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.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR INVITROGEN CORPORATION, ANALYTICAL & LIFE SCIENCE SYSTEMS ASSOCIATION, BIOCOM, AFFYMETRIX, INC., DIVERSA CORPORATION, QUANTUM DOT CORPORATION, SANGAMO BIOSCIENCES, INC., AND SYMYX TECHNOLOGIES, INC. AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Invitrogen Corporation sells research tool products and services to pharmaceutical and other commercial companies as well as to academic and government life science researchers. Invitrogen's 1500-page annual catalog offers inventors in the life sciences research community more than 10,000 tool products, based on well over 400 patents,[2] for use in the search for new disease treatments. Invitrogen's life science technologies improve and accelerate all areas of research, drug discovery, and commercial bioproduction.

The *Analytical & Life Science Systems Association (ALSSA)* is the primary industry trade association for companies that develop, manufacture, and market instrumentation, chemical reagents, consumables, software and services used for analysis and measurement in life science and chemistry applications. ALSSA members' products, services, and technologies are the tools that enable science and life science research by industrial, academic, and government institutions. These products, services, and technologies are an integral part of and essential to drug discovery and development. ALSSA's 81 members include both large and small companies: 14 companies report annual revenues in excess of $300 million; 29 report sales less than $10 million; and 12 report less than $1 million in annual revenues

BIOCOM, with 400 members, is the second largest life sciences association in the United States. BIOCOM members include industrial companies pioneering new biomedical

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[1] Letters from the parties consenting to the filing of this brief have been filed with the Clerk of this Court pursuant to Supreme Court Rule 37.3(a). No counsel for a party authored this brief in whole or in part, and no person or entity, other than the *amici curiae*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

[2] Invitrogen has a sublicense to peptides of the type involved in this case, but it has not exercised any rights in conjunction with those peptides and it has never been a party to this litigation.

technologies and diagnostics; the world's most successful pharmaceutical companies; top research and academic institutions; and leading service providers in the areas of intellectual property, workforce development, marketing, information technology, clinical and regulatory management, facility/environmental engineering, finance, etc. Since 1995 the organization has proactively addressed significant business and legislative issues, and developed programs and products to help biomedical companies operate efficiently and economically.

Affymetrix, Inc., is a pioneer in DNA microarrays, manufacturing these research tools with a patented photolithographic and combinatorial synthesis technology. DNA microarrays have revolutionized many areas of genetic science, including drug discovery. When Affymetrix started offering commercial DNA microarrays for sale in the mid-1990's, there was virtually no commercial market for these tools. Today, the market for microarrays and related technology is approaching a billion dollars in annual revenue. Affymetrix owns more than 300 United States issued patents. Researchers have published more than 3,000 articles in peer-reviewed journals based on Affymetrix's GeneChip® probe array technology.

Diversa Corporation is a leader in applying proprietary genomic technologies for the rapid discovery and optimization of novel protein-based products. Diversa has established alliances and joint ventures with market leaders, such as Bayer Animal Health, DuPont Bio-Based Materials, GlaxoSmithKline, Medarex, Merck, and Xoma. In addition, Diversa has formed a broad strategic relationship with Syngenta AG, a world-leading agribusiness company. Diversa has commercialized products both independently and in collaboration with strategic partners and licensees.

Quantum Dot Corporation (QDC) is a privately held bioscience company that pioneered the development and commercialization of Qdot® nanocrystals for bio-detection in discovery and clinical applications. QDC's current products include life-science kits and applications used by academic and pharmaceutical-discovery laboratories

worldwide. In addition, QDC recently launched its first integrated instrumentation, software, and bio-reagents platform, the Mosaic™ System, for rapid and quantitative multiplexed gene expression analysis. QDC collaborates with leading academic and industrial partners and has more than 150 patents and patents-pending.

Sangamo BioSciences, Inc. makes and sells genetically engineered DNA-binding proteins, known as zinc finger proteins, that control gene expression and cell function. Regulation of gene expression with Sangamo's engineered zinc finger proteins can be used for identification of genes as potential therapeutic targets, screening of potential therapeutic agents, and production of therapeutic proteins.

Symyx Technologies, Inc. is the pioneer of high-throughput experimentation for the discovery of materials, with proprietary technologies – including instrumentation, software and methods – to research and develop materials hundreds to thousands of times faster than traditional research methods, at a fraction of the cost. As the pioneer of the field, Symyx has built a broad intellectual property portfolio protecting its research methodology, discovered materials, research instruments, and software, including more than 230 issued patents and more than 400 patent applications pending worldwide.

SUMMARY OF ARGUMENT

A ruling by this Court that the exemption from infringement in 35 U.S.C. § 271(e)(1) extends to patented research tools would have a serious adverse impact on the discovery and development of the very life-saving drugs on which petitioner and its *amici* focus.

Research tools enable new biological understanding, facilitate new drug discoveries and development, and make it possible for researchers to work more quickly, more efficiently, and less expensively. If patents on such tools can be readily infringed in the course of developing information for submission to the Food and Drug Administration (FDA), the economic value of the patents will be essentially lost and the incentives crucial to support

creation of new and better tools in the future will be slowed, if not completely eliminated, along with the related discoveries, efficiencies, and cost-savings. Thus, extension of Section 271(e)(1) to research tools would hinder drug research and development.

A. Section 271(e)(1) does not allow companies who are developing new drugs for approval by the FDA to infringe the patents on the research tools that they use every day and in all phases of their work. Petitioner and the Solicitor General as *amicus* do not argue to the contrary. Both identify compelling evidence that Section 271(e)(1) does not apply to patented research tools based on the statute's text and structure. They both also indicate, however, that the Court should reverse the judgment without reaching the research tool question in this case. But such action could be interpreted as a ruling that Section 271(e)(1) does apply to research tools because the court below ruled that the patented inventions at issue in this case were used as research tools. Petitioner's *amici* would invoke such a ruling as permission to infringe every research tool patent. Thus, the judgment should be affirmed because Section 271(e)(1) does not apply to patented research tools and petitioner did not seek review of the court of appeals' ruling that the patented inventions were used as research tools.

