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

Counsel for Amicus Curiae
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

DATED: JANUARY 22, 2009

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.

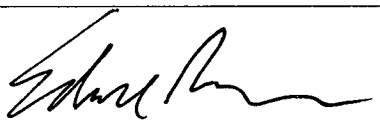
3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are:

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:

Teresa Stanek Rea **AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION**	**Edward R. Reines, Esq.** **Jill J. Ho, Esq.** **WEIL GOTSHAL & MANGES, LLP**

Dated: January 22, 2009

By: 

Edward R. Reines
WEIL GOTSHAL & MANGES, LLP

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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.[1] 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.

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[1] 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.[2] 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.

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[2] 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.[3] 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

[3] 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.

Notwithstanding the district court's caveats, the statements of a Supreme Court justice appear to have had an intimidating effect.

Second, the district court's conclusion that the *Lab. Corp.* patent is "similar" factually to the patents in this case ignores significant distinctions. As demonstrated above, the context of the invention in this case is the physical transformation of drugs into metabolites that can be measured to provide valuable diagnostic information. This physical transformation is integral to the invention and establishes patent eligibility under *Bilski* as explained above. However, the *Lab. Corp.* patent involves the measurement of homocysteines that, unlike the metabolites in this case, are not the result of a physical transformation of an administered drug. Thus, the *Lab. Corp.* patent does not involve the consumption of a drug that is transformed into a substance that can then be used for diagnostics. In other words, the *Lab. Corp.* patent claims do not require the physical transformation of a drug as an integral part of the invention. Thus, finding the transformation test satisfied in this case is consistent with the *Lab. Corp.* dissent, even if one were to accept that dissent as a correct statement of the law.

Third, the *Lab. Corp.* dissent is not correct on the law. As a threshold matter, the *Lab. Corp.* case was not sufficiently developed on the issue of patentable subject matter for reliable decision-making, having not

been raised until the case arrived at the Supreme Court. The majority of the Supreme Court rejected the dissent's opinion that patentable subject matter was properly adjudicated for the first time at the Supreme Court. Consequently, the dissent was out of place when it performed its § 101 analysis as though it were a trial court.

Fourth, and most importantly, the *Lab. Corp.* patent requires a test to determine the levels of homocysteine from a sample for purposes of evaluating vitamin deficiencies. That assay (the collection and purification of the different kinds of homocysteines in the blood) is the kind of physical transformation cognizable under the transformation test. To the extent the *Lab. Corp.* dissenters would have concluded otherwise, if certiorari had not been dismissed as improvidently granted, that would have been error.

C. This Case Is Distinguishable From Decisions That Have Rejected Patents For Claiming Ineligible Subject Matter

The claims here are easily distinguishable from others that have been rejected as unpatentable.

In *Bilski*, this Court concluded that the applicants attempted to claim "a non-transformative process" of hedging risk. 545 F.3d at 965. Thus, according to the *Bilski* opinion itself, the *Bilski* patent did not involve the physical transformation of a composition of matter as part of the invention,

such as the transformation of drugs into metabolites. The Court compared the *Bilski* claims to those rejected in *In re Meyer*, 688 F.2d 789, 792-93 (C.C.P.A. 1982), and *In re Grams*, 888 F.2d 835, 836-37 (Fed. Cir. 1989), as unpatentable subject matter because the Court concluded they were directed to fundamental mental processes. According to the *Bilski* opinion itself, the claims in those cases did not involve a physical transformation of a particular composition of matter as an integral part of a process. It is beyond reasonable debate that the claims at issue in this case involve exactly such a physical transformation.

D. The District Court's Refusal to Consider Prometheus' Claims as a Whole is Fundamental Error

The district court was only able to ignore the physical transformation of the drugs in this case by refusing to consider the claims as a whole. Of course, it is a bedrock principle of patent law that "claims must be considered as a whole" when addressing the question of patentable subject matter. *Diehr*, 450 U.S. at 176, 188.

Relying on *Parker v. Flook*, 437 U.S. 584, 590 (1978), the district court asserted that "an 'unpatentable principle' will not transform into a 'patentable process' simply by adding conventional method steps." Slip op. at 9. Addressing the patents in this case, the district court then performed its

analysis without regard to the consumption of the drug, and the physical transformation of it into metabolites, which are integral to the invention. The district court discarded them as merely "necessary data gathering steps." Slip op. at 9.

As explained by the Supreme Court in *Diehr*, however, this type of claim dissection is improper. *See Diehr*, 450 U.S. at 188 ("It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."). This fundamental principle was echoed by this Court in *Bilski*:

> After all, even though a fundamental principle itself is not patent-eligible, processes incorporating a fundamental principle may be patent-eligible. Thus, it is irrelevant that any individual step or limitation of such processes by itself would be unpatentable under § 101.

Bilski, 545 F.3d at 958 (emphasis added).

