United States Court of Appeals for the Federal Circuit

2008-1248

ARIAD PHARMACEUTICALS, INC; MASSACHUSETTS INSTITUTE OF TECHNOLOGY; THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH; and THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Plaintiffs-Appellees,

v.

ELI LILLY AND COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in Case No. 02-CV-11280, Judge Rya W. Zobel

Brief of Amici Curiae The Regents of the University of California, Wisconsin Alumni Research Foundation, The University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation of State University of New York, NDSU Research Foundation, and Research Corporation Technologies, Inc. on En Banc Rehearing in Support of Affirmance of Judgment

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CERTIFICATE OF INTEREST

Counsel for Amici Curiae The Regents of the University of California, Wisconsin Alumni Research Foundation, The University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation of State University of New York, NDSU Research Foundation, and Research Corporation Technologies, Inc. certifies the following pursuant to Federal Circuit Rule 47.4:

1. The full name of every party or amicus represented by me is:

The Regents of the University of California
Wisconsin Alumni Research Foundation
The University of Texas System
University of Rochester
Rensselaer Polytechnic Institute
STC.UNM
The Research Foundation of State University of New York
NDSU Research Foundation
Research Corporation Technologies, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

As indicated in item 1. In addition:

University of Wisconsin-Madison
University of New Mexico Board of Regents
North Dakota State University
State University of New York

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

> There are no parent corporations or any publicly held companies that own 10 percent or more of the stock of any amicus curiae represented by me, except as indicated above.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this case are:

Law Firm	Partners and Associates
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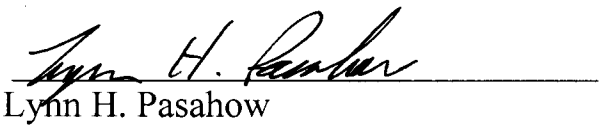
October 15, 2009

By: 

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STATEMENT OF AMICI CURIAE

I. IDENTIFICATION OF THE AMICI CURIAE

The Regents of the University of California is a board that governs the University of California system, which includes ten university campuses, three national laboratories that the University participates in managing, and five teaching medical centers. The University of California is a public university that educates students from undergraduate levels to the most advanced graduate levels, with a stated commitment to education, research and public service. Several of the University campuses as well as the Office of the President have technology transfer offices, which license University-developed inventions and implement the University's policy and obligation to develop and ensure broad utilization of federally-funded and other University technology so that the benefits can be enjoyed by the citizens of California and the national general public.

Amicus Wisconsin Alumni Research Foundation (WARF) was founded in 1925 as a nonprofit entity to promote, encourage and aid scientific investigation at the University of Wisconsin-Madison. One of WARF's first accomplishments was to patent a vitamin D discovery that eventually eliminated the childhood disease rickets worldwide. Since its founding, WARF has processed approximately 6000 inventions created by

UW-Madison faculty and staff, obtained 1900 U.S. patents on these inventions, entered into over 1600 license agreements with companies around the globe, and returned over $1 billion in licensing-fee income to UW-Madison to fund research programs and initiatives.

The Bayh-Dole Act has made it possible for WARF to make the contributions to the public good that it does today. In the middle to late 1960s, government agencies kept title to inventions that had been funded with federal money. As a consequence, invention disclosures to WARF – inventors' write-ups for patent counsel to use in preparing patent applications – had fallen to barely one per month and what few disclosures there were had fallen in quality. The situation improved somewhat when Institutional Patent Agreements (IPAs) were negotiated with (what is now) the Department of Health and Human Services in 1968 and the National Science Foundation in 1973. These IPAs gave WARF (and other universities) the right to elect to take title to inventions made with funds from those two agencies.

Since the enactment of Bayh-Dole, invention disclosures to WARF have mushroomed. Today, WARF (a) manages over 800 pending and 1000 issued U.S. patents on UW-Madison technologies, as well as over 2000 foreign equivalents; (b) offers more than 1000 technologies for licensing; (c)

maintains more than 500 active commercial license agreements, as well as about 460 academic licenses; (d) has over 160 license agreements with Wisconsin companies; and (e) holds equity in 40 UW-Madison spin-off companies. WARF's most important patents include the blood anticoagulant Warfarin, a coating 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.

