No. 03-1237

IN THE

Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and
THE BURNHAM INSTITUTE and
TELIOS PHARMACEUTICALS, INC.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE*, THE SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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THE INTEREST OF THE AMICUS CURIAE[1]

The *Amicus Curiae*, the San Diego Intellectual Property Law Association, is a non-profit organization comprising a representative cross-section of individuals in San Diego County with an interest in intellectual property matters. Its membership is drawn from attorneys and patent agents who address patent issues on behalf of companies, institutions, and inventors.

The San Diego region is home to a substantial share of the nation's biotechnology and pharmaceutical companies, and a number of not-for-profit research institutions, including the University of California at San Diego, Salk Institute for Biomedical Studies, The Scripps Research Institute, and the Burnham Institute. More than 300 biotechnology companies reside in San Diego County.

A 2004 study ranked San Diego first among U.S. biotechnology centers, based on two broad categories: the innovation pipeline (the infrastructure that allows a region to capitalize on its biotech knowledge and creativity) and the current impact assessment (an area's success in bringing ideas to the marketplace and creating companies, jobs and products). *See* Skip Rimer, *Study Ranks San Diego #1 Among U.S. Biotech Centers*, Biotechnology News, June 17, 2004, at I-2.

The interest of the *Amicus* is in ensuring that the scope of exemption under 35 U.S.C. § 271(e)(1) strikes the proper

[1] No counsel for any party authored this brief either in whole or in part, and no persons other than the *Amicus Curiae* and their counsel made any monetary contribution to its preparation or submission. The parties' written consents to the filing of this brief have been filed with the Clerk of the Court.

balance between the interests of biotechnology companies who invent new research tools for use in drug development and the interests of those who develop and commercialize life-saving drugs.

SUMMARY OF ARGUMENT

At issue in this case is the scope of the statutory exemption from patent infringement under 35 U.S.C. § 271(e)(1). The Court has granted certiorari to decide whether § 271(e)(1) applies to pre-clinical drug research and development activities. The interest of the *Amicus* is the effect of the scope of the § 271(e)(1) exemption on holders of research tool patents used in drug discovery and development. The *Amicus* submits that the nature of the "patented invention" and the nature of its "use" are the proper determinants for whether the § 271(e)(1) exemption should apply. Under such an analysis, the § 271(e)(1) exemption does not apply to research performed with (as opposed to on) patented research tools.

The issue presented is complex and affects the future of drug development in the United States. Preserving the balance between the rights of companies who invent the tools used in drug development and those who engage in drug development itself requires a comprehensive approach combining carefully-crafted legislative and judicial solutions. This Court has taken an important first step in granting *certiorari* in this case.

Any decision by this Court concerning the scope of the exemption under § 271(e)(1) will have far-reaching effects on the biotechnology and pharmaceutical industry in the United States and will affect the rights of patent holders of research tools. If the Court interprets the statutory exemption

broadly to encompass all drug development, without considering whether the patents pertain to the drugs themselves or the research tools used in drug development, research tool patent holders may not receive value for their inventions.

If, on the other hand, the Court interprets the exemption narrowly to apply only to clinical trial activities, drug developers will need a license to use research tools during pre-clinical activities. Some argue that if the exemption is interpreted narrowly to exclude pre-clinical activities, such as the Federal Circuit did in this case, it will undermine the purpose of § 271(e)(1) by making it impossible for companies engaged in drug development to reach the clinical trial threshold at which the exemption is triggered. If the exemption comes into play only when the research effort is approaching the point at which regulatory approval will be sought, then the exemption would never apply because preliminary research needed to identify such a compound would be barred by the patent laws. *See* Nicholas Groombridge and Sheryl Calabro, *Integra Lifesciences v. Merck - Good for Research or Just Good for Research Tool Patent Owners*? 22 Biotech Law Report 462, 469 (October 2003). In determining the proper scope of § 271(e)(1), this Court must balance these competing concerns.

