concerning biotechnology patent disputes may have caused the scale to tilt significantly toward the users of patented inventions.

Justice Scalia's decisions in *Merck* and *MedImmune* show both sides of the coin. On one hand, when there is a biotechnology patent dispute between two parties without involving license agreements, the court will determine whether the patented invention at issue falls under FDA exemption.[125] If the court finds that the patented invention falls under the exemption, the use of the patented invention will be exempted and does not constitute infringement.[126] On the other hand, when there is a license agreement between the parties, the court will determine whether the licensee is coerced, either by the patent holder or the fear of losing business, to pay royalties under the agreement.[127] If coercion is found, the licensee, a user of the patented invention, will be allowed to challenge the patent's invalidity in court without being required to breach the agreement first.[128] If the licensee decides to terminate the license agreement and refuses to pay royalties, the licensee's use of the patented invention will constitute patent infringement, but the licensee is still free to challenge the patent's invalidity in court.[129]

A broad interpretation of the *Merck* decision suggests that FDA exemption should cover research tools as well as drugs, as long as the use is reasonably related to FDA submission.[130] If the *Merck* decision is narrowly construed, it would suggest that the exemption only applies to chemical compounds, which physically incorporate into the end products.[131] A broad interpretation of the *MedImmune* decision suggests that a licensee can challenge patent validity, enforceability, and infringement while continuing to use the patented invention and pay royalties without breaching the agreement.[132] The extent of the "threat" or "coercion" asserted by the licensee would be disregarded in such circumstances. If the *MedImmune* decision is narrowly construed, it would suggest that the threat asserted by the

125 *See Merck KGaA*, 545 U.S. at 202–03.
126 *Id.* at 202.
127 *See* MedImmune, Inc. v.Genentech, Inc., 127 S.Ct. 764, 773–75 (2007).
128 *Id.* at 777.
129 *Id.* at 771–72.
130 *See* Mischnick, *supra* note 49, at 485–86.
131 *Id.* at 487.
132 *See MedImmune*, 127 S. Ct. at 777.

licensee must be "fatal" or at least an eighty percent loss of the business to justify a claim of patent invalidity in court without breaching the license agreement to meet the Article III "cases and controversy" requirement.[133]

Article III generally favors the users of patented inventions and disfavors patent holders if the *Merck* decision is broadly construed because the users will be exempted from paying royalties or infringement suits. Consequently, the burden and cost incurred from using research tools will reduce. This effect is especially significant in the field of biotechnology because "biotechnology researchers generally need access to a relatively greater number of proprietary research tools in order to conduct their research than do workers in other technologies."[134] The situation reverses if *Merck* is narrowly interpreted because biotechnology researchers will be required to pay a large amount of royalties before they are permitted to conduct their research. The stacking royalties required by conducting biotechnology research will impede, if not stifle, biotechnology progress, though research tools patent holders will be benefited for a foreseeable period of time.

A broad interpretation of *MedImmune* also favors the users of patented inventions and disfavors patent holders because it will vest the licensee's cause of action against the patent holders, while the patent holders cannot sue the licensees for infringement as a counterclaim. The licensors can do nothing in such situations except to defend their patents in court. As Justice Thomas has pointed out in his dissent, patent invalidity is considered "an affirmative defense to patent infringement, not a freestanding cause of action."[135] Moreover, "the Declaratory

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133 *See id.* at 775.

134 Mueller, *supra* note 21, at 12.

135 *MedImmune*, 127 S. Ct. at 780 (Thomas, J., dissenting); *see also* 35 U.S.C. § 282 (2000).

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.
>
> The following shall be defenses in any action involving the validity or

Judgment Act does not allow federal courts to give advisory rulings on the potential success of an affirmative defense before a cause of action has even accrued."[136] A broad interpretation of *MedImmune* will cause injustice to patent holders. On the contrary, the detrimental effect to patent holders will be restricted if *MedImmune* is narrowly interpreted.

As a result, a broad interpretation of *Merck* coupled with a broad interpretation of *MedImmune* would have a stacking effect detrimental to patent holders. A narrow interpretation of *Merck* coupled with a narrow interpretation of *MedImmune* would have a net effect that disfavors the users of patented inventions, especially for those who need access to a great number of patented research tools to conduct their biotechnology research.

A narrow interpretation of *Merck* coupled with a broad interpretation of *MedImmune* is not preferable either. As explained in Part II and III, a narrow interpretation of *Merck* is inconsistent with NIH policy, and the custom and practice of biotechnology research, while a broad interpretation of *MedImmune* will place patent holders and licensers in an unjust situation.

Therefore, a broad interpretation of the *Merck* decision coupled with a narrow interpretation of the *MedImmune* decision will better serve the interests of all parties, namely the patent holders, the users of patented inventions, and the general public. From a public interest perspective, a broad interpretation of the FDA exemption will benefit small start-up companies that are unable to locate their research overseas. As Harold C. Wegner has noted, foreign countries generally recognize a broad experimental use exemption,[137] which provides incentives for companies seeking research improvements in a patented

infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

35 U.S.C. § 282.

[136] *MedImmune*, 127 S. Ct. at 780 (Thomas, J., dissenting).

