

In The
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES,
DBA MAYO MEDICAL LABORATORIES, ET AL.,

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,

Respondent.

**On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit**

**BRIEF OF THE JUHASZ LAW FIRM, P.C.
AS AMICUS CURIAE SUPPORTING
PROMETHEUS LABORATORIES, INC.**

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QUESTION PRESENTED

Whether 35 U.S.C. §101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve “transformations” of body chemistry.

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**BRIEF OF THE JUHASZ LAW FIRM, P.C.
AS AMICUS CURIAE SUPPORTING
PROMETHEUS LABORATORIES, INC.**

INTEREST OF AMICUS CURIAE¹

The authors of this brief are registered patent practitioners with law and science degrees and are members of the patent firm The Juhasz Law Firm, P.C. Paul R. Juhasz has been practicing for 28 years and holds a B.S.Chem.E., a B.S.E.E., a J.D., and a P.E. Chris Frerking has been practicing for 13 years and holds B.S. and M.S. degrees in Computer Science, as well as a J.D. and an LL.M. Both Paul R. Juhasz and Chris Frerking deal with the issue of subject matter patentability for their clients on a regular basis. Mr. Juhasz has written extensively and is extensively published on the Supreme Court's *Bilski* decision and subject matter patentability under 35 U.S.C. §101. They file this brief solely on behalf of the Firm and not on behalf of clients of the Firm. Amicus represent neither party in this action, and offer the following views based on their extensive experience on this matter.



¹ Pursuant to Sup. Ct. R. 37.6, amicus notes that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae made a monetary contribution to its preparation or submission. Petitioners and Respondent have consented to the filing of this brief through blanket consent letters filed with the Clerk's Office. A courtesy notice of this filing was provided to both Petitioners and Respondent.

SUMMARY OF ARGUMENT

The court of appeals correctly held that respondent's patent claims are directed to patent-eligible subject matter.

I. For purposes of determining subject matter patentability under 35 U.S.C. §101, the claims in the *Prometheus* diagnostic method patents must be looked at "as a whole" as is done in chemical, mechanical, and electrical patents.

II. The "administering" and "determining" steps in the *Prometheus* claims are not token extra-solution activity but are transformations central to the claim, important to the subject matter patent eligibility determination.

III. The clue to patentability should lie in whether steps that are central to the claim (i.e., not token extra-solution activity) have a "physical" or "virtual" link to a specific physical or tangible object. The *Prometheus* claims have both a "physical" and a "virtual" link and so should be subject matter patentable under 35 U.S.C. §101.



ARGUMENT

I. For purposes of determining subject matter patentability under 35 U.S.C. §101, the claims in the *Prometheus* diagnostic method patents must be looked at “as a whole” as is done in chemical, mechanical, and electrical patents.

This Certiorari was granted on the following question: “Whether 35 U.S.C. §101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve ‘transformations’ of body chemistry.”

This question is framed in a manner that singles out the “observed correlation” step in the claim as the only step that should be considered in determining whether the claim satisfies 35 U.S.C. §101, since the other steps are characterized as being “well known.” While the other steps may or may not be well known, this has no effect on whether 35 U.S.C. §101 is satisfied (though it may be relevant to inquiries under 35 U.S.C. §102 and 35 U.S.C. §103).² To determine

² While the diagnostic methodology for working up a body chemistry to enable the observation of a correlation recited in the *Prometheus* claims may ultimately be invalid under 35 U.S.C. §102 and/or §103, that is not the question currently before the Court. The question before the Court concerns only whether the claims are directed to subject matter that is eligible to be patented under 35 U.S.C. §101.

whether 35 U.S.C. §101 is satisfied, it is necessary to consider the claim as a whole. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

“In determining the eligibility of respondents’ claimed process for patent protection under §101, their claims must be considered as a whole. 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 is particularly true in a process claim, because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.” *Ibid.*

Thus, the appropriate inquiry is whether the claim as a whole, including all of its steps, preempts all uses of a natural phenomenon, abstract idea, or law of nature. (“Claims that are close to ‘laws of nature, natural phenomena, and abstract ideas,’ *Diamond v. Diehr*, 450 U.S. 175, 185 (1981), do not count as ‘processes’ under §101, even if they can be colloquially described as such.” *Bilski v. Kappos*, 130 S. Ct. 3218, 3238-3239 (2010) (concurring opinion).)

