The Prometheus Case

Patent Law and The Therapeutic Window

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INTRODUCTION

What is patentable?

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition, 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

Exception

“Laws of nature, natural phenomena , and abstract ideas are not patentable”

Diamond v. Diehr, 450, U.S. 303, 309 (1981)

What is not patentable?

1. A new mineral or new plant
2. $E = mC^2$

Why? Because patenting such fundamental ideas/intellectual concepts hinder the progress of science.

But….

"… all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas"

Prometheus (Slip op. at 2)

Decision guideline for patentability

"[A]n *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection" (emphasis added)

Parker v. Flook, 437, U.S. 584, 590 (1978)

The PROMETHEUS Case
Mayo Collaborative Services v. Prometheus Lab., Inc.
Case No. 10-1150, slip op. U.S. Mar. 20, 2012

The Dispute

- In pertinent part, Prometheus Laboratories ("Prometheus"), as an exclusive licensee of US Patent No. 6,355,623 (the '623 patent), sells a test, based on the therapeutic window principle.
- At first, Mayo Clinic and affiliates ("Mayo") purchased this test from Prometheus.
- Later, Mayo designed a similar test.
- Prometheus brings a patent infringement suit against Mayo.

Patentable Claim?

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. (emphasis added)

District (Trial) Court: Mayo Won

- **Mayo was found to have infringed the patent (Claim 7 of the '623 patent); their range was 230 -400 pmol of 6-TG per 8 x 10^8 red blood cells**
- **However, the claim was unpatentable since it essentially covered a natural law (in this case the therapeutic window)**

MACHINE- OR TRANSFORMATION TEST

For a method claim to be patentable, it must:

- **" be tied to a particular machine or apparatus, or**
- **transform a particular article to a different state or thing."**

http://www.uspto.gov/web/offices/pac/dapp/opla/documents/bilski_guidance_memo.pdf

Federal (Appeals) Court: Mayo Loses

- **This court ruled (for the second time) that the claim is patentable because it met its "machine or transformation" test.**
- **The Appeals court construed the words "administering" and "determining" (underlined words in the claim shown earlier) as "transformation of the human body or patient blood sample") and hence patentable.**
- **Mayo appealed (second time) and the Supreme Court agreed again (*granted certiorari)* to listen this case.**

Supreme Court: Mayo Wins

To decide this case, the Court formulated the following question, "[W]hether the claims, [which] purport to apply natural laws describing the relationships between the concentrations in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects, have transformed these unpatentable natural laws into patent-eligible applications of those laws?" *Slip op* at 3.

Supreme Court: Mayo Wins

This Court did not accept the "transformation" arguments used by the appeals court, and concluded that "[t]hese additional steps . . . are [not] sufficient to transform the nature of the claim". *Slip op.* at 9.

Supreme Court: Mayo Wins

"A patent, for example, could not simply recite the law of nature and then add the instruction: apply the law?" *Slip op*. at 9

The Court concluded the "claimed processes have [not] transformed these unpatentable natural laws into patent-eligible applications of those laws. . . . and that therefore the processes are not patentable" *Slip op*. at 3.

Supreme Court: Mayo Wins

In further analysis, the Court cited 2 of its previous decisions as "most directly on point" to this case. (*Slip op*. at 11):

1. The *Diehr* case, where the claim is patent eligible.
2. **The *Flook* case, where the claim is not patent eligible.**

Diamond v. Diehr 450 U.S. 175 (1981) *("Diehr")*

A method to "cure" synthetic rubber, whose steps were carried out by the use of a computer program for the Arrhenius equation, was found not patentable by the USPTO because "[t]he examiner [mistakenly] concluded that the . . .claims defined and sought [patent] protection of a computer program for operating a rubber-molding press" (450 U.S. 175,179 (1981)).

The Supreme Court stated that "[b]ecause . . .[the] claims . . . [are] drawn to an industrial process . . . ", they are patent eligible.

