

No. 10-1150

IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (d/b/a MAYO MEDICAL
LABORATORIES) and MAYO CLINIC ROCHESTER,

Petitioners,

—v.—

PROMETHEUS LABORATORIES, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**BRIEF OF THE AMERICAN CIVIL LIBERTIES UNION
AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS**

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INTEREST OF AMICUS¹

The American Civil Liberties Union (“ACLU”) is a nationwide, nonprofit, nonpartisan organization with more than 500,000 members dedicated to the principles of liberty and equality embodied in the Constitution and this nation’s civil rights laws. Since its founding in 1920, the ACLU has frequently appeared before this Court in cases involving the First Amendment, both as direct counsel and as *amicus curiae*. Although this case arises under patent law, it also raises fundamental issues regarding freedom of thought and scientific inquiry that implicate important First Amendment values. The proper resolution of this case is, therefore, a matter of significant concern to the ACLU and its membership throughout the country.

STATEMENT OF THE CASE

This is a challenge to a series of patent claims on the grounds that the claims reach unpatentable subject matter. As described by the Federal Circuit, the patents “claim methods for determining the optimal dosage of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases.” Pet. App. 2a. What that means in practice is made clear by the language of the actual claims. For example, Claim 1 of Patent 623 states as follows:

¹ The parties have lodged blanket letters of consent to the filing of *amicus* briefs with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person other than *amicus curiae*, its members or its counsel made a monetary contribution to its preparation or submission.

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.

Pet. App. 4a.²

In other words, the patent holder, Prometheus, claims a method patent consisting of the following steps: (1) administer a drug; (2) determine the effect of the drug by measuring the metabolite levels in a patient's blood through an unspecified test; and (3) consider whether to adjust the dosage of the drug in light of the effect it had on the patient's metabolite level.

² Some of the claims at issue do not include the first, "administering" step. Pet. App. 4a-5a.

Prometheus does not base its assertion of infringement on a patent on any of the drugs covered by Step 1, nor on a patent on the test referenced in Step 2. And Step 3, on its face, refers only to a thought process; it may contemplate but does not expressly cover any additional action beyond reviewing the test results and thinking about their impact on the patient's therapeutic plan.

The district court found the patents invalid. As an initial matter, it concluded that the first two steps of the challenged method claim merely provide the background information necessary to assess whether the dosage of thiopurine should be adjusted. Pet. App. 63a. It then concluded that the correlation between metabolite levels in the blood and the efficacy/toxicity of thiopurine is not patentable for several interrelated reasons: first, consideration of the correlation is best understood as a "mental step" or thought process; second, the correlation itself is a natural phenomenon occurring within the body and not invented by the patent holder; and third, the patent claims preempt use of the correlation. Pet. App. 63a-78a.

The Federal Circuit reversed in an opinion issued prior to this Court's decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Pet. App. 25a. Applying its "machine or transformation test," the Federal Circuit upheld the challenged patents on the theory that Steps 1 and 2 – administering thiopurine and determining metabolite levels – transform the body. In the circuit court's view, that transformation by itself is sufficient to make the entire claim patentable, even though Prometheus is not alleging infringement based on the drugs administered in

Step 1 or the metabolite test used in Step 2, and even if the correlation between metabolite levels and drug efficacy could not be independently patented because it involves nothing more than a thought process and natural phenomenon. Pet. App. 39a-48a. After this Court remanded the case in light of *Bilski*, the Federal Circuit reaffirmed its prior holding based on the same rationale. Pet. App. 14a. This Court again granted certiorari.

SUMMARY OF ARGUMENT

The patent claims in this case are invalid under the well-established principle that a patent cannot be issued over an abstract idea or a natural phenomenon. These claims amount to a patent on the correlation between metabolite levels in the blood and the efficacy of thiopurine drugs, which is both an abstract idea and a natural phenomenon.

