ST. THOMAS UNIVERSITY SCHOOL OF LAW

INTRODUCTION TO LEGAL STUDIES (ILS)
CONDITIONAL, SECTION 1

PROFESSOR IRA STEVEN NATHENSON
WEEK OF JUNE 6-10, 2016

ASSIGNMENT FOR WEDNESDAY, JUNE 8

DAY 3 TOPIC: PATENTS

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DAY 3 ASSIGNMENT

ASSIGNMENT FOR DAY 3 (WEDNESDAY, JUNE 8)

First, read the study questions. They will help you with the readings.

Second, carefully read the materials in the order shown below. Fully brief any cases and bring your printed briefs to class:

- U.S. CONSTITUTION, Article I, sec. 8, cl. 8
- Statutory selections from 1952 Patent Act, as amended under the 2011 America Invents Act
- Sample Patent regulation
- Patent exercises
- *Mayo Collaborative Servs. v. Prometheus Labs.*

Finally, after you've read the assigned materials, answer the study questions and do the patent exercises. Be prepared to discuss all the materials in class. To answer the study questions, you will likely need to go back and reconsider the readings. To do the patent exercises, you will need to carefully review the statutes.

DAY 3 STUDY QUESTIONS

1. What provision(s) of Article I, section 8 might be used to justify Patent laws?
2. Section 101 is about "utility" patents, which includes "process" and "product" patents.
    a. "Process" is defined in section 100(b) as "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." A process can be a method of making something, doing something, or using something.
    b. The other three categories (machine, manufacture, and composition of matter) are "product" patents. The lines between the three can be fuzzy and an invention might conceivably fall in more than one category.
        i. A machine does something, such as a can opener or a general-purpose computer.
        ii. A manufacture is made from raw or prepared materials, such as clothing or a chair.
        iii. A composition of matter is substances mixed together such as drugs or motor oil.
3. Can I get patents on the following? Focus on 35 U.S.C. §§ 100, 101, and the *Mayo* case.
    a. A new type of peanut butter.
    b. A new and unauthorized improvement on the peanut butter invented in 3.a.
    c. A new method for making an existing type of peanut butter.
    d. A new method of using peanut butter to treat wounds.
    e. A new method for purifying gasoline that my mom invented.
    f. A new and non-functional perpetual motion machine.
    g. A new book about a method of accounting.
    h. A new method of accounting.
    i. A brand new tree found in the forest!
    j. Fresh sap from a tree in the forest.
    k. A new drug made from a chemically altered form of the sap from a tree in the forest.
4. Suppose Alpha invents a new and improved method of manufacturing glass smartphone screens. Alpha obtains a process patent. Beta studies Alpha's patent and realize that she can add a step to Alpha's method which will vastly increase the durability of smartphone screens. However, to practice Beta's improved method, she must also practice Alpha's patent.
    a. Can Beta obtain a patent for her improved method of making smartphone glass?
    b. Can Beta make her smartphone glass without Alpha's permission?
    c. Can Alpha practice Beta's improved method without Beta's permission?
5. Suppose Vino comes up with a method of removing sulfites from wine. Vino's mother Ruth realizes that the method had been practiced for centuries back in the old county. When Ruth helps Vino prepare his patent application, she doesn't have the heart to tell Vino the bad news. Does Ruth have a duty to fess up that Vino's invention is not novel? See 37 C.F.R. § 1.56.

PATENT EXERCISES

Question one. Pay close attention to the sequence of events below. All events take place in 2016.

- On January 1, Fiona Furst invents a new method of cooking waffles.
- On February 1, Sammy Secuna independently invents the same method of cooking waffles.
- On March 1, Sammy Secunda publishes an article in *The Huffington Post* detailing every element of his method of cooking waffles.
- On April 1, Fiona appears on *The Today Show* and demonstrates her method in full.
- On May 1, Sammy files an application for a patent for his method.
- On June 1, Fiona files an application for a patent for the same method.

Who, if anyone, is entitled to a United States patent? See 35 U.S.C. § 102.

Question two. Consider the patent below for a method of exercising a cat. The first claim states:

> What is claimed is:
>
> 1. A method of inducing aerobic exercise in an unrestrained cat comprising the steps of:
>
> (a) directing an intense coherent beam of invisible light produced by a hand-held laser apparatus to produce a bright highly-focused pattern of light at the intersection of the beam and an opaque surface, said pattern being of visual interest to a cat; and
>
> (b) selectively redirecting said beam out of the cat's immediate reach to induce said cat to run and chase said beam and pattern of light around an exercise area.