Until the Federal Circuit's decision in *Integra*, most companies ignored the rights of research tool patent-holders as long as they were engaged in the discovery and development of new drugs. 22 Biotechnology Law Report at 465-66. District court decisions such as *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer Inc.*, No. 42 Civ. 8833, 2001 U.S. Dist. Lexis 19361 (S.D.N.Y. Nov. 27, 2001), and *Nexell Therapeutics, Inc. v. Amcell Corp.,* 199 F. Supp. 2d

197 (D. Del. 2002), had held that such investigation was within the safe harbor provision of § 271(e)(1). The Federal Circuit in this case drastically narrowed the exemption, explicitly stating that it was concerned that a broader exemption would eliminate the value of research tool patents. *Integra Lifesciences I, Ltd. v. Merck kGaA*, 331 F.3d 860, 86 (Fed. Cir. 2003), *as modified by* 2003 U.S. App. Lexis 27796 (Fed. Cir. July 10, 2003).

The Court's decision in this case will influence the valuation of research tool patents. Should drug development companies be permitted to use patented inventions directed toward research tools without recompense to the research tool patent holders? The answer is critical to research tool companies whose business models and very survival depends on the commercialization of patented research technology. The scope and contours of the exemption as delineated by this Court will determine whether research tool patent owners receive the benefit of the patent bargain and are fairly compensated for their intellectual property. The *Amicus* submits that research tool patent-holders should receive the benefit of their contribution to drug development activities, as would any other patent holder.

The *Amicus* does not favor either position advocated by the parties in this case concerning the scope of the clinical trial exemption under § 271(e)(1). Merck takes the position that § 271(e)(1) should provide a blanket exemption to all drug discovery and development activities, regardless of the nature of the patent. Integra takes the opposing position that no drug discovery and pre-clinical development activities are

"reasonably related" to submission of information to FDA. While the § 271(e)(1) exemption may apply to uses of drug-specific patented inventions during both pre-clinical and clinical phases of the regulatory approval process, the *Amicus* believes it should not apply to the research tools used in drug development. Unlike drug-specific patents, research tool patents are not the "patented inventions" contemplated by § 271(e)(1).[2] These patents do not focus on methods of making drugs or treating patients. Instead, patented research tools are used to conduct research on other drug products that do not physically incorporate the patented research tool.

Neither party in this case directly focuses on the nature of the patents and the nature of the use of the patented invention in the drug development process in determining whether such activity is encompassed by § 271(e)(1). Such a focus is critical to a determination of the proper scope of the exemption to foster pharmaceutical innovation while preserving both the incentives of the patent system and the intellectual capital of innovative companies and institutions. Rather than focusing on *when* the patented invention is used in the drug development process, the *Amicus* submits that the nature of the "patented invention" and the nature of its use determine whether the § 271(e)(1) exemption should apply.

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[2] As discussed *supra*, the "patented invention" of § 271(e)(1) includes both patents relating to drug products and medical devices. However, because the product at issue in this case relates to a drug, the term "drug-specific" patent is used herein.

AN UNDERSTANDING OF RESEARCH TOOLS AND THEIR USE IN THE DRUG DEVELOPMENT PROCESS IS CRITICAL TO THE ANALYSIS OF THE SCOPE OF THE SECTION 271(e)(1) EXEMPTION

Although Petitioner and Respondent focus on when in the development process the exemption should apply, this case also raises the important issue of the impact of the scope of the § 271(e)(1) exemption on research tools used in the biotechnology/pharmaceutical industry. Understanding the diversity of research tools and how they are used during the drug development process is critical to a proper analysis of the scope of the exemption under § 271(e)(1). The starting point is a comprehensive definition of research tools.

A. Definition of Research Tools

Research tools have been defined in various ways. The FTC, in its recently released report on competition and patent law policy, provided a generalized definition of research tools: "A research tool is a technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product or properties of a potential drug product."[3]

Other definitions incorporate examples to demonstrate the diversity of research tools.[4] For example, one

[3] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* ch. 3, p. 16 (October 2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>

[4] Judge Newman defined research tools very simply: "A research tool is a product or method whose purpose is use in the conduct of (Cont'd)

commentator explained, "A research tool is generally understood as any resource commonly used by scientists in the laboratory to conduct research, and can include everything from a common chemical reagent to devices such as laboratory scales to mice or other laboratory animals genetically engineered for susceptibility to certain diseases." Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 Baylor L. Rev. 917, 955 (2004).

The majority in the opinion below relied on the widely used National Institutes of Health's ("NIH") definition of research tools, which supplies several examples to illustrate the term: "[R]esearch tools are defined to be 'tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.'" *Integra*, 331 F.3d 812, n.4, *quoting* Sharing Biomedical Research Resources: *Principles and Guidelines for Recipients of NIH Research Grants and Contracts*, 64 Fed. Reg. 72,090, 72092 n.1 (Dec. 23, 1999). Research tools encompass both compositions and methods, as well as the familiar tools used in the laboratory such as equipment and machines.