Application of Section 271(e)(1) to patented research tools would have grave consequences for scientific progress, particularly in drug research and development. Unlike the FDA-approved drugs and medical devices covered by Section 271(e)(1) which ultimately are sold more generally to the public, research tools typically are used only by researchers, drug developers, and the like. Therefore, tool patents would lose essentially all economic value if their infringement is allowed during drug research and development. There would no longer be an economic incentive for tool patent owners to continue to make their tools widely available for use in research and development. Rather, new tools would either be kept as trade secrets or their development would be slowed significantly.

Petitioner and its *amici* attempt to justify an unduly expansive reading of Section 271(e)(1) that would sweep

in research tools by asserting a general right to infringe any patent in order to develop new drugs to save lives. But Congress expressly addressed in another statute, 28 U.S.C. § 1498, the concern that patent rights could foreclose crucial research and development. Congress authorized the United States to use and manufacture any federally registered patented invention, regardless of the patent owner's consent, subject only to payment of the "reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498(a); *see also* 35 U.S.C. §§ 202(c)(4), 203(a) (regarding federally funded inventions). That authority safeguards national concerns while also maintaining the economic incentive for invention.

Petitioner plainly describes research tools as a "category of invention[s]" that "assist a scientist in conducting research," Pet. Br. 41, which is consistent with definitions set forth by the Solicitor General, the National Institutes of Health, and the Federal Trade Commission. Although some patented inventions can have both tool and non-tool uses, it is rarely difficult to distinguish between the two. In a close case, the question whether an invention is being used as a tool to conduct research is one for the jury, which in this case determined that petitioner's conduct did not fall within the scope of Section 271(e)(1).

B. Patented research tools do not fall within the scope of Section 271(e)(1) because they are not "patented inventions" within the meaning of Section 271(e)(1), as indicated by the text and structure of the statute. *See Rowland v. California Men's Colony*, 506 U.S. 194 (1993). This Court has held that Section 271(e)(1) and the simultaneously enacted Section 156 were intended "generally to be complementary" and both address unique problems caused by delay in the federal premarket regulatory approval process. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673 (1990). Research tools do not undergo that premarket approval process, however, and therefore interpreting Section 271(e)(1) to apply to research tools "would not address the problem Congress sought to solve," as the Solicitor General recognizes. U.S. Br. 29. Indeed, it

would substantially frustrate the purpose of Congress to ensure the continued development of new drugs for treatment of human disease. It also would undermine Congress's intent to minimize the taking of the economic value of patents.

ARGUMENT

A. A RULING THAT SECTION 271(e)(1) EXTENDS TO PATENTED RESEARCH TOOLS, A POSITION ON WHICH BOTH PETITIONER AND THE UNITED STATES CAST SIGNIFICANT DOUBT, WOULD UNDERMINE INVENTION OF NEW TOOLS AND DELAY OR PREVENT DISCOVERY OF NEW LIFE-SAVING DRUGS

Patented research tools, as petitioner explains, are a "category of invention[s]" that "assist a scientist in conducting research." Pet. Br. 41. They include a wide range of "devices, substances, or processes that are used to study other substances, in order to generate information about those other substances." U.S. Br. 28 (citing 64 Fed. Reg. 72,092 n.1). Research tools are of everyday importance to researchers and drug developers, as petitioner acknowledges, and consist of tools such as "a centrifuge, a dripless pipette, a cell line, or a special assay for screening compounds on the basis of certain properties." Pet. Br. 41 (citing National Institutes of Health, *Report of the NIH Working Group on Research Tools* 3 (June 4, 1998), *available at* http://www.nih.gov/news/researchtools (defining research tools to include "laboratory equipment and machines," "cell lines, monoclonal antibodies, reagents, animal models")).

The text and structure of Section 271(e)(1) demonstrate that it does not allow companies that are developing new drugs for approval by the Food and Drug Administration to infringe the patents on such research tools, as explained in detail in Part B below. *See* pages 23-29, *infra*. For the following reasons, a contrary ruling by this Court would devastate the Nation's research tool industry and

the work based thereon, including the development of the very life-saving drugs on which petitioner and its *amici* focus.

1. Petitioner And The Solicitor General Appropriately Decline To Argue That Section 271(e)(1) Applies To Patented Research Tools

a. Petitioner acknowledges that "it is not at all clear" that use of a research tool would be covered by the Section 271(e)(1) exemption. Pet. Br. 43. Also, the Solicitor General expressly recognizes that "[t]he context of Section 271(e)(1) suggests that Congress may not have intended to include research tools within the scope of affected inventions" under Section 271(e)(1). U.S. Br. 29. Petitioner and the Solicitor General both identify compelling evidence to support the view that Section 271(e)(1) does not apply to patented research tools.[3]

Petitioner points out that, in the past 20 years since enactment of Section 271(e)(1), "only one reported case has emerged in which a drug innovator invoked the [Section 271(e)(1)] exemption to claim the right to infringe a patent that could even arguably be called a research tool patent." Pet. Br. 42-43 (citing *Bristol-Meyers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 WL 1512597, at *6 (S.D.N.Y. Nov. 28, 2001)). The absence of litigation in which Section 271(e)(1) has been invoked to defend against infringement claims on research tools is consistent with the longstanding and common understanding among members of the patent and scientific communities, including pharmaceutical companies, that Section 271(e)(1) does not authorize infringing uses of patented research tools. If there had been a contrary view of Section 271(e)(1), there undoubtedly would have been such arguments pressed in defense

[3] Several *amici* specifically recognize that research tools are not covered by Section 271(e)(1). A few of petitioner's other *amici*, however, attempt to argue that such tools are covered but provide no sound basis for that view.

against other patent infringement actions. As petitioner demonstrates, there were not. *Cf. Bank of the United States v. Deveaux*, 9 U.S. (5 Cranch) 61, 88 (1809) ("Those decisions are not cited as authority * * * but they have much weight, as they show that this point neither occurred to the bar or the bench.").

