

2008-1248

**United States Court of Appeals
for the Federal Circuit**

ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH,
AND
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,
Plaintiff-Appellant,

v.

ELI LILLY & COMPANY,
Defendant-Appellee,

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

**BRIEF OF AMICUS CURIAE GLAXOSMITHKLINE
IN SUPPORT OF ELI LILLY & COMPANY**

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November 19, 2009

CERTIFICATE OF INTEREST

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

GlaxoSmithKline LLC d/b/a/ GlaxoSmithKline

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

NONE

3. All parent corporation(s) and any publicly held companies that own 10 percent or more of the stock of *amicus curiae* represented by me are:

GlaxoSmithKline Holdings (Americas) Inc.; GlaxoSmithKline Finance PLC; GlaxoSmithKline Holdings LTD; GlaxoSmithKline PLC

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

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TABLE OF CONTENTS

STATEMENT OF INTEREST OF AMICUS CURIAE.....	1
I. ARGUMENT.....	2
A. Changes in Well Settled Requirements for Patentability Inject Uncertainty and Instability into Long Term Business Decisions and Risk the Wasting of Vital Business Capital	2
B. Changing the Written Description Requirement May Inject Uncertainty into the More Than 2.5 Million Patents Prosecuted Under the Current Legal Regime.....	5
C. The Supreme Court has Cautioned that Stare Decisis is of Particular Importance in Patent Law Where Expectations Drive Investment	6
D. Unforeseeable Changes in Law are Particularly Damaging to not only the Pharma/Biotech Industry but the Public at Large as Well.....	8
II. CONCLUSION.....	9

TABLE OF AUTHORITIES

CASES

<i>Chevron Oil Co. v. Huson</i> , 404 U.S. 97 (1971).....	7
<i>Consolidated Fruit-Jar Co. v. Wright</i> , 94 U.S. 92 (1876).....	6
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002).....	8
<i>In re Deuel</i> , 51 F.3d 1552 (Fed. Cir. 1995)	4
<i>In re DiLeone</i> , 436 F.2d 1404 (C.C.P.A. 1971).....	5
<i>In re Kubin</i> , 561 F.3d 1351 (Fed. Cir. 2009)	4
<i>In re Ruschig</i> , 379 F.2d 990 (C.C.P.A. 1967).....	5
<i>In re Wilder</i> , 736 F.2d 1516 (Fed. Cir.1984), cert. denied, 469 U.S. 1209 (1985).....	5
<i>KSR Int’l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007).....	3-4
<i>Regents of the University of California v. Eli Lilly & Co.</i> , 119 F.3d 1559 (Fed. Cir. 1997)	4
<i>United States v. Title Insurance & Trust Co.</i> , 265 U.S. 472 (1924).....	7
<i>Vas-Cath, Inc. v. Mahurkar</i> , 935 F.2d 1555 (Fed. Cir. 1991)	5, 6

Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,
520 U.S. 17 (1997) (Ginsburg, J., concurring)..... 8

STATUTES

35 U.S.C. § 112..... 5, 6

35 U.S.C. § 103..... 3

OTHER AUTHORITIES

J Health Econ 22(2): 151-85;
DiMasi, J. A., R. W. Hansen, et al. (1991)..... 2

Managerial and Decision Economics,
Vol 28 (4-5), 469 (2007)..... 2

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STATEMENT OF INTEREST OF AMICUS CURIAE

In 2008, the United States pharmaceutical industry spent more than \$50 billion on research and development, working on thousands of drugs, many of which were treatments for cancer, heart disease, diabetes and AIDS. GSK, the second largest pharmaceutical company in the world, invested more than \$6.5 billion in R&D in 2008. To protect that investment, GSK seeks to obtain patent protection for its medical innovations. GSK files more than 300 patent applications per year in the United States Patent and Trademark Office. It currently has over 1,500 pending U.S. patent applications and over 2,000 granted U.S. patents. A significant number of GSK's patents were prosecuted over a decade ago. Protecting and encouraging scientific investment like GSK's large research and development effort is not possible without a long-term predictable, stable, legal system that provides sufficient confidence to invest and sufficient time to recoup investment and secure a reasonable return. Retroactively changing standards for patent protection, standards that for the most part have been in place since at least the enactment of the 1952 Patent Act, introduces uncertainty and instability, risks the invalidation of once

valid patents, and potentially nullifies investment-backed business decisions based on then-correct interpretations of the law.

I. ARGUMENT

A. **Changes in Well Settled Requirements for Patentability Inject Uncertainty and Instability into Long Term Business Decisions and Risk the Wasting of Vital Business Capital**

According to long-term tracking studies, the cost of drug development has increased from approximately \$230 million in the early 1980's to \$1.2 billion today, with R&D currently requiring about 10-15 years.¹ The patents that protect today's pharmaceutical products were often filed more than a decade ago. For example, GSK is currently in patent infringement litigation to protect innovator drugs covered by patents that were filed in 1991-1993. Conversely, a patent application filed today by GSK on a new pharmaceutical medicine will likely not be litigated until around 2025 (10 years of drug development followed by a period of five years of Hatch Waxman data exclusivity after drug approval.)