For nearly 130 years, The University of Texas System has been responding to the changing needs of Texas by advancing educational opportunities for Texas students, by educating tomorrow's leaders, thinkers, and workers, providing world-class healthcare to Texas residents and expanding research programs that fuel economic growth. The University of Texas System is comprised of nine academic universities and six health institutions. UT System faculty and research staff play a critical role in generating new ideas and harnessing them through patent protection to create new companies and products that contribute to the state, national and world economy.

University of Rochester is a private research university that provides undergraduate, graduate and professional education. Its sole mission is to

further education, research, and clinical care. University of Rochester believes that it has a role and a duty to help find solutions to the increasingly complex challenges of society. University faculty seek to apply basic medical, engineering and scientific research both to help their country and the world at large. Rochester has two offices of technology transfer that patent faculty discoveries and inventions and endeavor to license this knowledge to companies that they determine will best make the benefits of faculty research widely available.

As the nation's oldest technological university, Rensselaer Polytechnic Institute offers more than 145 programs at the bachelor's, master's, and doctoral levels. Rensselaer's Office of Technology Commercialization supports researchers in protecting intellectual property and licensing their discoveries. Its efforts advance Rensselaer's policy of transferring technology from the laboratory to the marketplace so that new discoveries and inventions benefit human life, protect the environment, and strengthen economic development.

STC.UNM (STC) is a non-profit corporation formed and wholly owned by the University of New Mexico (UNM) Board of Regents. STC supports the University of New Mexico and its partners as the source for innovation management and commercial development. As the technology-

transfer arm for UNM, STC connects the business community and UNM by transferring intellectual property – technologies developed at UNM – to the marketplace through appropriate legal protection and commercialization. Additionally, STC assists companies and organizations who wish to access UNM facilities, expertise, and research.

The Research Foundation of State University of New York (RF) is a private, nonprofit corporation that supports the research mission of the State University of New York (SUNY). Established in 1951, RF charter enumerates three purposes, which are to (1) assist in developing and increasing the facilities of SUNY to provide more extensive educational opportunities for and services to its students, faculty, staff and alumni, and to the people of the State of New York, by making and encouraging gifts, grants, contributions and donations of real and personal property to or for the benefit of SUNY; (2) receive, hold, and administer gifts or grants, and to act without profit as trustee of educational and charitable trusts, of benefit to and keeping with the educational purposes and objectives of SUNY, and (3) finance the conduct of studies and research in any and all fields of the arts and sciences, of benefit to and in keeping with the educational purposes and objectives of SUNY. Through its ability to bring together the resources of organizations having different legal and management systems, the RF makes

it possible for SUNY to build strategic partnerships with government, business and industry and other higher education institutions.

NDSU Research Foundation is a nonprofit corporation established to own and manage intellectual property that is assigned to it from North Dakota State University. The NDSU Research Foundation is the entity responsible for licensing these university-developed inventions to industry.

Research Corporation Technologies, Inc. (RCT) is an independent technology management company that has been involved in providing commercialization services to academia and other institutions, tracing its roots to 1912. It has been pivotal to the success of many important pharmaceuticals, diagnostics, biotechnology products, and new materials and processes. Recent products include the widely used therapeutic compounds cisplatin and carboplatin, the PSA (Prostate Specific Antigen) test for diagnosing and monitoring prostate cancer, and lacosamide for the treatment of patients with refractory epilepsy.

II. STATEMENT OF INTEREST OF THE AMICI CURIAE

The issues under review have far-reaching implications for the patentability of research, particularly in the field of biotechnology, being conducted at universities and other non-profit institutions. Universities and research institutions depend on licensing activities (which in turn depend on

the ability to secure patent rights) to commercialize their discoveries and fund continued research and innovation. The current written description law negatively impacts the ability of university researchers to obtain recognition and patent protection for their innovations, and further jeopardizes the viability of technology transfer programs at universities.

III. AUTHORITY TO FILE

The Amici Curiae have authority to file pursuant to the Court's August 21, 2009 Order granting rehearing *en banc* and allowing the filing of amicus briefs without leave of court.