Under this Court’s precedent, the transformative steps of “administering” and “determining” in the diagnostic method claims before this Court should be considered in deciding the subject matter patentability question under 35 U.S.C. §101, even if those transformative steps are well-known in the art. Further, the “well-known” transformative steps in the present

case are not unlike transformative steps this Court has routinely addressed and has not excluded from the claim in its subject matter patent eligibility discussion in chemical, mechanical, and electrical patent cases.

The Federal Circuit characterized claims 1 and 46 of U.S. Pat. No. 6,355,623 (“the ’623 patent”) as representative of the claims at issue in the present case. Claim 1 recites:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Claim 46 is similar, except that it dispenses with the “administering” step and claims only the step of “determining” 6-TG or 6-MMP levels “in a subject

administered a [thiopurine] drug * * * , said subject having said immune-mediated gastrointestinal disorder.” ’623 patent, col. 23, l. 42 to col. 24, l. 18 *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 2010 U.S. App. LEXIS 25956, *, 628 F.3d 1347, 97 U.S.P.Q.2D (BNA) 1097 (Fed. Cir. 2010), *cert. granted*, ___ S. Ct. ___, 2011 WL 973139 (June 20, 2011).

The diagnostic step of “administering a drug [to a human body]” in *Prometheus* is not unlike the step of “adding a chemical A to a chemical B” in a chemical process, which is a conventional recitation in the claims of chemical process patents. In this example, the “drug” is to “chemical A” as the “human body” is to “chemical B.” Similarly, the step of “determining the level of [the drug’s metabolite in the body]” is not unlike “determining the level of (*e.g.*) acidity of a solution,” which is another conventional recitation in the claims of many granted and enforced chemical process patents. When viewed in this way, as appears was done below by the Federal Circuit in *Prometheus*, the diagnostic method claims at issue arguably become no different than subject matter that has routinely been seen as patent eligible in chemical process claims.

For example, the subject matter patentability of chemical process patents is evident in *Cochrane v. Badische*, 111 U.S. 293 (1884), involving a reissued

patent on a product-by-process claim.³ Although not before the Court in *Cochrane*, the issue of subject matter patentability of the process claim was obliquely addressed by the Court when the Court explained that “another view of the case” is that patentability of the claim lies in the *process* for making the product and not in the product. *Id.*, at 311. The claim in the reissued patent recited: “artificial alizarine, produced from anthracene or its derivatives, by either of the methods herein described, or by any other method which will produce a like result.” *Id.*, at 293. Steps very familiar to chemical practitioners such as “adding one part chemical A to one part chemical B,” “heating,” “obtaining a chemical C,” “distilling,” “cooling” were not excluded from the claim by the Court in its subject matter patent eligibility discussion. See, Reissue 4,320, Col. 1, para. 2, for example.

In *Tilghman v. Proctor*, 102 U.S. 707 (1880), the chemical process claim recited generally: “the manufacturing of fat acids and glycerin from fatty bodies by the action of water at a high temperature and pressure.” *Id.*, at 709. Steps also very familiar to chemical practitioners such as “manufacturing chemical A and chemical B from chemical C,” “by the action of water,”

³ The patent reissued from U.S. Pat. No. 95,465 which was surrendered and actually reissued in two parts, one for a process for the production of artificial alizarine (RE 4,320) and the other for artificial alizarine produced by either of the methods described in the patent or by any other method producing a like result (RE 4,321). Only the reissued product-by-process claim recited in RE 4,321 was before the Court.

“at a high temperature and pressure,” also were not excluded by the Court as to subject matter patent eligibility.

Both product and process claims were before the Supreme Court in *American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931). The Court held the product claims to be not patentable subject matter but set aside the process claims as anticipated. *Id.*, at 14. The process claim recited:

“3. In the preparation of fresh fruit for market, the process which comprises subjecting fruit to the action of an aqueous solution of borax, the fluidity, strength and temperature of the treating solution, and the duration of the treatment, being such that exposed rind or skin tissues of the fruit are effectively impregnated with borax and rendered resistant to blue mold decay, while at the same time the fruit is not scalded nor is its freshness or edibility otherwise substantially impaired.”