The Federal Circuit held the claims patentable by focusing on two steps in the claims that consist of administering a drug and then performing a test to determine the effects of the drug. However, the essence of the claims is found in the third step: mentally considering what to do once the effects are determined. This Court's opinions on the patentability of abstract ideas and natural phenomena can best be understood as requiring that the Court look past steps added by drafters in an effort to achieve patentability and instead focus on the essence of the claim. When that analysis is performed in this case, it is clear that the claims are invalid.

The claims are also invalid under the First Amendment. The First Amendment has not

traditionally been applied to patent claims, but the principle that you cannot patent abstract ideas is not only compatible with the First Amendment, but compelled by it.

The First Amendment principle that abstract ideas cannot be patented applies, moreover, regardless of whether the abstract idea represents the essence of the patent claim. Here, the third step of the challenged claim prohibits what both courts below aptly described as a “mental step” – namely, whether the metabolite levels of a patient’s blood indicate a need to change the dosage of thiopurine drugs. Because the First Amendment does not allow the government to patent thought under any circumstances, the decision below must be reversed.

ARGUMENT

I. THE CHALLENGED CLAIMS PATENT ABSTRACT IDEAS AND NATURAL PHENOMENA, AND ARE THEREFORE INVALID UNDER SECTION 101.

Section 101 of the Patent Act provides that “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” is eligible to obtain a patent if “the conditions and requirements” of the Patent Act are otherwise met. 35 U.S.C. § 101.

It has long been understood that the language of Section 101 does not reach abstract ideas or natural phenomena, which are not patentable. *Bilski*, 130 S. Ct. at 3225. What is less clear is how to determine whether a patent claim that includes abstract ideas and/or natural phenomena, like those

at issue in this case, is nonetheless patentable because of other elements in the claim.

When confronted with that problem in the past, this Court has focused on the essence of the claim and determined patent eligibility on that basis. *Amicus* acknowledges that the Court's opinions have not been explicit in that focus; we nonetheless believe that it is the best way to reconcile the relevant decisions, particularly this Court's instruction to analyze the claim "as a whole."³ *Diamond v. Diehr*, 450 U.S. 175, 188 (1981); *Parker v. Flook*, 437 U.S. 584, 594 (1978).

Adoption of this pragmatic approach allows the Court to see through clever drafting that otherwise obscures what lies at the heart of the claim. *Diehr*, 450 U.S. at 192. A key component of the Court's inquiry into a claim's essence is to determine whether the claim preempts or has the "practical effect" of patenting a thought or natural phenomenon. *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972). When a claim has preempted others from using an abstract idea or law of nature, the Court has invalidated it. *Bilski*, 130 S. Ct. at 3231. Employing this reasoning, the Court has rejected patents that at their essence claim natural phenomena or abstract ideas, even when they superficially appear, based on the insertion of

³ The Federal Circuit has referred to the essence of the claim in making Section 101 determinations. Pet. App. 20a (describing the "essence" of the claim at issue in *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989)); *In re Comiskey*, 554 F.3d 967, 981 (Fed. Cir. 2009); *In re Nuijten*, 500 F.3d 1346, 1357 n.7 (Fed. Cir. 2007) (describing claim at issue in *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994)).

limitations or extrasolution steps, to be patent eligible. *Id.* at 3229-30.

Once these principles are applied to the challenged patents, they do not survive Section 101. The insertion of Steps 1 and 2 into the patent claim – administering a drug that Prometheus has not patented and then measuring its effect on the blood through a test that Prometheus has also not patented – cannot and does not alter the fact that the essence of the claim is the correlation between thiopurine drugs and metabolite levels in the blood. That correlation constitutes both an unpatentable abstract idea and natural phenomenon, as the district court recognized and the Federal Circuit did not dispute. This conclusion is reinforced by the preemptive effect of the claims on mental consideration of what a metabolite level suggests about drug efficacy, as well as on use of the naturally-occurring correlation in medical practice.

A. This Court’s Precedent Makes Clear That Section 101 Requires Examination Of The Essence Of The Claim And Whether The Claim Has The Practical Effect Of Patenting An Abstract Idea Or Natural Phenomenon.