[137] *See* Harold C. Wegner, *Post-*Merck *Experimental Use and The "Safe Harbor,"* 15 FED. CIR. B.J. 1, 33 (2005).

technology to locate their research overseas.[138] Consequently, jobs related to the companies' research move overseas as well.[139] Also, as exemplified in *Merck*, a broad interpretation of the FDA exemption will hasten the research of currently incurable diseases, such as cancer.[140] Similarly, a narrow interpretation of the *MedImmune* decision will guarantee that the protection only extends to small companies rather than large companies, which have better resources and means to divert the risk.[141]

V. CONCLUSION

Justice Scalia's holdings in *Merck* and *MedImmune* were expected to have a grave impact on biotechnology research and practice.[142] Numerous parties expressed their concern over these two cases by filing *amici* briefs to the Supreme Court when the cases were pending.[143] Some of them, including the American Intellectual Property Law Association, filed *amici* briefs in both cases.[144] The far-reaching effect of both decisions can be understood without explanation.

Also, the two cases are not independent from each other. The stacking effect of both decisions may destabilize the current patent system, at least in the field of biotechnology research, depending on how future courts will interpret and apply these two cases. Therefore, a carefully conducted balancing test taking each party's interests into account is necessary.

To minimize the impact and conform to the general practice of biotechnology research, the Supreme Court's *Merck* decision should be read broadly to include the use of biotechnology

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138 *See id.*

139 *Id.*

140 *See id.* at 23–24.

141 *See* Greenhouse, *supra* note 18, at C3.

142 *See* Brief of American Intellectual Property Law Association as Amicus Curiae Supporting Respondents, *MedImmune, Inc. v. Genentech, Inc*., *supra* note 1, at 2.

143 Twenty-one briefs of *amici curiae* have been filed in *Merck KGaA v. Integra Lifescience I, Ltd*. Nine of them were in support of Merck, the user of patented invention, and five were in support of Integra, the patent holder; Seventeen briefs of *amici curiae* have been submitted in *MedImmune, Inc. v. Genentech, Inc*. Eleven of them were in support of Genentech, the licenser, and five were in support of MedImmune, the licensee.

144 *See* Brief of American Intellectual Property Law, *supra* note 1; *see also* Amicus Curiae Brief of the American Intellectual Property Law Association in Support of Neither Party, Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005) (No. 03-1237), 2005 WL 435890.

research tools under FDA exemption because (1) it conforms with NIH policy and the custom of biotechnology research; (2) it is impractical, if not impossible, to ask courts to analyze which is drug and which is research tools on a case-by-case basis judging from the complexity of science and technology; (3) it has been established that sharing technologies and processes has greatly enhanced the progress of biotechnology; (4) a broad scope of experimental use exemption is consistent with the international trend;[145] and (5) even if a broad definition of research tools is adopted, the use of another party's patented inventions is not unlimited. The use is still subject to the restriction that it must be "reasonably related" to FDA submission to fall into the 35 U.S.C. § 271(e)(1) safe harbor.

Moreover, biotechnology research tool inventors will still benefit from selling tools, such as patented chemical reagents or genetically modified laboratory mice,[146] to other researchers. It is time efficient and economically sound for researchers to purchase certain research tools which are not easy to prepare by the researchers themselves. Only those patented research tools which are easy for researchers to prepare themselves will be affected by a broad exemption.

On the other hand, the *MedImmune* decision should be read narrowly so that the licensee, a user of another party's patented invention, must be threatened with a loss of business grave enough, such that it is "fatal" or at least an eighty percent loss of its total revenue, to justify its challenge of the licenser's patent invalidity in court without breaching the license agreement first to meet Article III "cases and controversy" requirement.

It is worth noting that the user of the patented inventions in *Merck* did not profit from the other party's patent. The "threat" of losing eighty percent of the business in *MedImmune* can be phrased in another way: unlike *Merck*, the licensee in *MedImmune* was profiting from the other party's patented invention and the profit accounted for eighty percent of the licensee's revenue. The licensee had benefited from another

[145] *See* Wegner, *supra* note 137, at 29–31 (The German Supreme Court recognized that the realities and costs of genetic engineering make research in the commercial sector a necessity that should be protected in appropriate circumstances. Also, Japanese patent laws provide that "[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of experimentation or research. . . . [T]he Japanese law applies to any 'experimentation or research.'").

[146] *See* Mueller, *supra* note 21, at 15.

party's patented invention regardless of the patent's invalidity, which was a question the Court did not answer. Therefore, a narrow interpretation of *MedImmune* to prevent potential harassment against biotechnology patent holders from numerous licensees is proper.