Assume that a search of "prior art" (information such as publications, prior patents, public sale, and more) reveals a 1970s Hollywood film where a young child uses a small hand-held flashlight to tease a dog and make it run around after the light. What arguments can you make that the patent is invalid? See 35 U.S.C. §§ 102 and 103.

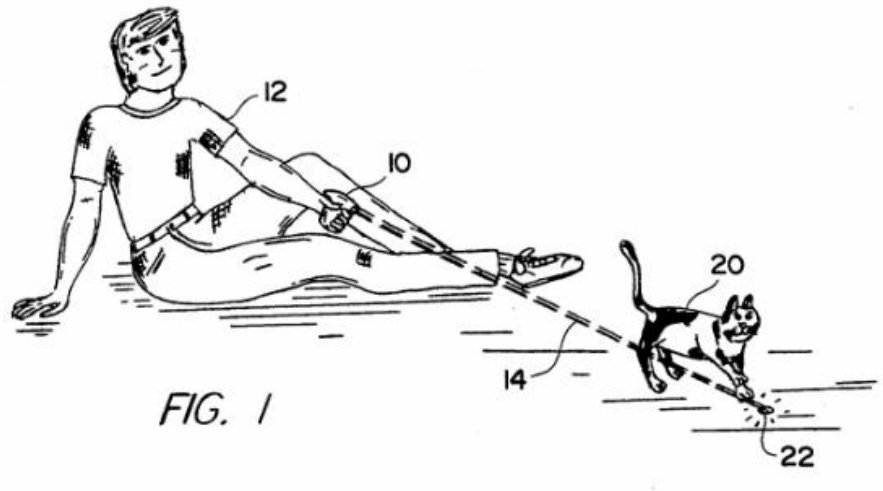
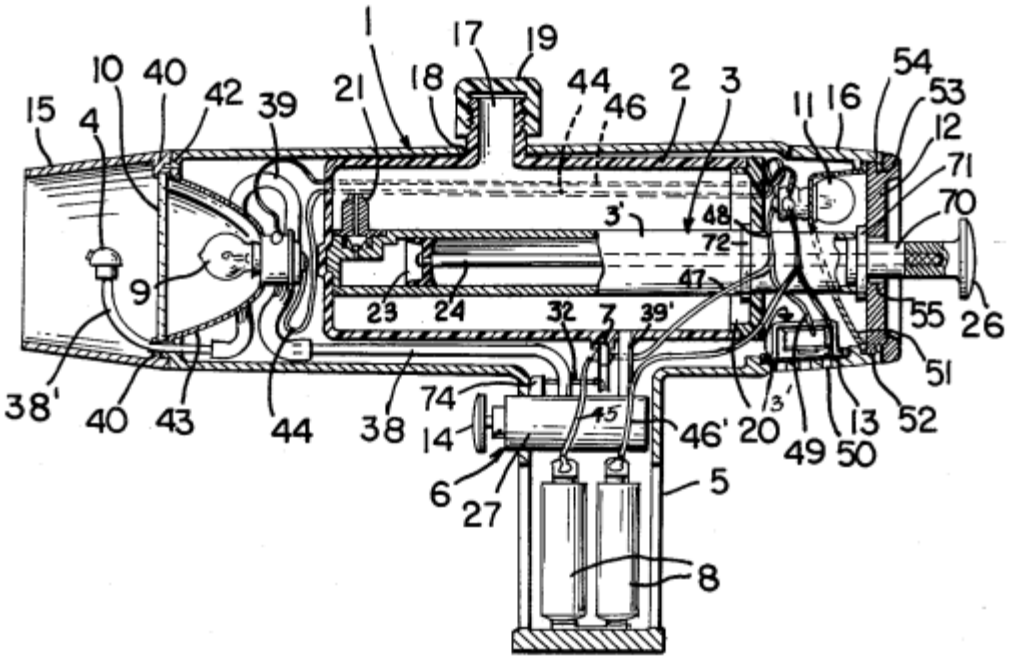


FIG. 1

Question three. Your client ToyCo makes a water pistol that has a detachable external water tank. The owner of the patent below, PatenTee, has written your client asserting that your client is infringing claim 1 of the PatenTee water-pistol patent. PatenTee demands that your client pay a licensing fee to continue use of the patent, and if your client does not agree to pay, then PatentTee threatens to file a patent infringement lawsuit.

Provided below is the text of claim 1 and a drawn of PatenTee's invention.

> 1. A toy comprising an elongated housing having a chamber therein for a liquid, a pump including a piston having an exposed rod end extending rearwardly of said toy facilitating manual operation for building up an appreciable amount of pressure in said chamber for ejecting a stream of liquid therefrom an appreciable distance substantially forwardly of said toy, and means for controlling the ejection.