As this Court reiterated most recently in *Bilski*, patent law does not grant proprietary rights over laws of nature, products of nature, physical or natural phenomena, and abstract ideas. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). *See also Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980). This core understanding of patent law is 150 years old, *Le Roy v. Tatham*, 55 U.S. 156, 174-75

(1852), is directly tied to the constitutional mandate that patents “promote the Progress of Science,” *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting), and reflects the recognition that these non-patentable subjects represent “the basic tools of scientific and technological work.” *Benson*, 409 U.S. at 67. Because laws of nature, natural phenomena, and abstract ideas are “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), they do not qualify as patentable inventions under 35 U.S.C. § 101.

In deciding whether a proposed patent describes a genuine invention or an abstract idea, this Court has said that Section 101 imposes “[t]he obligation to determine what type of discovery is sought to be patented.” *Flook*, 437 U.S. at 593. In other words, the Court has looked to the essence of the claim to determine whether it is truly an invention or simply an unpatentable idea. *See Diehr*, 450 U.S. at 191-92. A determination of patentable subject matter that depends “simply on the draftsman’s art,” the Court has noted, “would ill serve the principles underlying the prohibition against patents for ‘ideas’ or phenomena of nature.” *Flook*, 437 U.S. at 593. Thus, the Court has dismissed efforts to insert limitations or steps in patents that do not convert what is claimed into a true invention. 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 extrasolution activity, such as data-

gathering steps. *Diehr*, 450 U.S. at 191-92; *see also Bilski*, 130 S.Ct. at 3231 (“limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable”).

The Court’s key cases illustrate this pragmatic approach. *Bilski*, *Benson*, and *Flook* all rejected patent claims that at their essence covered abstract ideas. The Court dismissed attempts to justify patentability based on limitations to a particular technological field, *see Bilski*, 130 S. Ct. at 3231 (claims on abstract idea of hedging risk limited to use in commodities and energy markets) and *Benson*, 409 U.S. at 71-72 (claims on formula limited to use with digital computer). Likewise, the Court dismissed attempts to justify patent eligibility based on the addition of extrasolution activity, *see Bilski*, 130 S. Ct. at 3231 (claims included instructions for using well-known analysis techniques to help establish inputs into the hedging equation) and *Flook*, 437 U.S. at 590 (claims included post-solution activity of adjusting the alarm limit to the figure computed according to the formula).

Preemption of an abstract idea or law of nature has been a crucial factor in determining invalidity. Because the *Benson* algorithm had “no substantial practical application” except in connection with the digital computer, the claim’s limitation to use with a computer was meaningless. 409 U.S. at 71-72. “[T]he patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself.” *Id.* at 72. Similarly, the *Bilski* court found that the patent claims at issue covered the abstract concept of hedging risk and thus “would preempt use of this

approach in all fields, and would effectively grant a monopoly over an abstract idea.” 130 S. Ct. at 3231. In contrast, the method for curing synthetic rubber at issue in *Diehr* that relied on a mathematical formula was patentable because the patent holders “do not seek to pre-empt the use of that equation.” 450 U.S. at 187. The equation could be applied with respect to other processes that did not involve the numerous steps detailed in the claim: installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through use of the formula and a digital computer, and automatically opening the press at the proper time. *Id.*

These cases make clear that, though the machine-or-transformation test is “a useful and important clue” as to process patentability, it is far from an “exhaustive or exclusive test.” *Bilski*, 130 S.Ct. at 3226-27. The Court in *Bilski* chose to reject the Federal Circuit’s adoption of the machine-or-transformation test as the sole test for process patents under Section 101, a ruling it need not have reached given the circuit court’s finding of invalidity. Such a rigid test, however, could not be reconciled with the analysis of *Benson*, *Flook*, and *Diehr*, particularly because it is entirely possible for a natural phenomenon to inherently involve transformation – *e.g.*, aging. Indeed, chemical “transformations” occurred during the claimed catalytic chemical conversion of hydrocarbons in the *Flook* method found invalid by the Court. 437 U.S. at 586, 596-98.