The district court's reliance on *Flook* for the supposed proposition that "conventional method steps" are not cognizable in the § 101 analysis is unsupported. This approach blindly ignores the Supreme Court's post-*Flook* decision in *Diehr*. In *Diehr*, the Supreme Court explained that its decision in *Flook* stood for "nothing more" than the basic long-established

principles providing that natural phenomena cannot be patented. *Diehr,* 450 U.S. at 185, 191. *Diehr* also limited *Flook* tightly to its facts:

> We were careful to note in *Flook* that the patent application did not purport to explain how the variables used in the formula were to be selected, nor did the application contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm unit. All the application provided was a "formula for computing an updated alarm limit."

Id. at 193, n.14 (citations omitted).

In any event, the Supreme Court in *Diehr* flatly rejected the claim dissection approach employed by the district court. Although the district court relied on *Flook* as its justification for ignoring "old" claim steps, the Supreme Court in *Diehr* has already explained that this is a misuse of *Flook*:

> It is argued that the procedure of dissecting a claim into old and new elements is mandated by our decision in *Flook* which noted that a mathematical algorithm must be assumed to be within the "prior art." It is from this language that the [Government] premises [its] argument that if everything other than the algorithm is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in *Flook* that the mathematical algorithm could not be considered at all when making the §101 determination. To accept the analysis proffered by the [Government] would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their

> implementation obvious. The analysis suggested by the [Government] would also undermine our earlier decisions regarding the criteria to consider in determining the eligibility of a process for patent protection. *See, e.g.*, [*Benson*, 409 U.S. at 63; *Cochrane v. Deener*, 94 U.S. 780 (1876)].

Id. at 189 n.12.

Although the claims must be understood as a whole, and cannot be dissected as the district court attempted to do, the Supreme Court in both *Flook* and *Diehr* acknowledged that fallacious draftsmanship cannot be used to circumvent the rule against patenting natural phenomena. For example, the addition of "insignificant" post-solution activity to claims was deemed insufficient to make natural phenomena patentable. But, as *Diehr* confirms, "insignificant" in this context does not mean old in the prior art. Rather, "insignificant" in this context refers to a step that has no *bona fide* relationship to the invention.

Applying these principles to this case, it is beyond legitimate debate that the physical transformation that flows from the use of the drugs in the patented processes in this case is not "insignificant" post-solution activity. Rather, it enables the invention, provides its factual context, and is necessarily intertwined with what makes it an innovation.

E. The District Court Employed The Wrong Test And Misapplied It In Any Event

While patentees should not be allowed to preempt *all* uses of a natural phenomenon by patenting it, they should be able to preempt others from using a particular application of a natural phenomenon that they invent. *See Diehr*, 450 U.S. at 187. Indeed, by definition, a patent grants an inventor the right to exclude, *i.e.*, *preempt*, others from practicing his or her invention, and all patents at some level include natural phenomena at their core.

In *Bilski*, this Court explained the pitfalls of attempting to apply a "preemption" test, which is nearly impossible in the abstract. *See* 545 F.3d at 954. Instead, the Court stated that the machine-or-transformation test is the best tool for determining whether a process claim is patent-eligible because it acts as a proxy for whether a fundamental principle is wholly preempted:

> [A] claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article.

Id.

The reliance on a "preemption" test by the district court instead of the transformation test is thus plain legal error. Moreover, the district court's

application of the much-criticized preemption test was flawed and shows how difficult it can be to apply correctly.

As explained by the appellant below, the claimed methods do *not* preempt uses of the correlation between 6-TG levels and therapeutic efficacy such as: (1) use in research; (2) use in treating diseases other than the autoimmune or gastrointestinal diseases to which the claims are limited; (3) use when measuring 6-TG or 6-MMP in units other than pmol per $8x10^8$ red blood cells; (4) use in building upon the correlations; (5) use in publishing articles in scientific journals; and (6) use in testing and determining metabolite levels without giving a warning. *See* slip op. at 18. In addition, the correlations could be used (1) with other synthetic drugs that create similar metabolites, (2) to detect the level of enzymatic activity itself, or (3) to indirectly measure the body's metabolism of naturally occurring thiopurines.

The district court's conclusion that these alternative uses of the natural phenomenon are not practical enough is confused. An inventor is responsible for discovering a useful application of a natural phenomenon that involves a machine or transformation. But an inventor is not responsible for ensuring that there are other commercially viable or medically promising alternative applications of the natural phenomenon she or he has harnessed for

a particular application. Such a rule would perversely punish the pioneer in favor of the incrementalist.

