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 AMICI CURIAE WISCONSIN ALUMNI RESEARCH FOUNDATION, THE AMERICAN COUNCIL ON EDUCATION, BOSTON UNIVERSITY, THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, RESEARCH CORPORATION TECHNOLOGIES, THE SALK INSTITUTE FOR BIOLOGICAL STUDIES, UNIVERSITY OF ALBERTA AND UNIVERSITY OF OKLAHOMA IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit ("Federal Circuit") correctly ruled that the safe harbor of 35 U.S.C. § 271(e)(1) does not encompass general biomedical experimentation, thereby protecting the value of, *inter alia*, drug research patents.

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INTEREST OF THE *AMICI*[1]

The *Amici* include the Wisconsin Alumni Research Foundation ("WARF"), the Regents of the University of California, the American Counsel on Education, Research Corporation Technologies, The Salk Institute for Biological Studies, Boston University, the University of Oklahoma, and the University of Alberta.[2]

The *Amici* are generally interested in the management, development, licensing, and enforcement of university-related intellectual property that forms a substantial part of the new drug discovery pipeline. As has been recently observed, these institutions, along with biotechnology companies, "perform the risky experiments that lead who knows where. They also develop the cutting-edge tools that permit this research – such as screening methods for new chemicals that might be transformed into medical cures and computer programs to better design those chemicals." Warburg, R.J., *et al.*, *Warning: Research Dollars at Risk!*, 26 Legal Times IP Magazine (March 24, 2003). As explained herein the university sector's ability to patent technology arising from its research efforts is the basis for transferring such technology to the public for its use and benefit.

To expand the safe harbor of 35 U.S.C. § 271(e)(1) beyond the limits set forth in the statute's plain meaning and

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[1] Pursuant to S. Ct. R. 37.6, the *Amici Curiae* state that no counsel for either the Petitioner or the Respondents has authored any portion of this brief. No financial contribution has been made to the preparation of this brief by anyone other than the *Amici* and their counsel. Pursuant to S. Ct. R. 37.3(a), the *Amici* represent that the parties to this matter have consented to the filing of this brief.

[2] A detailed description of each *Amicus* is appended hereto at A-1–A-4.

identified by the court of appeals below would have an adverse effect on the research community as a whole, and the university research community in particular. Given the normal expectation that innovation follows invention, the corresponding erosion of patent rights that would necessarily accompany an undue expansion of the safe harbor would also bring with it a lag in innovation. Without the protection afforded by viable patents, there would be a lessened interest within the private sector to support university-related research functions.

The performance of the university sector in transferring technology under the seminal University and Small Business Patent Procedures Act, Pub. L. No. 96-517, sec. 6(a), 94 Stat. 3019 (1980), *codified as amended at* 35 U.S.C. § 201, *et seq.* (2000) (commonly known as "the Bayh-Dole Act") has been exemplary. The success of the Act can be traced to two fundamental features embraced in the Patent Act: (1) the certainty and security of title that is essential for academic and non-profit institutions to transfer their patented technologies to the private sector; and (2) the right to exclude others from practicing the patented technology afforded to such institutions under the patent laws. Contravening these features would be anathema to the ability of universities to transfer the technology derived from the conduct of their research functions.

The President's Council of Advisors on Science and Technology (PCAST) reported to the President in 2003 that judicial decisions on "research exemptions," especially as concerns research tool patents, "could be an important factor in future technology transfer practices." Report of the President's Council of Advisors on Science and Technology (May 15, 2003) at 17. PCAST also concluded, and recommended generally, that "[e]xisting technology-transfer legislation works and should not be altered." *Id.* at 8.

Moreover, and without question, the university sector is a key in the discovery of new drugs, as well as other breakthrough technologies, which have served to make the United States the world's technology leader. As an example, the biotechnology industry as we know it today began on university campuses in the United States. With the continued "downsizing" of corporations in this country, the private sector is heavily dependent upon the academic community to perform the basic research function that advances technologies, and yields new products and processes that benefit mankind the world over.

As holders of many of the patents directed to inventions which are or may be utilized directed to experimental pursuits, the *Amici* have a substantial interest in the principal question to be resolved by the Court, namely the appropriate scope of the infringement safe harbor of section 271(e)(1) of the Patent Act.

