

2008-1403

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United States Court of Appeals  
For The Federal Circuit

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Prometheus Laboratories, Inc.,  
*Plaintiff-Appellant,*

v.

Mayo Collaborative Services (doing business as Mayo  
Medical Laboratories)  
and Mayo Clinic Rochester,  
*Defendants-Appellees.*

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APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF CALIFORNIA IN CASE NO. 04-CV-1200,  
JUDGE JOHN A. HOUSTON.

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**PETITION OF DEFENDANTS-APPELLEES FOR HEARING  
EN BANC ON REMAND FROM THE SUPREME COURT**

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**July 26, 2010**

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Prometheus Labs v. Mayo Collaborative

No. 2008-1403

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Mayo Collaborative and Mayo Clinic Rochester certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Mayo Collaborative Services (doing business as Mayo Medical Laboratories) and Mayo Clinic Rochester

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:

N/A

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:

Mayo Clinic is the parent organization of Mayo Clinic Rochester. Mayo Clinic and Mayo Health Companies are the parent organizations of Mayo Collaborative Services.

4. [ ] There is no such corporation as listed in paragraph 3.

5. 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 court are:

Fish & Richardson P.C. -- Jonathan Singer, Juanita Brooks, Michael Kane, Jennifer Bush, Thomas McClenahan, Deanna Reichel

July 26, 2010
Date

[Signature]
Signature of counsel
Jonathan Singer
Printed name of counsel

Reset Fields

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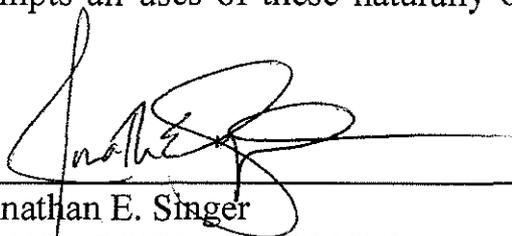
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## STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. In light of the Supreme Court's decision in *Bilski v. Kappos*, 561 U.S. \_\_\_\_ (2010), what criteria should this Court use in applying the Supreme Court's precedent concerning 35 U.S.C. § 101's prohibition against patent claims that cover laws of nature, natural phenomena, and abstract ideas?
2. Under the proper criteria, is 35 U.S.C. § 101 satisfied by a patent claim that covers observed correlations between patient test results and patient health, so that the claim effectively preempts all uses of these naturally occurring correlations?

July 26, 2010



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Counsel for Defendants-Appellees

## INTRODUCTION

On June 28, 2010, the Supreme Court in *Bilski v. Kappos* affirmed this Court's *en banc* ruling that Bilski's claims were unpatentable under Section 101, at the same time disapproving this Court's reasoning in reaching that conclusion. The next day, the Supreme Court granted certiorari in this case, vacated this Court's panel decision that reversed the district court's ruling that Prometheus's claims were invalid under Section 101, and remanded the case for reconsideration

in light of *Bilski*. In light of the Supreme Court's remand, Mayo respectfully submits this petition for *en banc* review and suggestion as to the briefing schedule.

The Prometheus patents in this case attempt to exclude the medical community from using test results of naturally-occurring human metabolism, making physicians and medical researchers infringers simply for thinking about the correlations between patient health and levels of certain chemicals in a patient's blood. Because these broad claims preempt all practical uses of the natural correlations, they are impermissible under controlling Supreme Court precedent.

A panel of this Court found the claims patent-eligible by applying the machine-or-transformation test as *the definitive* standard for patentability—a position the Supreme Court rejected in *Bilski* and again when it granted certiorari and vacated the panel's decision here. Though the *Bilski* Court was divided as to some questions, all nine Justices agreed on the issues that control here—that it is critical to strike the proper balance between patent rights and ensuring that natural phenomena and abstract ideas remain in the public domain where they belong, and that claims should not “preempt” use of subject matter. *See Bilski* at 15. Declining to endorse any “interpretations of Section 101” that this Court “has used in the past,” the Supreme Court left to this Court the job of “developing other limiting criteria [aside from the machine-or-transformation test] that further the purposes of the Patent Act.” *Id.* at 16.