SUMMARY OF ARGUMENT

Once a doctrine used only to police claims to priority of invention, written description has evolved judicially into a separate and oftentimes insurmountable requirement, particularly when applied to biological inventions. The Federal Circuit's creation of this separate barrier to patentability, first articulated in *The Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997), effectively imposes an actual reduction to practice requirement on biotechnology inventions. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1325 (Fed. Cir. 2003) (noting that *Lilly* creates a "super-enablement" standard, "requiring more disclosure than necessary to enable one skilled in the art to make and use the invention") (J. Rader concurring). Such a requirement prejudices universities and research institutions that do not have the resources to reduce each pioneering biotechnological innovation to a "precise definition." *Lilly*, 119 F.3d at 1566; *see Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 983 (Fed. Cir. 2003) (recognizing the rule "prejudices university or small inventors who do not have the expensive and time-consuming resources to process every new biotechnological invention") (J. Rader dissenting to denial of rehearing *en banc*). Such prejudice reaches far beyond university campuses, negatively impacting the public's access to important

technologies and innovation in general, with its accompanying adverse effect on economic growth.

There is no statutory support and certainly no policy rationale for the technology-specific impact the current written description law has on the university and scientific research community. Indeed, the current incarnation of written description is not only at odds with the Federal Circuit's own jurisprudence bestowing broader patent protection to pioneering inventions, it muddies clear federal policy with respect to the role of the patent system. Patent exclusivity granted for pioneering biological inventions fuels the creation and recruitment of commercial entities willing to undertake the huge investments necessary to refine and develop foundational university research into medical and biopharmaceutical products widely accessible to the general public. Denial of patent protection for university inventions removes the incentive for private investment in the commercialization of biotechnological inventions, keeping important and possibly life-saving advancements out of the public's reach and depriving universities and research institutions of the opportunity to generate funds for continued scientific research, education, and innovation.

As a result, the perpetuation of this separate written description requirement stymies innovation and threatens the important relationship that

exists between those that carry out the necessary basic research at educational institutions primarily through the use of federal funds and those that stimulate economic growth and further innovation by bringing university research to the marketplace, benefitting the public. The Court should take the opportunity now to realign the written description law with the constitutional, statutory, and policy rationales that underlie the patent system, and return the doctrine to its proper role of assessing new matter rejections and claims to priority.

ARGUMENT

I. SECTION 112 DOES NOT CONTAIN A WRITTEN DESCRIPTION REQUIREMENT SEPARATE FROM AN ENABLEMENT REQUIREMENT

Section 112, paragraph 1, provides that:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. As stated in the United States' brief as *amicus curiae* in *Enzo*, a straightforward reading of the statute requires only a description sufficient to enable a person skilled in the art to make and use the invention. *Enzo*, 323 F.3d at 977 (J. Rader dissenting).

There is nothing to suggest that beyond describing the invention in such full, concise, and exact terms as to enable any person skilled in the art to make and use the invention, a patent applicant must further describe the invention. Requiring a "description of the invention beyond a description of the invention" makes little sense. Therefore, in reviewing the requirements of the patent statute, the Supreme Court understood the written description language of section 112 to require only an enabling disclosure. *JEM Ag Supply, Inc. v. Pioneer Hi-Bred Int'l Inc.*, 534 US 124, 144 (2001) (noting that "quid pro quo" of patent exclusivity under section 112 requires description of the invention with sufficient specificity to enable one to make and use the invention).

In re Ruschig, 379 F.2d 990 (CCPA 1967), has been cited as the first case to recognize a written description requirement separate from enablement. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed. Cir. 1991); *Enzo*, 323 F.3d at 978. But the decision in *Ruschig* was not based on section 112. When faced with the question of whether the applicant complied with the requirements of section 112, the *Ruschig* court stated, "we doubt that the rejection is truly based on section 112." *Ruschig*, 379 F.2d at 995. Indeed, the court went on to note that "[w]e have a specification that describes appellants' invention. The issue here is in no

wise a question of its compliance with section 112." *Id*. at 995-96.