ToyCo has asked for your advice on what to do. How will you advise your client? Consider whether or not ToyCo's water pistol falls within the scope of PatenTee's claim 1. See also 35 U.S.C. § 271(a).

Question four. Another one of your clients Unfrunger Mfg., makes water-pistol tanks that are identical to the tank as used in Claim 1 of the patent above. Unfrunger does *not* make or sell complete water pistols. Instead, Unfrunger makes the tank that is used by another company (KnockEmOff LLC) that makes "knock-off" water pistols. Review all of 35 U.S.C. § 271. Do you think Unfrunger is liable? If so, under what part(s) of section 271?

CONSTITUTION, STATUTES, REGULATIONS

U.S. Constitution, Article I, Section 8, clauses 3, 8, and 18

The Congress shall have power . . .

. . . .

[3] To regulate commerce with foreign nations, and among the several states, and with the Indian tribes;

. . . .

[8] 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;

. . . .

[18] To make all laws which shall be necessary and proper for carrying into execution the foregoing powers, and all other powers vested by this Constitution in the government of the United States, or in any department or officer thereof.

35 U.S.C. § 100 - Definitions

When used in this title unless the context otherwise indicates—

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

(c) The terms "United States" and "this country" mean the United States of America, its territories and possessions.

(d) The word "patentee" includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.

. . . .

(f) The term "inventor" means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention. . . .

[other portions omitted]

35 U.S.C. § 101 - Inventions patentable

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

35 U.S.C. § 102 - Conditions for patentability; novelty

(a) Novelty; Prior Art.—A person shall be entitled to a patent unless—

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> . . . .

(b) Exceptions.—

> (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
>
> > (A) the disclosure was made by the inventor . . . ; or
> >
> > (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor . . . .

[other portions omitted]

35 U.S.C. § 103 - Conditions for patentability; non-obvious subject matter

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 271 - Infringement of patent.

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

[other portions omitted]

37 C.F.R. § 1.56. Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. . . .

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> > (i) Opposing an argument of unpatentability relied on by the Office, or
> >
> > (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

> (1) Each inventor named in the application;
>
> (2) Each attorney or agent who prepares or prosecutes the application; and
>
> (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, the applicant, an assignee, or anyone to whom there is an obligation to assign the application.

[other portions omitted]

MAYO COLLABORATIVE SERVS. V. PROMETHEUS LABS., INC.

Supreme Court of the United States

132 S. Ct. 1289

Argued Dec. 7, 2011

Decided Mar. 20, 2012

Justice Breyer delivered the opinion of the Court.

[1] Section 101 of the Patent Act defines patentable subject matter. It says:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

[2] The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); see also *Bilski v. Kappos*, 561 U.S. 593, ___ (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980) . . . . Thus, the Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, supra, at 309 (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

[3] "Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

[4] The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in *Diehr* the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" 450 U.S., at 187. It added that "an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, supra, at 187. And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939):

> "'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'" 450 U.S., at 188 (quoting *Mackay Radio*, supra, at 94). . . .

[5] Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, e.g., *Benson*, supra, at 71-72.

[6] The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

[7] Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook*, supra, at 593. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. . . .

[8] We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

A

[9] The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

[10] At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites . . . were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. See U.S. Patent No. 6,355,623, col. 8, ll. 37-40, 2 App. 10 . . . But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.

[11] More specifically, the patents—U.S. Patent No. 6,355,623 ('623 patent) and U.S. Patent No. 6,680,302 ('302 patent)—embody findings that concentrations in a patient's blood of [certain] metabolite[s] beyond a certain level (400 and 7000 picomoles per 8x108 red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of [one of the metabolites] lower than a certain level (about 230 picomoles per 8x108 red blood cells) indicate that the dosage is likely too low to be effective.

[12] The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

"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 8x108 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 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, ll. 10-20, 2 App. 16.

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

B

[13] Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the '623 and '302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test . . . . Prometheus then brought this action claiming patent infringement.

[14] The District Court found that Mayo's test infringed claim 7 of the '623 patent. . . . Nonetheless the District Court ultimately granted summary judgment in Mayo's favor. The court reasoned that the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages-and so are not patentable. . . . [Editor's note: after the District Court's decision, the case went up to the Federal Circuit on appeal. That decision was then appealed to the Supreme Court, which sent the case back to the Federal Circuit. In its second opinion, the Federal Circuit held that the patents did "not encompass laws of nature." The Supreme Court granted certiorari after the second decision by the Federal Circuit, leading to the opinion you are now reading.]

