Patent Law

Prof. Roger Ford
Wednesday, October 18, 2017
Class 15 – Patentable subject matter: introduction; laws of nature

Recap

Recap

- → Level of skill in the art
- → Available prior art and the analogous-art doctrine
- → Scope and timing of § 103 prior art
- → Secondary considerations of nonobviousness

Today's agenda

Today's agenda

- → Overview of patentable subject matter
- → The implicit exceptions
- → Laws of nature

PSM overview

PSM overview

→ 3+1 core requirements for patentability

- Utility (§ 101)
- Novelty (§ 102)
- Nonobviousness (§ 103)
- Patentable subject matter (§ 101)

(Post-AIA) 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.

PSM overview

→ Not usually disputed

- Most things clearly fall within "process, machine, manufacture, or composition of matter"
- Issues arise in a few specific areas

→ But important when it does come up

PSM overview

→ The practical inquiry

- Step 1: Is it a process, machine, manufacture, or composition of matter?
- Step 2: If so, does it fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?

PSM overview

→ Step 1: Is it a process, machine, manufacture, or composition of matter?

- Usually this is pretty simple
- Few things cannot be conceived as either a physical thing or a process

PSM overview

→ Step 1: Is it a process, machine, manufacture, or composition of matter?

- Law of gravity?
- Law of continental drift?
- Idea of strict liability?
- New mineral or plant I find in nature?

PSM overview

→ Step 2: If so, does it fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?

- This is where all the interesting cases are

PSM overview

→ Federal Circuit's history:

- Over time, the exception (laws of nature, physical phenomena, abstract ideas) was read more narrowly
- Federal Circuit adopted a test for PSM: whether a patent claimed something with a "useful, concrete, and tangible result"
- Then, Federal Circuit adopted the "machine or transformation" test: whether the patent claim is implemented by a machine or transforms an article

PSM overview

→ Since 2010, four big Supreme Court cases:

- *Bilski v. Kappos* (2010) – method of hedging risk in a commodities transaction
- *Mayo v. Prometheus* (2012) – method of determining the correct dose of a drug
- *Ass'n for Molecular Pathology v. Myriad Genetics* (2013) – isolated DNA and complementary DNA
- *Alice Corp. v. CLS Bank* (2014) – system for mitigating settlement risk

PSM overview

→ These cases have had a transformative effect on patentable subject matter

- *Mayo* and *Myriad*: biotech, medicine, pharmaceuticals
- *Bilski* and (especially) *Alice*: business methods and computer software

PSM overview

→ The policy question:

- Do these cases add anything valuable that the "new and useful" limitations do not?
- This is one of the big debates in patent law

Implicit exceptions

Diamond v. Chakrabarty

→ Technology?

Diamond v. Chakrabarty

→ Technology?

- New bacteria that can break down crude oil
- Takes a preexisting bacteria and inserts two preexisting plasmids that break down hydrocarbons
- Combination never existed before

Diamond v. Chakrabarty

→ Three kinds of claims:

- Process of making bacteria
- Inoculum of straw, water, and bacteria
- Bacteria itself

→ Why are the first two not good enough?

Diamond v. Chakrabarty

→ Step 1: is this a process, machine, manufacture, or composition of matter?

Diamond v. Chakrabarty

→ Step 1: is this a process, machine, manufacture, or composition of matter?

- Court: "production of articles for use from raw materials or prepared materials by giving to those materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery"

Diamond v. Chakrabarty

→ Step 1: is this a process, machine, manufacture, or composition of matter?

- Court: "composition[ ] of two or more substances and … all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids"

Diamond v. Chakrabarty

→ "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity 'having a distinctive name, character [and] use.'"

Diamond v. Chakrabarty

→ Is there anything physical that <u>doesn't</u> qualify as a "composition of matter"?

Diamond v. Chakrabarty

→ Is there anything physical that doesn't qualify as a "composition of matter"?

- "two or more substances"
- Maybe an element?
- But, a mixture of quarks?

Diamond v. Chakrabarty

→ Step 2: does this fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?

Diamond v. Chakrabarty

→ Step 2: does this fall within an implicit exception as a law of nature, physical phenomenon, or abstract idea?

- Nope
- Upshot: The courts don't carve out new exceptions; they stick with these three (which are 150 years old)

Diamond v. Chakrabarty

→ The statutory-interpretation question: what to make of plant patents?

- Three kinds of patents: utility patents; design patents; plant patents
- Why would plant patents tell us anything about bacteria?