A definition of research tools that is particularly useful in the § 271(e)(1) context, however, makes clear that the resulting drug product does not incorporate the research tool.

(Cont'd)
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)." *Integra,* 331 F. 3d at 878.

Jian Xiao, *Carving Out a Biotechnology Research Tool Exception to the Safe Harbor Provision of 35 U.S.C. § 271(e)(1),* 12 Tex. Intell. Prop. L.J. 23, 49 (2003) (A biotechnology research tool refers to "a tool used in development of drug products, therapeutic devices or diagnostic methods that do not themselves physically incorporate the tool."). *See also* Janice M Mueller, *No Dilettante Affair*: *Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 14 (2001) (similar definition). The intended use of research tool patents is to conduct research with the tool that leads to a drug product. Implicit in the intended use of the research tool is the concept that the resulting drug product does not physically incorporate the research tool. The Amicus believes that any definition of research tool should include this concept.

B. Nature of Use of Patented Invention

The *Amicus* contends that the proper focus of a § 271(e)(1) analysis should be on the nature of the patented invention and its use, and not on when that use takes place. The policy debate in this case concerns, in part, on whether the patented peptides were used as a research tool or used as a new composition (*i.e.*, a drug-specific invention.) As illustrated by the facts, it is not always easy to characterize the nature of the use of the patented invention. In close cases, use of a patented invention may be characterized as drug-specific by an accused infringer attempting to find safe harbor within the § 271(e)(1) exemption and as use of a research tool by a patentee eager to obtain damages and injunctive relief for infringement.

Merck maintains that the use of the patented peptides by Scripps researchers was experimentation on the patented invention itself and not the use of the patented invention as a research tool (*i.e.*, a drug-specific patent).[5] *Integra*, 331 F.3d at 863. Merck concludes that such use is protected under the § 271(e)(1) exemption. *Id.* Judge Newman agreed, and explained in her dissent that Integra's patented RGD peptides are not research tools, "but simply new compositions having certain uses." *Id.* at 878 (Newman, J., dissenting).

Integra, on the other hand, argues that its patented peptides were used as a research tool to find a drug candidate, and that such use is not exempt under § 271(e)(1). *Integra*, 331 F.3d at 863. The majority in the opinion below agreed, commenting, "The dissent does not explain why one of those 'certain uses' cannot embrace use of an RGD peptide as a laboratory tool to facilitate the identification of a new therapeutic." *Id.* at 872, n.4. In fact, as expressly stated by the majority, the conclusion that the exemption was narrow and did not cover pre-clinical uses of patented inventions, was based, in part, on its desire to avoid vitiating the patent rights of the biotechnology research tool industry. *Id.* at 867 ("[E]xpansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents.").

To determine whether the scope of the § 271(e)(1) exemption covers pre-clinical activities, the Court must

[5] The Solicitor General also weighed in on the issue, emphatically stating that this case "has nothing to do with research tools." Brief for the United States as *Amicus Curiae* on Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit at 16 n.5, *Merck kGaA v. Integra Lifesciences I, Ltd.* (No. 03-1237).

consider the research tool issue. If the Court interprets the scope of § 271(e)(1) broadly without considering the nature of the use, the patent rights of many research tools will be lost. The majority below, in narrowly interpreting the scope of the exemption, made this point. "[E]xaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions." *Integra,* 331 F.3d at 867. If the Court affirms the Federal Circuit's ruling that the scope of § 271(e)(1) is narrow and does not encompass pre-clinical activities based on the timing rationale alone[6], research tool patent holders will be compensated for the use of their tools during the pre-clinical phase. Other uses of patented inventions during the pre-clinical phase, however, that are reasonably related to development and submission of information to the FDA will not be covered by the exemption.

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[6] The Federal Circuit, did not distinguish pre-clinical activities from basic research and drug discovery, simply stating that the exemption does not encompass the full range of "general biomedical experimentation." *Id*. at 868. Implicit in the statutory language of § 271(e)(1) is a fundamental timing constraint. The natural dividing line, however, is not between the pre-clinical and clinical phases, as the court below found, but rather between the basic research and pre-clinical development phases. The statute cannot cover the entire continuum of basic research, drug discovery and drug development because the use of the "patented invention" cannot be "solely for uses reasonably related to the development and submission of information" to the FDA until the drug candidate has been identified. 35 U.S.C. § 271(e)(1). If the activity is so early in the drug development process that it is not reasonably related to the development and submission of information" to the FDA, it cannot possibly be exempt.

