

2008-1403

---

**IN THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

---

PROMETHEUS LABORATORIES, INC.,

*Plaintiff-Appellant,*

v.

MAYO COLLABORATIVE SERVICES (doing business as Mayo Medical  
Laboratories) AND MAYO CLINIC ROCHESTER,

*Defendants-Appellees.*

---

Appeal From The United States District Court For The  
Southern District Of California In Case No. 04-CV-1200,  
Judge John A. Houston.

---

**BRIEF OF AMICUS CURIAE  
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION  
IN SUPPORT OF APPELLANT**

Teresa Stanek Rea  
*President*

AMERICAN INTELLECTUAL PROPERTY  
LAW ASSOCIATION  
241 18th Street, South, Suite 700  
Arlington, VA 22202  
(703) 415-0780

Edward R. Reines, Esq.  
*Principal Attorney*

Jill J. Ho, Esq.  
WEIL GOTSHAL & MANGES, LLP  
201 Redwood Shores Parkway  
Redwood Shores, CA 94065  
(650) 802-3000

DATED: JANUARY 22, 2009

*Counsel for Amicus Curiae*  
AMERICAN INTELLECTUAL PROPERTY  
LAW ASSOCIATION

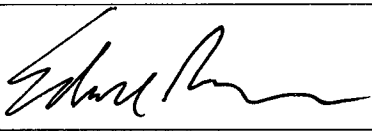
**CERTIFICATE OF INTEREST**

Counsel for amicus curiae, the American Intellectual Property Law Association, certifies the following:

1. The full name of every party represented by me is:  
**American Intellectual Property Law Association**
  
2. The names of the real parties in interest (if the party named in the caption is not the real party in interest) represented by me is:  
**Not Applicable.**
  
3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are:  
**None.**
  
4. The names of all law firms and the partners or associates that appeared for the parties now represented by me in the trial court or agency or are expected to appear in this Court are:

<b>Teresa Stanek Rea AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION</b>	<b>Edward R. Reines, Esq. Jill J. Ho, Esq. WEIL GOTSHAL &amp; MANGES, LLP</b>
---	---

Dated: January 22, 2009

By:   
Edward R. Reines  
WEIL GOTSHAL & MANGES, LLP

## TABLE OF CONTENTS

	Page
CERTIFICATE OF INTEREST .....	i
TABLE OF CONTENTS.....	ii
TABLE OF AUTHORITIES .....	iii
I. STATEMENT OF INTEREST .....	1
II. SUMMARY OF ARGUMENT.....	2
III. ARGUMENT.....	5
A. The Claimed Methods Meet The Machine-or-Transformation Test Embraced By This Court In <i>Bilski</i> .....	6
B. The District Court Overreacted To The <i>Lab. Corp.</i> Dissent.....	9
C. This Case Is Distinguishable From Decisions That Have Rejected Patents For Claiming Ineligible Subject Matter.....	11
D. The District Court’s Refusal to Consider Prometheus’ Claims as a Whole is Fundamental Error.....	12
E. The District Court Employed The Wrong Test And Misapplied It In Any Event.....	16
F. Biomedical Diagnostic Tools Should Remain Patent-Eligible Subject Matter.....	18
IV. CONCLUSION.....	22
CERTIFICATE OF SERVICE .....	23
CERTIFICATE OF COMPLIANCE.....	24

## TABLE OF AUTHORITIES

Page(s)

### CASES

<i>In re Bilski</i> , 545 F.3d 943 (Fed. Cir. 2008) (en banc) .....	passim
<i>Cochrane v. Deener</i> , 94 U.S. 780 (1876).....	15
<i>In re Comiskey</i> , No. 2006-1286, 2009 WL 68845 (Fed. Cir. Jan. 13, 2009).....	7
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980).....	2, 6
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981).....	passim
<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972).....	passim
<i>In re Grams</i> , 888 F.2d 835 (Fed. Cir. 1989).....	12
<i>Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.</i> , 548 U.S. 124 (2006).....	passim
<i>In re Meyer</i> , 688 F.2d 789 (C.C.P.A. 1982).....	12
<i>Parker v. Flook</i> , 437 U.S. 584 (1978).....	passim