Diamond v. Chakrabarty

→ The statutory-interpretation question: what to make of plant patents?

→ Two ways to read the different kinds of patents:

- Designed to be wholly separate, or
- Designed to cover specific domains, but can overlap when appropriate

Diamond v. Chakrabarty

→ The statutory-interpretation question: what to make of plant patents?

- Court: plant patents do not implicitly limit § 101
- So the basic rule of this case: everything made by man is patentable

Harvard College v. Canada

→ Technology: Mouse that has been modified to increase susceptibility to cancer

Harvard College v. Canada

→ Canada's patentable-subject-matter law is similar to U.S. law:

- § 101: "process, machine, manufacture, or composition of matter"
- Canada § 124: "art, process, machine, manufacture or composition of matter"

Harvard College v. Canada

→ Yet the Canadian court didn't agree with *Chakrabarty*:

- A "manufacture" is a "non-living mechanistic product or process"
- A "composition of matter" cannot encompass every kind of matter or it would render the other terms redundant

Harvard College v. Canada

→ The implications of extending patentability to living creatures are best left to Parliament:

- Biological creatures are "living and self-replicating"
- Biological creatures are "incapable of full description"

Implicit exceptions

→ Three implicit exceptions to § 102:
- Laws of nature
- Natural phenomena
- Abstract ideas

→ Should there be more?

Implicit exceptions

→ *Diamond v. Chakrabarty*: Court rejects new exception for living creatures
- Over 5-4 dissent

→ *Bilski v. Kappos*: Court rejects new exception for business methods
- Over 5-4 concurrence / partial dissent
- (Lost majority?)

Implicit exceptions

→ So the big question: What's so special about laws of nature, physical phenomena, and abstract ideas?

Implicit exceptions

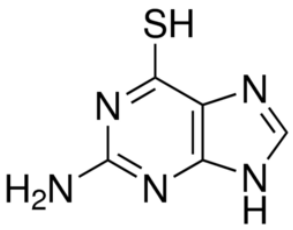
→ So the big question: What's so special about laws of nature, physical phenomena, and abstract ideas?

- Maybe: Not man-made?
- Maybe: Preempts too much work?
- Maybe: Fails cost-benefit analysis?
- (More on this later too)

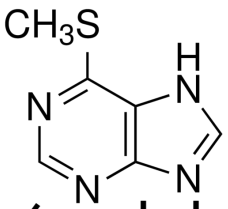
Laws of nature

Mayo v. Prometheus

→ Treating Crohn's disease with 6-thioguanine



6-thioguanine
(oral administration)

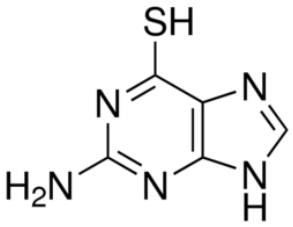


6-methyl-
mercaptopurine

filtered
by kidneys

Mayo v. Prometheus

→ Treating Crohn's disease with 6-thioguanine



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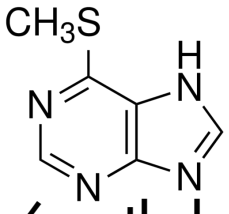

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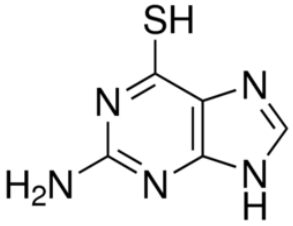
Mayo v. Prometheus

→ Treating Crohn's disease with 6-thioguanine



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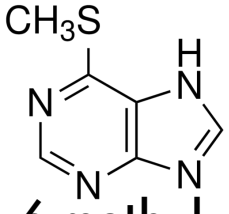

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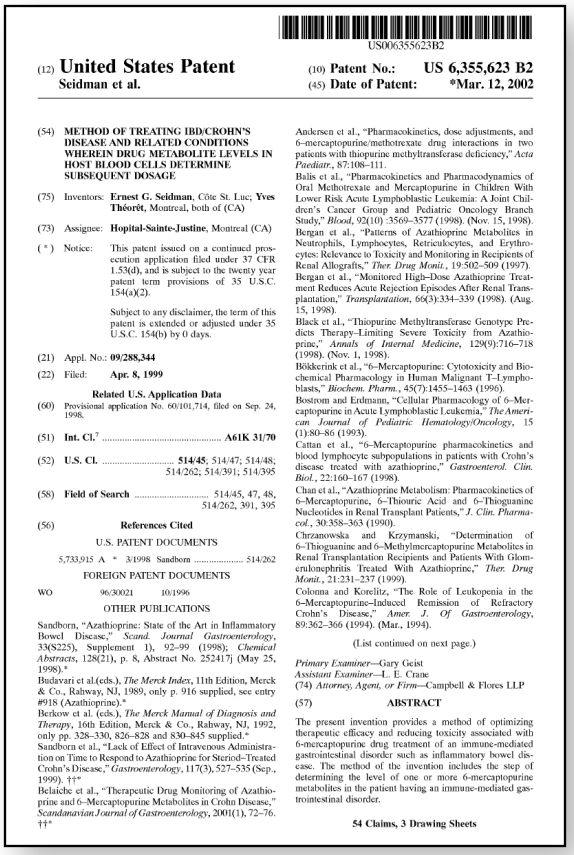