Id., at 6. Steps very familiar to chemical practitioners such as “subjecting product A to the action of a solution B,” “the fluidity, strength and temperature of solution B being such that. . .” were not excluded by the Court as to subject matter patent eligibility. Rather, the Court held those process claims to be anticipated – an inquiry that need only be made when the claims are patentable subject matter.

Although *Cochrane*, *Tilghman*, and *American Fruit Growers* were decided before the enactment of 35 U.S.C. §101, this makes no difference to the

analysis. Similar claims are routinely considered to be patent eligible under 35 U.S.C. §101, as the Court in *Diehr, supra*, at 175, recognized when embracing *Tilghman* in its 35 U.S.C. §101 analysis.

In finding that a physical and chemical process for molding precision synthetic rubber products falls within the Section 101 categories of patentable subject matter, the *Diehr* Court relied on *Tilghman v. Proctor*, a case involving the original patent Charles Goodyear received on his process for “vulcanizing” or curing rubber, where it was explained that:

“A manufacturing process is clearly an art within the meaning of the law. Goodyear’s patent was for a process, namely, the process of vulcanizing india rubber by subjecting it to a high degree of heat when mixed with sulphur and a mineral salt.” *Diehr, supra*, at footnote 8.

The *Diehr* Court further relied on *Corning v. Burden*, 56 U.S. 252, 267-268 (1853), where it was explained that:

“The term machine includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. *But where the result or effect is produced by chemical action, by the operation or application of some element or power of nature, or of one substance to another, such modes, methods, or operations are called processes.* A new process is usually the result of discovery;

a machine, of invention. The arts of tanning, dyeing, making waterproof cloth, vulcanizing India rubber, smelting ores, and numerous others are usually carried on by processes, as distinguished from machines. One may discover a new and useful *improvement in the process of tanning, dyeing, &c.*, irrespective of any particular form of machinery or mechanical device. And another may invent a labor-saving machine by which this operation or process may be performed, and each may be entitled to his patent. *As, for instance, A has discovered that, by exposing India rubber to a certain degree of heat, in mixture or connection with certain metallic salts, he can produce a valuable product, or manufacture; he is entitled to a patent for his discovery, as a process or improvement in the art, irrespective of any machine or mechanical device. B, on the contrary, may invent a new furnace or stove, or steam apparatus, by which this process may be carried on with much saving of labor and expense of fuel, and he will be entitled to a patent for his machine as an improvement in the art. Yet A could not have a patent for a machine, or B for a process; but each would have a patent for the means or method of producing a certain result, or effect, and not for the result or effect produced. It is for the discovery or invention of some practical method or means of producing a beneficial result or effect that a patent is granted, and not for the result or effect itself. It is when the term process is used to represent the means or method of producing*

a result that it is patentable, and it will include all methods or means which are not affected by mechanism or mechanical combinations.” (*emphasis added*) *Diehr, supra*, at footnote 7.

So even in *Diehr*, one of the trilogy of cases that along with the definition of §100(b) the *Bilski* Court points to for guidance on what constitutes patentable subject matter, *Bilski, supra*, at 3231, the Court recognized the subject matter patentability of transformative chemical processes based on process steps very familiar to chemical practitioners like “subjecting composition A to a high temperature,” and “mixing a composition A with a composition B and a composition C,” as in the Goodyear patent for making rubber.

Thus, the issue in *Prometheus* is not simply about an “observed correlation,” as the question presented strongly suggests. Rather, it is also about a methodology including chemical transformative steps for working up a chemistry inside of the body (to enable the observation of a correlation) not unlike transformative steps that work up a chemistry outside of the body which are not excluded by the Court as to subject matter patent eligibility in chemical process patents. The fact that the “observed correlation” is occurring on body chemistry should be of no consequence. Under this Court’s “claim as a whole” precedent, the transformative steps of “administering” and “determining” for working up a body chemistry to enable the observation of a correlation in a diagnostic method patent should be considered no differently

than transformative steps in chemical, mechanical, and electrical process patents.