### STATUTES

35 U.S.C. § 101 .....	passim
35 U.S.C. § 102.....	21

## TABLE OF AUTHORITIES

	Page(s)
35 U.S.C. § 103 .....	21
35 U.S.C. § 112 .....	21

## OTHER AUTHORITIES

H.R. REP. NO. 82-1923 (1952) .....	2
S. REP. NO. 82-1979 (1952) .....	2
U.S. Pat. No. 6,087,090.....	21
U.S. Pat, No. 6,355,623.....	2
U.S. Pat. No. 6,680,302.....	2
U.S. Pat. No. 6,770,029.....	21
U.S. Pat. No. 7,348,149.....	21
U.S. Pat. Appl. No. 2008/0318219 (filed Mar. 16, 2007).....	20
Mara G. Aspinall & Richard G. Hammermesh, <i>Realizing the Promise of Personalized Medicine</i> , HARV. BUS. REV., Oct. 2007, at 108.....	18, 19, 20
Frank R. Ernst & Amy J. Grizzle, <i>Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model</i> , 41 J. AM. PHARM. ASS'N 192 (2001).....	19
Peter Huber, <i>Who Pays for a Cancer Drug?</i> , FORBES, Jan. 12, 2009, at 72.....	21
Jason Lazarou, et al., <i>Incidence of Adverse Drug Reactions in Hospitalized Patients</i> , 279 J. AM. MED. ASS'N 1200 (1998).....	19

## TABLE OF AUTHORITIES

	Page(s)
Michael O. Leavitt & Raju Kucherlapati, <i>The Great Promise of Personalized Medicine</i> , BOSTON GLOBE, Dec. 26, 2008, at A19 .....	19
ANDREW MCWILLIAM, ET AL., AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES, HEALTH CARE SAVINGS FROM PERSONALIZING MEDICINE USING GENETIC TESTING: THE CASE OF WARFARIN (Nov. 2006), available at <a href="http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-23_topost.pdf">http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-23_topost.pdf</a> .....	20
Rick Mullin, <i>Personalized Medicine</i> , CHEMICAL & ENGINEERING NEWS, Feb. 11, 2008, at 17.....	18, 20
Brian B. Spears, et al., <i>Clinical Application of Pharmacogenetics</i> , 7 TRENDS IN MOLECULAR MED. 201 (2001).....	19

## I.

### STATEMENT OF INTEREST

American Intellectual Property Law Association (AIPLA) is a voluntary bar association of more than 17,000 members—including attorneys in private and corporate practice, in government service, and in the academic community—who work with patents, trademarks, copyrights, trade secrets, and other legal issues affecting intellectual property.

AIPLA's interest in this appeal is to improve the intellectual property laws of the United States as explained below. A robust and balanced intellectual property regime promotes innovation and this brief explains why patenting in the area of diagnostics is good law and good policy. AIPLA has no interest in any party to this litigation or stake in the outcome of this appeal.

AIPLA submits this *amici curiae* brief with the consent of all parties, provided by joint letter to the Court dated January 8, 2009.

## II.

### SUMMARY OF ARGUMENT

At stake in this appeal is whether, and to what extent, patents for diagnostic tools should be prohibited in light of the Supreme Court's recognition that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952) and H.R. REP. NO. 82-1923, at 6 (1952)).

While it has become again vogue, at least in some quarters, to belittle the value of patents to innovation, the incentive to innovate provided by the patent system is no less important in the area of diagnostics than in other areas. Indeed, the development of diagnostic tests and techniques requires a substantial investment of scarce research and development resources. Such investments would be discouraged if the resulting inventions cannot be protected by patents and thus can be easily imitated. In the end, the temptation to succumb to patent skeptics must be resisted where to do so would be at odds with law, logic, and the development of advanced technologies. As explained below, this is such a case.