Dissecting a claim to determine whether a “transformation” exists in one or more steps, and ending the Section 101 inquiry at that point, departs from this Court’s focus on the essence of what is claimed. Patents must be examined to determine whether, once extrasolution steps and technological field limitations are stripped away, abstract ideas or natural phenomena are the essence of the claim, and whether the claim’s practical effect is to preempt what is unpatentable.

B. The Challenged Patents Claim the Abstract Idea of Considering A Patient’s Metabolite Level And The Natural Correlation Between That Level And Drug Efficacy And Toxicity.

In light of this precedent, the court below erred in its Section 101 analysis. Rather than considering the claims as a whole for their essence, the Federal Circuit’s conclusion was rooted in the flawed assumption that the “claim as a whole” analysis could be satisfied by the addition of data-gathering steps that could be characterized as involving “transformation” to an otherwise mental process. This Court’s precedent clearly establishes that simply including technological field limitations – such as the context of autoimmune and gastrointestinal diseases – and extrasolution steps – such as administering a drug and measuring its effects – does not allow claims on natural phenomenon and abstract ideas to survive Section 101 scrutiny. The appellate court compounded its error by misapprehending the claims’ preemptive

effect on thought and naturally-occurring medical correlations.

The Federal Circuit misconstrued this Court’s admonition to analyze the “claim as a whole,” in deciding that claims containing data-gathering steps that involve some “transformation” satisfy Section 101. It focused on what it deemed to be transformative in the first two steps and discounted the centrality of the mental steps in the wherein clauses, because “[t]he data that the administering and determining steps provide for use in the mental steps are obtained by steps well within the realm of patentable subject matter.” Pet. App. 21a. However, the fact that two of the steps might involve “transformation” does not resolve the patentable subject matter question, especially when whatever “transformations” occur in these steps are not central to what is patented. As Justice Breyer explained in the context of *Metabolite*: The patented process “instructs the user to (1) obtain test results and (2) think about them. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all.” 548 U.S. at 136.

Like *Metabolite*, and as in *Benson*, the claims here are “not limited to any particular art or technology, to any particular apparatus or machinery, or to any particular end use.” *Benson*, 409 U.S. at 64. The steps of administering a drug and determining metabolite levels are not limited to a particular methodology, nor tied to particular machinery. Furthermore, the claims do not direct a

particular end use by reciting, for example, a third step of administering a certain dosage of a specified drug in response to the metabolite levels that are found. It is entirely possible to infringe on the claims by carrying out the administering and determining steps, thinking about the significance of the resultant level, and doing nothing more. While *Prometheus* attempts to frame the claims here as directed at optimizing treatment of a disease, the claims do not mandate any action by the physician after considering the natural correlation.

The Federal Circuit's discussion of *Grams* highlights its misplaced focus on "transformations" in the first two steps. The invalidated *Grams* claim was on a process of performing a clinical test on an individual and determining, by using an algorithm, if an abnormality existed and its possible causes. *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989). In its effort to distinguish *Grams*, the *Prometheus* court noted that the *Grams* clinical test was just to "obtain data." Pet. App. 20a. The court opined that the claim would have survived had it recited the "performing of clinical tests on individuals that were transformative – and thus rendering the entire process patentable subject matter." *Id.* (citing *Grams*, 888 F.2d at 840). According to the Federal Circuit, therefore, had the *Grams* claim been slightly modified, so that it specified a clinical test that could be deemed "transformative" – like the routine assaying of blood found to be transformative by the court in *Prometheus* – it would have been patentable. Its Section 101 analysis myopically zeroes in on any type of "transformation" in the claim, one that could be manufactured by attorneys in drafting, while failing to determine the essence of the claim. As the Court

has said, such an interpretation “exalts form over substance.” *Flook*, 437 U.S. at 590.