SUMMARY OF ARGUMENT

The statutory safe harbor provided in section 271(e)(1) was designed by Congress to solve a very specific problem – the *de facto* extension of a patentee's exclusivity resulting from a competitor's inability to conduct experimentation to obtain regulatory approval necessary to bring otherwise infringing products to market upon the expiration of a patent. The express language of section 271(e)(1), which exempts only those acts "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products," is purposefully narrow to accomplish that goal. The Petitioner argues for the expansion of section 271(e)(1) that may, in turn, result in an exemption of more than was ever intended by Congress – *i.e.*, general pharmaceutical research.

In addition to being well beyond the intended scope of section 271(e)(1), such an expansion would nullify the commercial value of an entire class of patents – drug research patents, which are paramount tools in the drug discovery process. Not only would such a result be clearly contrary to statutory language, the legislative purposes and objectives of the Bayh-Dole Act, but it would be contrary to treaty obligations entered into by the United States. In the final analysis, it would result in a serious detriment to the drug discovery process, which would benefit neither institutions, such as the *Amici*, nor pharmaceutical companies such as the Petitioner.

ARGUMENT

I. Introduction

It is a policy conflict that originated well before this case began – the desire to provide the widest range of affordable, lifesaving drug products to the U.S. population versus the recognition that, in order to ensure that such products are developed, the need to provide for patent exclusivity for such products, and the various economic results arising from such exclusivity.

Ironically, large pharmaceutical companies, such as the Petitioner, generally find themselves among the group favoring patent exclusivity, especially in the face of low-priced competition from generic drug manufacturers. Here, of course, the Petitioner argues for drug availability to the detriment of broader patent protection.

In making their stand for narrower patent protection, the Petitioner, and the *Amici* that have thus far weighed in on behalf of the Petitioner, mischaracterize the issue below as a distinction somehow drawn between generic and pioneer drug products. *See, e.g.,* Petitioner's Br. at 5, *et seq.*[3] In fact, the Federal Circuit's decision was not based on any such distinction. Rather, the Federal Circuit ruled, as it should have, in light of the plain language of section 271(e)(1), that, in the safe harbor of that statutory provision exempts from an infringement charge acts "*solely* for uses reasonably related to the development and submission of information under a

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[3] As an aside, the *Amici* note that, while the Petitioner presented its question at the petition stage as whether pre-clinical "animal studies" should enjoy the safe harbor of section 271(e)(1), on the merits, Petitioner now seeks to exonerate "animal *and* test tube studies." *Compare* Petition at i and Petitioner Br. at i.

Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. § 271(e)(1).

In light of the afore-quoted language, the Federal Circuit correctly ruled that "general biomedical experimentation" was not embraced by the narrow safe harbor to infringement charges provided under section 271(e)(1). *Integra Lifesciences I, Ltd. v. Merck KGaA*, 2003 U.S. App. LEXIS 26547 (Fed. Cir. June 6, 2003) at *19, *cert. granted, Merck KGaA v. Integra Life Sciences I, Ltd.*, ____ U.S. ____, 125 S.Ct. 823 (2004).

The *Amici* do not contest the view that the words "reasonably related" in the statute give courts limited leeway to engage in a fact-specific inquiry about whether making, using, or selling a patented invention in the United States are "solely for uses reasonably related" to the statutory safe harbor. *See* Amicus Br. of Biotechnology Industry Organization.

II. Section 271(e)(1) is a Limited Exemption to an Infringement Charge by Design

A. The Original Purpose of Section 271(e)(1)

Section 271 (e)(1), under which the Petitioner originally sought safe harbor below, provides as follows:

> It shall not be an act of infringement to make, use, or sell within the United States...a patented invention . . . *solely* for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1) (emphasis added).

This section was originally part of the Drug Price Competition and Patent Term Restoration Act of 1984 Pub. L. 98-417 (1984), sec. 201, 98 Stat. 1598-1602, *codified as amended at* 35 U.S.C. § 156 (2002) ("the Act"), which was designed to respond to an unintended extension of the statutory patent term in certain circumstances resulting from the requirement that certain products, such as pharmaceuticals, receive pre-market regulatory approval. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990).[4] Prior to the enactment of the Act, a patentee's potential competitors were often delayed from entering the market once a patent expired because such competitors could not seek their own regulatory approval prior to the expiration of the patent. *Id.*

This patent term distortion was exacerbated by the Federal Circuit's decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.* 733 F.2d 858 (Fed. Cir.1984), *cert. denied,* 469 U.S. 856 (1984), which "decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement . . . even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval." *Eli Lilly,* 496 U.S. at 670.