The real issue in *Ruschig* was whether a new claim added during prosecution was properly rejected as new matter (and therefore not supported by the original patent application). *See id*. at 991-92; *see also* 35 U.S.C. § 132 ("No amendment shall introduce new matter into the disclosure of the invention"). It is thus noteworthy that the cases after *Ruschig* purporting to apply a separate written description requirement were limited to those involving (1) the presentation of claims not presented in the application when originally filed, (2) entitlement to the benefit of an earlier filing date for claims in a later-filed application, and (3) interference proceedings. *See Vas-Cath*, 935 F.2d at 1560. Each of those "written description" cases involved evaluating the sufficiency of the claims in accordance with statutes governing a patent claim's entitlement to priority and the prohibition against adding new matter. *Id*.; *see also* 35 U.S.C. §§ 119-120 (priority) & 132 (new matter rejections); *see also TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1118 (Fed. Cir. 2001) (recognizing the new matter prohibition of 35 U.S.C. § 132 to be the corollary of the written description requirement).

It was not until *Lilly* that a truly separate written description requirement – untethered to any other patent statute – was first created.

Beyond evaluating the sufficiency of claims added during prosecution, written description became a device for evaluating the sufficiency of disclosures in already-issued patents. There was, however, no statutory change or legislative pronouncement to justify departing from the previous thirty years of precedent that limited written description to its corollary function of policing priority.

The *Lilly* court instead cited *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993). *Lilly*, 119 F.3d at 1559. *Fiers*, however, did not apply the written description requirement outside the priority context; rather it involved an interference proceeding and whether certain claims were entitled to the benefit of earlier filing dates. 984 F.2d at 1167. Thus, while the written description analysis in *Fiers* was confined to assessing the sufficiency of claims in the traditional context of priority disputes, *Lilly* nevertheless cited *Fiers* as its sole authority for expanding the doctrine to assess the sufficiency of disclosures in the context of an issued patent.

This expansion of the written description law is not only unsupported, it is unnecessary. The enablement inquiry already considers factors intended to assess the sufficiency of the disclosure. *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Whether a disclosure enables an invention depends on the: (1) the quantity of experimentation necessary, (2) the amount of direction or

guidance presented, (3) the presence or absences of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of claims. *Id.* at 737.

By considering all these factors, the enablement requirement ensures that patents contain a disclosure that allows the public to freely use, exploit, and commercialize the invention after expiration of the patent term. Indeed, the Federal Circuit has successfully relied upon the enablement requirement in the past to police the sufficiency of disclosures with respect to overbroad patent claims. *See e.g., Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1212-13 (Fed. Cir. 1991) (disclosures regarding isolation and structure of human EPO gene were insufficient to support claims to any DNA encoding any polypeptide "sufficiently duplicative" of EPO).

Thus, there is no need or support for a separate free-standing written description requirement. Nor is there any guidance in section 112 or otherwise as to what separate purpose such a requirement would serve. Any legitimate application of a separate written description requirement to serve the *quid pro quo* function of the patent bargain would be redundant of the enablement requirement. *See JEM Ag Supply*, 534 US at 144 (equating patent *quid pro quo* with enablement).

II. THE CURRENT WRITTEN DESCRIPTION REQUIREMENT CONFLICTS WITH UNDERLYING PATENT LAW AND POLICY

Moreover, to the extent there is a separate written description requirement, to be separate and distinguishable from enablement, it must require something more than the *quid pro quo* of teaching one of ordinary skill how to make and use the invention. *See Moba*, 325 F.3d at 1325 ("the only way to distinguish the *Lilly* rule from enablement is to construe *Lilly* as requiring more disclosure than necessary to enable one of skill to make and use the invention") (J. Rader concurring).

Under the current written description requirement as announced in *Lilly* and applied in *Ariad*, that something more requires disclosure of "a precise definition, such as by structure, formula, chemical name, or physical properties." *Lilly*, 119 F.3d at 1566 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). In the case of biotechnology inventions, this effectively means, to achieve adequate coverage and scope, there must be an actual reduction to practice of not only the invention, but of each patented application of the invention. *See Lilly*, 119 F.3d at 1567 (prophetic example describing how to obtain claimed cDNA and describing the protein it encodes was insufficient to satisfy written description requirement; sequence information must also be disclosed). This "super-enablement" requirement

for biotechnology patents has been interpreted to require disclosure of the actual claimed genetic material, or in some cases, the tedious recitation of countless biological permutations. *See, e.g.*, *Enzo*, 323 F.3d at 970 (actual deposit of genetic material in a public depository was sole basis for finding adequate written description); *Lilly*, 119 F.3d at 1566-67 (claims to human insulin cDNA not described where specification contained no sequence information indicating which nucleotides constitute human cDNA). Moreover, it is applied regardless of whether the patent teaches one of ordinary skill in the art to make and use the invention.