¹ DiMasi, J.A., Grabowski, H.G., "The cost of biopharmaceutical R&D: is biotech different?" *Managerial and Decision Economics*, Vol 28 (4-5), 469 (2007); DiMasi, J. A. (2002). "The value of improving the productivity of the drug development process: faster times and better decisions." *Pharmacoeconomics* 20 Suppl 3: 1-10; DiMasi, J. A., R. W. Hansen, et al. (2003). "The price of innovation: new estimates of drug development costs." *J Health Econ* 22(2): 151-85; DiMasi, J. A., R. W. Hansen, et al. (1991). "Cost of innovation in the pharmaceutical industry." *J Health Econ* 10(2): 107-42.

Changing interpretations of the standards for patentability after those patents were prosecuted and granted can result in a different patent regime when the patent is litigated than governed at the time of the decision to file and the prosecute such patents. Businesses like GSK make investment decisions every day which determine how capital will be spent, how personnel will spend their time and which inventions should be developed. These decisions are affected by an economic analysis of the potential product, which includes patentability and freedom to operate considerations. Innovator health care businesses are required to, and do, use their best efforts to understand and comply with the current law at the time the decisions are made. When courts change the law on which necessarily long-range decisions are made, these business decisions can be rendered retroactively incorrect. This alters investment-backed expectations. It can also result in wasted capital, which is a loss to society as a whole.

For example, in 2007, the U.S. Supreme Court re-interpreted the requirement for patentability under 35 U.S.C. § 103 in its decision in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007). Two years later, *KSR* has already had an effect on prior made investments in the pharma/biotech field because it changed the standard by which

pharma/biotech patents are judged. In the mid-1990's, *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995) and *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) set the standard for the patentability of DNA inventions. In 1998, while those cases were the controlling law, Amgen filed a patent application on the isolated and sequenced human gene that encodes the Natural Killer Cell Activation Inducing Ligand. Eleven years later, in 2009, the patent application was finally denied because the Supreme Court had criticized the law upon which it was based – *Deuel. KSR*, 550 U.S. at 414, 421 (criticizing *In re Deuel*) ; *In re Kubin*, 561 F.3d 1351, 1358 (Fed. Cir. 2009). Thus, an innovation likely patentable for over a decade suddenly became unpatentable because of a change in judicial law. Lost with that rejected patent application on that invention was any chance to recover the research money and lost employee time invested in the invention's discovery and development based on a good faith compliance with the law in effect at the time the application was filed.

B. Changing the Written Description Requirement May Inject Uncertainty into the More Than 2.5 Million Patents Prosecuted Under the Current Legal Regime

Since Judge Rich, writing for the Court, first explained the written description requirement in *In re Ruschig*, applicants have been drafting and prosecuting patents in reliance on his interpretation of the Patent Act. *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967). And that proclamation has been studiously followed by the Courts since. See e.g., *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A. 1971) (noting that “it is possible for a specification to *enable* the practice of an invention as broadly as it is claimed, and still not *describe* that invention.”) (emphasis added); *In re Wilder*, 736 F.2d 1516, 1520, (Fed. Cir.1984), cert. denied, 469 U.S. 1209 (1985) (holding that “[t]he description requirement is found in 35 U.S.C. § 112 and is separate from the enablement requirement of that provision.”); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (holding “[t]his court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement.”).

Since the *Vas-Cath* decision in June of 1991, more than 2.5 million patents have been prosecuted and issued based on the fundamental premise that 35 U.S.C. § 112, first paragraph contains a written description section separate and distinct from an enablement requirement. Should the Court change that well settled understanding of the law by either removing the written description requirement from the current § 112 analysis or by changing the interpretation of the enablement requirement, some patents that businesses thought were valid might now be considered invalid if litigated, and patents that have been thought invalid might now be held valid. This particularly affects pharmaceutical and biotech patents that seem to be more often the focus of a § 112 review. Both outcomes can change prior long-term investment-backed decisions with the potential result of wasted capital and research or new-found patent infringement exposure.

C. The Supreme Court has Cautioned that Stare Decisis is of Particular Importance in Patent Law Where Expectations Drive Investment

“A patent for an invention is as much property as a patent for land. The right rests on the same foundation and is surrounded and protected by the same sanctions.” *See Consolidated Fruit-Jar Co. v.*

Wright, 94 U.S. 92, 96 (1876). The Supreme Court has long recognized the importance of stability and precedential consistency to protect investment-backed expectations in the law of real property.