Congress responded to this distortion by providing a narrowly-tailored safe harbor exemption for otherwise infringing activity where such activity is "solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). In enacting this provision, Congress had in mind the particular plight of competitor drug manufacturers, who would thenceforth be permitted "a limited amount of testing so that generic

[4] This purpose was expressly recognized by the Federal Circuit in the decision below. *See Integra Lifesciences,* 2003 U.S. App. LEXIS at *10, *citing Eli Lilly*, 496 U.S. at 669-70.

manufacturers can establish the bioequivalency of a generic substitute." H.R. Rep. No. 98-857, 98th Cong., 2d Sess., *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2692 (1984). The Federal Circuit recognized, and relied upon, this objective in rendering its decision below. *See Integra Lifesciences*, 2003 U.S. App. LEXIS at *11.

There is nothing in either section 271(e) itself or in the legislative history therefor that suggests an intent on the part of Congress to exempt from an infringement charge general research. To expand the scope of section 271(e)(1) in a manner so as to include such research "would not confine the scope of § 271(e)(1) to *de minimis* encroachment on the rights of the patentee." *Id.* at 18.

On the other hand, the Petitioner, and *Amici* the United States, AARP, and Wyeth, attempt to focus attention on the distinction between pioneer drugs, which require preclinical trials, and generic drugs, which do not, as somehow being the lynchpin of the Federal Circuit's opinion below. The Federal Circuit, of course, made no such bright line distinction in determining the proper scope of the safe harbor of section 271(e)(1). Rather, the Federal Circuit looked at whether the type of research at issue below was "solely . . . reasonably related to the development and submission of information' to the FDA," and whether exempting such research from an infringement charge would have more than a *de minimis* effect on the patentee's rights. *Integra Lifesciences*, 2003 U.S. App. LEXIS at *18.

Nowhere did the Federal Circuit rule that pioneer drug testing is always excluded. In fact, as *Amicus* the United States notes, "the court of appeals issued an '*errata*' sheet indicating that 'the scope of the safe harbor is not limited to generic drug approval'." United States Brief at 12, *citing* Pet. App. 36a.

Rather, the Federal Circuit's inquiry, as it should have been, is whether the research in question, irrespective of whether such research pertains to pioneer or generic drugs is solely reasonably related to the development and submission of information to the FDA.

Indeed, as *Amicus* the United States acknowledges:

> To be sure, not all research that occurs before the commencement of the clinical phase will necessarily fall within the FDA exemption . . . the initial stages of basic exploratory research may not be covered by section 271(e)(1).

United States Brief at 13.

Further, as *Amicus* Wyeth notes, "the FDA requires certain preclinical tests to be conducted in accordance with the FDA's Good Laboratory Practice regulations, which are designed to ensure the quality of the studies that form the basis for the application." Wyeth Brief at 9. These Good Laboratory Practices require, *inter alia*: an FDA inspection (21 C.F.R. § 58.15(a)); particular training and experience levels for laboratory personnel (21 C.F.R. § 58.29); a quality assurance unit (21 C.F.R. § 58.35); animal care and supply facilities (21 C.F.R. §§ 58.43 & 58.45); and many more specific requirements regarding equipment, facilities, and procedures (*see generally* 21 C.F.R. Part 58).

The record below shows that the 1995 agreement between the Petitioner and Scripps imposed the requirement of assuring Good Laboratory Practices on Scripps. *See* Petitioner Br. at 14. However, the Petitioner is seeking a safe harbor under section 271(e)(1) for experiments conducted before the 1995 agreement, as well as after. Petitioner Br. at 11-12. In

any event, and at the very least, an accused infringer seeking safe harbor for preclinical testing under section 271(e)(1) should be required to make at least a showing that all of the experiments for which safe harbor is sought were conducted according to Good Laboratory Practices, as required by the FDA.

On a related issue, the Petitioner submits that the court below correctly observed that "'all the research conducted under the Scripps-Merck [1995] agreement' was 'pre-clinical research'." Petitioner Br. at 37. However, it is not clear that the Federal Circuit was using the term "pre-clinical" in the same fashion as the Petitioner, insofar as the Federal Circuit referred to a "pre-clinical" stage antibody that was the subject of a 1990 agreement, well before any "pre-clinical" (as the Petitioner uses that term) research was being conducted. *See Integra Lifesciences*, 2003 U.S. App. LEXIS at *28.