A. The Separate Written Description Requirement Prejudices Universities and Their Inventors

This current written description requirement operates to prejudice inventors at universities and other research institutions who often make the most important basic scientific discoveries. Universities do not have the resources to support the time and labor-intensive process of reducing every species of a genus to practice or describing, for example, every possible amino acid or DNA sequence in exhausting detail as needed to "precisely define" and adequately describe a biological invention. *See Moba*, 325 F.3d at 1325 ("compliance may tax a drafter [of biotechnological patents] beyond reasonable limits") (J. Rader concurring); *Enzo*, 323 F.3d at 983 (noting

prejudice to university and small inventors) (J. Rader dissenting). As a result, university researchers are denied the recognition and reward of inventorship due solely to lack of available resources rather than lack of inventive contribution. Indeed, under the current law, universities themselves will be denied recognition for their inventive contribution, recognition that is often crucial to attracting talent and additional funding for continued scientific research and advancements.

The effects of erecting patentability barriers that have a disparate impact on university inventions extend well beyond the individual interests of the institutions and their inventors. It is the basic scientific research conducted at universities and other research institutions that has spawned many major advances in biotechnology, including:

- Recombinant DNA technology (Stanford University and University of California).
- Embryonic stem cell technology (University of Wisconsin-Madison)
- Hepatitis B vaccine (University of California and the University of Washington);
- Citracal® calcium supplement (University of Texas Southwestern Medical Center);
- Haemophilus B conjugate vaccine (University of Rochester);
- Vitamin D metabolites and derivatives (University of Wisconsin);
- Artificial lung surfactant for use with newborn infants (University of California).

See Council on Governmental Relations, "The Bayh-Dole Act: A Guide to

the Law and Implementing Regulations," available at http://www.ucop.edu/ott/faculty/bayh.html; Michael Remington, "The Bayh-Dole Act at Twenty-Five Years: Looking Back, Taking Stock, Acting for the Future," *Journal of the Association of University Technology Managers* XVII:1 (Summer 2005), 15-31; University of Wisconsin-Madison website at http://newsroom.stemcells.wisc.edu/16672.

These are just a few examples of the numerous biotechnological advancements that could not have been commercialized and made available for the benefit of the public without patent protection for university-developed inventions. The grant of patent exclusivity to universities and its subsequent transfer to commercial entities is key to incentivizing private investment in the expensive task of bringing laboratory research to market. *See* H.R. No. 98-1062, 1984 U.S. Code Cong. and Adm. News at 5801 (recognizing that removing limits on universities' ability to exclusively license technology to businesses is "particularly important with technologies such as pharmaceuticals, where long development times and major investments are usually required prior to commercialization").

The current written description law, however, calls into question the validity of inventions like these and threatens universities' ongoing ability to meet the burdensome patentability requirements imposed on

biotechnological innovations. In 2007, biotechnology represented the single largest category of invention disclosures within universities and research institutions. *See* Association of University Technology Managers, *AUTM U.S. Licensing Activity Survey, FY2007: A Survey Summary of Technology Licensing (and Related) Activity for U.S. Academic and Nonprofit Institutions and Technology Investment Firms* ("AUTM 2007 Licensing Summary") at 26, available online at http://www.autm.net/FY_2007_Licensing_Activity_Survey.htm. Unable to secure patent protection for these inventions, universities will have little choice but to leave many of their pioneering discoveries undeveloped and outside the reach of the general public.

