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Obtaining Patents that will Survive 35 U.S.C. §101

in Light of

***Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,**

United States Supreme Court, March 20, 2012

April 17, 2012

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Patentable Subject Matter

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

Prometheus Laboratories :

Laws of Nature are not patentable subject matter.

But:

- "'[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Id.* at *2.

- "[A]ll inventions at some level embody, use reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.*

- So how do we tell what is patentable and what is a law of nature? Is there a test to apply?

Bilski's Machine or Transformation Test

"[a] claimed process is ... patent-eligible under §101 if: (1) it is tied to a particular machine or apparatus, ***or*** (2) it transforms a particular article into a different state or thing." *Id*. at 953.

US Supreme Court: the machine or transformation test is "a useful and important … investigative tool, for determining whether some claimed inventions are processes under § 101." *Bilski*, 130 S. Ct. at 3227.

But, "[t]he machine-or-transformation test is not the sole test." Is it a test at all?

So if a patent claim involves a machine or a transformation of matter, is it directed to patentable subject matter?

Not necessarily . . . .

Prometheus: The machine or transformation test cannot "trump" the law of nature exclusion. *Id*.

When the law of nature aspects of a claim are put aside, and there is no remaining **"inventive concept,"** a claim cannot be saved by a known machine or transformative process

Machine or Transformation Test

If failing the Machine or Transformation test does not mean failing patentable subject matter under §101, and passing the Machine or Transformation test does not mean satisfying §101, does the Machine or Transformation test mean anything?

Is the new test “inventive concept?”

Inventive Concept?

Isn't "inventive concept" a validity issue under 35 U.S.C. §§ 102 and 103?

Didn't the US courts abandon "inventive concept" years ago in favor of analyzing the "claim as a whole"?

Inventive Concept

The Court dispelled any doubt that it meant to include a novelty or obviousness component to the § 101 analysis when a claim recites a law of nature:

"[w]e 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 the case." *Id.* at *16.

The Prometheus Claims at Issue

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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject. (emphasis added)

What does Prometheus' the claim cover?

To infringe this claim,
the Prometheus Patents require a user to:

1) administer a thiopurene drug;

2) determine the patient's level of 6-thioguanine; and

3) stand back and do not necessarily do anything.

The Prometheus Patent Claims

The "administering" step merely identified the relevant audience– doctors. *Id*. at 9.

The determining steps simply required the doctor to "engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Id*.

The "wherein clauses" merely "trust[ed] them to use those laws appropriately." *Id*.

The claims were nothing more than a recitation of a natural law and a recommendation to **apply it**. *Id*.

Prometheus Ruling

Prometheus Patents improperly claimed patent ineligible laws of nature:

"[p]henomena of nature, though just discovered, mental processes, and abstract intellectual processes are not patentable, as they are the basic tools of scientific and technological work."

However, "an ***application*** of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Prometheus*, 2012 WL 912952, at *4 (emphasis added)

Applications of Laws of Nature

To qualify as 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.'" *Id*. at *5.

There must be some "additional features that provide practical assurance that the process is more than a **drafting effort** to monopolize the law of nature itself." *Id* at *8.

The "inventive concept" test was designed to determine whether a patent was overbroad and covered a law of nature, disguised by artful draftsmanship. *Id*. at *3.

A Groundbreaking Ruling Invalidating Thousands Of Patents?

The court likely intended to limit its new test to claims that "refer to, but do not necessarily apply a law of nature" such as those presented by the Prometheus Patents.

The Court's "conclusion rest[ed] upon an examination of the particular claims before [it]." Id. at *5.

In every hypothetical situation presented by the Court, the hypothetical claim involved nothing more than a sheer recitation of a law of nature and a recommendation to refer to it.

Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010)

A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

Patentable Application of a Process

Diamond v. Diehr, 450 U.S. 175, 185 (1981)

The Claim: energy constant (C) is unique to the compound being molded; constant (x) is dependent on the geometry of the particular mold; (Z) is the temperature of the mold, (v) is time, then apply the Arrhenius equation : ln(v)=CZ+x; and

open the mold at the right time.

The steps added to the Arrhenius equation were not "obvious, already in use, or purely conventional." *Id*. at *12

Parker v. Flook, 437 U.S. 584 (1978).

A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of Bo + K wherein Bo is the current alarm base and K is a predetermined alarm offset which comprises:

(1) Determining the present value of said process variable, said present value being defined as PVL;

(2) Determining a new alarm base B1, using the following equation: B1=Bo(1.0-F) + PVL(F) where F is a predetermined number greater than zero and less than 1.0;

(3) Determining an updated alarm limit which is defined as B1 + K; and thereafter

(4) Adjusting said alarm limit to said updated alarm limit value.

Hypothetical Example

A claim to a hypothetical iron containing magnetic resin, comprising a heretofore unknown 4-4.5% iron-aluminium alloy, that also referred to Gauss' Law to identify the cured resin's magnetic properties.

Should be acceptable. Recites, but applies a law of nature, to the extent the composition aspects of the claim are new, useful and non-obvious.

PTO Bulletin Re *Mayo* Ruling

Examiners must continue to ensure that claims, particularly process claims, are not directed to an exception to eligibility such that the claim amounts to **a monopoly on the law of nature**, natural phenomenon, or abstract idea itself.

In addition, to be patent-eligible, a claim that includes an exception should include other elements or combination of elements such that, in practice, the claimed product or process amounts to **significantly more than a law of nature**, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto.

Claim Drafting Tips

- Look out for law of nature claims!
- Require a machine or person to do something, to apply the law, not just consider results
- Don’t ignore machines and transformations
- Draft claims of varying scope
- If you are merely using clever draftsmanship, are you being clever enough and should you add some dependent claims?

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ありがとうございました

ご質問等ございましたら、下記までお気軽に
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