THE CRITICAL DISTINCTION TO DETERMINE WHETHER THE § 271(e)(1) EXEMPTION APPLIES IS THE NATURE OF THE PATENTED INVENTION AND THE NATURE OF ITS USE

The question before this Court is whether the § 271(e)(1) exemption applies to any uses of "patented inventions" during the pre-clinical phase.[7] An analysis based on when in the development process the use occurs does not definitively settle this issue. Instead, a determination of the proper scope of the exemption also must analyze the nature of the use of patented invention and whether the use is "reasonably related to the development and submission of information" to the FDA. This analysis, which has been employed under the common law experimental use exception[8], also has application in the context of § 271(e)(1).

In determining the proper scope of the § 271(e)(1) exemption, the Court must consider whether the type of patent that is being used is a drug-specific patent or a research

[7] Under the Federal Food, Drug and Cosmetic Act ("FDCA"), a drug developer must conduct an extensive investigation of a new drug to obtain FDA approval. During the pre-clinical phase, which takes approximately three to six years, the drug developer "must generate in vitro and animal data about the drug candidate, including chemical structure, safety, efficacy, and toxicology of the drug." 12 Tex. Intell. Prop. L. J. at 27. This data is submitted in an Investigational New Drug Application ("IND"). The approval of the IND signals the beginning of the clinical trials on human subjects. *Id.*

[8] While the *Amicus* understand that the common law experimental use exception is not at issue here because it was not raised or addressed by the parties below, the analytical framework of the exception is nevertheless instructive.

tool patent. Drug-specific patents cover the new drug *per se*, its manufacturing methods, starting materials, and intermediates to make the drug, formulations of the drug *i.e.*, the particular formulation of the drug administered to products, and methods of treatment. The focus of these drug-specific patents is the nature of the drug itself. In contrast, the focus of research tool patents is on the methods, equipment and compositions used to conduct research on drug products, *i.e.*, the research tools are not physically incorporated into the drug product. Katherine J. Strandburg, *What Does The Public Get? Experimental Use and the Patent Bargain*, *Experimental Use and the Patent Bargain*, 2004 Wis. L. Rev. 81, 123 (2004).

Drug-specific patents and research tool patents, however, are not always readily distinguishable. A biotechnology/ pharmaceutical invention may be both a valuable end product and a basic tool used in the discovery and development of an end product. 12 Tex. Intell. Prop. L.J. at 48. In the broader context of experimental use, commentators widely accept the "experimenting on" versus "experimenting with" dichotomy to determine whether the use is of the patented drug itself or of a research tool employed in drug development. 56 Baylor L. Rev. at 956-57. Such an analysis also is useful to distinguish types of "use" in the context of § 271(e)(1).[9]

[9] There is a parallel between the experimental use exception and § 271(e)(1). Section 271(e)(1) is a legislative outgrowth of the common law experimental use exception. Section 271(e)(1) was enacted to overturn the ruling in *Roche Products, Inc. v. Bolar Pharmaceutical Co.* that the common law experimental use exception did not apply to the development and submission of information to the FDA during generic drug development. *See Roche Prods., Inc. v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 863 (Fed. Cir.

(Cont'd)

One way to differentiate between these two types of use is to ask whether experimental use of the invention could be replaced with more information about the patented invention. 2004 Wis. L. Rev. at 118-19. If the answer is yes, the use falls into the "experimenting on" category and should be exempt under § 271(e)(1).

The use of drug-specific patents is to gather information about the invention itself. Experimental use aimed at understanding, designing around, or improving a patented invention is an extension of the disclosure requirement that is part of the quid pro quo of the patent bargain.[10] *Id.* "Experimenting on" uses the inventive idea.

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1984). The logical underpinnings of the experimental use exception and § 271(e)(1) should be the same, *i.e.*, experimenting on a patented invention is exempt from patent infringement. Section 271(e)(1) includes the additional requirement that the use of the patented invention must be reasonably related to the development and submission of information to the FDA.

[10] The purpose of the patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technologic knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance. The right to conduct research to achieve such knowledge need not, and should not, await expiration of the patent. That is not the law and it would be a practice impossible to administer.