Petitioner and the Solicitor General emphasize that there are many "indication[s] that Congress did not intend to include research tools within the scope of the inventions to which Section 271(e)(1) applies." Pet. Br. 43; U.S. Br. 29-30. In addition to the statutory text and structure, *see* pages 23-29, *infra*, the fact that Section 271(e)(1) does not authorize infringing uses of patented research tools is confirmed by the robust, nationwide research tool industry. The very existence of the *amici* companies that develop, create, and sell research tools, including to biotechnology and pharmaceutical companies, attests to the widely recognized economic worth to their customers of their products and the underlying patents.

Indeed, the worldwide market for life science and analytical products and services now is estimated to be more than $26 billion. The wide range of products include DNA sequencers and synthesizers, liquid chromatograph-mass spectrometers, microarrays, consumables for gene expression and amplification, consumables for protein labeling and detection, restriction and modifying enzymes, automated liquid handling and robotic automation systems, and software for laboratory data management, to name only a few.

The major pharmaceutical companies, including petitioner's various *amici*, are all customers of the *amici* companies here or other research tool companies and regularly purchase patented research tools and pay for the right to use them in their drug research and development. Furthermore, those customers sometimes pay license fees to use patented tool technology developed by *amici* companies in order to make such tools themselves. None has suggested before that they could purchase such tools once

and then freely infringe the patents by replicating the tools in their own labs.

2. Application Of Section 271(e)(1) To Research Tools Would Devastate Future Research And Development Of New Drugs

a. The half-hearted attempts by petitioner and the Solicitor General to downplay the adverse impact that would result from a ruling that Section 271(e)(1) applies to research tools are off point. The fact is that reading Section 271(e)(1) to permit infringement of research tool patents – or even creating doubt about whether such patents are within the Section 271(e)(1) exemption – would devastate the multi-billion dollar industry devoted to the invention and distribution of such tools, thereby undermining the discoveries and efficiencies in drug research and development that regularly result from invention of new and better research tools.

Modern efforts to create and test new drugs require increasingly complex research tools to identify drug candidates, drug targets, and to allow more reliable and accurate testing procedures. For example, the patented and broadly licensed Cohen-Boyer tool for recombinant DNA, which offered a way to reproduce a desired gene in unlimited quantities, provided "the basis for the creation of the biotechnology industry as we know it." John P. Walsh et al., *Research Tool Patenting and Licensing and Biomedical Innovation*, in *Patents in the Knowledge-Based Economy* 285, 305 (Wesley M. Cohen & Stephen A. Merrill eds., 2004).

Pharmaceutical companies themselves have acknowledged that "new research tools" offer "the greatest potential" for "transform[ing] all areas of pharmaceutical R&D," and specifically are useful to "identify previously undiscovered genes that trigger the production of natural proteins in the body involved in major diseases" which "sometimes prove to be outstanding biotech drug candidates," either in their natural version or modified. Eli Lilly and Company, *Straight Talk: 2000 Annual Report* 3 (2001); *see also Abbott Laboratories: Companies Recognized for*

Invention of Innovative Drug Discovery Tool, Biotech Week, Nov. 20, 2002, at 13 (Abbott Laboratory employees explain that invention of a robotic system for automated pharmaceutical drug sample handling "has enabled [Abbott] to understand the structure of more than 500-drug protein complexes [in 2001] alone, which is 20 times more than just 5 years ago. More importantly, this advance has guided the discovery of many promising drug candidates."); *see generally* Stephen H. Friend & Roland B. Stoughton, *The Magic of Microarrays*, 286 Sci. Am. 44, 46 (Feb. 2002) ("DNA microarrays, first introduced commercially in 1996, are now mainstays of drug discovery research, and * * * promise * * * to pave the way for faster, more accurate diagnoses of many conditions and help doctors personalize medical care").

Research tools also permit researchers to work more efficiently. For example, thanks to the invention of DNA microarrays, such as those made by *amicus* Affymetrix, "what used to take a post-doc[toral student] in the laboratory approximately six months with proper front-end research can now be done in 20 minutes." Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Ch. 3 at 19-20 (Oct. 2003). Or consider, for example, the patented research tool sold by *amicus* Invitrogen that is a high-density microarray which helps a researcher determine how proteins interact with each other and, thus, learn how to develop more effective drugs. It used to be that only two proteins could be tested at a time. With this newly invented protein array technology, however, the interactions of more than 1800 human proteins can be tested simultaneously, allowing results to be obtained in as little as four hours rather than in a matter of weeks as would previously have been required.

Current research and development of high throughput automation in the laboratory will enable the next generation of drug discovery labs. Research tools are the engine for drug discovery; absent innovation in tools, the rate of discovery will not accelerate. *See* Tim Chapman, *Drug Discovery: The Leading Edge*, 430 Nature 109, 109 (July 1, 2004) (automation and miniaturization have "revolutionized the process of

drug discovery" by allowing "companies to screen hundreds of thousands of compounds against disease targets"); *id.* at 111, 113 (describing computer system designed to analyze screening results that will allow Pfizer to reduce "the time taken to go from initial screening to preclinical drug candidate * * * to 9-18 months from an industry standard of 2½-3 years").

Improved efficiencies resulting from new and improved research tools lead directly to lower costs and time-savings at every stage of the drug discovery process, which are economically valued by the industry. *See* Walsh, *supra*, at 301 (survey respondents believe costs of research tools "to be within reason largely because the productivity gains conferred by the licensed research tools were thought to be worth the price"); Joseph A. Dimasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 181 (2003) (noting that costs of "discovery and preclinical development" were growing, "but much more slowly than in the past," and hypothesizing that "[t]he widespread use of discovery technologies, such as combinatorial chemistry techniques and high-throughput screenings * * * may have created enough efficiency gains to slow down the * * * costs").

b. The patent system, as it presently operates, provides the incentive necessary to fuel the development of innovative and beneficial research tools by granting an inventor the exclusive right to control the use of his invention for a limited time. Patent law's basic premise is reflected in the text of the Constitution's grant of authority to Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries." Art. I, § 8, cl. 8. It is through the patent system that an inventor discloses to the public the means for replicating his new invention so that it becomes usable for the public good and available to others who seek to improve upon it, subject only to allowing the inventor to gain exclusive economic benefit from it for a limited time period. As the major pharmaceutical manufacturers have explained, "[t]he patent incentives ensconced in the U.S.