US006355623B2

(12) **United States Patent**
Seidman et al.

(10) **Patent No.: US 6,355,623 B2**
(45) **Date of Patent: *Mar. 12, 2002**

(54) **METHOD OF TREATING IBD/CROHN'S DISEASE AND RELATED CONDITIONS WHEREIN DRUG METABOLITE LEVELS IN HOST BLOOD CELLS DETERMINE SUBSEQUENT DOSAGE**

(75) Inventors: **Ernest G. Seidman**, Côte St. Luc; **Yves Théorêt**, Montreal, both of (CA)

(73) Assignee: **Hopital-Sainte-Justine**, Montreal (CA)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/288,344**

(22) Filed: **Apr. 8, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/101,714, filed on Sep. 24, 1998.

(51) **Int. Cl.**[7] **A61K 31/70**

(52) **U.S. Cl.** **514/45**; 514/47; 514/48; 514/262; 514/391; 514/395

(58) **Field of Search** 514/45, 47, 48, 514/262, 391, 395

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5,733,915 A * 3/1998 Sandborn 514/262

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WO 96/30021 10/1996

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(List continued on next page.)

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(74) *Attorney, Agent, or Firm*—Campbell & Flores LLP

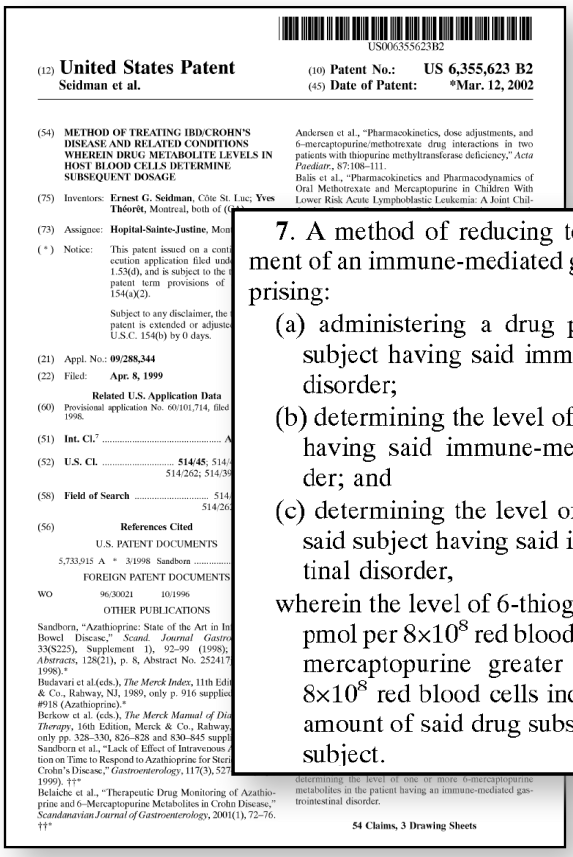
(57) **ABSTRACT**

The present invention provides a method of optimizing therapeutic efficacy and reducing toxicity associated with 6-mercaptopurine drug treatment of an immune-mediated gastrointestinal disorder such as inflammatory bowel disease. The method of the invention includes the step of determining the level of one or more 6-mercaptopurine metabolites in the patient having an immune-mediated gastrointestinal disorder.

54 Claims, 3 Drawing Sheets

U.S. Patent No. 6,355,623

→ "Method of treating IBD/ Crohn's disease and related conditions wherein drug metabolite levels in host blood cells determine subsequent dosage"



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(*) Notice: This patent issued on a cont ecution application filed und 1.53(d), and is subject to the patent term provisions of 154(a)(2).

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(58) **Field of Search** 514 514/26

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7. A method of reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder;

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder; and

(c) determining the level of 6-methyl-mercaptopurine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells or the level of 6-methyl-mercaptopurine greater than about 7000 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

determining the level of one or more 6-mercaptopurine metabolites in the patient having an immune-mediated gastrointestinal disorder.

54 Claims, 3 Drawing Sheets

U.S. Patent No. 6,355,623

→ "Method of IBD/ disease ted ns drug ite levels lood ermine ent dosage"

Mayo v. Prometheus

→ History

- In *Bilski,* the Supreme Court says the "machine or transformation" test is just one clue to patentability
- Federal Circuit continues to rely heavily on that test
- Federal Circuit upholds Prometheus patent: "administering" and "determining" steps are transformative

Mayo v. Prometheus

→ History

- Supreme Court takes case
- Most people expect Court to affirm Federal Circuit
- Instead, the Supreme Court reverses unanimously

Mayo v. Prometheus

→ What's the rule in this case?

- The new test for patentability

Mayo v. Prometheus

→ What's the rule in this case?

- The new test for patentability
- Look at the claim and see if it sets forth a natural law
- If so, look at the claim without the natural law and see if there's an inventive concept
- This is our new two-step framework

Mayo v. Prometheus

→ Step 1: Does the claim set forth a natural law?

Mayo v. Prometheus

→ Step 1: Does the claim set forth a natural law?

- "[T]he relation itself exists in principle apart from any human action" and is "a consequence of … entirely natural processes"

Mayo v. Prometheus

→ Step 2: Do the other elements add an inventive concept?

Mayo v. Prometheus

→ Step 2: Do the other elements add an inventive concept?

- "[A]ssurance that the process is more than a drafting effort designed to monopolize the law of nature itself"
- Additional steps can't "consist of well-understood, routine, conventional activity"
- "[O]rdered combination" can't add more than what is already present

Mayo v. Prometheus

→ Step 2: Do the other elements add an inventive concept?

- Note: this brings novelty out of § 102 and into the § 101 inquiry
- This is a common critique of these cases
- Idea: If the only new thing in your patent is a natural law, it's not patentable

Mayo v. Prometheus

→ *Diehr* (1981) versus *Flook* (1978)

- For a long time, *Diehr* was interpreted as basically overturning *Flook*

584 OCTOBER TERM, 1977

Syllabus 437 U.S.

PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS *v.* FLOOK

CERTIORARI TO THE COURT OF CUSTOMS AND PATENT APPEALS

No. 77–642. Argued April 25, 1978—Decided June 22, 1978

Respondent's method for updating alarm limits during catalytic conversion processes, in which the only novel feature is a mathematical formula, *held* not patentable under § 101 of the Patent Act. The identification of a limited category of useful, though conventional, post-solution applications of such a formula does not make the method eligible for patent protection, since assuming the formula to be within prior art, as it must be, *O'Reilly* v. *Morse*, 15 How. 62, respondent's application contains no patentable invention. The chemical processes involved in catalytic conversion are well known, as are the monitoring of process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for "automatic process monitoring." Pp. 588–596.

559 F. 2d 21, reversed.

STEVENS, J., delivered the opinion of the Court, in which BRENNAN, WHITE, MARSHALL, BLACKMUN, and POWELL, JJ., joined. STEWART, J., filed a dissenting opinion, in which BURGER, C. J., and REHNQUIST, J., joined, *post*, p. 598.

Deputy Solicitor General Wallace argued the cause for petitioner. On the briefs were *Solicitor General McCree, Assistant Attorney General Shenefield, Richard H. Stern, Joseph F. Nakamura,* and *Jere W. Sears.*

D. Dennis Allegretti argued the cause for respondent. With him on the brief were *Charles G. Call, Edward W. Remus,* and *Frank J. Uxa, Jr.**

**John S. Voorhees* and *Kenneth E. Krosin* filed a brief for the Computer Business Equipment Manufacturers Assn. as *amicus curiae* urging reversal.

Briefs of *amici curiae* urging affirmance were filed by *Carol A. Cohen* for Applied Data Research, Inc.; and by *Morton C. Jacobs* and *David Cohen* for the Association of Data Processing Service Organizations.

Briefs of *amici curiae* were filed by *James W. Geriak* for the American

Parker v. Flook (1978)

→ *In re Application of Flook*

584 OCTOBER TERM, 1977

Syllabus 437 U.S.

PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS *v.* FLOOK

CERTIORARI TO THE COURT OF CUSTOMS AND PATENT APPEALS

Claim 1 of the patent describes the method as follows:

"1. 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 B_1, using the following equation:

$$B_1=Bo(1.0-F)+PVL(F)$$

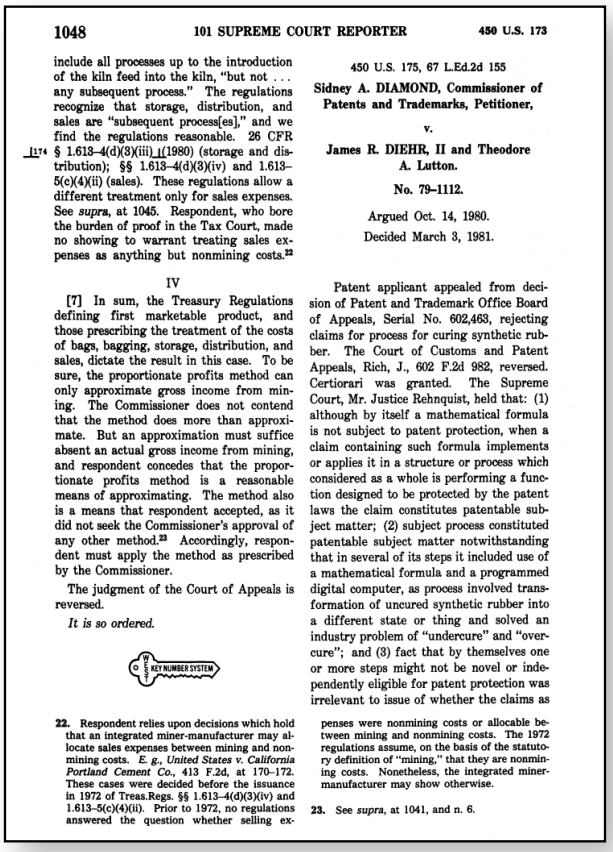
"where F is a predetermined number greater than zero and less than 1.0;

"(3) Determining an updated alarm limit which is defined as B_1+K; and thereafter

"(4) Adjusting said alarm limit to said updated alarm limit value." App. 63A.

Parker v. Flook (1978)

→ *In re Application of Flook*



1048 101 SUPREME COURT REPORTER 450 U.S. 173

include all processes up to the introduction of the kiln feed into the kiln, "but not . . . any subsequent process." The regulations recognize that storage, distribution, and sales are "subsequent process[es]," and we find the regulations reasonable. 26 CFR [1174] § 1.613–4(d)(3)(iii) (1980) (storage and distribution); §§ 1.613–4(d)(3)(iv) and 1.613–5(c)(4)(ii) (sales). These regulations allow a different treatment only for sales expenses. See *supra*, at 1045. Respondent, who bore the burden of proof in the Tax Court, made no showing to warrant treating sales expenses as anything but nonmining costs.[22]

IV

[7] In sum, the Treasury Regulations defining first marketable product, and those prescribing the treatment of the costs of bags, bagging, storage, distribution, and sales, dictate the result in this case. To be sure, the proportionate profits method can only approximate gross income from mining. The Commissioner does not contend that the method does more than approximate. But an approximation must suffice absent an actual gross income from mining, and respondent concedes that the proportionate profits method is a reasonable means of approximating. The method also is a means that respondent accepted, as it did not seek the Commissioner's approval of any other method.[23] Accordingly, respondent must apply the method as prescribed by the Commissioner.

The judgment of the Court of Appeals is reversed.

It is so ordered.

KEY NUMBER SYSTEM

22. Respondent relies upon decisions which hold that an integrated miner-manufacturer may allocate sales expenses between mining and nonmining costs. *E. g., United States v. California Portland Cement Co.*, 413 F.2d, at 170–172. These cases were decided before the issuance in 1972 of Treas.Regs. §§ 1.613–4(d)(3)(iv) and 1.613–5(c)(4)(ii). Prior to 1972, no regulations answered the question whether selling expenses were nonmining costs or allocable between mining and nonmining costs. The 1972 regulations assume, on the basis of the statutory definition of "mining," that they are nonmining costs. Nonetheless, the integrated miner-manufacturer may show otherwise.

23. See *supra*, at 1041, and n. 6.

450 U.S. 175, 67 L.Ed.2d 155

Sidney A. DIAMOND, Commissioner of Patents and Trademarks, Petitioner,

v.

James R. DIEHR, II and Theodore A. Lutton.

No. 79–1112.