As this Court stated in *Gottschalk v. Benson*, 409 U.S. 63 (1972): “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Id.*, at 70. Just as the clue to the patentability of a chemical process patent is a chemical transformation, so too one clue to the patentability of diagnostic method claims involving a chemical transformation central to the claim should be a “transformation.” The Court’s precedent in connection with transformations recited in mechanical and electrical patents further support such a conclusion.⁴

⁴ Similarly, just as the clue to the patentability of a mechanical process and electrical process patent involving a transformation would appear to be a mechanical or electrical transformation, so too one clue to the patentability of diagnostic method claims involving a transformation central to the claim should be a “transformation.” See, for example, *Expanded Metal Co. v. Bradford*, 214 U.S. 366 (1909), where transformation steps very familiar to mechanical practitioners such as simultaneous “slitting and bending,” and alternate “slitting and bending” were not excluded as to subject matter patent eligibility. *Id.*, at 377. In *Smith v. Snow*, 294 U.S. 1 (1935), transformation steps very familiar to mechanical practitioners, such as “arranging [things in an order]” and “applying a current of heated air” were not excluded in its subject matter patent eligibility discussion. *Id.*, at 7-8. In *The Telephone Cases*, 126 U.S. 1 (1888), steps very familiar to electrical practitioners such as “producing [undulations],” “transmitting [vocal or other sounds],” and “causing electrical [undulations]” were not excluded as to subject matter patent eligibility. *Id.*, at 13-14.

This is not to say that every transformative step is “central,” thereby making any diagnostic method claim into patentable subject matter. As this Court has held, token extra-solution activity will not transform an otherwise unpatentable claim into patentable subject matter under 35 U.S.C. §101. *Diehr, supra*, at footnote 14.

The “administering” and “determining” steps and their “central-ness” or “insignificance” to the claim must be considered in deciding the subject matter patentability question under this Court’s “claim as a whole” precedent and this Court’s treatment of transformative steps in chemical, mechanical, and electrical patents.

II. The “administering” and “determining” steps in the *Prometheus* claims are not token extra-solution activity but are transformations central to the claim, important to the subject matter patent eligibility determination.

Just because a method claim involves a transformative step (i.e., a step that performs a transformation) does not mean that the method claim is automatically subject matter patentable. As this Court stated in *Benson*: [t]ransformation and reduction of an article “to a different state or thing” is the *clue* to the patentability of a process claim that does not include particular machines. *Benson, supra*, at 70 (*emphasis added*). In the case of a method claim including a transformative step, the transformation is thus an

important indicator that the subject matter may be patentable. The mere existence of the transformation in the claim, however, does not make the claim subject matter patentable *per se*. For guidance on what makes a “process” claim subject matter patentable, the *Bilski* Court pointed to the definition of the term “process” in 35 U.S.C. §100(b) and the *Benson*, *Flook*, and *Diehr* precedent. *Bilski*, *supra*, at 3231.

Unlike the algorithm in *Benson*, the mathematical formula used for monitoring conditions during the catalytic conversion process in the petrochemical and oil-refining industries in *Parker v. Flook*, 437 U.S. 584 (1978) was limited so that it could still be freely used outside the petrochemical and oil-refining industries. *Id.*, at 589, 590. Nevertheless, the *Flook* Court rejected “[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process.”

“The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques. [Footnote 11] The concept of patentable subject matter under §101 is not ‘like a nose of

wax, which may be turned and twisted in any direction. . . .’ *White v. Dunbar*, 119 U.S. 47, 119 U.S. 51.”

Id., at 590.

As the Court later stated in *Diehr*, *Flook* stands for the proposition that the prohibition against patenting abstract ideas “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment” or adding “insignificant post solution activity.” See *Diehr*, *supra*, at 191-192. Significantly, the Court noted that “[w]e were careful to note in *Flook* that the patent application in *Flook* 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 limit. *Ibid.* All the application provided was a “formula for computing an updated alarm limit.” *Id.*, at footnote 14. The claims in *Diehr*, however, are not limited to the isolated step of “programming a digital computer,” the Court found; rather, they describe a process of curing rubber beginning with the loading of the mold and ending with the opening of the press and the production of a synthetic rubber product that has been perfectly cured – a result heretofore unknown in the art. *Id.*, at footnote 15. As the *Diehr* Court explained, “[w]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g.,

transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of 35 U.S.C. §101.” *Id.*, at 192. Because the Court did not view respondents’ claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products, the *Diehr* Court affirmed the judgment of the Court of Customs and Patent Appeals. *Id.*, at 192, 193.

Finally, in finding the commodity claims in *Bilski* to be non-statutory subject matter, the *Bilski* Court explained that:

“Petitioners’ remaining claims are broad examples of how hedging can be used in commodities and energy markets. *Flook* established that limiting an abstract idea to one field of use or adding token post solution components did not make the concept patentable. That is exactly what the remaining claims in petitioners’ application do.”