Constitution and specified by Congress encourage the development of new medicines by attempting to provide a level of certainty to inventors." Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2004* at 29 (2004). That same incentive applies equally to research tools.

Application of Section 271(e)(1) to patented research tools would have grave consequences for progress in research and development generally and particularly in the drug research field. Unlike patented inventions such as drugs that may have therapeutic uses for patients and are ultimately sold as such to the general population, there typically is no market for patented research tools other than researchers, drug developers and the like. Therefore, if Section 271(e)(1) were extended to allow such users to infringe research tool patents, the economic value of the patents would be essentially eliminated.

Interpreting Section 271(e)(1) to authorize infringement of research tool patents, as some of petitioner's *amici* urge, is shortsighted because it would mean a one-time giveaway of drug discovery and development technology to the pharmaceutical industry, only to remove the incentive to develop the next generation of drug research tools. Investment in research tools results, in large part, from the willingness of investors to contribute capital to research tool inventors based on the value of the patents they can obtain. FTC, *supra*, Ch. 2 at 1 ("Biotechnology start-ups rely on their ability to patent their innovations to attract investment and continue innovating.").

Without patent protection, capital markets would not invest in innovative small companies with groundbreaking new technology. Instead, the technology would either languish with limited capitalization from federal grants or would be developed and maintained within the confines of well-funded research organizations such as pharmaceutical companies that would have to protect their investment as a trade secret and limit its dissemination. By contrast, the patent system provides a means to encourage investment in innovative new and unproven

technologies and, when those technologies prove successful, encourages their wide commercial availability and licensing as a means of recouping that investment.

c. Patents on research tools do not impede research or development. In fact, patented research tools are widely available. When drug researchers and developers purchase a patented research tool product or service from *amici*, they typically obtain with the product the right to use the item as a research tool under a limited use license. A study funded by the National Academies concluded that "many of the more fundamental (general purpose) research tools, such as genomics databases, DNA chips, recombinant DNA technology, PCR, etc., are made widely available through nonexclusive licenses." Walsh, *supra*, at 323 (based on survey data obtained from leading pharmaceutical companies, biotechnology firms, university researchers, trade associations and government employees).

In 2003, the FTC explicitly addressed a concern voiced by some business representatives that patents on the research tools used to assist in the discovery of new drug products "could obstruct the commercialization of new products, thereby hindering follow-on innovation." FTC, *supra*, Ch. 3 at 1. The FTC found that not to be the case, explaining that the evidence presented to date "suggests that such problems have not emerged." *Ibid.*

Similarly, the study funded by the National Academies revealed that, although the "patenting of research tools has made the patent landscape more complex," "almost none of [the] respondents reported commercially or scientifically promising projects being stopped because of issues of access to IP rights to research tools." Walsh, *supra*, at 331. Other recent systemic studies have reached like conclusions. *See* National Research Council, *A Patent System for the 21st Century* 111 (Stephen A. Merrill et al. eds., 2004) ("Obtaining licenses to use such technologies may entail an immediate cost in licensing fees * * * , but being denied access to the technologies is not usually a problem because their sole or principal market is research applications."); Organisation for Economic Co-Operation

and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* 50 (2002) ("There is in fact little evidence so far of breakdowns in negotiations over IP rights or evidence that biomedical research has slowed."); *ibid* ("Most of these 'general tools' * * * are licensed broadly.").

The National Academies funded study also found that, even on those rare occasions when an owner of a particular patent may demand a price that some in the market are not willing to pay (or elects to deal exclusively with a single purchaser), such actions do not impede the development of new drugs. Walsh, *supra*, at 301. To the contrary, because of incentives for invention inherent in the patent system, the market is awash in a diversity of research tools. Each research tool is distinct, but very few, if any, are indispensable. Thus, there generally are substitutes available for most research tools currently under patent (albeit perhaps less efficient or more time-consuming) and they create the competitive market necessary to prevent inventors from demanding excessive prices.

Absent this continued wide availability of new and better research tools, however, discovery and development of many new inventions would be stymied, including new, life-saving drugs. Efficiencies also would be lost in the drug development process which would increase costs. The National Research Council has explained that the nation "should encourage, not discourage, the observance of intellectual property to promote investment in the development of new and better research tools." National Research Council, *supra*, at 111.

d. Petitioner suggests, however, that any damage from expanding Section 271(e)(1) to patented research tools is limited because, in petitioner's view, no drug researcher would manufacture his own research tools and infringe on research patents "just because he thinks the FDA exemption would let him get away with it." Pet. Br. 42. This is a remarkable assertion. First, *amici* and other research tool patent owners (as well as the investors on

whom they depend) cannot rely on the good graces of their customers to continue to purchase their research tool products and services rather than infringe their patents if the Court suggests that Section 271(e)(1) authorizes such infringement. Economic realities of business would likely require such a company to not observe patent rights. This is particularly true when the patented research tool at issue, such as biological products or processes referenced by petitioner (Pet. Br. 42), can be easily copied in a laboratory without duplication of the significant capital investment that was required to invent the patented invention in the first instance. Second, petitioner completely ignores the fact that other manufacturers would likely attempt to argue, at the behest of pharmaceutical companies, that under an expanded Section 271(e)(1) that covers research tools, they have the right to make the patented tool for resale to pharmaceutical companies. And manufacturers claiming such a right would be able to sell the tool at a cost lower than that charged by the tool patent owner who had to incur the significant expenses for the research and development of the tool.