II

[15] Prometheus' patents set forth laws of nature-namely, relationships between concentrations of

certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that if the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x108 red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body-entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

[16] The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that apply natural laws? We believe that the answer to this question is no.

A

[17] If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

[18] What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

[19] First, the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. . . .

[20] Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision making (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).

[21] Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12-65. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. Thus, this step tells doctors to engage in well understood, routine,

conventional activity previously engaged in by scientists who work in the field. . . .

[22] Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

[23] The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

B

. . . .

2

[24] Other cases offer further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable. . . . In *Bilski* the Court considered claims covering a process for hedging risks of price changes by, for example, contracting to purchase commodities from sellers at a fixed price, reflecting the desire of sellers to hedge against a drop in prices, while selling commodities to consumers at a fixed price, reflecting the desire of consumers to hedge against a price increase. One claim described the process; another reduced the process to a mathematical formula. 561 U.S., at _____, 130 S. Ct. 3218. The Court held that the described "concept of hedging" was "an unpatentable abstract idea." Id., at ___, 130 S. Ct. 3218, 3225. . . .

[25] Finally, in *Benson* the Court considered the patentability of a mathematical process for converting binary coded decimal numerals into pure binary numbers on a general purpose digital computer. The claims "purported to cover any use of the claimed method in a general purpose digital computer of any type." 409 U.S., at 64. The Court recognized that "'a novel and useful structure created with the aid of knowledge of scientific truth'" might be patentable. Id., at 67 (quoting *Mackay Radio*, 306 U.S., at 94). But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. For the mathematical formula had "no substantial practical application except in connection with a digital computer." *Benson*, supra, at 71. Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said "apply the algorithm."

3

[26] The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in *Morse* the Court set aside as unpatentable Samuel Morse's general claim for "'the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances,'" 56 U.S. 62. The Court explained:

> "For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff 's specification. His invention may be less complicated less liable to get out of order less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee." Id. at 113.

[27] Similarly, in *Benson* the Court said that the claims before it were "so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]." 409 U.S., at 67, 68, 93 S. Ct. 253, 34 L. Ed. 2d 273. In *Bilski* the Court pointed out that to allow "petitioners to patent risk hedging would preempt use of this approach in all fields." 561 U.S., at ___, 130 S. Ct. 3218. And in *Flook* the Court expressed concern that the claimed process was simply "a formula for computing an updated alarm limit," which might "cover a broad range of potential uses." 437 U.S., at 586.

[28] These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson*, supra, at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. . . .

[29] The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The "determining" step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

[30] We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent.

III

[31] We have considered several further arguments in support of Prometheus' position. But they do not lead us to adopt a different conclusion. First, [discussion omitted]. Second, Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and

specific, the patents should be upheld. Thus, it encourages us to draw distinctions among laws of nature based on whether or not they will interfere significantly with innovation in other fields now or in the future.

[32] But the underlying functional concern here is a relative one: how much future innovation is foreclosed relative to the contribution of the inventor. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research.

[33] In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. See, e.g., *Flook*, 437 U.S. 584 (holding narrow mathematical formula unpatentable). And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building block" concern.

[34] Third, the Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy § 101's demands. Brief for United States as Amicus Curiae. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions-those that insist that a claimed process be novel, 35 U.S.C. § 102, that it not be "obvious in light of prior art," § 103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, § 112 can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under § 102.

[35] This approach, however, would make the "law of nature" exception to § 101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. . . .

[36] We recognize that, in evaluating the significance of additional steps, the § 101 patent eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

[37] What role would laws of nature, including newly discovered (and "novel") laws of nature, play in the Government's suggested "novelty" inquiry? Intuitively, one would suppose that a newly discovered law of nature is novel. The Government, however, suggests in effect that the novelty of a component law of nature may be disregarded when evaluating the novelty of the whole. But §§ 102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. *Diehr*, 450 U.S., at 188. And studiously ignoring all laws of nature when evaluating a patent application under §§ 102 and 103 would "make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." Id., at 189 . . . . These considerations lead us to decline the Government's invitation to substitute §§ 102, 103, and 112 inquiries for the better established inquiry under § 101.

[38] Fourth, Prometheus, supported by several amici, argues that a principle of law denying patent

coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Br. for Respondent 52.

[39] Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association . . . and other medical organizations tell us that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." Brief for American College of Medical Genetics et al. as Amici Curiae 7 . . . .

[40] We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another.

[41] In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U.S.C. §§ 161-164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

* * *

[42] For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered.