

## Mayo Collaborative Services, *et al.* v. Prometheus Laboratories, Inc

(Supreme Court of the United States, 566 U. S., 2012.)

Prepared by UNCTAD's Intellectual Property Unit

### Summary

The Supreme Court of the United States decided that:

- An application of a natural law is not patentable if the steps used to apply the natural law involve well-understood, routine, conventional activity previously engaged in by researchers in the field.
- Additional features in a claimed inventions that add nothing specific to the laws of nature, natural phenomena, or abstract ideas other than what is well-understood, routine, conventional activity, previously engaged in by those in the field, do not make the claim patentable.

### Facts

Section 101 of the Patent Act of the United States provides for patent protection of any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. The prevailing jurisprudence provides that the provision contains an important implicit exception that:

1. Laws of nature, natural phenomena, and abstract ideas are not patentable. Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are manifestations of nature, free to all men and reserved exclusively to none. They are the basic tools of scientific and technological work and monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.
2. However, an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.
3. In order for an application of a natural law to be patentable, one must do more than simply state the law of nature while adding the words “apply it.”

Thiopurine is a drug used in the treatment of autoimmune diseases. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. However, the way 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. Scientists understood that the levels of certain metabolites in a patient's blood were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. But those in the field did not know the precise correlations between metabolite levels and the likely harm or ineffectiveness. Two U.S. patents (No. 6,355,623 and No. 6,680,302), with a priority date of 24 September 1998, for a method of optimizing therapeutic efficacy, embody the findings of thiopurine-metabolite

correlations, and claim patents for a set of processes for administering the drug on a patient by doctors; determining the level of the relevant metabolites and for adjusting the dosage. The patents identified the correlations between thiopurine-metabolite levels with some precision.

Prometheus Laboratories, Inc. (Prometheus) is the sole and exclusive licensee of the two 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—a test using somewhat higher metabolite levels to determine toxicity. Prometheus then brought legal action claiming patent infringement. The District 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. In 2009, the Federal Circuit reversed the decision and held that in addition to the natural correlations, the claimed processes specify the steps of administering a drug to a patient and determining the resulting metabolite level. Mayo filed a petition for certiorari with the Supreme Court. In 2010, the Supreme Court vacated the judgment of the Federal Circuit, and remanded the case for reconsideration. The same year the Federal Circuit reaffirmed its earlier decision. Mayo again filed a petition for certiorari, which the Supreme Court granted.

### **Legal issues**

According to the Supreme Court, the question is whether 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.

The claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. The additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim:

- The “administering” step simply identifies a group of people who will be interested in the correlations, namely, doctors who used thiopurine drugs to treat patients suffering from autoimmune disorders. A prohibition against patenting abstract ideas “cannot be circumvented by attempting to limit the use of the formula to a particular technological environment”;<sup>1</sup>
- The “determining” step tells a doctor to measure patients’ metabolite levels, through whatever process the doctor wishes to use. Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field;

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<sup>1</sup> See page 2 of the syllabus.

- The third step, indicating the need to increase or decrease the dosage, simply tells a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions.

According to the Court, the jurisprudence further supports 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.

Prometheus argued that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld, thus, encouraging the Court 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. The Supreme Court, however, concluded that courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. Therefore, the jurisprudence has 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.

The Supreme Court further addressed the view stated by the US government in its *brief*. The government had argued 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. The government had based this broad approach on the view that other statutory provisions—those that require that a claimed process be novel, non-obvious, and fully, clearly, concisely and exactly described — can perform the screening function. In particular, the government argued that the claims in the two patents of Prometheus likely fail for lack of novelty. For the Supreme Court, the approach proposed by the government, however, would make the “law of nature” exception to patentability a dead letter. To shift the patent eligibility inquiry entirely to these other statutory provisions risks creating significantly greater legal uncertainty, while assuming that those provisions can do work that they are not equipped to do.

### **Points of Significance**

1. Exclusion from patentable subject matter of laws of nature, natural phenomena, abstract ideas, and mathematical formulas may not be provided explicitly under patent laws. The test used in the United States to exclude certain subject matter from patentability is whether the subjects are the basic tools of scientific and technological work and monopolization of those tools through the grant of a patents might tend to impede innovation more than it would tend to promote it. See also the decision of the Supreme Court denying patents on naturally occurring genes in *Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al.*, 569 U.S. 12-398 (2013).<sup>2</sup> This jurisprudence was further elaborated by the United States Court of Appeals for the Federal Circuit in *iNO Therapeutics LLC v. Praxair Distribution Inc.*<sup>3</sup>

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<sup>2</sup> See the summary of that decision in this database.

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2. The case also clarifies the difference between eligibility of a subject matter for patent protection (i.e. the term of “invention”), and the patentability criteria (novelty, non-obviousness and industrial applicability of an invention) and the written description requirements. Only patent eligible subject matter is subject to the patentability criteria and the written description requirement. According to the Supreme Court, examining eligibility of a subject matter for patent protection provides more legal certainty than relying on the patentability criteria. This is because the law of nature not disclosed in prior art may not destroy novelty and non-obviousness.
3. Together with the U.S. Supreme Court decision in *Association for Molecular Pathology et al. v. Myriad Genetics* concerning naturally occurring substances, the decision of natural processes/phenomena had significant influence on subsequent practices of the US Patent and Trademark Office (USPTO). The USPTO immediately reacted to the Court's decision by publishing new guidelines on subject matter eligibility. It set out a three-step inquiry in the form of questions to be asked:
  - (1) Does the Mayo decision apply in principle? (I.e. does the invention address a process, defined as an act, or a series of acts or steps?)
  - (2) Does the patent application address a contentious subject matter? (I.e. does the invention focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation?)
  - (3) Does the subject matter meet the requirements laid down under the *Mayo* decision? (Does the patent application refer to additional elements/steps or a combination of elements/steps that integrate the natural principle into the invention such that the natural principle is practically applied? Is this sufficient to ensure that the invention amounts to significantly more than the natural principle itself?)

**Key words:** law of nature, natural phenomena, application of law of nature.

**Available at:** <http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>