Petitioner and the Solicitor General also suggest that there might still be some value left for some research tools even if Section 271(e)(1) applied to them, noting that some tools are useful in basic research not covered by Section 271(e)(1) and some might be difficult for others to manufacture. But they suggest no justification for the elimination of patent rights for those tools that are primarily or exclusively used in drug research and development and petitioner and various *amici* take a very expansive view of just how much research is included under Section 271(e)(1).

3. Congress Expressly Authorized, Under Other Statutes, The Use Of A Patent Without Owner Consent Where Necessary To Address National Health Concerns

Petitioner and its *amici* attempt to justify an unduly expansive reading of Section 271(e)(1) by citing a general

need to develop new drugs to save lives. A few *amici* latch onto that hyperbole to try and sweep research tools within the scope of Section 271(e)(1). The arguments on petitioner's side of the case are so broad that they would appear to allow pharmaceutical companies to infringe patents on inventions such as the computer software they use in analyzing and preparing their data for submission to the FDA, and the special copying or other equipment they use in preparing documentation to submit to the FDA. But other than their rhetoric, the *amici* present no support for their argument that Congress enacted Section 271(e)(1) to effect such a radical change in the patent system.

The doomsday scenario of the Nation's health care being imperiled by recalcitrant patent owners is without foundation and was not before Congress when it enacted Section 271(e)(1). Rather, as we discuss further in Part B, pages 23-29, *infra*, Section 271(e)(1) was enacted as a means of balancing the rights of, on the one hand, owners of patented inventions that are delayed in getting on the market because of the FDA approval process and, on the other hand, those who want to compete with the patent owners once the patents expire, but whose products are delayed in getting on the market because of the FDA approval process.

Moreover, Congress expressly addressed the issue of recalcitrant patent holders in another federal statute. Congress has vested the United States, under 28 U.S.C. § 1498, with the authority to use and manufacture any federally patented invention regardless of the patent owner's consent, and to authorize its use and manufacture by others. That national government authority is not an unlimited right to infringe the patented invention, however, as petitioner's *amici* would have this Court interpret Section 271(e)(1) to allow to private actors. The United States' use or manufacture of a patented invention without permission of the patent owner subjects it to an action for payment of the "reasonable and entire compensation for such use and manufacture." 28 U.S.C. § 1498(a).

Section 1498 thus provides the federal government with a compulsory license, in effect, to use all patents issued in the United States, contingent on being liable for payment of a reasonable royalty. That authority safeguards national concerns while, at the same time, maintaining the economic incentive for invention.

Section 1498 "has been utilized mainly for drug purchases by federal agencies" in order to ensure that the United States can obtain drugs for public health purposes at reasonable prices. Milton M. Silverman & Philip R. Lee, *Pills, Profits, and Politics* 187 (1974). For example, "[t]he Defense Supply Agency (DSA) of the Department of Defense * * * has found it necessary at times to purchase patented prescription drugs from unlicensed domestic or foreign manufacturers because the domestic patent holder's prices (and those of his licensees) were considered too high." U.S. Dep't of Health, Education & Welfare, *Background Papers of the Task Force on Prescription Drugs: The Drug Makers and The Drug Distributors* 41 (1968). Starting in the late 1950s, the United States invoked this authority to purchase and use the antibiotic tetracycline for the United States military from an overseas firm at a much lower price than it was being sold by those with the patent rights in this country, and the military "later placed purchase orders for other essential drugs with low-cost suppliers." Silverman & Lee, *supra*, at 187. Similarly, in the 1970s, the United States military made and used the tranquilizer meprobamate without the patent holder's permission. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does The Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 Berk. Tech. L.J. 853, 868 (2003). Most recently, in light of the anthrax terrorism in the fall of 2001, the United States' "threat of a compulsory license was used to drive down the price of the patented drug Cipro by almost 50%." *Ibid.*

The United States also wields a significant power over the right to use patented inventions under the Bayh-Dole Act of 1980 as a result of the large role of federal funding in research. In that statute, Congress reserved for the federal government the right to practice, or to have

practiced for it or on its behalf, any invention developed with the use of federal funds. *See* 35 U.S.C. § 202(c)(4). In addition, the Act has a mandatory licensing provision under which the federal funding agency can require the granting of a license for a federally-funded invention to third parties "upon terms that are reasonable under the circumstances" when it determines that such action is necessary "to alleviate health or safety needs," or to achieve practical application of a subject invention within a field of use. 35 U.S.C. § 203(a).

In sum, Congress specifically addressed the Nation's need to ensure that patent rights do not trump public health needs, but it did not do so in Section 271(e)(1). That purported problem should not be used to distort Section 271(e)(1) beyond its intended reach.

4. Reversal Of The Federal Circuit Would Risk Being Interpreted As A Ruling On Research Tools Because Petitioner Failed To Seek Review Of The Court Of Appeals' Ruling That The Inventions At Issue Were Used As Research Tools

Petitioner asserts that "this case does not present the research tool question" because, in petitioner's view, "the patented inventions were the subject of the research, not just a tool used to study that subject." Pet. Br. 41, 42. The Solicitor General repeats petitioner's position that the case does not involve research tools. U.S. Br. 28 n.11. They suggest that the Court could reverse the judgment below without addressing the issue.