Bilski, supra, at 3231.

Simply put, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. *Diehr, supra*, at 191, 192. To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection. *Id.*, at 192.

It could be argued that calling an element an “insignificant extra-solution activity” is tantamount to disregarding that element in the 35 U.S.C. §101

analysis in violation of this Court's precedent that a "claims . . . as a whole" analysis must be performed when making any 35 U.S.C. §101 determination. *Id.*, at 188. That argument misses the mark of this Court's precedent on "insignificant extra-solution activity." While it is true that a claim must be viewed as a whole, not every element of a claim must be given the same weight. Indeed, it is only by looking at the claim as a whole that the elements of the claim that are central can be separated from those that are merely extra-solution activity.

As this Court has explained, a determination of which elements of a claim amount to nothing more than insignificant extra-solution activity plays an important role in deciding whether a claim is subject matter patentable under 35 U.S.C. §101. However, recognizing when an element amounts to an insignificant extra-solution activity is not always easy. This Court has provided valuable guidance on this point in *Bilski* and in the *Diehr*, *Flook*, and *Benson* decisions. *Bilski*, *supra*, at 3231. The Federal Circuit has recently provided further useful guidance on this issue in *Classen Immunotherapies, Inc. v. Biogen IDEC*, 2011 U.S. App. LEXIS 18126, * (Fed. Cir. 2011).

In *Classen*, the Federal Circuit was asked to decide whether three patents on a method for improving an immunization schedule involving method claims directed to identifying a safe vaccine regimen and involving a step of immunizing mammals is patentable subject matter. The patents before the Court were U.S. Pat. Nos. 6,638,739; 6,420,139; and 5,723,283.

Following the precedent of this Court on token extra-solution activity, in *Classen*, the court impliedly cast aside the notion that generally all transformative steps are patentable subject matter and introduced a “subject matter patentability filter” through which all transformation steps in a claim must pass. *Id.*, at *24-25. This “subject matter patentability filter” may be helpful in weeding out transformative steps in a process that add no meaningful limitations to the claim and hence amount to token extra-solution activity. In *Classen*, claims of one of the three patents before the court, the ’283 patent, failed to pass the “subject matter patentability filter,” impliedly because they amounted to an insignificant or token activity. *Id.*, at *25-26. As the court explained, “[t]he ‘immunizing’ in the ’283 patent refers [only] to the gathering of published data, while the ‘immunizing’ of the ’139 and ’739 patent claims is the physical implementation of the mental step claimed in the ’283 patent.” *Id.*, at *26. The different treatment given by the court to the two sets of patents turned on the different construction the court gave to the two sets of claims.

In both patents, the court keyed in on the “immunizing” step. In the ’139 and ’739 patents, the recitation occurred *after* a screening step was performed to derive a subject specific immunization schedule for use in the immunizing step and in the ’283 patent, the immunizing step was recited *before* a comparing step to generate data merely for comparison to known information in that comparing step. *Id.*, at *27. While facially both sets of patents recited

“immunizing” steps that were transformative, the court opined that the “immunizing” step of the ’283 patent failed to pass through the “subject matter patentability filter.” *Id.*, at *25-26. The court held that a transformation for data gathering purposes to develop a body of knowledge, as was recited in the ’283 patent, is not patentable, while a transformation that “puts this knowledge to practical use,” as was recited in the ’139 and ’739 patents comports with 35 U.S.C. §101. *Id.*, at *26-27. Thus, according to *Classen*, gathering data simply for the purpose of developing a body of knowledge is extra-solution activity whereas gathering data for practical application in later steps in the method is not extra-solution activity.

Thus, in both representative claims 1 and 46 of *Prometheus*, the “determining” step is not merely token extra-solution data gathering activity, which was the death knell of the ’283 patent in *Classen*, since the knowledge that is collected in this step is put to practical use in the other steps in the claim. The “determining” step generates data *applied to enable adjustment of the drug dosage in the recited observed correlation*. It manipulates the chemistry of a body to this application, or, as the *Classen* court put it, “puts this knowledge to practical use.” *Ibid.* Additionally, claim 1 further recites an “administering” step which further generates data *applied to enabling the adjustment of the drug dosage in the recited observed correlation*. As such, the transformative steps of “administering” and “determining” are “essential” and central to the claim and so should be included in the

35 U.S.C. §101 determination, not treated as token extra-solution activity and disregarded in the 35 U.S.C. §101 analysis.