B. The Written Description Requirement's Impact on Universities Frustrates Federal Patent Policy

The patent system was intended to promote the economic stimulus achieved through the synergy between universities and commercial corporations enabled by robust patent protection for university invention. In passing the Bayh-Dole Act, Congress made explicit its goal of using the patent system "to promote collaboration between commercial concerns and nonprofit organizations, including universities" and "to ensure that inventions made by nonprofit organizations are used in a manner to promote free competition and enterprise." 35 U.S.C. § 200. It was apparent, even

soon after enactment, that the Bayh-Dole Act's facilitation of university technology transfers "increased business support and collaborations in university research." H.R. No. 98-1062, 1984 U.S. Cong. and Adm. News at 5800. Encouraging and facilitating technology transfers from universities:

> has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States.

H. Con. Res. 319.

While it is true – as this Court noted in *Rochester* – that the Bayh-Dole Act was not intended to relax the statutory requirements for patentability, it is not correct to conclude that there is "no connection between the Bayh-Dole Act and the legal standards that courts employ to assess patentability." *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 (Fed. Cir. 2004). The legislation is a clear reflection of federal patent policy and sheds light on the proper interpretation and understanding of the statutory requirements for patentability.

Founded on the constitutional mandate to "promote the progress of science and useful arts," the patent statutes were intended to encourage

innovation and economic growth. Patent protection for university research (and its transfer to the private sector) accomplishes exactly that. In 2003 alone, 472 new products were introduced to the commercial marketplace based on technology originating from just thirty educational and research institutions. *See* AUTM, *Annual Licensing Survey: FY2003*. In 2007, university and research institutions executed over 5000 technology licenses to private companies for further development and commercialization of university research. *See* AUTM 2007 Licensing Summary at 35. Such licensing efforts were responsible for the formation of 555 new startup companies, totaling almost 3400 ongoing start up companies created from the transfer of university-developed technology. *See id*. at 37.

A statutory interpretation of the written description requirement that unfairly prejudices biotechnology and university inventions impedes this growth and frustrates the goals of the patent system. It limits universities' ability to obtain biotechnology patents, depriving the public of the full economic benefits and potentially life-saving products that flow from licensing relationships between universities and private corporations. Thus, the innovation the patent system is intended to promote is best facilitated by a statutory interpretation that reinforces the critical role universities play in scientific discovery, while reserving commercialization to the private

business sector. Rather than promote progress, the current written description law's creation of impractical technical requirements specific for patentability of biotechnological inventions and discoveries forces universities to assume the role of business in reducing inventions to practice, hindering innovation, and consequently, economic growth.

C. The Technology-Specific Written Description Standard Is Inconsistent With Established Law

Universities and other research institutions have been pioneers in advancing the biotechnology arts, including recombinant DNA technology, stem cell research, hepatitis B vaccine and many other inventions. *See Westinghouse v. Boyden Power Brake Co.*, 170 U.S. 537, 561-62 (1898) (defining "pioneering" as "a patent covering a function never before performed, a wholly novel device, or one of such novelty or importance as to mark a distinct step in the progress of the art, as distinguished from a mere improvement or perfection of what has gone on before"); *see also MAC Corp. v. Williams Patent Crusher & Pulverizer Co.*, 767 F.2d 882, 884 n.3 (Fed. Cir. 1985).

It is in the interests of the patent system to reward rather than impede pioneering breakthrough inventions, and the law traditionally provides such inventions broader protections. Indeed, "it is well settled in the patent law"

that pioneering patents are "entitled to liberal construction of the claims." *Morley Sewing Machine Co. v. Lancaster*, 129 U.S. 263, 273 (1889). The Federal Circuit itself has granted greater breadth to pioneering inventions. *See Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301 (Fed. Cir. 1999) ("pioneering inventions deserve a broader range of equivalents"), *citing Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed, Cir. 1987) and *Thomas & Betts Corp. v. Litton Sys., Inc.*, 720 F.2d 1572, 1579 (Fed. Cir. 1983).

In evaluating claim scope and patent coverage in the context of the doctrine of equivalents, the Federal Circuit bestows pioneer patents with broad claim scope:

> Pioneers enjoy the benefits of their contribution to the art in the form of broader claims. Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field. Thus, claim scope itself generally supplies broader exclusive entitlements to the pioneer.