In sum, the proper question in this matter ultimately becomes whether the research in question relates solely and reasonably to the submission of information to the FDA – not whether such information pertains to pioneer versus generic drug testing. The Federal Circuit answered the proper question below in reaching its decision regarding the scope of section 271(e)(1).

B. The Word "Solely" in Section 271(e)(1) Limits the Infringement Exemption Contained Therein

Given the purpose for which section 271(e)(1) was enacted, *i.e.*, to allow a patentee's competitors to position themselves to enter the market upon the expiration of a patent, it is not surprising that the word "solely" appears therein. Exempting otherwise infringing acts that are *solely* for uses

reasonably related to the development and submission of regulatory information serves the purpose behind the enactment of section 271(e)(1). Exempting acts committed for other purposes would not.

The foregoing distinction based upon the inclusion of the word "solely" in the statute is meaningful especially in light of the Constitutional provision empowering Congress to enact a patent law in the first place:

> The Congress shall have Power . . . [t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

U.S. Const., art. I, § 8, cl. 8.

The more one limits the patent rights conferred by Congress, the less one promotes the progress of science -- thus, the inclusion of the word "solely" in section 271(e)(1). Indeed, Congress intended that section 271(e)(1) only work "a *de minimis*" limitation on a patentee's rights:

> The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.

H.R. Rep. No. 98-857, 98th Cong., 2d Sess. (1984), *reprinted in* 1984 U.S. Code Cong. & Admin. News 2647, 2692. *See also id.* at 2714 ("the nature of the interference is *de minimus* [*sic*]").

As noted above, section 271(e)(1) was enacted to rectify a patent term distortion that was exacerbated in the Federal

Circuit's decision in *Roche*. This Court has characterized the holding in *Roche* as determining that an otherwise proscribed act is still an infringement "even if it was for the *sole* purpose of conducting tests and developing information necessary to apply for regulatory approval." *Eli Lilly*, 496 U.S. at 670, *citing Roche*, 733 F.2d at 858 (emphasis added). The *Amici,* WARF, *et al.,* submit that it was more than mere coincidence that this Court opted to employ the word "sole" in pointing out the problems with the law prior to the enactment of section 271(e)(1).

This Court recognized, as did Congress, and the Federal Circuit below, that otherwise infringing acts *solely* for uses reasonably related to the development and submission of information to obtain regulatory approval are entitled to an exemption from an infringement charge. There is, however, no basis in law or policy to so exempt a broader universe of acts, including general research directed to the identification of lead compounds.

The Federal Circuit stated the issue well when it characterized the subject research work below:

> The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval. For instance, the FDA does not require information about drugs other than the compound featured in an Investigational New Drug application.

Integra Lifesciences, 2003 U.S. App. LEXIS 27796 at *15.

In addition to the Federal Circuit decision below, other lower courts have correctly focused upon the term "solely" in section 271(e)(1) to resolve questions of infringement under that provision. For example, in *American Standard, Inc. v.*

Pfizer Inc., 722 F. Supp. 86 (D. Del. 1989), the defendants exploited their infringing orthopedic products prior to the expiration of the subject patent. Although the defendants in *American Standard* argued that such exploitation was related to obtaining regulatory approval for the subject products, the Court held that the exploitation was not exempt under section 271(e), as such exploitation was not "*solely* for investigative purposes to submit information to the FDA for approval of the [subject] products." *Id.* (emphasis in original).

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, the court stated:

> The construction of § 271 (e)(1) that Genentech urges the Court to adopt would, in effect eliminate the express statutory limitation 'solely for' and hereby immunize any use of a patented invention so long as some aspect of that use is reasonably related to FDA testing. This broad construction defies the plain mandate of the statute and the intent of Congress.

Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987).

The Petitioner accuses the majority below of ignoring the language of the statute, relying upon the (allegedly contradictory) legislative history instead. *See* Petitioner Br. at 24. It is, however, the Petitioner which ignores the plain language of the statute, repeatedly omitting, both expressly and impliedly, the term "solely" therefrom.

- "Congress immunized any 'use' of a patented invention 'reasonably related to the development and submission of information under a Federal law which regulates the

manufacture, use, or sale of drugs'" (Petitioner's Br. at 28);

- "If some subset of research tool patents can be infringed freely by drug researchers, it is because the statute refers broadly to 'uses reasonably related to the development . . . of information' headed for the FDA" (Petitioner's Br. at 42);

- "It means only that the research on this structure had progressed to the point where it was reasonable to begin generating data with an eye toward the FDA approval process. That is all the FDA exemption requires" (Petitioner's Br. at 45);

- "[T]he use must be of a sort that is reasonably likely to generate data that the FDA would be interested in considering" (Petitioner's Br. at 46).