Accepted at face value, the patents-in-suit (U.S. Patent Nos. 6,355,623 and 6,680,302) provide techniques to help relieve the pain for those

suffering from Crohn's disease and other debilitating diseases of the digestive system.<sup>1</sup> As explained in the patents, the inventors discovered the key to minimizing the hazardous side effects of the available medicines for such diseases, while also optimizing their healing effect. The patents describe how medicine for Crohn's disease, containing a specific class of chemical compounds, is transformed into particular metabolites that do not naturally exist in the body, and that, if one measures the identified metabolites, the levels can indicate the optimal treatment range for that particular individual.

This invention is an example of the trend towards personalized medicine. This new era in healthcare is based on the recognition that not all people respond similarly to disease, medicine, or the environment. Development teams increasingly have the technology to develop diagnostic tests and techniques that can be used to intelligently tailor medical treatments to each person. Personalized medicine allows the health establishment to move past the crude "one size fits all" approach that has characterized much of modern medicine.

---

<sup>1</sup> AIPLA has not independently validated the accuracy of the statements in the patents-in-suit or evaluated whether the patents meet conditions of patentability beyond 35 U.S.C. § 101. For purposes of this brief, both are presumed.

The district court's holding that such treatment methods are altogether unpatentable predated this Court's *In re Bilski* decision, 545 F.3d 943 (Fed. Cir. 2008) (en banc), and is squarely at odds with it.<sup>2</sup> The district court's rejection of the diagnostic patents appears to stem from a misreading of, and overreaction to, Justice Breyer's animated dissenting opinion in *Lab. Corp.*, which garnered the support of only two other justices. *See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.* 548 U.S. 124 (2006) (Breyer, J., dissenting).

As demonstrated below, the patents at issue are well within the realm of patentable subject matter and it is important that this Court so hold. The patent-inspired incentive to develop advanced diagnostic technologies depends on it.

---

<sup>2</sup> Although this brief accepts that, under the rule of *stare decisis*, the test set forth in *Bilski* governs this appeal at the panel stage, AIPLA respectfully notes that its views on the proper scope of patentable subject matter differ from those set forth in *Bilski*. *See* Brief of Amicus Curiae American Intellectual Property Law Association in Support of Appellants for Hearing En Banc, *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (No. 2007-1130). Nothing in this brief should be misunderstood to suggest that AIPLA has abandoned the views previously set forth in its *Bilski* brief.

### III.

#### ARGUMENT

This Court in *Bilski* held that a process is statutory subject matter under 35 U.S.C. § 101 “if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.” 545 F.3d at 954. The district court’s analysis, however, does not comport with *Bilski* or with the Supreme Court decisions interpreted therein.

Indeed, the district court flatly refused to apply the “transformation” test, which is governing law under *Bilski*, reasoning that it was “not required” to apply that test. Slip op. at 16. Instead, the district court incorrectly used the “preemption” test, which was criticized by this Court as “hardly straightforward” and “of limited usefulness.” *Bilski*, 545 F.3d at 954. The district court’s decision was wholly inconsistent with this Court’s conclusion that the machine-or-transformation test is not “optional or merely advisory,” but rather a “definitive test” for determining whether a claimed process involving a fundamental principle preempts the principle itself. *Id.* at 954 & 956 n.11.

**A. The Claimed Methods Meet The Machine-or-Transformation Test Embraced By This Court In *Bilski***

The relevant statute, 35 U.S.C. § 101, provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

It is often quoted, but also important to be reminded, that § 101 was intended to render patentable “anything under the sun made by man,” assuming the other conditions of patentability are fulfilled. *Ch akrabarty*, 447 U.S. at 309.