This error is particularly troubling in the medical context, where it is easy to draft claims that require a “transformative” determination of the existence of a natural phenomenon in order to claim the natural phenomenon itself. “Indeed, to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter.” *Metabolite*, 548 U.S. at 136 (Breyer, J., dissenting). Should the Federal Circuit’s opinion stand, it would send a clear message to patent applicants: So long as you include a step that involves processing a sample to determine a concentration of a substance, even though the method of processing is routine and well-known in the field, the claim will survive Section 101.

The challenged claims also cannot cross the Section 101 threshold because they preempt a physician from considering whether the test drug dosage was too high or low – an abstract idea – and from using the medical correlation between the patient’s 6-thioguanine level and the efficacy of thiopurine drugs – a natural phenomenon – in considering whether to adjust the dosage. In this case, the evidence established that the correlation has no known practical use other than the context described in the claim – treatment for gastrointestinal or autoimmune disease. Pet. App. 75a-77a. Thus, Prometheus’ argument that the correlation could be used with respect to other diseases is entirely speculative. As in *Benson*, the

correlation between the metabolite levels and drug efficacy have “no substantial practical application” except in the context of these diseases, and for that reason, the patent preempts the naturally-occurring correlation. *Benson*, 409 U.S. at 71. This correlation was not invented by the patent holder. And it cannot be invented around because how a dosage of a thiopurine drug will be metabolized by a patient is a natural phenomenon, one that varies patient by patient.

Furthermore, the claims preempt abstract thought. Any physician who receives a patient’s metabolite levels and thinks about their significance is subject to liability. The Federal Circuit found otherwise, asserting without further explanation that a physician who only evaluates the resulting metabolite level, without carrying out the administering and determining steps, would not infringe. Pet. App. 21a-22a. Yet, courts have found that physicians would be in violation of a patent for considering test results, and the laboratories that provided the results have been held liable for inducing physicians to infringe. In *Metabolite*, Lab. Corp. was found liable for performing the test and educating doctors about the medical correlation; the doctors who review test results and “automatically reach a conclusion about whether or not a person was suffering from a vitamin deficiency” were also infringing. 548 U.S. at 130.

The likelihood of infringement liability for physicians who simply consider the test results illustrates the preemptive effect of these claims. Presented with a patient’s 6-thioguanine level, a doctor risks liability merely by thinking about

whether the level calls for an increase, decrease, or continuation of a drug dosage. Indeed, Mayo's researcher was accused of ongoing infringement because, while studying skin conditions, she previously had received a report containing the therapeutic ranges claimed by Prometheus. Pet. for a Writ of Cert., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* 8-9 (2011) (No. 10-1150). Even though she no longer received reports that included the ranges, they were in her memory, and so she continued to infringe in respondent's view. *Id.* The patents claim the exclusive right to thinking about a patient's metabolite levels and their relationship to drug efficacy. This erodes physicians' ability to provide quality patient care and threatens to stifle innovation. *See Metabolite*, 548 U.S. at 138.

Accordingly, because these claims patent the abstract idea of considering adjustment of a drug dosage in light of a patient's metabolite levels and the natural correlation between metabolite levels and drug efficacy and toxicity, they are invalid under Section 101.

II. THE FIRST AMENDMENT LIMITS THE REACH OF CONGRESS' POWER UNDER THE INTELLECTUAL PROPERTY CLAUSE.

Prometheus in this case is attempting not only to patent an abstract idea – the fact that thiopurine drugs affect metabolite levels in the blood – but also the mental process involved in thinking about how altered metabolite levels should affect a patient's drug dosage. As noted above, that claim is invalid as a matter of patent law. But there is more involved in this case than merely patent law. The principle that

government may not license abstract ideas or regulate freedom of thought is central to the First Amendment. Thus, even if the Patent Act were construed to allow the patent claims in this case, the First Amendment would prohibit it. By construing Section 101 to bar the patent claims in this case, the Court can and should avoid the constitutional problems that would otherwise arise if the decision of the Federal Circuit were affirmed. *See, e.g., Skilling v. U.S.*, 130 S.Ct. 2896, 2929-30 & n.40 (2010); *NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490, 500-01 (1979).