III. The clue to patentability should lie in whether steps that are central to the claim (i.e., not token extra-solution activity) have a “physical” or “virtual” link to a specific physical or tangible object. The *Prometheus* claims have both a “physical” and a “virtual” link and so should be subject matter patentable under 35 U.S.C. §101.

Benson, *Flook*, *Diehr*, and *Bilski* stand for the proposition that a process claim taken as a whole and excluding extra-solution activity must be tailored narrowly enough to encompass only a particular application of a fundamental principle (i.e., a law of nature, natural phenomenon, or an abstract idea) rather than to preempt the principle itself. The 35 U.S.C. §101 challenge post-*Bilski* thus is to define the boundary line of an invention involving an abstract idea, law of nature, or natural phenomenon beyond which the invention preempts one of these categories and is therefore unpatentable subject matter, and within which it is patentable.

While it is expected that there is no bright line rule that will work in every case, for guidance on where to define this boundary line, the *Bilski* Court pointed to the trilogy of *Benson-Flook-Diehr* as precedent. *Bilski*, *supra*, at 3231. From the *Benson-Flook-Diehr*

spectrum of inventions involving a fundamental principle, the threshold for subject matter patentability may be gleaned; to wit, the existence of a link of the invention to a specific physical or tangible object. The invention in *Diehr* was held patentable because it connected to (more specifically, the electrical signals or data generated by the software *manipulated*) the physical and, in this case, also tangible objects of a “mold” and a “press” through the steps of “loading of the mold” and “opening of the press.” Patentability in *Flook* failed since the claims were without any such link.

More specifically, the *Diehr* Court stated that “[w]e 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 limit.” *Diehr, supra*, at footnote 14. All the application provided was a “formula for computing an updated alarm limit.” *Ibid.* One interpretation of these comments on *Flook* in *Diehr* is that there was no “link” of the data to a physical or tangible object. “Diehr’s claims, however, are not limited to the isolated step of programming a digital computer,” the Court explained. *Id.*, at footnote 15. Rather, “they describe a process of curing rubber beginning with the loading of the mold and ending with the opening of the press and the production of a synthetic rubber product that has been perfectly cured – a result heretofore unknown in the art.” *Ibid.* In other words, there was a “link”

of the data to a specific physical or tangible object (i.e., a “manipulation” by the data of a physical or tangible object).

Hence, in *Diehr*, software that *manipulates* a specific physical or tangible object (i.e., “physically links” to a physical or tangible object) is patentable subject matter (e.g., the software manipulated data in *Diehr* signaled a device when to open the molding press and remove the cured rubber product). The same should be considered true for “virtual links,” where the data that are manipulated, while not physical or tangible objects themselves, *are representations of a specific physical or tangible object*, as in the fifth claim of *Morse* (e.g., Morse code dot and dash signs representing the change in state of a physical (e.g., switch) or tangible object, such as on-off tones, lights, or clicks, in telegraphic use were held patentable). *O’Reilly v. Morse*, 56 U.S. 62, 112 (1853).⁵ An invention that manipulates data representing a specific physical or tangible object (i.e., that contains a “virtual link”) should also be subject matter patentable under the Supreme Court’s *Morse* precedent.

⁵ Morse’s fifth claim recites: “Fifth. I claim as my invention the system of signs, consisting of dots and spaces, and of dots, spaces, and horizontal lines, for numerals, letters, words, or sentences, substantially as herein set forth and illustrated, for telegraphic purposes.” *Morse, supra*, at 86. The Court “perceive[d] no well founded objection to the description which is given of the whole invention and its separate parts, nor to his right to a patent for the first seven inventions set forth in the specification of his claims. The difficulty arises on the eighth.” *Id.*, at 112. See also *id.*, at 94-95 for characters recorded and how they are read.