Where courts vacillate and overrule their own decisions on the construction of statutes affecting the title to real property, their decisions are retrospective and may affect titles purchased on the faith of their stability. Doubtful questions on subjects of this nature, when once decided, should be considered no longer doubtful or subject to change.

United States v. Title Insurance & Trust Co., 265 U.S. 472, 486-7

(1924). Similarly, because patents are also property, changes in patent law after a patent is granted also work retrospectively and can disturb settled expectations.² Congress addresses this issue by making federal legislation prospective only, but courts are less willing to do so as it could appear that the court is creating instead of construing law.

² The general rule is that changes in patent law apply retroactively to patents which have been granted but not litigated before the decision that changes the law. That is fraught with peril. Retroactive application of a court decision to patents that have already issued could arguably work an unconstitutional taking of investment that was made based on reliance before the Court changed the law. In instances where courts believed that they should depart from stare decisis, (amicus does not suggest that is the case in these circumstances) the court could consider announcing the change effective prospectively only. The court could then accomplish the goal of “modernizing” the law, if that was appropriate, without upsetting prior good faith business decisions based on prior case law. Further, a prospective only change would protect the billions of dollars invested in innovation over the last two decades. See, e.g., *Chevron Oil Co. v. Huson*, 404 U.S. 97, 107 (1971) (concluding that applicable statute of limitations “should not be applied retroactively in the present case”).

However, there is not much practical difference between changing a long-standing interpretation of a statute and changing the wording of the statute.

Consequently, the Supreme Court stresses that the doctrine of stare decisis is of particular importance in patent law. “Fundamental alterations in [patent laws] risk destroying the legitimate expectations of inventors in their property.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002); *see also Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 (1997) (Ginsburg, J., concurring) (“The new presumption, if applied woodenly, might in some instances unfairly discount the expectations of a patentee who had no notice at the time of patent prosecution that such a presumption would apply.”). Where corporations collectively have invested billions based on settled interpretations of law, stare decisis counsels against departure from prior interpretations of the law. *See also*, Brief of Eli Lilly and Company, at p. 37-39.

D. Unforeseeable Changes in Law are Particularly Damaging to not only the Pharma/Biotech Industry but the Public at Large as Well

Developing the next generation of pharmaceuticals is enormously expensive and the cost is growing. That investment, if

unprotected, not only damages the companies that make it but the public at large. Drugs sold today fund the research and development of the drugs of tomorrow. The \$50 billion spent last year on research for treatments for cancer, heart disease, and others was generated from the sale of drugs that were developed decades ago. Those sales are largely made possible by the patent protection afforded those products. But those patents were prosecuted over a decade ago based on the law in place at *that* time. Dramatic change in the settled law upon which those patents rest risks the revenue those products can generate and the resources available for the development of the next generation of drugs.

II. CONCLUSION

It is more important than ever that the US patent system provide a strong foundation for long term accurate business investment.

Pharmaceutical companies must be able to trust that they can make long term decisions based on current law that will remain correct over the 10-15 years needed to get a product approved and then during its patented years. For this reason, the Court should protect the investment-backed expectations of patent holders by ensuring the law

remains stable and predictable, and is not subject to dramatic changes
in statutory interpretation.

Respectfully submitted,

Dated: November 19, 2009

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CERTIFICATE OF SERVICE

Ariad Pharmaceuticals v. Eli Lilly, 2008-1248

I, Karen L. Pierangeli, being duly according to law and being over the age of 18, upon my oath depose and say that:

Byron S. Adams was retained by GlaxoSmithKline to print this document. I am an employee of Byron S. Adams.

On 19th Day of November 2009, I caused 2 copies of the within **Brief Of Amicus Curiae Glaxosmithkline In Support Of Eli Lilly & Company** to be served upon the following:

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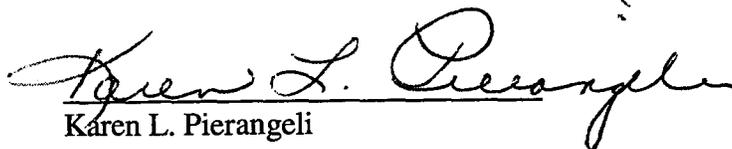
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November 19, 2009


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(State whether representing appellant, appellee, etc.)

November 19, 2009

(Date)

Declaration of Authority Pursuant to Fed. Cir. 47.3(d)

I hereby declare that:

1. Sherry M. Knowles, Esq. is attorney of record for Amicus Curiae GlaxoSmithKline LLC in the above captioned case;
2. Ms. Knowles is unavailable to sign the Brief of Amicus Curiae GlaxoSmithKline in Support of Eli Lilly & Company and supporting documents ;
3. Ms. Knowles has given me actual authority to sign the Brief of Amicus Curiae GlaxoSmithKline in Support of Eli Lilly & Company and supporting documents on her behalf.

I declare under the penalties of perjury that the foregoing is true and correct.

Executed on November 19, 2009.

Respectfully Submitted,



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