F. Biomedical Diagnostic Tools Should Remain Patent-Eligible Subject Matter

Diagnostic methods such as those claimed by the patents-in-suit should remain patentable subject matter, among other things, to protect and encourage the development of personalized medicine. As referenced above, "personalized medicine" is the practice of catering therapies to the specific needs of individual patients. *See, e.g.*, Rick Mullin, *Personalized Medicine*, CHEMICAL & ENGINEERING NEWS, Feb. 11, 2008, at 17. By contrast, most physicians today provide drug treatment on a trial-and-error basis: if, after a period of time, a particular drug dosage is ineffective or has hazardous side effects, the doctor may change the dosage or try another drug or diagnosis entirely. This cycle is repeated until the correct diagnosis and treatment plan is hopefully found. *See* Mara G. Aspinall & Richard G. Hammermesh, *Realizing the Promise of Personalized Medicine*, HARV. BUS. REV., Oct. 2007, at 108, 110.

This trial-and-error approach is extremely costly in both human and economic terms. Less than 60% of the drug treatments that are prescribed are effective. *See* Aspinall & Hammermesh, *supra*, at 111 (citing

Brian B. Spears, et al., *Clinical Application of Pharmacogenetics*, 7 TRENDS IN MOLECULAR MED. 201 (2001)). For example, standard drug treatments have only a 25% rate of efficacy in cancer patients. *See id.* This is not necessarily a result of shortcomings in the drugs themselves but rather because each patient is biologically unique. Michael O. Leavitt & Raju Kucherlapati, *The Great Promise of Personalized Medicine*, BOSTON GLOBE, Dec. 26, 2008, at A19. Incorrect or imprecise treatments not only create unnecessary side effects but also threaten the lives of those with acute diseases who cannot afford to wait through a trial-and-error process. *See* Aspinall & Hammermesh, *supra*, at 110. Indeed, adverse reactions to drugs cause over a hundred thousand deaths and cost up to $177 billion annually. *See* Frank R. Ernst & Amy J. Grizzle, *Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model*, 41 J. AM. PHARM. ASS'N 192 (2001); Jason Lazarou, et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients*, 279 J. AM. MED. ASS'N 1200 (1998).

Personalized medicine has the potential to save lives and precious healthcare dollars by changing the traditional trial-and-error routine that physicians currently use to treat patients. Diagnostic methods such as those claimed here are the lifeblood of this new approach. They allow physicians to take into account the patient's unique physiology such as the patient's

ability to metabolize particular drugs. *See* Aspinall & Hammermesh, *supra*, at 110.

The patents-in-suit are an example of technology useful for personalized medicine. By disclosing a method for optimizing the dosage of the drug 6-MP used to treat inflammatory bowel disease, and by measuring metabolite levels in an individual after drug treatment, the claimed invention thereby allows a doctor to take into account a particular patient's unique ability to metabolize 6-MP and "personalize" the patient's dosage accordingly. This strategy maximizes the effectiveness of treatment, minimizes adverse effects, and ultimately saves time, money, and lives.

The industry for personalized medicine is nascent but growing.[4] *See* Mullin, *supra*. In reliance on the state of the law since *Diehr*, many patents for diagnostic and optimization methods have been issued as a result of

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[4] One recent example is the development of diagnostic tests for sensitivity to warfarin, a blood-thinning drug whose under- and over-dosing results in serious bleeding and strokes that alone cost the healthcare system $1.1 billion annually. *See* 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* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/WP06-23_topost.pdf; *see also* U.S. Pat. Appl. No. 2008/0318219 (filed Mar. 16, 2007) (claiming methods for determining individualized dosages of warfarin by identifying indicators in an individual's genotype).

these efforts. *See, e.g.*, U.S. Pat. No. 7,348,149 ("Methods of Diagnosing Parkinson's Disease"); U.S. Pat. No. 6,770,029 ("Disease Management System and Method Including Correlation Assessment"); U.S. Pat. No. 6,087,090 ("Method for Predicting Drug Response").

Patent protection is essential for continuing investment and innovation in the field of personalized medicine. Determining optimal treatments can be very costly, since variations can be numerous and each affected sub-population can be small. *See* Peter Huber, *Who Pays for a Cancer Drug?*, FORBES, Jan. 12, 2009, at 72. Without the promise of patent protection, researchers would be deterred from customizing or optimizing treatments with a known drug, especially those relevant to smaller populations.

This Court should not now narrow the scope of patentability to exclude diagnostic methods under § 101. The public domain is properly protected by a host of conditions for patentability under Title 35, including the novelty, non-obviousness, and disclosure requirements of §§ 102, 103 and 112. Diagnostic inventions are often the first steps that lead to further biomedical innovations because the ability to diagnose a disease more precisely lays the groundwork for developing custom-tailored treatments and, ultimately, preventative measures. Discouraging innovation at the front end threatens all the innovation that follows.

IV.

CONCLUSION

For the aforementioned reasons, this Court should reverse the district court's judgment that the claims of the patents-in-suit are invalid pursuant to 35 U.S.C. § 101.

Dated: January 22, 2009

Respectfully submitted,

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
Attorneys for Amicus Curiae
AMERICAN INTELLECTUAL PROPERTY
LAW ASSOCIATION