Also instructive on “virtual links,” that is, the idea that *manipulation of data representing a physical or tangible object* is sufficient to provide patentable subject matter, is *In re Abele*, 684 F.2d 902 (CCPA 1982). In *Abele* the Court of Customs and Patent Appeals held unpatentable a broad independent claim reciting a process of graphically displaying variances of data from average values. *Id.*, at 908. That claim did not specify any particular type or nature of data; nor did it specify how or from where the data was obtained or what the data represented. One dependent claim, however, was drawn to patent-eligible subject matter where it recited that “said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner.” *Id.*, at 908-909. As was explained by the Federal Circuit in *In re Bilski*, 2008 U.S. App. LEXIS 22479, *, 545 F.3d 943, 88 U.S.P.Q.2D (BNA) (Fed. Cir. 2008) (en banc), the data in *Abele*: “clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly claimed process patent-eligible.” *Id.*, at *50.

This link of data to something “real” (either by “physical” manipulation of a physical or tangible object, or by “virtual” manipulation of data representing a physical or tangible object) may thus provide a useful clue to the patent eligibility of inventions involving processes, under this Court’s *Diehr* and *Morse* precedent. The term “physical” or “tangible” covers all things that exist in the real world rather than things

that are imaginary or that exist only in the mind. Anything existing in the real world includes both those things that can be directly perceived, touched, or manipulated, and physical phenomena, such as electrical signals, electromagnetic radiation, or chemical properties which, while existing in the real world, may only be perceived or manipulated indirectly, such as with the assistance of a machine or apparatus, or by a chemical reaction. The “physical link” and “virtual link” patent claim approach may thus be helpful in defining that boundary line beyond which a claim preempts a fundamental principle (i.e., a law of nature, natural phenomenon, or an abstract idea) and within which the claim does not.

In the context of this threshold, the patentability of the claims in *Prometheus* becomes clearer. From the discussion in Part II above, the “administering” step and the “determining” step are not token extra-solution activity and so should be included in the 35 U.S.C. §101 determination. From the following discussion, the “determining” and “administering” steps each provide a “physical” link to (i.e., they each “manipulate”) a specific physical or tangible object (i.e., blood). Thus, when considered as a whole, the claim that includes these steps as something more than token extra-solution activity is patentable subject matter, since the claim is drawn to manipulating a specific physical or tangible object, and is not just a natural phenomenon, abstract idea, or law of nature, or a process that completely preempts one of these. See *Diehr, supra*, at 192-193.

The “determining” and “administering” steps in *Prometheus* plainly manipulate a specific physical or tangible object. The “administering” step is a transformation of the human body and of its components following the administration of a particular class of drugs and the various chemical and physical changes of the drugs into their metabolites, *Prometheus*, at *24. This transformative step is not merely gathering data. Rather, as explained in Part II above, the “administering” step generates data applied to enable adjustment of the drug dosage in the recited observed correlation. The “determining” step necessarily also involves a manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims, or some other modification of the substances to be measured, which is necessary to extract the metabolites from a bodily sample and determine their concentration. *Id.*, at *26. This transformative step likewise is not merely data gathering. Rather, it too generates data applied to enabling the adjustment of the drug dosage in the recited observed correlation. The claims in *Prometheus* hence “physically link” to (i.e., they “directly manipulate”) a physical or tangible object (e.g., the administered drug “physically” so manipulates the blood chemistry in the “administering” step and the body chemistries are so manipulated to extract the 6-thioguanine level by the “determining” step). Just as the software manipulated data in *Diehr*, signaling a device when to open the molding press and remove the cured rubber product, rendered the claim as a whole to be subject matter patentable, so too the *Prometheus* “administering” and “determining” steps

should be found to make the claim as a whole subject matter patentable.

In addition, the “observed correlation” step, in combination with the “determining” step, and, in the case of claim 1, also the “administering” step, provide a “virtual link” to (i.e., the observed correlation data manipulates *representations of*) a specific physical or tangible object (i.e., the blood) which alternatively and additionally makes the claims subject matter patentable. Apposite is *Morse, supra*, at 112. See also *Abele, supra*, at 908-909.