The assertion by petitioner and the Solicitor General that the case does not involve research tools is contrary to the ruling of the court of appeals, which held that the patented peptides at issue in this case were used as research tools. Petitioner has not sought review of that ruling. As a result, this Court could decide the case without addressing the research tool question, but only if the Court affirms the court of appeals' judgment. That is because a reversal of the court of appeals' judgment to hold

that petitioner's use of the patents is covered by the Section 271(e)(1) exemption could be interpreted to suggest that research tools are covered by Section 271(e)(1).

a. The court of appeals determined that the patented peptides at issue in this case were used as research tools. It explained that "expansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents." Pet. App. 13a-14a. The court repeatedly referred to the use of the patented peptides in this case as "research tools" when discussing the challenge facing the district court on remand for calculation of damages and a reasonable royalty, noting that where "[t]he value * * * of *research tools* lies" varies depending on their use, and explaining that "a *research tool* enabling the identification of a drug candidate during high throughput screening, for instance, may supply more value to the ultimate invention than a *research tool* used to confirm an already recognized drug candidate's safety or efficacy." *Id.* at 21a (emphasis added); *see also id.* at 21a-22a (noting that, on remand, "the presence or absence of stacking royalties for *research tools* may color the character of a hypothetical negotiation [the means for calculating the royalty] between Merck and Integra for access to the RGD peptide technology").

The holding of the court of appeals that the patented peptides at issue in this case were used as research tools is confirmed by the dissent. Judge Newman observed that her "colleagues on [the] panel appear to view the Integra patents as for a 'research tool,'" and she emphasized that she viewed that as a "misdefinition." Pet. App. 35a. The panel majority responded to the dissent's assertion that patented peptides at issue "are not research tools" by quoting NIH's "research tool" definition, noting that the dissent does not explain why "certain uses" cannot "embrace use of an RGD peptide as a laboratory *tool* to facilitate the identification of a new therapeutic," and concluding that regardless of label, the points regarding the value of the patented peptides in a hypothetical negotiation are valid. *Id.* at 22a n.4 (emphasis added).

Notwithstanding the court of appeals' ruling that the patented peptides in this case were used as research tools, petitioner does not seek review of that question. Petitioner, instead, focuses on an argument regarding the temporal scope of Section 271(e)(1). But that argument cannot overcome the unchallenged holding that the patented peptides were used as research tools. Absent alteration of that ruling, the judgment of the court of appeals must stand because, as suggested by petitioner itself and the Solicitor General and as detailed further below, Section 271(e)(1) does not extend to research tools.[4]

b. Affirmance of the court of appeals' judgment is required because petitioner has not met its burden of demonstrating that the jury erred in finding that petitioner's infringing conduct fell outside the reach of Section 271(e)(1). The jury, after a full trial, entered a special verdict that petitioner did not show that its use of the patented peptides fell within the scope of Section 271(e)(1). *See* Pet. App. 10a-11a. That verdict is presumed correct and, in order to obtain a judgment as a matter of law under Federal Rule of Civil Procedure 50, petitioner bears the burden of showing that no rational jury could have reached that result. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 148 (2000); *Lavender v. Kurn*, 327 U.S. 645, 653 (1946).[5]

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[4] In *Laboratory Corp. of America v. Metabolite Laboratories, Inc.*, *petition for cert filed*, 73 U.S.L.W. 3298 (U.S. Nov. 3, 2004) (No. 04-607), the Court has invited the Solicitor General to file a brief expressing the views of the United States on whether the patent in that case is "invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas'? *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)." The validity of the patents infringed by petitioner are not challenged here and *amici* do not take a position on the applicability, if any, of this citation from *Diamond v. Diehr* to the patents at issue in this matter.

[5] The jury was not instructed to distinguish between use as a research tool and other uses in assessing petitioner's invocation of the exemption, but the content of the jury instruction is irrelevant in determining whether the jury's verdict in favor of respondents lacked sufficient support in the record to entitle petitioner to a judgment as a

(Continued on following page)

Petitioner attempts to avoid that insurmountable hurdle by focusing on the temporal reach of Section 271(e)(1) and the record evidence on that point. Pet. Br. 28-32, 43-50. But that issue is irrelevant because the jury's verdict can be sustained on the ground that petitioner has not established that the evidence introduced at trial, when viewed in the light most favorable to respondents, required that the jury find that the patented peptides at issue in this case were *not* used as research tools. Petitioner did not, and cannot now, make that showing on the record before the Court.

5. Patented Research Tools Are Generally Readily Identifiable And Unusual Instances That Present A Close Question Are For A Jury To Resolve

Research tools are generally easily identified. Although a few of petitioner's *amici* suggest that the term has no settled meaning, that suggestion is disingenuous and is belied by the arguments of petitioner and the Solicitor General. Petitioner plainly describes research tools as a "category of invention[s]" that "assist a scientist in conducting research," Pet. Br. 41, and gives examples such as "a centrifuge, a dripless pipette, a cell line, or a special assay for screening compounds on the basis of certain properties." *Ibid.* The Solicitor General states that "[i]n general, research tools are devices, substances, or processes that are used to study other substances." U.S. Br. 28. Those definitions are consistent with the NIH definition quoted by the court of appeals: "research tools are defined as '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.'" Pet. App.

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matter of law. *See Boyle v. United Technologies Corp.*, 487 U.S. 500, 513-514 (1988).

22a n.4. Similarly, the Federal Trade Commission has explained that when a patented invention "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," that invention is a research tool. FTC, *supra*, Ch. 3 at 18.

These are precisely the types of items sold by *amici*, whose products include, for example: laboratory pipettes; incubators; cyclers; spectrometers; robotic automation systems; laboratory information management software; nucleic acid purification kits; a transfection reagent that is optimized to ensure highly efficient gene delivery for lower density cell cultures; screening services that provide rapid profiling of compounds submitted by the customer against a panel of kinases; a large protein starter kit that provides the first reliable method for electrophoresis and analysis of big proteins; DNA microarrays, instrument and software systems to interpret information obtained from microarrays, and related equipment such as fluidics stations and hybridization ovens; and a software product line of highly integrated desktop bioinformatics applications which improves the design of experiments and enables the analysis, presentation, and management of sequence and biological data.

As the Solicitor General notes, U.S. Br. 28, some inventions can have both tool and non-tool uses. But it is rarely difficult to distinguish between the two, and the retail tool market has not had problems in doing so. For example, erythropoietin (EPO) is a hormone that stimulates the body's production of red blood cells. It was developed by Amgen as a drug for the treatment of anemia and, when studied as a drug, was subject to Section 271(e)(1). *See Amgen, Inc. v. Hoeschst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998). In the meantime, Amgen also sold non-therapeutic forms of EPO in the tool market – a highly concentrated form known as "Ultrapure EPO" and a less concentrated, tissue culture grade form known as "TC EPO." *See Techne Corp. v. Amgen, Inc.*, 2001 WL 1690062 (D. Minn. Jan. 7, 2001). Thus, the EPO used for therapeutic use is easily distinguished from the EPO used for non-therapeutic

purposes because of the different concentrations and tissue culture grades, as well as by the licensing arrangements, and because, in one instance research was conducted into the therapeutic properties of EPO and in the other, EPO was used in order to conduct research.

In a close case, it is for the jury to determine whether a patented invention is being used as a tool to conduct research. As we discuss above, petitioner is bound by the jury's verdict that the uses of the patented peptides at issue were not covered by Section 271(e)(1).

B. THE STATUTORY TEXT AND STRUCTURE DEMONSTRATE THAT PATENTED RESEARCH TOOLS DO NOT FALL WITHIN THE SCOPE OF SECTION 271(e)(1)

Section 271(e)(1) provides that it does not constitute an act of infringement "to make, use, offer to sell, or sell" 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). The statute does not provide a specific definition of "patented invention" for purposes of Section 271(e)(1). In 35 U.S.C. § 100(a), however, Congress defined "invention" generally to mean "invention or discovery," but Congress further specified that that general definition does not govern if "the context otherwise indicates."

In assessing whether the "context" of a statute "otherwise indicates" with regard to the definition of a particular term, one must take into account the statutory text surrounding the term at issue, the "larger context of the whole statute and other laws related to it," and whether the statute's purpose would be "substantially frustrated" by the adoption of a particular definition. *Rowland v. California Men's Colony*, 506 U.S. 194, 199, 209, 210 (1993) (interpreting phrase "context indicates otherwise" as used in the Dictionary Act). Examining these features, as directed by Congress, demonstrates that the term

"patented invention" in Section 271(e)(1) does not include patented research tools.

1. Determination of whether the context of Section 271(e)(1) indicates that Congress meant "patented invention" in Section 271(e)(1) to mean something other than all patented inventions and discoveries must begin with "the text of the Act of Congress surrounding the word at issue, or the texts of other related congressional Acts." *Rowland*, 506 U.S. at 199; *see Stewart v. Dutra Constr. Co.*, 125 S.Ct. 1118, 1124 (2005) (assessing the "context surrounding the [statute's] enactment" in determining whether general definition applies in a particular circumstance).

Section 271(e)(1) was enacted as part of the same Act of Congress as 35 U.S.C. § 156 and this Court has recognized that Congress intended the two provisions "generally to be complementary." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 672, 673 (1990); *see* Pet. Br. 4, 35-36; U.S. Br. 12-14. Section 156 allows extension of the patent term on certain products to address the problem of some patentees being denied the ability to reap financial rewards during the early years of their patent terms because the invention was bogged down by delays in the FDA premarket approval process. *See Eli Lilly*, 496 U.S. at 669-670. Section 271(e)(1) addresses the problem of a patented invention gaining an unintended extension of its patent term because the FDA premarket approval process for its competitor's product could not commence until the patent's expiration. That left the previously patented product without competition even after expiration of the patent, for as long as the FDA premarket review of the competitor's product lasted. *See Eli Lilly*, 496 U.S. at 670 (discussing Congress's intent to remedy effect of Federal Circuit's interpretation of the Patent Act in *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, *cert. denied*, 469 U.S. 856 (1984)).

It is clear that Section 156 does not apply to patented research tools because they are not "products" under Section 156, which defines "products" to mean "[a]ny medical device, food additive, or color additive subject to

regulation under the Federal Food, Drug, and Cosmetic Act" and any "drug product" which is defined as "the active ingredient of" a new drug, antibiotic drug, or human biological product (as elsewhere defined). 35 U.S.C. § 156(f). Research tools do not fall within those categories and, thus, are not eligible for patent term extensions under Section 156. And it makes sense that research tools are not covered by Section 156 because, unlike the items covered by Section 156, research tools are not subject to FDA premarket approval and, consequently, do not suffer the adverse consequences of FDA delay to merit the extension allowed by Section 156.

Similarly, absent premarket regulatory approval, the problem addressed by Section 271(e)(1) does not arise. The patent terms on research tools do not receive the inadvertent extension that warranted the Section 271(e)(1) exemption because competing tools are not delayed from getting on the market by the FDA premarket approval process. Thus it makes sense to interpret Section 271(e)(1) not to apply to research tools.

Research tools are unlike the medical devices at issue in *Eli Lilly* that the Court found subject to Section 271(e)(1). Those medical devices were "products" within the scope of Section 156 that were subject to FDA premarket approval, and thus could gain the benefit of a Section 156 extension. *See* 496 U.S. at 674. In *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997), the court of appeals held that Section 271(e)(1) applied to a medical device that fell within the scope of Section 156's definition of "product" even if that class of medical devices was not entitled to a patent extension under Section 156. But even that medical device required some premarket regulatory approval and the purpose underlying Section 271(e)(1) therefore still applied. *AbTox* provides no support for extending Section 271(e)(1) to inventions that are not "products" within the scope of Section 156 because they do not go through premarket regulatory approval. *See Infigen v. Advanced Cell Tech., Inc.*, 65 F. Supp. 2d 967 (W.D. Wis. 1999) (holding, based on *Eli Lilly* and *Abtox*, that Section 271(e)(1) does not extend to an invention that was not a

"product" under Section 156). To the contrary, the simultaneous enactment of Section 156 and Section 271(e)(1) provides a strong indication that the term "patented invention" in the latter was not intended to extend to patented research tools.