Integra, 331 F.3d at 873 (Newman, J., dissenting)

Id. at 148. "'Experimenting on' a patented invention can, and should be broadly permitted, regardless of commercial intent, as a means of ensuring that the public receives the benefit of the patent bargain with respect to follow-on innovation." *Id.* at 146. "Experimenting on a patented invention is primarily a way of effectuating the patent disclosure to achieve its recognized purposes." *Id.* at 100. For this reason, experimentation *on* the patented invention that is reasonably related to the development and submission of information to the FDA should be exempt under § 271(e)(1).

Such research use of drug-specific patents fosters the incentives of the patent system and furthers the purposes of § 271(e)(1), even in the drug discovery and pre-clinical testing phases of drug development. In the case of drug-specific patents, the purpose of the statute is thus achieved. The disclosure requirements of the patent statute benefit the public interest in faster-paced innovation by permitting the "use" of the patented invention in developing improvements or different inventions during the patent term. 2004 Wis. L. Rev. at 101.

In contrast, researchers experiment *with* patented research tools to conduct drug discovery and development on drug products. For example, microscopes are tools a researcher would use to develop a drug product. The resulting drug product does not physically incorporate the microscope. In other words, if the microscope were patented, the researcher would be experimenting with the patented product. Therefore, the nature of the patent and the nature of the use of the patent must be examined before a determination can be made regarding whether the activity is exempt from a patent infringement claim under § 271(e)(1).

A more complex example is a mouse model of a human disease (*e.g.*, Alzheimer's) which is a tool to study the effects of different drug candidates on the disease. The resulting drug candidate that is identified using the mouse model is distinct from the mouse model itself. Use of the microscope or mouse model in drug development research is quite different from the study of the microscope or the mouse itself. *Integra*, 331 F.3d at 878 (Newman, J., concurring-in-part and dissenting-in-part) ("Use of any existing tool in one's research is quite different from study of the tool itself."). Under a proper interpretation of § 271(e)(1), the former activity should not be exempt from a patent infringement claim whereas the latter should be.

THE "PATENTED INVENTION" OF SECTION 271(e)(1) IS LIMITED TO DRUG-SPECIFIC PATENTS

Consideration of whether the term "patented invention" encompasses both drug-specific patents and research tool patents is integral to ascertaining the proper scope of the § 271(e)(1) exemption. This Court previously has interpreted the "patented invention" language of § 271(e)(1) to mean a patent relating to a drug product or a patent relating to a medical device.[11] *Eli Lilly and Co. v. Medtronic, Inc.,* 496 U.S. at 667 (1990) (The centrally important distinction in this legislation … [is] between patents relating to drugs and patents relating to devices. If only the former patents were meant to be included, there were available such infinitely more clear and simple ways of expressing that intent. . . . The provision might have read, for example, "It shall not be

[11] Both drug products and medical devices must be subject to the regulatory approval process.

an act of infringement to make, use, or sell a *patented drug invention* . . . solely for uses reasonably related to the development and submission of information. . . .").

The purpose of the 1984 Act was to eliminate distortion from both ends of the patent period due to the requirement that certain products must receive pre-market regulatory approval. *Eli Lilly,* 496 U.S. at 669. Section 201 of the Act created a patent term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to approval. *Id*. at 670. Section 202 addressed the distortion at the other end by adding § 271(e)(1) to the patent statute to "allow competitors, prior to the expiration of the patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Id*.

The two sections are complementary. *Eli Lilly*, 496 U.S. at 673 ("[T]here are textual indications that sections 201 and 202 are meant generally to be complementary.") Interpreting § 271(e)(1) to include medical devices within its scope "appears to create a perfect 'product' fit between the two sections." *Id*. "All of the products eligible for a patent term extension under § 201 are subject to § 202, since all of them — medical devices, food additives, color additives, new drugs, antibiotic drugs, and human biological products — are subject to pre-market approval under various provisions of the FDCA." *Id*. at 674. Likewise, all of the products not eligible for a patent term extension under § 201 are excluded from § 202. *Id*.