The “observed correlation” recited in the *Prometheus* claims manipulates data representing a specific physical or tangible object. The “level of 6-thioguanine” is data representing a specific physical or tangible object (i.e., the blood, and in particular, the 6-thioguanine in the blood). Those data, representing a specific physical or tangible object, are manipulated by the association of those data with a drug adjustment indicator generated by the “observed correlation” step. The “association” is by the tagging of the 6-thioguanine level data *with a specific drug adjustment level indicator* (i.e., the “need to increase” or the “need to decrease” data which is generated by the “observed correlation” step). The indicator biases and hence “manipulates” the “level of 6-thioguanine” data toward increased drug administration if the level of 6-thioguanine is less than about 230 pmol per 8×10^8 red blood cells and toward decreased drug administration if the level is greater than 400 pmol per 8×10^8 . It is the biasing or manipulation of the “level of 6-thioguanine” data in the direction of the drug

adjustment indicator generated by the “observed correlation” step that provides the manipulation of the level of 6-thioguanine data, which represents the physical or tangible object (i.e., the blood). In effect, the drug adjustment level indicator generated through the step of the “observed correlation” defines a direction for the “level of 6-thioguanine” data that directs further drug administration.

Without the “determining” step and in the case of claim 1, also the “administering” step, the “observed correlation” does not provide a “virtual” link to data representing a physical or tangible object and so amounts to nothing more than textbook knowledge, the claiming of which would preempt a natural phenomenon, abstract idea, or law of nature in violation of 35 U.S.C. §101 under this Court’s precedent. However, this is not the case in *Prometheus*. As indicated in Parts I and II above, the claim must be considered as a whole, and neither the “administering” or “determining” step is taken extra-solution activity. And as explained in Part III above, the “observed correlation” in the presence of “administering” and/or “determining” steps has the necessary *virtual link* to (i.e., the “observed correlation” data manipulates *representations of*) a specific physical or tangible object that further makes the claims subject matter patentable under this Court’s precedent.

It is the enabled adjustment of the drug dosage in the recited “observed correlation” of the specific sample of data generated by the “administering” and “determining” steps in claim 1 and the “determining” step in claim 46 that gives rise to the “virtual link.”

Without the chemical transformative steps of “administering” and “determining” that work up the body chemistry into a specific sample of data that enables the adjustment of the drug dosage in the recited “observed correlation” recited in the *Prometheus* claims; that is to say, if an “observed correlation” is removed from a specific sample of data and is done in a vacuum, it is no different than an “observed correlation” taught in medical books (i.e., general medical information) which is “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.” *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The “observed correlation” recited in the *Prometheus* claims manipulates data representing a physical or tangible object because the enabled adjustment of the drug dosage in the recited “observed correlation” is possible by use of the specific sample of data that is generated by the “determining step” (i.e., the manipulation occurs through the “observed correlation” in combination with the “determining” step), and, in the case of claim 1, the enabled adjustment of the drug dosage in the recited “observed correlation” is also possible by use of the specific sample of data that is generated by the “administering” step (i.e., the manipulation occurs in this case through the “observed combination” in combination with “administering” and “determining” steps). This manipulation provides each of claims 1 and 46 with a “virtual link” to a physical or tangible object, thereby providing a further basis for the subject matter patentability of the *Prometheus* claims under 35 U.S.C. §101, in view

of *Morse, supra*, at 112. See also *Abele, supra*, at 908, 909. This “virtual link” basis for subject matter patentability of the *Prometheus* claims is independent from and additional to the subject matter patentability that the transformative “administering” and “determining” steps provide to these claims through the creation of “physical links” to a specific physical or tangible object (i.e., the blood), under *Diehr, supra*, at footnote 15.

Just as the software manipulated data in *Diehr* signaling a device when to open the molding press and remove the cured rubber product was found by this Court to be subject matter patentable, so too the *Prometheus* “administering” and “determining” steps that provide “physical” links to the blood chemistry of a body should be subject matter patentable under 35 U.S.C. §101. Alternatively, or in addition, just as the manipulated data representations of a physical or tangible object in the fifth claim of *Morse* (e.g., Morse code dot and dash signs representing the change in state of a physical (e.g., switch) or tangible object, such as on-off tones, lights, or clicks, in a telegraphic use) was found by the *Morse* Court to be subject matter patentable, so too the *Prometheus* enabled adjustment of the drug dosage in the recited “observed correlation” step in combination with the “determining” step, and, in the case of claim 1, also the “administering” step, provide a “virtual link” to (i.e., they manipulate representations of) a specific physical or tangible object (i.e., blood) and so should likewise be subject matter patentable under 35 U.S.C. §101.



CONCLUSION

The judgment of the court of appeals reversing the district court's ruling under 35 U.S.C. §101 should be affirmed.

Respectfully submitted,

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