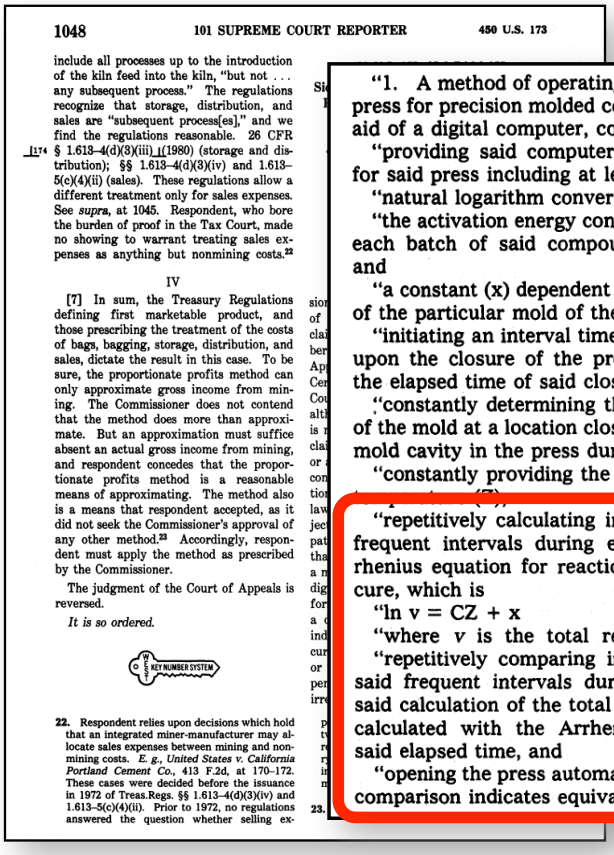
Argued Oct. 14, 1980.

Decided March 3, 1981.

Patent applicant appealed from decision of Patent and Trademark Office Board of Appeals, Serial No. 602,463, rejecting claims for process for curing synthetic rubber. The Court of Customs and Patent Appeals, Rich, J., 602 F.2d 982, reversed. Certiorari was granted. The Supreme Court, Mr. Justice Rehnquist, held that: (1) although by itself a mathematical formula is not subject to patent protection, when a claim containing such formula implements or applies it in a structure or process which considered as a whole is performing a function designed to be protected by the patent laws the claim constitutes patentable subject matter; (2) subject process constituted patentable subject matter notwithstanding that in several of its steps it included use of a mathematical formula and a programmed digital computer, as process involved transformation of uncured synthetic rubber into a different state or thing and solved an industry problem of "undercure" and "overcure"; and (3) fact that by themselves one or more steps might not be novel or independently eligible for patent protection was irrelevant to issue of whether the claims as

Diamond v. Diehr (1981)

→ *In re Application of Diehr*



1048 101 SUPREME COURT REPORTER 450 U.S. 173

include all processes up to the introduction of the kiln feed into the kiln, "but not . . . any subsequent process." The regulations recognize that storage, distribution, and sales are "subsequent process[es]," and we find the regulations reasonable. 26 CFR [1174] § 1.613–4(d)(3)(iii) (1980) (storage and distribution); §§ 1.613–4(d)(3)(iv) and 1.613–5(c)(4)(ii) (sales). These regulations allow a different treatment only for sales expenses. See *supra*, at 1045. Respondent, who bore the burden of proof in the Tax Court, made no showing to warrant treating sales expenses as anything but nonmining costs.[22]

IV

[7] In sum, the Treasury Regulations defining first marketable product, and those prescribing the treatment of the costs of bags, bagging, storage, distribution, and sales, dictate the result in this case. To be sure, the proportionate profits method can only approximate gross income from mining. The Commissioner does not contend that the method does more than approximate. But an approximation must suffice absent an actual gross income from mining, and respondent concedes that the proportionate profits method is a reasonable means of approximating. The method also is a means that respondent accepted, as it did not seek the Commissioner's approval of any other method.[23] Accordingly, respondent must apply the method as prescribed by the Commissioner.

The judgment of the Court of Appeals is reversed.

It is so ordered.

KEY NUMBER SYSTEM

22. Respondent relies upon decisions which hold that an integrated miner-manufacturer may allocate sales expenses between mining and nonmining costs. *E. g., United States v. California Portland Cement Co.*, 413 F.2d, at 170–172. These cases were decided before the issuance in 1972 of Treas.Regs. §§ 1.613–4(d)(3)(iv) and 1.613–5(c)(4)(ii). Prior to 1972, no regulations answered the question whether selling ex-

"1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

"providing said computer with a data base for said press including at least,

"natural logarithm conversion data (ln),

"the activation energy constant (C) unique to each batch of said compound being molded, and

"a constant (x) dependent upon the geometry of the particular mold of the press,

"initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

"constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

"constantly providing the computer with the

"repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is

"$\ln v = CZ + x$

"where v is the total required cure time,

"repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

"opening the press automatically when a said comparison indicates equivalence.

Diamond v. r (1981)

re
pplication
Diehr

Mayo v. Prometheus

→ *Diehr* (1981) versus *Flook* (1978)

- So what's the difference?

Mayo v. Prometheus

→ *Diehr* (1981) versus *Flook* (1978)

- So what's the difference?
- *Diehr*: "the additional steps of the process integrated the equation into the process as a whole" and were "an inventive application of the formula"
- *Flook*: "doing nothing other than" providing a new formula, with other, conventional steps

Mayo v. Prometheus

→ What policy concerns drive the Court?

Mayo v. Prometheus

→ What policy concerns drive the Court?

- Laws of nature, natural phenomena, abstract ideas: all have preemptive effect
- Are the basic building blocks of scientific inquiry
- Are too broad, and would block too much other work

Mayo v. Prometheus

→ Back to the patent bargain

- Inventor contributes invention to society
- Society gives limited monopoly
- But here the monopoly is, the Court thinks, too great a cost

Mayo v. Prometheus

→ Is this argument persuasive?

Mayo v. Prometheus

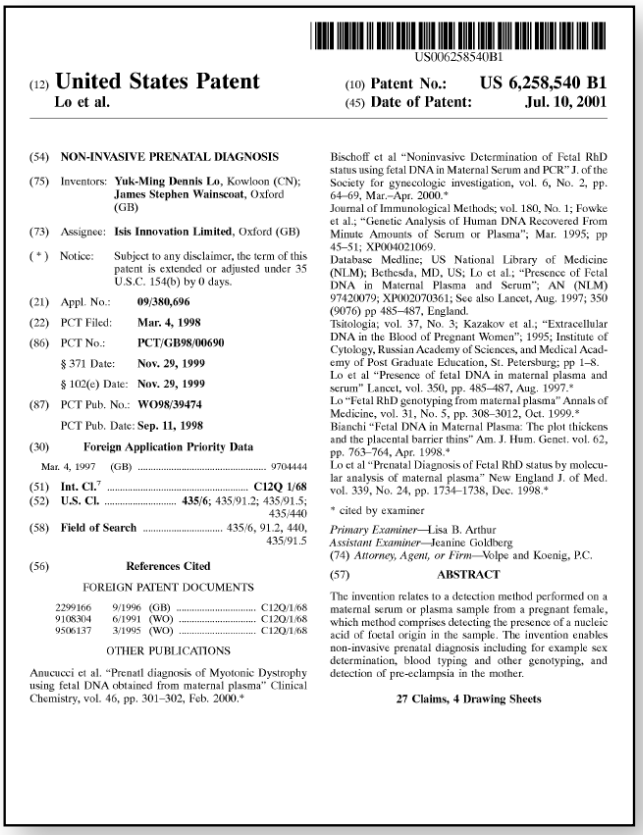
→ Is this argument persuasive?

- Scientific principles are really valuable – maybe we want to encourage people to discover them
- And the monopoly is limited
- And, this is a narrow law!
- But maybe it's impossible to avoid a scientific law once you know it exists

Ariosa v. Sequenom

→ The Federal Circuit's response to *Mayo v. Prometheus*

- Discovery: cell-free fetal DNA (cffDNA) in maternal plasma and serum
- Claims: methods for detecting and amplifying cffDNA and using it to diagnose fetal characteristics



US006258540B1

(12) **United States Patent**
Lo et al.

(10) **Patent No.: US 6,258,540 B1**
(45) **Date of Patent: Jul. 10, 2001**

(54) **NON-INVASIVE PRENATAL DIAGNOSIS**

(75) Inventors: **Yuk-Ming Dennis Lo**, Kowloon (CN); **James Stephen Wainscoat**, Oxford (GB)

(73) Assignee: **Isis Innovation Limited**, Oxford (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/380,696**

(22) PCT Filed: **Mar. 4, 1998**

(86) PCT No.: **PCT/GB98/00690**

§ 371 Date: **Nov. 29, 1999**

§ 102(e) Date: **Nov. 29, 1999**

(87) PCT Pub. No.: **WO98/39474**

PCT Pub. Date: **Sep. 11, 1998**

(30) **Foreign Application Priority Data**

Mar. 4, 1997 (GB) 9704444

(51) **Int. Cl.**[7] **C12Q 1/68**
(52) **U.S. Cl.** **435/6**; 435/91.2; 435/91.5; 435/440
(58) **Field of Search** 435/6, 91.2, 440, 435/91.5

(56) **References Cited**

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2299166	9/1996	(GB)	C12Q/1/68
9108304	6/1991	(WO)	C12Q/1/68
9506137	3/1995	(WO)	C12Q/1/68

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Primary Examiner—Lisa B. Arthur
Assistant Examiner—Jeanine Goldberg
(74) *Attorney, Agent, or Firm*—Volpe and Koenig, P.C.