Under this Court's precedent, the statutory language "patented invention" is limited to a patented drug product or

a patented medical device product. As a further limitation on which patented inventions are subject to the exemption, use of that patented invention must be reasonably related to the development and submission of information to the FDA.[12]

THE USE OF PATENTED RESEARCH TOOLS IN DRUG DEVELOPMENT IS NOT "USE" OF "A PATENTED INVENTION" THAT IS REASONABLY RELATED TO THE DEVELOPMENT AND SUBMISSION OF INFORMATION TO THE FDA

Unlike drug-specific patents, research tool patents are not "patented inventions" within the meaning of § 271(e)(1). These patents do not focus on methods of making drugs or treating patients. Instead, patented research tools are used to conduct research on other drug products that do not physically incorporate the patented research tool.

To determine whether § 271(e)(1) applies to the use of patented research tools during drug development, the Court also should consider the statutory language "use." A distinction should be made between use that is experimenting *on* the patented invention (use of a patented drug product) and experimenting *with* the patented invention to develop another drug product (use of a patented research

[12] Section 202, if interpreted to apply to all products regulated by the FDCA and other drug-regulating statutes, has a product coverage larger than that of § 201. But the product coverage is further limited by the "reasonably related" statutory language: "[F]or the § 202 exemption to be applicable, the patent use must be 'reasonably related to the development and submission of information under' the relevant law." *Eli Lilly,* 496 U.S. at 674.

tool). In contrast to the use of drug-specific patents during the drug development process, the use of research tools does not foster the incentives of the patent system or further the purposes of § 271(e)(1). The use of patented research tools to develop another drug product that does not incorporate the patented tool does not benefit the public interest because it does not permit the development of improvements or design-arounds of the tool itself.

The express language of § 271(e)(1) excludes uses that are not "reasonably related to the development and submission of information" under the FDCA. Section 271(e)(1) should not apply to uses of research tools to research and develop products that do not incorporate the patented invention. For example, a research tool may be used to screen hundreds of thousands of potential therapeutics or drugs to find one lead candidate — "use" clearly not "reasonably related to the development and submission of information" to the FDA. The basic dividing line between what is exempted under § 271(e)(1) and what is not rests on whether the use is on the patented invention, such as bioequivalency testing and the development of the patented invention as a drug product, or with a research tool to develop other drug products. In effect, § 271(e)(1) codified this public policy that such use of the drug-specific patented invention is permissible during drug development. Because use of a research tool is not experimentation on the research tool itself, but rather experimentation with the tool to develop an another drug product, its use should not be exempted under § 271(e)(1).

A BROAD SCOPE OF EXEMPTION UNDER SECTION 271(e)(1) THAT INCLUDES RESEARCH TOOL PATENTS WILL DESTROY THE INTELLECTUAL CAPITAL OF SMALL BIOTECHNOLOGY AND PHARMACEUTICAL COMPANIES WHO FOCUS ON DRUG DISCOVERY TECHNOLOGY

The rationale for the enactment of § 271(e)(1) is that the harm to the patent-holder is *de minimis*. The patent holder retains the right to exclude the drug developer from entering the marketplace until the patent expires. *See* H.R. Rep. No. 857, at 8, reprinted in 1984 U.S.C.A.N.N. 2684, 2692 ("The patent holder retains the right to exclude others from the major commercial market place during the life of the patent.") The infringement action is merely delayed rather than precluded. *See Integra*, 331 F.3d at 877 ("After a product loses the § 271(e)(1) protection, it is subject to the full force of any adversely held patents.") The exemption permits experiments to develop information to submit to the FDA, but does not permit the drug developer to reap any profit until after the patent expires. This rationale does not hold for all research tools used in drug development.

Those that favor the extension of the § 271(e)(1) exemption to uses of research tools in developing drugs say that drug development will be blocked or become exorbitantly expensive if research tools are not covered by either § 271(e)(1) or a broadened common law (or new legislative) experimental use exception.

> The concern with patented research tools arises from the fear that a research tool may give the

> tool inventor the ability to block technological progress by controlling the research that may be performed using the tool in a way that maximizes the return to the tool patentee at the expense of society.

2004 Wis. L. Rev. at 123.

Under what circumstances can a research tool patent-holder control the progress of drug development? If the research tool patent holder commercializes the tool and sells or licenses it on the open market, there is no concern about the research tool patent-holder controlling the progress of drug development. *Id*. at 124. Widespread commercial availability of the tool thus "decouples control over research using the tool from recovering the toolmaker's investment." *Id*. at 124 n.157. For research tools that are commercially available, there is no reason for the exemption to apply. Further, if there are available substitutes for the research tool, then the decision whether to commercialize or license the tool will not hinder drug development progress. *Id.* In this case, where a substitute is available, the exemption also need not apply.