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

The patent claim rejected by the USPTO involves a method for catalytic chemical conversion of hydrocarbons with 3 steps:

1. **"[A]n initial step which merely measures the present value of the process variable (e.g., the temperature);**
2. **"[A]n intermediate step which uses an algorithm to calculate an updated alarm limit value"**
3. **"[A] final step in which the actual alarm limit is adjusted to the updated value" *Flook* at 585-587**

Flook

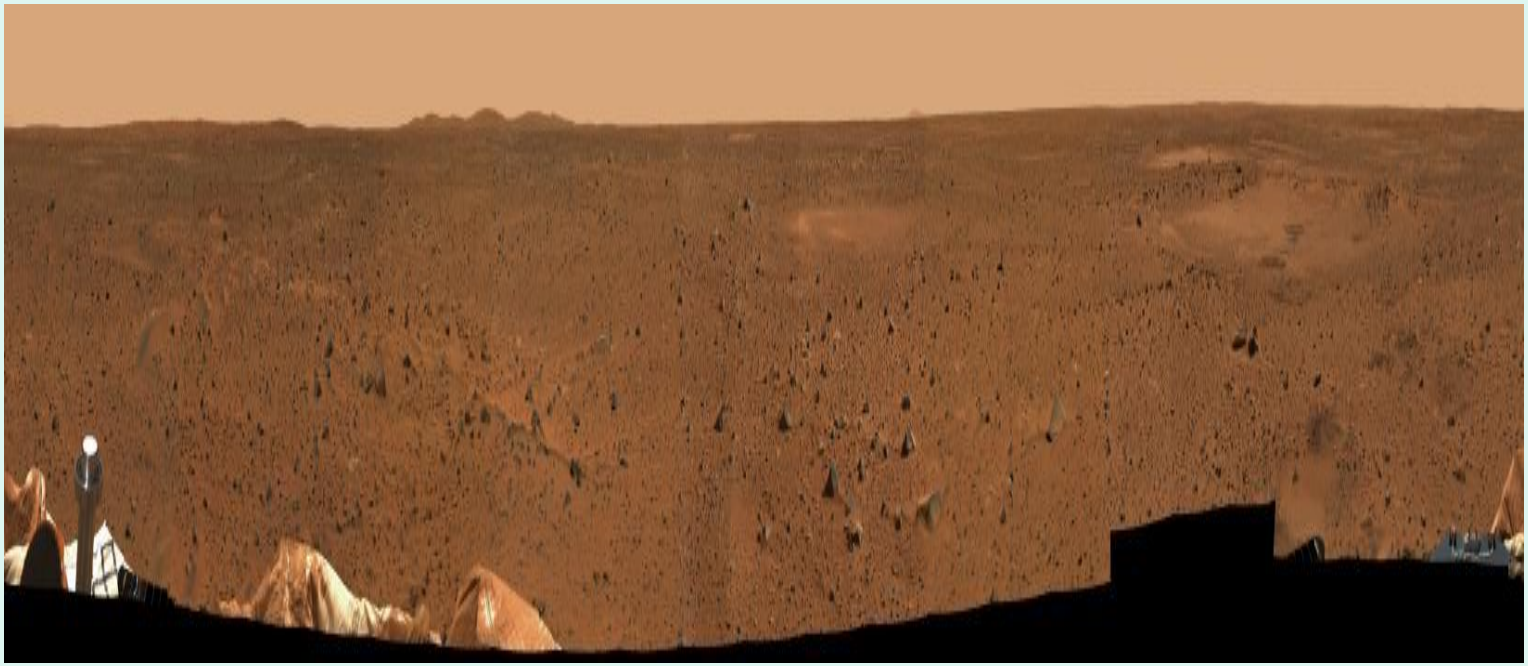
The Supreme Court concluded that the mathematical algorithm of step 2 was the only new aspect of this claim.

"Reasoning that an algorithm or mathematical formula is a like of law of nature, [the Court] applied the established rule that a law of nature cannot be the subject of a patent" (*Flook* at 589)

DISCUSSION QUESTION

Should methods to adjust a drug's dosage based on its blood concentrations (therapeutic window) be patentable?

Is a new mineral discovered in the Gusev crater, Mars (picture below) patentable?



"Thus, a new mineral discovered in the earth . . . is not patentable subject matter".
***(emphasis added) Slip op* at 1.**