Augustine Medical, 181 F.3d at 1301 (discussing the doctrine of equivalents). But what this Court grants to pioneering inventions with one hand, it takes away with the other. With its separate written description requirement, the Court has invalidated these same patents, claiming the patent disclosures do not support the breadth of their claims. Such a requirement values minor incremental improvements well-suited to precise

description over the monumental advances in technology often incapable of precise written description. It is inconsistent for Federal Circuit jurisprudence to acknowledge pioneer patents' entitlement to broad claims, while applying a written description standard that invalidates them on those same grounds.

III. ANY SEPARATE WRITTEN DESCRIPTION REQUIREMENT SHOULD BE LIMITED TO THE PRIORITY CONTEXT

In light of these constitutional, statutory, and policy considerations, the written description requirement is best returned to its role in the context of determining entitlement to priority. There is no support in the language of section 112 or elsewhere in the patent statutes for the current technology-specific incarnation of the written description requirement. Therefore, consistent with its historic role in patent law, the written description requirement should be used only to ensure that later-filed claims are entitled to the benefit of an earlier filing date or to ensure that later amendments do not run afoul of the prohibition against adding new matter to the original application. *See Vas-Cath*, 935 F.2d at 1560.

This Court has summarized the proper scope of the written description requirement, stating that written description serves

> to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. When the applicant adds a claim or otherwise amends his specification

> after the original filing date ... the new claims or other added material must find support in the original specification.

TurboCare, 264 F.3d at 1118. Application of this standard gives effect to the patent statutes, while allowing universities and research institutions to continue their research pursuits and developing partnerships with industry to bring the results of that research to market.

CONCLUSION

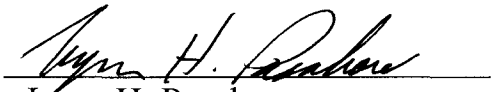
For the foregoing reasons stated above, the Amici Curiae support a finding that section 112, paragraph 1 does not contain a written description requirement separate from the enablement requirement.

To the extent any separate written description requirement exists, it is the Amici Curiae's position that the written description doctrine be returned to its historic role in the priority context, ensuring that later-filed claims are supported by the disclosures in an earlier-filed patent application.

Dated: October 15, 2009

Respectfully submitted,

FENWICK & WEST LLP

By: 

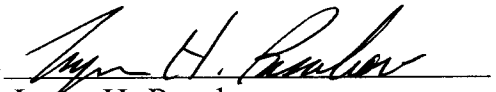
Lynn H. Pasahow

Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that the foregoing Brief of Amici Curiae The Regents of the University of California, Wisconsin Alumni Research Foundation, The University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation of State University of New York, NDSU Research Foundation, and Research Corporation Technologies, Inc. on En Banc Rehearing in Support of Affirmance of Judgment contains 5,243 words and is in compliance with Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

Dated: October 15, 2009

By: 

Lynn H. Pasahow
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 15, 2009, two (2) true and correct copies of the foregoing Brief of Amici Curiae The Regents of the University of California, Wisconsin Alumni Research Foundation, The University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation of State University of New York, NDSU Research Foundation, and Research Corporation Technologies, Inc. on En Banc Rehearing in Support of Affirmance of Judgment were served on counsel for Plaintiffs-Appellees, counsel for Defendant-Appellant, and counsel for Amicus Curiae at the following addresses via Federal Express, Standard Overnight Service:

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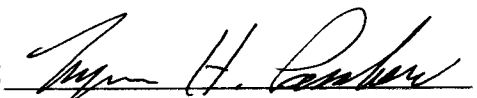
The undersigned also certifies that on October 15, 2009, I caused fourteen (14) copies of the foregoing Brief of Amici Curiae The Regents of the University of California, Wisconsin Alumni Research Foundation, The University of Texas System, University of Rochester, Rensselaer Polytechnic Institute, STC.UNM, The Research Foundation of State University of New York, NDSU Research Foundation, and Research

Corporation Technologies, Inc. on En Banc Rehearing in Support of Affirmance of Judgment (including one designated as the original) to be filed with the Court at the following address:

Clerk
United States Court of Appeals for the Federal Circuit
717 Madison Place NW
Washington, DC 20439

Dated: October 15, 2009

By: 
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