- "[T]hese experiments had to have been 'reasonably related to the development and submission of information' in connection with an IND application" (Petitioner's Br. at 49).

Clearly, this attempted distortion of the plain language of section 271(e)(1) is illegitimate. The term "solely" meaningfully and unambiguously appears in the statute for the reasons set forth above. That term cannot be ignored in the name of expanding the scope of the statute's safe harbor, as the Petitioner proposes.

Amicus Wyeth, for its part, relies upon this Court's decision in *Eli Lilly* in attempting to read the word "solely" out of section 271(e)(1). Wyeth argues that, as in *Eli Lilly*, "the *entire* FDA approval process for new drugs constitutes a

'Federal law which regulates the manufacture, use, or sale of drugs'." Wyeth Brief at 3 (emphasis in original). According to Wyeth, if medical devices are entitled to safe harbor under section 271(e)(1), then pioneer drugs should be similarly entitled. *Id.* at 1-2.

This analysis, however, misses the point. It is not the type of product that dictates whether an act is exempt from an infringement charge under section 271(e)(1), but rather the type of information being generated about that product. In *Eli Lilly*, there was no question that the subject information that formed the basis for the infringement allegation was anything other than that necessary (*i.e.* "solely") to obtain FDA marketing approval for a medical device under 21 U.S.C. § 360(e). *Eli Lilly*, 496 U.S. at 663. The decision in *Eli Lilly* simply cannot be used to expand the scope of section 271(e)(1) as Wyeth contends.

The Federal Circuit correctly noted that, given the inclusion of the term "solely," "[t]he exemption cannot extend at all beyond uses with the reasonable relationship specified in § 271(e)(1)." *Integra Lifesciences*, 2003 U.S. App. LEXIS 27796 at *14.

III. Research Patents

A. Reading "Solely" Out of the Statute Would Commercially Neuter Research Patents

Congress certainly could have passed a provision including a safe harbor for *any* use of a patented invention that related in any way to developing information for submission to the FDA. Doing so, however, would have left all pharmaceutical research patents bereft of value. No research

activity that would have otherwise been an infringement of such a patent would have been actionable, as any research activity relates, at least in some remote fashion, to the submission of information to the FDA for approval. Congress, of course, opted not to adopt such a provision, electing rather to adopt the narrower language of section 271(e)(1) containing the word "solely" therein.

Although not an issue with regard to the patents in suit below, a statutory construction that reads the word "solely" out of section 271(e)(1) would effectively neuter all research patents issued in the United States in the afore-described way. Such a construction would be inconsistent with the plain language of section 271(e)(1), as well as the Constitutional authority behind the enactment of the Patent Statute, and would violate the intent of Congress that any effect on the rights of patentees resulting from the enactment of section 271(e)(1) be *de minimis*.

The Federal Circuit put it most persuasively in its opinion below:

> Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions. Needless to say, the 1984 Act was meant to reverse the effects of Roche under limited circumstances, not to deprive entire categories of inventions of patent protection.

Integra Lifesciences, 2003 U.S. App. LEXIS 27796 at *18-19.

The risk to pharmaceutical research patents in the event the scope of section 271(e)(1) is judicially expanded is empirically shown in *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.* In that case, the defendant used patented intermediate products to run "hundreds of experiments for purposes of identifying a drug candidate." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*2001 U.S. Dist. LEXIS 19361 (S.D.N.Y. Nov. 27, 2001) at *14. The types of experiments in which the patented intermediates were used took place very early in the drug discovery and development process. *Id.* at *15-16. Nonetheless, the court in *Bristol-Myers* held that the subject research was entitled to the infringement exemption under section 271(e)(1). *Id.* at *19-20.

In ruling the way it did, the court in *Bristol-Myers* focused upon "the likelihood of the information generated being relevant to information sought by the FDA, not the likelihood of submission of the new product to the FDA." *Id.* at *25. In other words, according to this reasoning, otherwise infringing preliminary research in which thousands of compounds are screened would be entirely immune under section 271(e)(1) if the type of information generated from such research would be submitted to the FDA if a promising drug product is ultimately identified. This exemption would apply, according to the court in *Bristol-Myers*, whether such a drug product is identified or not.