Because this case raises critically important issues that affect patient care and the cost of healthcare delivery in all areas of medicine, as well as medical and educational facilities, as set forth in the numerous *amicus* briefs previously filed in this appeal, clarity is especially important. The issue's great complexity and importance strongly counsel the Court to speak authoritatively, and for each member of the Court to have a chance to consider the issue in an *en banc* hearing.

### STATEMENT OF FACTS

Prometheus' claims, broadly interpreted at Prometheus' urging, cover a process of recognizing naturally-occurring correlations between levels of certain chemicals in a patient's blood and the patient's health. The claims contain no requirement that any action be taken with respect to the correlations; in other words, a doctor infringes the claims without using the correlations in any way with respect to the patient's treatment. [See, e.g., A12538-40; A29.]<sup>1</sup> As Prometheus' own expert testified, merely seeing a document with test results causes infringement even if a doctor "crumples it up, throws it away, reads it, acts on it, doesn't act on it, any assumptions you want to come up with." [A13557-58; A13805-06.] Thus, the claims cover all possible uses of the natural, biological correlations recited in Prometheus' claims.

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<sup>1</sup> All citations in the format "A\_\_" refer to the Joint Appendix that was filed by the parties in connection with this appeal.

Prometheus demonstrated how its claims effectively preempt all uses of the claimed correlations by accusing Mayo Clinic Rochester of infringement through the research of Dr. Rokea el Azhary. In her research, Dr. el-Azhary was seeking new correlation levels for dermatological diseases, and was not concerned about Prometheus' claimed levels. Because she had seen those levels and not erased her mind, however, Prometheus accused her of infringement without her having to do anything with her natural and unavoidable mental recognition. [See, e.g., A12788; A12821-22; A12846; A12848-50; A12852-54; A13805-06; A13360-61.]

The district court, on summary judgment, carefully applied the longstanding Supreme Court precedent that prohibits claims that preempt all practical use of a natural phenomenon. After concluding that the only active steps of the claims were data-gathering steps necessary for any use of the correlations, and that the final step was a mental step that required no action on the physician's part, the court concluded that the claims failed the preemption test. The district court reasoned: "Because the claims cover the correlations themselves, it follows that the claims 'wholly preempt' the correlations." [A37.] In its decision, the district court took into account the important three-Justice dissent from the dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) ("*Labcorp*"), finding the reasoning to be persuasive and the *Labcorp* claims to be highly similar to Prometheus' claims.

On appeal, the panel of this Court applied the machine-or-transformation test as the single, definitive test in reversing the district court and finding Prometheus' claims patent-eligible—and it thus did not address the more fundamental issue of preemption of the natural correlations. The panel did not cite *Labcorp* except in a brief footnote, which did not discuss or take account of the dissent's reasoning.

The Supreme Court's *Bilski* decision overrules the reasoning and analysis that the panel used in deciding this appeal, with each of the Justices' three opinions putting the focus back on the policies behind Section 101 and the prohibition against preempting all uses of natural phenomena. Opinions joined by five Justices cited favorably the dissenting opinion from *Labcorp*, which would have found unpatentable claims like the Prometheus claims here. Accordingly, the day after it issued its opinion in *Bilski*, the Supreme Court issued a GVR order in this appeal.

## ARGUMENT

### **I. It is Essential that this Court Provide an Authoritative National Resolution of the Critically Important Issues Presented by this Case.**

The issues involved in this appeal are of great public importance, directly affecting both medical professionals and patients and having significant potential effects on both the cost and the quality of health care. Like *Labcorp*, which five Justices in *Bilski* cited with approval, this case involves patents in the medical field that attempt to cover the results of naturally-occurring bodily processes and that threaten doctors with infringement for merely thinking about potential patient

treatment. Failing to address these issues now may, in the words of the three justices in *Labcorp*, “inhibit doctors from using their best medical judgment,” “divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations,” and “raise the cost of health care while inhibiting its effective delivery.” *Labcorp*, 548 U.S. at 138-39. *En banc* consideration of this appeal would thus be highly appropriate to resolve these critical issues in a timely manner with the input and wisdom of the entire Court.

As evidenced by the number of amici who have filed briefs both in this case (7 briefs before this Court and 3 before the Supreme Court<sup>2</sup>) and previously in *Labcorp* (20 briefs before the Supreme Court), the issues addressed here are far-reaching and have a substantial impact on many different entities, from doctors, hospitals, and laboratories, to patients and educational institutions. The American Medical Association has criticized this Court’s ruling in *Prometheus* as a “radical expansion of Section 101,” as failing to recognize that *Prometheus*’ claims “preempt all uses” of “recognizing a particular natural result,” and as “bring[ing] the patent laws into conflict with the First Amendment.” Br. *Amici Curiae* Am. Med. Ass’n et al. in *Bilski* at 11-13 & n.5. The American College of Medical Genetics and other genetics and pathology associations have explained that

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<sup>2</sup> For the Court’s convenience, Mayo has separately submitted a supplemental addendum containing the briefing related to its petition for certiorari, the three *amicus* briefs filed in support of its petition, and the American Medical Association’s *amicus* brief from the *Bilski* case.

Prometheus' efforts to prevent physicians from acting on their knowledge of test results violates physicians' "longstanding ethical obligations," "increase[s] health care costs significantly," and "erode[s] doctors' ability to provide quality patient care." Br. *Amici Curiae* of Am. College of Med. Genetics et al. in Support of Certiorari at 9-13. See also Br. *Amici Curiae* Quest Diagnostics Inc. et al. in Support of Certiorari at 15-18. Given all these important considerations, it is critical that the law provide the authoritative guidance in this area that would result from this Court's *en banc* consideration of the issues. See *Bilski*, Stevens op. at 1 (stressing the importance of clear guidance "in light of the uncertainty that currently pervades the field").

At the heart of this appeal—and at the heart of all three opinions in *Bilski*—is the central issue of striking the proper balance between encouraging innovation through the patent system, yet not offering so much protection that others are foreclosed from using ideas and processes that the patent system was not designed to protect. The resolution of this appeal will be crucial to setting that balance. The Supreme Court in *Bilski* cautioned that, if the law fails to set a high enough bar for the grant of patents, "patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change." *Bilski* at 12. It also stressed the importance of "striking the balance between protecting inventors

and not granting monopolies over procedures that others would discover by independent, creative application of general principles.” *Id.* at 10.

The concurring opinions of Justice Stevens and Justice Breyer echoed these very same concerns. Citing *Diehr*, Justice Stevens (joined by Justices Ginsburg, Breyer, and Sotomayor) explained that “no one can patent ‘laws of nature, natural phenomena, and abstract ideas’”—the “‘basic tools of scientific and technological work’”—because allowing these basic tools to be patented “would stifle the very progress that Congress is authorized to promote.” *Bilski*, Stevens op. at 39. *See also, e.g., id.* at 38. Justice Breyer (joined by Justice Scalia) emphasized that all nine Justices agreed on the need for a balance to be reflected in the Court’s limitations on Section 101, observing that the Court has “been careful in interpreting the Patent Act to ‘determine not only what is protected, but also what is free for all to use.’” *Bilski*, Breyer op. at 2 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989)).

Because the claims at issue in this appeal cover correlations that occur naturally in the human body and impact the freedom that doctors will have in using those correlations for research and for the treatment of patients, achieving the proper balance between the competing interests is critical. And the way in which the balance is struck in this appeal is likely to have wide-ranging effects on other similar patents, further underscoring the importance of *en banc* hearing.

**II. The Supreme Court Overruled the Panel’s Section 101 Analysis Based on the Machine-or-Transformation Test and Reaffirmed that an Analysis that Focuses on Preemption is Proper.**

**A. The GVR Order Signifies that The Supreme Court Believes it “Reasonably Probable” that the Panel’s Decision Rests on an Incorrect Premise.**

The fact that the Supreme Court issued a GVR order in this case and did not deny Mayo’s petition as Prometheus had requested is significant to the merits of the case and was not an automatic result of the *Bilski* decision. Indeed, the Supreme Court issues a GVR order only where:

intervening developments, or recent developments that we have reason to believe the court below did not fully consider, reveal a *reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration*, and where it appears that such a redetermination may determine the ultimate outcome of the litigation.

*Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (emphasis added); *see also Wellons v. Hall*, 130 S. Ct. 727, 731 (2010).