A. The First Amendment Prohibits The Patenting Of Abstract Ideas.

The structure of intellectual property is created by Article 1, section 8, clause 8, which covers copyrights and patents: Congress has the power “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Like other legislative powers conferred on Congress by Article I, the power to award copyrights and patents is limited by the First Amendment.

In copyright, where the potential conflict between copyright law and the First Amendment is more obvious, various doctrines, such as fair use, or the distinction between idea and expression, exist to accommodate the First Amendment’s values. Although these doctrines are incorporated into the copyright statute, the Court has suggested that these doctrines are required by the First Amendment. *Harper & Row, Publs. v. Nation Enters.*, 471 U.S.

539, 555-560 (1985); *Eldred v. Ashcroft*, 537 U.S. 186, 219 (2003).

The doctrine of patent law that abstract ideas and natural laws are not patentable is based on interpretation of the Patent Act, but has not been previously described as compelled by the First Amendment. 35 U.S.C. § 101. However, the “abstract idea” doctrine that is central to this case – and strikingly similar to the idea/expression distinction in copyright – protects fundamental First Amendment values. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (“excluded from such patent protection are ... abstract ideas.”); *Eldred*, 537 U.S. at 219.

Here, the essence of Prometheus’ claims is the idea that certain lab results may indicate a need to change the thiopurine dosage. It is, in that respect, no different than saying, “if your headache doesn’t go away, consider taking a second aspirin.” At best, this observation simply describes the natural phenomena that have taken place in the body and/or the abstract idea that certain test results indicate the drug has not reached maximum effectiveness. At worst, the claim is essentially prohibiting a physician from thinking “I need to change the dosage.”

Freedom of thought lies at the very core of the First Amendment. Indeed, freedom of speech and belief would be meaningless without it. Granting Prometheus or any other patent holder a monopoly on abstract ideas is incompatible with a constitutional regime that protects freedom of thought. In this case, the language of the challenged claims makes that connection explicit. What Prometheus seeks to monopolize through its patents

is the right to think about the correlation between thiopurine drugs and metabolite levels, and the therapeutic consequences of that correlation. The patents, if upheld, would also presumably prevent a medical researcher from discussing the correlation (if the researcher had also administered the drug and measured its impact) with her colleagues, or at a professional conference, or in a published paper.

The First Amendment does not permit that result. The ability to think without constraint is an essential attribute of human autonomy and an essential cornerstone of the First Amendment. See Laurence Tribe, *AMERICAN CONSTITUTIONAL LAW*, § 12-1 (2d ed. 1988); Thomas Emerson, *THE SYSTEM OF FREEDOM OF EXPRESSION* 6 (1970). In Justice Harlan's words, "No other approach would comport with the premise of individual dignity." *Cohen v. California*, 403 U.S. 15, 24 (1971). Or, as Justice Brandeis famously stated in an opinion joined by Justice Holmes, the First Amendment protects the "freedom to think as you will and to speak as you think." *Whitney v. California*, 274 U.S. 357, 375 (1927) (Brandeis, J., concurring).

Echoing that theme, *Palko v. Connecticut*, 302 U.S. 319, 326-27 (1937), described "freedom of thought and speech" as "the matrix, the indispensable condition, of nearly every other freedom." See also *Stanley v. Georgia*, 394 U.S. 557, 564-66 (1969); *Griswold v. Connecticut*, 381 U.S. 479, 482 (1965) ("The right to freedom of speech ... includes not only the right to utter or to print, but the right to ... freedom of inquiry, freedom of thought ... "); *U.S. v. Reidel*, 402 U.S. 351, 355-56 (1971). More recently, in *Ashcroft v. Free Speech Coalition*,

535 U.S. 234, 253 (2002), the Court stated that, “First Amendment freedoms are most in danger when the government seeks to control thought or justify its laws for that impermissible end. The right to think is the beginning of freedom”

The Patent Clause of Art. 1, § 8 undoubtedly provides a compelling interest in granting an exclusive license on properly patentable items. However, there can be no compelling interest in granting an exclusive license on abstract ideas or every possible expression of those ideas. Even in copyright, the government does not claim a compelling interest in licensing an idea or every possible expression of that idea.