In the event that the safe harbor of section 271(e)(1) is unduly expanded, decisions such as that in *Bristol-Myers* will become commonplace, whittling away at the value of pharmaceutical research patents until nothing is left. The Federal Circuit recognized the value that such patents bring in terms of the discovery of new drugs, an issue in which the Petitioner purports to be deeply concerned -- "[a]fter all, patented tools often facilitate general research to identify

candidate drugs, as well as downstream safety-related experiments on those new drugs." *Integra Lifesciences*, 2003 U.S. App. LEXIS at *18-19. Expanding section 271(e)(1) to exempt general pharmaceutical research would completely vitiate this value.

The Petitioner, in attempting to deflect the issue regarding pharmaceutical research tool patents, argues that the inventions of such patents could be used "in any context, not just drug research," thereby preserving at least a portion of the value of such patents. *See* Petitioner Br. at 41. *See also* United States Br. at 30. One of the very examples cited by the Petitioner – patents directed to a "special assay for screening compounds on the basis of certain properties" - belies this statement, however. *See id.* In other words, there would be *no* use other than drug research for such patents.[5] Should the safe harbor of section 271(e)(1) be expanded to include general pharmaceutical research, it is inconceivable that such research patents will have any value left.[6]

Finally, the Petitioner hypothesizes that, notwithstanding any expansion here of the section 271(e)(1) safe harbor, lower courts in the future may very well create judicial exceptions to the safe harbor for drug research patents.

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[5] *Amicus*, the United States urges that drug screening should be covered by the section 271(e)(1) safe harbor. United States Br. at 18.

[6] Indeed, the safe harbor expansion sought is not as limited as the Petitioner would have the Court believe. On one occasion, the Petitioner goes so far as to say that "[e]xtending the exemption beyond the clinical phase – to cover preclinical research, *or even a few steps before* – is not tantamount to insulating all drug research from the patent laws." Petitioner Br. at 37 (emphasis added). One is left to wonder what those "few steps before" preclinical research are intended to entail.

Petitioner Br. at 43. This, of course, is pure conjecture. The more likely outcome is that any expansion of the safe harbor by this Court will be read by the courts below as pertaining to all categories of patents, including drug research patents. At the very least, it will be difficult, if not impossible, to draw the bright line that the Petitioner suggests. The end result is that there will be little, if any, value left to such patents.[7]

B. Neutering Research Patents Would Have the Effect of Thwarting the Purposes of the Bayh-Dole Act and the Attendant Research that the Act Promotes

The ability of universities to obtain intellectual property protection for, *inter alia*, the research that they perform was a primary aim of the Bayh-Dole Act. The following is the National Institutes of Heath's description of the Act, and the rights and obligations that the Act confers:

> The Bayh-Dole Act . . . provides the statutory basis and framework for federal technology transfer activities, including the patenting and licensing of federally funded inventions by recipient organizations. The Act permits recipients of federal grants and contracts to elect title to patentable 'subject inventions' that arise with the use of federal funds. If recipients elect title, the Act *requires* them to file patent applications, seek commercialization opportunities, and report back to the funding agency on efforts to obtain utilization of their inventions.

Report of the National Institutes of Health (NIH) Working

[7] Even *Amicus* the United States is forced to concede that "the impact of the court of appeals' holding on research tools is unclear." United States Br. at 30.

Group on Research Tools, Appendix B (Definitions Related to Technology Transfer and Research Tools) (June 4, 1998) (emphasis added).

This characterization of the Bayh-Dole Act was echoed by the Council on Governmental Relations:

> [U]nder the Bayh-Dole Act, universities have a mandate to ensure, to the extent possible, that inventions arising from federally funded research are commercialized. It is an obligation they have increasingly embraced since 1980 when the law was enacted.

Council on Governmental Relations, *Technology Transfer in U.S. Research Universities: Dispelling Common Myths* (March 2000) at 1.

One of the co-sponsors of the Bayh-Dole Act, Senator Birch Bayh, described the Act as being "a step in the direction of encouraging innovation and productivity in the United States." Bayh, B., *Plenary Session: Celebrating 30 Years of AUTM and the Bayh-Dole Act*, Recollections: Celebrating the History of AUTM and the Legacy of Bayh-Dole (2004) at 7. Further, university investigators "understand that the act provides them the possibility of their advancing mankind, as Pasteur did, which explains their growing enthusiasm to participate." Latker, N.J., *The Evolution of Modern Technology Transfer*, Recollections: Celebrating the History of AUTM and the Legacy of Bayh-Dole (2004) at 19.