Only if there are no close substitutes for the patented research tool and no close substitutes for the drug development projects that require the tool, does the research tool patent holder have the capacity to impede or negatively impact the progress of drug development by refusing to license his patent or attempting to extract reach-through royalties on the downstream drug product. *Id*.

The solution, however, is not a broad application of the § 271(e)(1) exemption to cover all uses of patented inventions, but rather legislative solutions that protect the value of patented research tools.[13]

If § 271(e)(1) is applied broadly, the harm is not *de minimis* with respect to research tool patents. For those research tools whose only use is in conducting experiments during the exemption period, the entire value is achieved during that period, and not after the exemption period expires. The harm amounts to a loss of the entire value of the research tool patent.

THE DETERMINATION OF THE PROPER SCOPE OF SECTION 271(e)(1) IS PART OF THE POLICY DEBATE OVER RESEARCH TOOLS

Since the start of the biotechnology revolution fifty years ago, "scientists have continued to develop new drugs, laboratory methods and research tools at a staggering pace." David C. Hoffman, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing*

[13] One of the gnawing issues with respect to research tools is how to determine their value. In exchange for promoting the "progress of the sciences and the useful arts," the patent owner receives the right to exclude others from using the patented invention. But what is the appropriate value of research tools? Reach-through royalties based on the blockbuster drug that is commercialized many years after the use of the research tool? Compulsory licensing? A collective rights licensing regime that controls licensing? As long as the scope of the exemption under § 271(e)(1) does not impinge upon the patent rights of research tool patent holders, the market will determine how to value such tools.

A Broad Experimental Use Exception," 89 Cornell L. Rev. 993, 994-95 (2004). The governmental agencies responsible for setting policy with respect to biotechnology have been unable to keep up with the explosion of economic, ethical and practical issues raised by this new field. *Id*. at 995. The challenge is to develop a systematic and comprehensive approach to balancing the need for "unfettered access to scientific information and essential research tools with the desire to provide sufficient economic incentives to fuel scientific innovation." *Id.* at 995-996.

The issue presented in this case, the scope of the § 271(e)(1) exemption, is just one piece of this biotechnology puzzle. In determining the proper resolution of this issue, the Court should consider the entire landscape and bear in mind how such decisions may spur or retard the growth of the biotechnology industry in the United States. This case, and recent cases such as *Madey v. Duke*[14] (the scope of the common law experimental use exception), *Bayer v. Housey*[15] (whether § 271(g) applies to information generated by a use of a research tool overseas and imported into the United States), the *University of Rochester v. G.D. Searle*[16] (the standard for written description with respect to biotechnology inventions), are fundamentally related and illustrate the need for a comprehensive approach to the issues raised by this industry.

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[14] *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied* by *Duke Univ. v. Madey*, 538 U.S. 959 (2003).

[15] *Bayer v. Housey Pharms., Inc*. 340 F.3d 1367 (Fed. Cir. 2003).

[16] *University of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303 (Fed. Cir. 2004), *cert denied*, 125 S. Ct. 629 (2005).

To avoid a deleterious effect on biotechnology and pharmaceutical innovation in the United States, the Court must carefully weigh the policy concerns and balance the interests of research tool patent holders with the interests of other parties. It is indisputable that research tool patent holders should receive proper value for their inventive contributions. The patent system should promote the continued growth of biotechnology companies that invent and commercialize new research tools. 22 Biotechnology Law Report at 471. A blanket exemption under § 271(e)(1) that sweeps in research tools is unwarranted and will have unintended consequences. At the same time, the Court must also encourage fundamental biomedical research and ensure that the patent system does not hinder the development and commercialization of life-saving drugs. *Id.* Focusing on the nature of the patented invention and the nature of its use, rather than on when in the drug development process such use occurs, to determine the scope of the § 271(e)(1), strikes the proper balance.

CONCLUSION

A determination of the proper scope of the exemption will foster pharmaceutical innovation while preserving both the incentives of the patent system and the intellectual capital of innovative companies and institutions. Rather than focusing on when the patented invention is used in the drug development process, the *Amicus* submits that the nature of the "patented invention" and the nature of its use determine whether the § 271(e)(1) exemption should apply.

Respectfully submitted,

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