Consistent with the broad language of § 101, the Supreme Court has recognized only a few exceptions to patentable subject matter, including the one relied upon by the district court below, the patenting of pure “natural phenomena.” *Diehr*, 450 U.S. 175, 185 (1981). Yet, while a natural phenomenon may itself be unpatentable, “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” *Id.* at 187 (emphasis in original). As the Supreme Court wisely explained in *Diehr*, “all inventions can be reduced to underlying principles of nature.” *Id.* at 189 n.12. As such, the fact that an invention is

premised on the application of a principle of nature cannot be sufficient to disqualify it from patenting. *Id.*

In *Bilski*, this Court sitting en banc held that a process is patent-eligible if (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. *Id.* The district court's analysis, at its root, contradicted this Court's *Bilski* decision by refusing to apply the transformation test. Slip op. at 16.

While *Bilski* focused on the patentability of a business method for hedging risk, the instant appeal presents a simpler case. Indeed, this Court expressly recognized that “[i]t is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter.” *Bilski*, 545 F.3d at 962 (emphasis in original). Even more recently, this Court reaffirmed that process patents with claims reciting an algorithm or abstract idea can nonetheless meet § 101 “if, as employed in the process, it is embodied in, operates on, transforms, or otherwise involves another class of statutory subject matter, *i.e.*, a machine, manufacture, or composition of matter.” *In re Comiskey*, No. 2006-1286, 2009 WL 68845, at \*8 (Fed. Cir. Jan. 13, 2009) (emphasis added). On the other hand, “a mental process standing alone and untied to another category of statutory subject matter” is unpatentable. *Id.*, at \*9.

Here, the invention involves the physical transformation of a composition of matter, in this case a drug, into metabolites.<sup>3</sup> The District Court explained that, as it construed the claims, each claim at issue included the step of administering the drug to a subject and determining the resulting metabolite levels to evaluate an adjustment in dosage. Slip op. at 9. Neither the administered drug (*i.e.*, 6-mercaptopurine (6-MP) or azathioprine (AZA)) nor the resulting metabolites (*i.e.*, 6-thioguanine (6-TG) or 6-methyl-mercaptopurine (6-MMP)) of the patent claims are naturally occurring compounds. Obviously, no purely natural phenomenon encompasses the transformation of these administered drugs to these resultant metabolites. More importantly, even if the compositions of matter involved were naturally occurring, to be patent-eligible, the *Bilski* test merely requires a physical transformation of a composition of matter as part of the invention.

In its analysis, the district court placed too much weight on the fact that “6-TG and 6-MMP are products of the natural metabolizing of thiopurine drugs.” Slip op. at 11. That the physical transformation occurs with the aid of a naturally-existing enzyme is irrelevant. Indeed, almost all

---

<sup>3</sup> As pointed out in Appellant’s Brief, at 21-30, there are also other transformations associated with the patented processes, such as the transformation of a blood sample in order to measure metabolite levels and the improvement to the patient’s health as a result of the improved therapy.

patentable compositions of matter are created via naturally-occurring chemical reactions. *See, e.g., Gottschalk v. Benson*, 409 U.S. 63, 69 (1972) (describing naturally occurring processes such as “the use of chemical substances or physical acts, such as temperature control” to physically change raw materials). What matters is that a metabolite resulted from the physical transformation of a drug provided as part of a process created by man.

**B. The District Court Overreacted To The *Lab. Corp.* Dissent**

A review of the district court’s opinion helps explain why it committed error. The dissent in *Lab. Corp.* weighed heavily in the district court’s analysis. The district court spent pages on the *Lab. Corp.* dissent and expressed disquiet that the patent in this case is, in its view, similar to the patent criticized by Justice Breyer in dissent. While the district court insisted that it was not treating the *Lab. Corp.* dissent as binding, its use of that dissent is problematic for four reasons.

First, and most obviously, the *Lab. Corp.* dissent was only joined by two other justices and thus simply cannot be treated properly as the view of the Supreme Court as an institution. As a dissent, by definition it has no precedential force. Indeed, if there is any conclusion one can draw from *Lab. Corp.*, it is the outright refusal by five other justices, a majority of the Court, to express any agreement with the views in Justice Breyer’s dissent.