(57) **ABSTRACT**

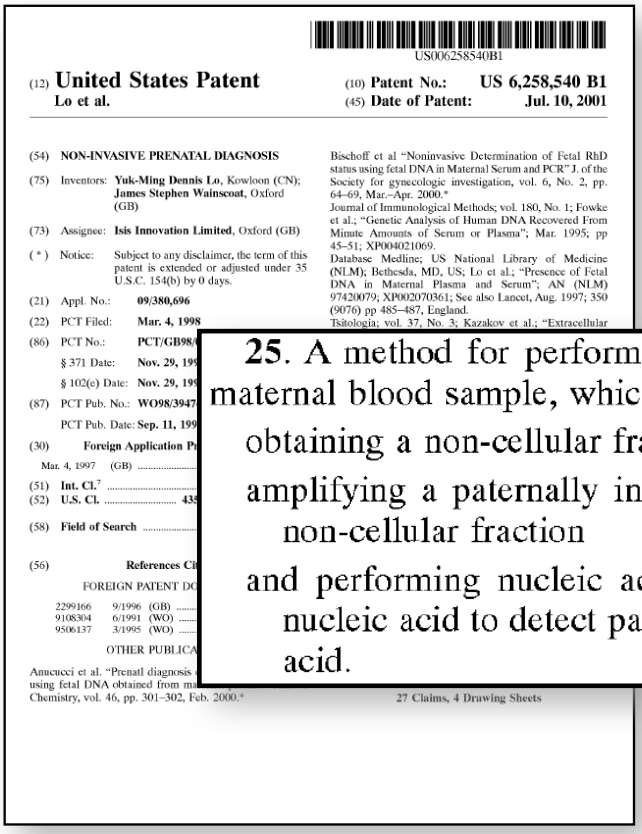
The invention relates to a detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample. The invention enables non-invasive prenatal diagnosis including for example sex determination, blood typing and other genotyping, and detection of pre-eclampsia in the mother.

27 Claims, 4 Drawing Sheets

U.S. Patent No. 6,258,540

→ "Non-invasive prenatal diagnostics"

→ Issued July 10, 2001



US006258540B1

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§ 371 Date: **Nov. 29, 19**

§ 102(e) Date: **Nov. 29, 19**

(87) PCT Pub. No.: **WO98/3947**

PCT Pub. Date: **Sep. 11, 19**

(30) **Foreign Application P**

Mar. 4, 1997 (GB) .....

(51) **Int. Cl.**[7] .....
(52) **U.S. Cl.** **43**
(58) **Field of Search** .....

(56) **References Ci**

FOREIGN PATENT DO

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9108304	6/1991	(WO)	
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using fetal DNA obtained from ma
Chemistry, vol. 46, pp. 301–302, Feb. 2000.*

27 Claims, 4 Drawing Sheets

U.S. Patent No. 6,258,540

→ "Non-invasive prenatal diagnostics"

25. A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises

obtaining a non-cellular fraction of the blood sample

amplifying a paternally inherited nucleic acid from the non-cellular fraction

and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

Ariosa v. Sequenom

→ Step 1: Does the claim set forth a natural law?

Ariosa v. Sequenom

→ Step 1: Does the claim set forth a natural law?

- Kind of?
- Maybe "cffDNA exists in the noncellular fraction of maternal blood"?

Ariosa v. Sequenom

→ Step 2: Do the other elements add an inventive concept?

- Obtain non-cellular fraction of maternal blood
- Amplify DNA
- Run DNA analysis

Ariosa v. Sequenom

→ So what counts as an inventive element?

Ariosa v. Sequenom

→ So what counts as an inventive element?

- Court: these additional elements must themselves be new and useful – basically, independently patentable
- Here, "[t]he only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum"

Ariosa v. Sequenom

→ Concurrence: the Supreme Court screwed up

→ *En banc* denial: the Supreme Court screwed up

- "[I]t is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court." –Judge Lourie

→ Sequenom petitioned for cert., which was denied

Next time

→ More patentable subject matter