If the Supreme Court had believed that its ruling in *Bilski* did not have a potentially outcome-determinative effect on this appeal, it would not have issued a GVR order. Indeed, Prometheus, in its opposition to Mayo’s petition for certiorari, argued that there was no need to remand unless the Supreme Court set “articulates a substantially *more demanding* standard under § 101.” [Prometheus’ Opp. to Pet. for Cert. at 31.] Notably, the Supreme Court denied certiorari in *Ferguson v. Patent & Trademark Off.*, No. 08-1501 (U.S. June 29, 2010), thus showing that it

could dispose of a case decided under this Court’s machine-or-transformation test if it did not believe that its *Bilski* standard could change the outcome. Yet the Supreme Court chose to issue a GVR here despite Prometheus’ objections, demonstrating that it is necessary for this Court to reconsider the issues in this appeal in light of *Bilski* and that such reconsideration has a “reasonable probability” of leading to a different outcome.

**B. The Proper Balance Under Section 101 is Struck By Application of the Supreme Court’s Precedent on Preemption—Precedent that the Panel Did Not Apply.**

The Supreme Court rejected the *Bilski* standard applied by the panel, holding that “[a]dopting the machine-or-transformation test as the sole test for what constitutes a ‘process’ (as opposed to just a useful and important clue) violates ... statutory interpretation principles,” and that “[t]he Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test.” *Bilski* at 6-7. According to the Court, “the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether *some* claimed inventions are processes under § 101.” *Id.* at 8 (emphasis added).

A proper analysis, the Supreme Court observed, should examine whether the claims would “wholly preempt” the use of a natural phenomenon or abstract idea such that it would amount to a patent on the phenomenon or idea itself. *Gottschalk*

*v. Benson*, 409 U.S. 63, 71-72 (1972); *Bilski* at 13; *see also Bilski*, Breyer op. at 2 (“allowing individuals to patent these fundamental principles would ‘wholly preempt’ the public’s access to the ‘basic tools of scientific and technological work’” (citations omitted)). The decisions in *Benson*, *Flook*, and *Diehr* illustrate this preemption analysis in action. In *Benson*, the claims recited no actions after the claimed algorithm was applied, so they covered (and thus preempted) all possible implementations of the algorithm. In *Flook*, the claims recited an algorithm-calculated alarm limit but did not require that any action be taken with respect to that alarm limit, thus preempting all practical use of it. *Parker v. Flook*, 437 U.S. 584, 586 (1970). But in *Diehr*, the claims recited a particular use, or implementation, of the Arrhenius equation, and thus did not preempt the equation. *Diamond v. Diehr*, 450 U.S. 175, 187-88 (1981). The Prometheus claims are like those in *Benson* and *Flook*, and unlike *Diehr*—i.e., they recite the mental correlation but do not recite any implementation of that correlation, and thus preempt all uses of it.

Unlike *Bilski*, whose facts were perhaps so easy that reliance on fundamental principles was not even needed, an analysis focusing on preemption is equally applicable in other major technology areas. For example, as indicated by *Flook* and *Diehr*, software claims that recite an algorithm may be patent-eligible if they are limited to a particular real-world use of that algorithm, but not if they preempt

all practical use of it. Similarly, claims such as the Prometheus claims are not patent-eligible if they recite no actual use of a natural phenomenon and instead prevent all practical use of that phenomenon. Furthermore, the Supreme Court's limitations, reaffirmed in *Bilski*, that prevent a patentee from avoiding the preemption rule merely by, for example, claiming insignificant extra-solution activity, can also be applied across all technology areas.

It is through the thoughtful and reasoned application of this Supreme Court precedent that the proper balance is to be struck between granting patents and keeping natural phenomena as "part of the storehouse of knowledge of all men ... free to all men and reserved exclusively to none." *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Mayo's petition for certiorari relied on this precedent in arguing that Prometheus' broad claims ensnaring doctors' thought processes concerning natural correlations could not meet the requirements of Section 101. And the Supreme Court has now invited this Court, in its application of that precedent, to provide "development of other limiting criteria that further the purposes of the Patent Act." *Bilski* at 16. Mayo submits this is a task appropriate for the *en banc* Court in this appeal.

**C. The *Labcorp* Opinion Provides a Roadmap for Deciding this Case.**

In analyzing this appeal under the Supreme Court's case law, it would also be prudent to consider the reasoning of the *Labcorp* dissent from the dismissal of

certiorari, which applies the Supreme Court's preemption precedent to claims highly similar to those at issue in this appeal, finding that similar natural correlations are an unpatentable "natural phenomenon." *Labcorp*, 548 U.S. at 137-38. Two current Justices signed that opinion, and, in *Bilski*, three additional Justices have joined opinions citing *Labcorp* with approval.