Diminishing or eliminating the value of research patents owned by universities and university-related research institutions via the section 271(e)(1) safe harbor would thwart the afore-described aims of the Bayh-Dole Act, leaving

universities without an effective means of protecting technology generated from their research efforts through the patent laws, and substantially hindering their ability to commercialize the results of such research.

In pursuing patent protection, universities also ensure dissemination of the technology resulting from their basic research activities. Universities, such as the *Amici*, "develop the cutting-edge tools that permit this research." Warburg, R.J., *et al.*, *Warning: Research Dollars at Risk!*, 26 Legal Times IP Magazine (March 24, 2003). Patent protection for such research tools ensures the benefits derived by the developers of such tools. *Id.*

On the other hand, dissemination of technology is not a given for the private sector, which may very well opt for trade secret protection, thereby curtailing knowledge of scientific advances, as well as the opportunity to build upon information developed and disclosed via the patent system. An overextended safe harbor as applied to research patents may encourage more universities to protect technology as trade secrets, licensing the technology as such, thereby resulting in a similar, corresponding reduction in the dissemination of scientific information.

Also of importance to the university sector is the protection of researchers' rights to publish the results of their research, as advancement in academics is generally dependent upon such publication.[8] Effective patent protection ensures the continued ability to publish, and share with the public, such

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[8] By way of example, according to the Association of University Technology Managers ("AUTM"), U.S. universities and research institutes filed more than 7,900 new U.S. patent applications and received more than 3,900 new U.S. patents in 2003. AUTM Licensing Survey: FY 2003 Interim Report (2004) at 4.

results, while ensuring that a goal of the Bayh-Dole Act, *i.e.*, the commercial viability of such research, is met.

The proposed expansion of the safe harbor risks contravening express Congressional language and intent that section 271(e)(1) interfere only nominally with the rights of the patent holder. Should the afore-described devaluation of drug research patents result from the urged expansion of the section 271(e)(1) safe harbor, the result would be the impairment of the drug discovery process, as well as the frustration of the purpose of another section of the Patent Act, the Bayh-Dole Act.

Established rules of statutory construction are entirely consistent with a holistic approach, wherein the entirety of a statute is to be consulted to determine the proper construction of any one part thereof. From its earliest cases, this Court has followed the "whole act" rule in construing statutory provisions. *See, e.g., United States v. Fisher*, 6 U.S. (2 Cranch) 358, 386 (1805); and *Priestman v. United States*, 4 U.S. (Dall.) 29 (1800) (*per curiam*).

As this Court observed in *United Savings Association of Texas v. Timbers of Inwood Forest Associates, Ltd.*:

> Statutory construction, however, is a holistic endeavor. A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme -- because the same terminology is used elsewhere in a context that makes its meaning clear, see, *e. g.*, *Sorenson* v. *Secretary of Treasury*, 475 U.S. 851, 860 (1986), or because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law, see, *e. g., Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 54 (1987); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412

U.S. 609, 631-632 (1973); *Jarecki* v. *G. D. Searle & Co.*, 367 U.S. 303, 307-308 (1961).

United Savings Association of Texas v. Timbers of Inwood Forest Associates, Ltd., 484 U.S. 365, 371 (1988).

Application of the plain meaning of the statute, coupled with the "whole act" rule, counsel against the proposed broadening of the safe harbor of section 271(e)(1).

C. Neutering the Value of Pharmaceutical Research Patents Would Violate the Obligations Imposed on the United States Under TRIPS

The United States is a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) ("TRIPS Agreement"). Pursuant to the TRIPS Agreement:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

TRIPS, Art. 27(1).

It is true that, pursuant to Article 27(3)(a) of TRIPS, a member state can exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." However, once a member nation has determined to provide patent protection for a particular class of inventions, a patent owner is to have the exclusive right to prevent others

from making, using, offering for sale, selling, or importing the patent subject matter. TRIPS, Art. 28.

A member state provide for:

> [L]imited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

TRIPS, Art. 30.

No less an authority than the United States Constitution provides that treaties made under the authority of the United States, such as TRIPS, "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, § 2, cl. 2. Any judicial expansion of the section 271(e)(1) safe harbor that would, in essence, strip pharmaceutical research patents of their value, would violate the United States' obligations under TRIPS, and should, therefore, be resisted.

CONCLUSION

For the foregoing reasons, this Court should affirm the decision of the Federal Circuit that general research is not exempt from an infringement charge under section 271(e)(1).