The narrowness of the statutory text itself confirms that the term "patented invention" in Section 271(e)(1) does not include patented research tools. Section 271(e)(1) includes a series of narrowing terms to tailor the exemption to the particular problem posed by the FDA premarket approval process. Congress specified that, in order not to constitute infringement, the making, use or sale of a patented invention must be "solely" for the uses described in Section 271(e)(1), and that such uses must be "reasonably related" to the "development and submission of information under" particular federal laws. These terms of limitation all confirm that the Section 271(e)(1) exemption was not intended to cover research tools because they were not affected by the problems created by the federal premarket regulatory approval process.[6]

2. Other key factors to consider in determining whether Congress indicated that research tools are not "patented inventions" within the meaning of Section 271(e)(1) are "[t]he larger context of the whole statute and other laws related to it" and whether the "statute's purpose" would be "frustrated" if the term "patented invention" in

[6] The fact that Section 271(e)(1) was amended in 1988 to extend to animal drugs unless they are manufactured through biotechnology, *see* Pub. Law No. 100-670, tit. II, § 201(i), 102 Stat. 3971, 3988 (1988), so as to ensure continued advancements in biotechnology, *see, e.g.*, 134 Cong. Rec. H9786 (daily ed. Oct. 6, 1988) (Rep. Moorhead), does not indicate that research tools are covered. Concerns about protecting biotechnology innovation apply with even greater force to research tools that promote human drug development. But there was no need to amend Section 271(e)(1) to exclude biotechnology research tools because research tools were not covered by Section 271(e)(1) in the first place since they do not undergo the federal premarket regulatory approval process that animal drugs do and, therefore, their patents were not being unintentionally extended.

Section 271(e)(1) were interpreted to include research tools. *Rowland*, 506 U.S. at 209-210; *see id.* at 211 n.12 ("A focus on statutory text * * * does not preclude reasoning from statutory purpose" because "a statute's meaning is inextricably intertwined with its purpose"). In order to adopt an interpretation of "invention" for purposes of Section 271(e)(1) that is different from the all-encompassing general Section 100 definition, it is sufficient that the context in which "invention" is used in Section 271(e)(1) indicate a different usage by Congress. It need not be that usage of the general definition would result in an absurd result. *Id.* at 200-201 (interpretation other than general definition is justified when use of general definition "raise[s] a specter short of inanity, with something less than syllogistic force").

Enactment of Section 271(e)(1) was directed primarily at addressing the prejudice to both patent holders and competitors caused by lengthy delays that result from federal premarket regulatory approval requirements. Petitioner acknowledges that this is the purpose of the statute, Pet. Br. 4, as does the Solicitor General, U.S. Br. 29. Therefore, the statute's purpose would not be furthered by applying the Section 271(e)(1) exemption to research tools because, as noted above, they do not go through FDA premarket approval. The Solicitor General agrees with this point as well, specifically declaring that inclusion of research tools "would not address the problem Congress sought to solve and might cause a greater diminution in patent value than Congress intended." U.S. Br. 29. It cites that as an indication that Congress "may well not have intended to include tool patents" under Section 271(e)(1). *Ibid.*

Congress's overall purpose in enacting Section 271(e)(1) was to ensure the continued development of new drugs for treatment of human disease. Contrary to the picture painted by petitioner, broadening the reach of Section 271(e)(1) would not serve this goal because that would destroy the incentives for innovation in research tools which are critical to drug development. A patented

research tool would be put at a significant disadvantage because it would be subject to the same patent term that applies to all other patented inventions, but would not have a right to exclude its primary customers from making or using its invention at any point during the patent's life. "This context of congressional silence" on the subject of patented research tools "in the face of obvious problems" further indicates that "Congress simply was not thinking" that research tools would be subject to Section 271(e)(1). *Rowland,* 506 U.S. at 207, 208-209 & n.11.

3. Reading the term "patented invention" to include research tools would also substantially frustrate Congress's efforts to avoid violating the Takings Clause. *See Rowland,* 506 U.S. at 211. Congress recognized that Section 271(e) could pose problems under the Takings Clause because it eliminates a patent owner's right to control the use of its property in certain circumstances and could cause significant diminishment in economic value. *See William Cramp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co.*, 246 U.S. 28, 39-40 (1918) (patents are property protected by Takings Clause).

Congress intended to foreclose such claims by tailoring the statute, as a whole, to have a "*de minimis*" effect on patent holders by ensuring that FDA approved patented drugs have a full (but not longer) term of patent after FDA approval. H.R. Rep. No. 98-857, pt. II at 30 (1984).[7] During the period following FDA approval, the

[7] *See also id.* pt. I at 46 ("view [was] that experimental activity does not have any adverse economic impact on the patent owner's [property] during the life of the patent"); *id.* pt. II at 30 (because Section 271(e) is limited to "test[ing] the [patented] drug for purposes of submitting data to the FDA for approval" it does not interfere with the patent owner's commercial exploitation of the patent during the life of the patent); *see also id.* pt. II at 30 n.19 (the provision "does not result in the total extinguishment of the patent owner rights, because the patent owner still maintains a right to exclude others from the commercial marketplace").

patented product can be commercially sold to the public exclusively by the patent holder and that is how the patent holder derives its primary economic value from the patent. But that is not the case for patented research tools which derive their primary economic value from their commercial sale to those in research and development rather than to the general public. Thus, to read Section 271(e)(1) to permit infringement of such tools by those conducting research and development suggests the existence of a significant problem under the Takings Clause that should caution against an interpretation of Section 271(e)(1) that so significantly diminishes the value of a large class of patents. *See United States v. Security Indus. Bank*, 459 U.S. 70, 78 (1982).

The Patent Act's system of creating incentives for innovation has proven itself over time. The limited-time monopoly granted a patent owner to make and use his invention has been a cause for innovation. An unduly broad interpretation should not be accorded Section 271(e)(1) to reach research tools because that would upend this longstanding system in exchange for one in which the research tool inventor loses his exclusive rights to his invention and receives nothing in return. That cannot have been Congress's intent.

CONCLUSION

For the reasons set forth above and in respondents' brief, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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