Justice Stevens' *Bilski* concurrence, joined by Justices Breyer, Ginsberg, and Sotomayor, cites approvingly to *Labcorp* in its discussion of the important balancing act involved in granting patents, one of the central themes of all three opinions in *Bilski*. Justice Stevens uses language from *Labcorp* in explaining that, if the balance is not set correctly, patents can discourage research and innovation. *Bilski*, Stevens op. at 43 ("[E]ven when patents encourage innovation and disclosure, 'too much patent protection can impede rather than "promote the Progress of ... useful Arts."") (quoting *Labcorp*, 548 U.S. at 126-27)). Furthermore, Justice Breyer's concurring opinion, joined by Justice Scalia, also cites to *Labcorp* in its discussion of the limits of patentability under Section 101, explaining that the Court has never endorsed a useful, concrete, and tangible result standard for patentability and that such a standard "would cover instances where this Court has held the contrary." *Bilski*, Breyer op. at 3 (quoting *Labcorp*, 548 U.S. at 136).

The panel opinion in this appeal dismissed *Labcorp* in a footnote, stating that it “is not controlling law and also involved different claims from the ones at issue here.” Panel slip op. at 15 n.3. Though the *Labcorp* dissent may not be controlling law, its reasoning may still be looked at as persuasive on points that are central to the analysis under Section 101. The endorsement of *Labcorp*’s reasoning by five Justices would suggest that it *should* be looked at as persuasive and that it is certainly important enough to merit substantive analysis. Furthermore, although the claims may not be identical to the ones at issue here, they are far closer than the claims in any other case that the Supreme Court has decided under Section 101. For that reason as well, *Labcorp* warrants substantive consideration by the *en banc* Court.

**D. Prudential Reasons Strongly Support *En Banc* Treatment of the Supreme Court’s Remand.**

This litigation has already been protracted, having commenced in 2004. The facts in the case are fully developed, the Section 101 issue was the only issue decided on summary judgment and was cleanly briefed, and both parties have the resources to ably present the issue to the Court. The medical community and the public who depend on them need a prompt and authoritative answer to the questions presented in this case, on which the day-to-day conduct of medical treatment and research depends. *En banc* review will provide the certainty that is urgently needed in the wake of the Supreme Court’s announcement that “nothing

[in its opinion in *Bilski*] should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past.” *Bilski* at 16.

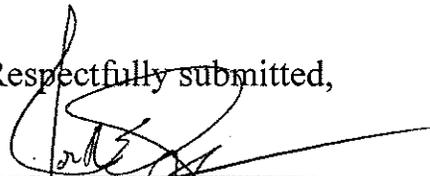
Furthermore, it seems unlikely that any efficiency would be gained by having this case considered in the first instance by the panel, because the original panel cannot be reconstituted, given Judge Michel’s retirement and the participation in the panel of visiting District Judge Clark. In all the circumstances, *en banc* consideration is warranted.

### CONCLUSION

For the foregoing reasons, Mayo respectfully requests that this Court hear this remanded appeal *en banc*. To assist the Court in considering the issues in light of the Supreme Court’s *Bilski* decision, Mayo proposes that the parties simultaneously submit 10,000 word opening briefs within 30 days of the Court’s action on this petition, and 5,000 word responsive briefs within 20 days after service of the opening briefs.

July 26, 2010

Respectfully submitted,



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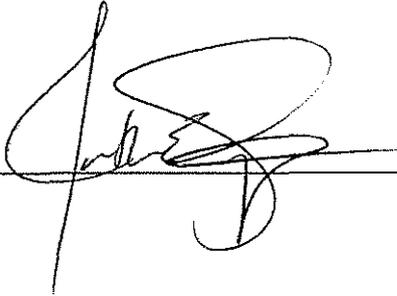
**CERTIFICATE OF FILING AND SERVICE**

I certify that on July 26, 2010, two copies of the PETITION OF  
DEFENDANTS-APPELLEES FOR HEARING EN BANC ON REMAND FROM  
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