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APPENDIX

The American Council On Education ("ACE"), founded in 1918, is a nation's coordinating higher education association. ACE is dedicated to the belief that equal educational opportunity and a strong higher education system are essential cornerstones of a democratic society. ACE's 1,800 members include accredited, degree-granting colleges and universities from all sectors of higher education and other education and education-related organizations. ACE is a forum for the discussion of major issues related to higher education and its potential to contribute to the quality of American life. The American Counsel on Education represents regularly before the United States Supreme Court, other federal courts, Congress, and federal agencies.

Boston University is the fourth-largest independent university in the United States, with an enrollment of more than 29,000 students in its 17 schools and colleges. The University offers an exceptional grounding in the liberal arts, a broad range of programs in the arts, sciences, engineering, and professional areas, and state-of-the-art facilities for teaching and research. The University has been a leader in technology transfer and commercialization. The Technology Development Fund was established in 1975, making it the oldest continuously operating university-linked venture capital fund in the US. Its Office of Technology Fund was established in 1976. The University has two incubators, two applied research centers and a research park.

The Regents of the University of California provides for technology transfer from ten campuses and five medical schools in the State, and three national laboratories operated by the University system on behalf of the U.S. Department of Energy. Currently, there are more than 3,000 ongoing research projects supervised by 13,000 principal investigators. These efforts in the last ten years have led to three Nobel laureates in

a long list of pioneering research discoveries in biochemistry, bioengineering, cell biology, disease procedures, developmental biology, endocrinology, genetics, immunology, neurobiology, oral biology, pharmacy, and pharmacology. Examples of specific discoveries include: the Cohen Boyer process for gene splicing (a co-invention of Stanford University and the University of California San Francisco ("UCSF"); the Hepatitis B vaccine (UCSF); a human growth hormone; and a method to treat aneurysms by use of a catheter instead of opening the skull (UCLA). UCSF also has contributed to cochlear implants to help the hearing impaired. UC Davis has contributed to a method detecting feline immune deficiency virus. Lawrence Livermore National Laboratory has contributed to a method for detecting chromosome abnormalities, now successfully commercialized through FDA approvals to a company dedicated to the technology. UC Irvine has contributed to a laser system to enhance treatment of skin conditions. UC Riverside has contributed to a new phosphorus fertilizer. UC Berkeley and UC San Diego have contributed to fluorescence detection systems used in manipulation of cells. UC Santa Barbara has contributed to a new atomic force microscope.

Research Corporation Technologies is an independent technology management company that provides commercialization services to academia and industry and has been pivotal in the success of many important pharmaceuticals, diagnostics, biotechnology products, new materials and processes.

The Salk Institute for Biological Studies is an independent, nonprofit organization whose scientists carry out biological research. The Institute transfers its early stage patent protected technology to the private sector where it is developed into products that improve human health. Maintaining the

scope and breath of patent protection under U.S. patent law is essential for involving private sector development.

University of Alberta in Calgary, Alberta, is one of the major research institutions in Canada. Through its Technology Transfer Program, run by TEC Edmonton, the University of Alberta helps researchers bring inventions, innovations and processes to the marketplace, through support for market research, technology evaluation, protection of intellectual property, technology marketing, and the building of strategic relationships with industry. The University of Alberta holds more than 130 United States patents.

University of Oklahoma, through its Office of Technology Development (OTD), stimulates the creation of intellectual property and manages the resulting assets in support of the University's mission. The University of Oklahoma owns over 170 United States patents, a number of which have research applications.

Wisconsin Alumni Research Foundation ("WARF") was established as a non-profit entity to promote, encourage, and aid scientific investigation and research at the University of Wisconsin-Madison. To achieve this goal, its primary activities include promoting innovation, managing patents, and funding research. Founded in 1925, among its first actions was to patent Professor Harry Steenback's breakthrough discoveries in vitamin D. In 1927, WARF granted its first license for vitamin D supplements, which ultimately led to the worldwide elimination of rickets by the 1940's. Today, among WARF's most important patents are: the blood anticoagulant Warfarin; a coding process making pills easier to swallow; treatments for osteoporosis and cancer; magnetic resonance techniques; and a discovery known as the "Wisconsin Solution" that prolongs the use of transplant organs. All of WARF's 3,000 discoveries are

administered with a commitment to continuing research, public education, and vigilance in protecting the public interest by enforcing quality control and preventing the unscrupulous exploitation of technologies.