The same First Amendment principles apply to patent law. Assume, for example, that the government decided that the way to encourage mathematical innovation was to grant specific universities exclusive rights to study specific fields of mathematics. There can be no serious doubt that such exclusivity would be unconstitutional. Indeed, the First Amendment is based on exactly the opposite conclusion – that progress is best achieved through a marketplace of ideas that cannot exist if thought is strictly controlled.

In upholding the patents in this case, the Federal Circuit misapplied patent law and misapplied the First Amendment.

B. The First Amendment Prohibits Patents That Prevent A Person From Thinking A Particular Thought.

The patents in this case would be unconstitutional under the First Amendment even if the

Federal Circuit were correct that the essence of the patents did not involve an abstract idea. That is because Step 3 of the claim still describes what the Federal Circuit acknowledged is a “mental step,” which is to say a thought. Pet. App. 21a.

As Prometheus’ own expert explained to the district court, once a physician reads the results of the test ordered at Step 2, the physician would be infringing if he “crumples it up, throws it away, reads it, acts on it, doesn’t act on it, any assumptions you want to come up with.” 1JA 42. The wherein clauses are obviously intended to alert the physician to act in a therapeutic setting, but the claim is not limited to the therapeutic setting or to any action taken as a result of the test levels. No physician having ordered the administration of the drug and the test may think about whether to increase or decrease dosage without permission from the patent holder.

Whatever patent law allows in these circumstances, the First Amendment does not permit the government to control thoughts, whether it does so directly through regulation or by delegating that authority to a private party through the grant of a patent. As a matter of First Amendment law, moreover, it is immaterial whether the constraint on thought is ultimately characterized as essential to the patent claim. Even incidental restrictions on speech (let alone thought) are unconstitutional if they are directed at the suppression of ideas or content-based. *United States v. O’Brien*, 391 U.S. 367 (1968). This patent claim is both.

Assuming other patent criteria are met, a patent can, of course, be granted on a drug. It can be

granted on an otherwise patentable method of administering a drug. It can be granted on an otherwise patentable method of testing for the effectiveness of the drug. It cannot be granted on thinking about the results of the test. That is true even if the patent claim is a method claim that includes all of these steps. If any portion of a claim restricts a person's ability to think about a specified subject, it is unconstitutional under the First Amendment. Because the final step in this claim does exactly that, it is invalid.

An analogy may be helpful. Assume Henry Ford obtained a patent on the process of the moving assembly line consisting of first having one person put on the hood and then, after the body of the car has been moved by a conveyor belt, a second person put on the trunk. Assume that is a patent eligible process. Assume further that General Motors obtained a patent on the same hood-trunk process by adding a third step, "wherein if the process takes more than 5 minutes consider whether to reverse the order." Applying the Federal Circuit's transformation analysis, the hood-trunk "transformative" steps would justify General Motors' claim if other patent law criteria were satisfied, even though the third step describes pure thought. In our view, the First Amendment prohibits such a patent even if patent law does not.

Under this hypothetical patent, General Motors' engineers could think about reversing the order in which parts are assembled based on the speed of the assembly line. Personnel at Ford, or any other plant, who engaged in the same "mental step" would be infringing the patent. This case presents

precisely the same situation. Prometheus personnel who administer the drug and the test can look at the results and think about the dosages. Researchers who are simply reviewing dosage studies can think about dosages. People at Mayo can lawfully administer the drug and the test. But, people at Mayo cannot look at the results and think about the dosages.

All patents of course begin with a thought, but thought itself is not patentable. The principle that private thoughts are beyond government control is so basic to our constitutional scheme that we are unaware of any case in which the authority to control pure thought has been at issue. In this context, however, the absence of direct precedent merely highlights the extraordinary nature of the asserted claim.

A patent that explicitly targets and restricts thought cannot be reconciled with the First Amendment.

CONCLUSION

For the reasons stated above, the judgment of the court of appeals should be reversed.

Respectfully submitted,

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