

Patent Law

Prof. Roger Ford

Wednesday, March 30, 2016

Class 17 – Patentable subject matter II:
laws of nature and abstract ideas

Recap

Recap

- Overview of patentable subject matter
- Products of nature

Today's agenda

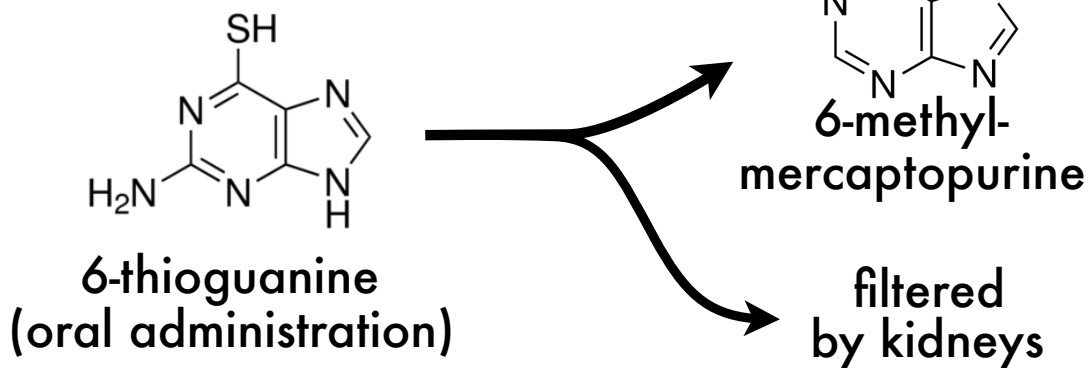
Today's agenda

- Laws of nature
- Abstract ideas
- A unified framework

Laws of nature

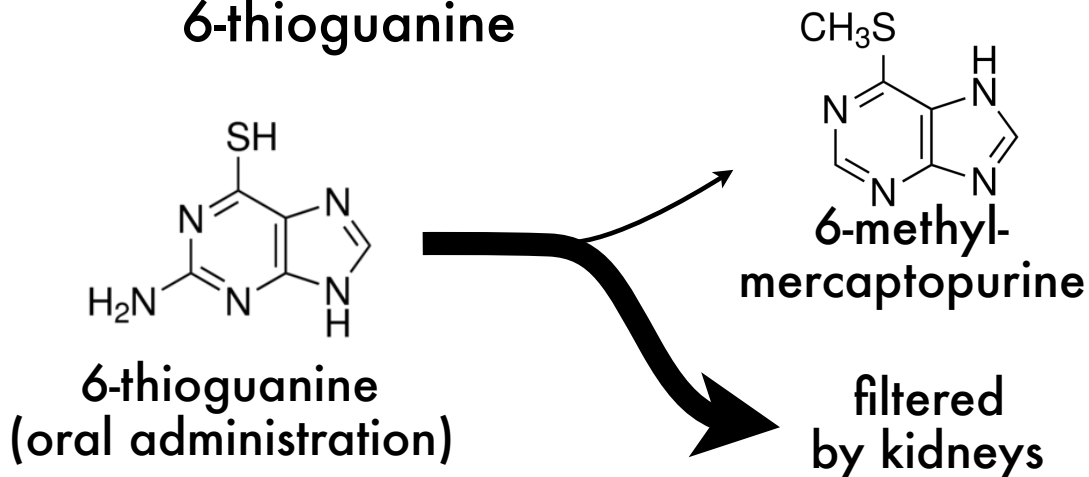
Mayo v. Prometheus

→ Treating Crohn's disease with
6-thioguanine



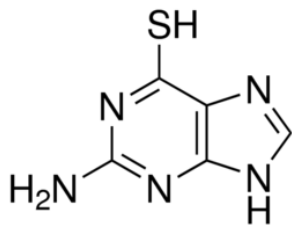
Mayo v. Prometheus

→ Treating Crohn's disease with
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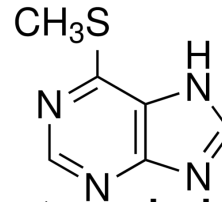
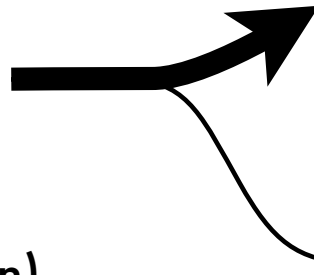


Mayo v. Prometheus

→ Treating Crohn's disease with
6-thioguanine



6-thioguanine
(oral administration)



6-methyl-
mercaptapurine

filtered
by kidneys



US06355623B2

(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 Théoret, Montreal, both of (CA)

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

(*) **Notice:** This patent issued on a continued prosecution application filed under 37 CFR 1.536(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; 514.595

(58) **Field of Search** 514.45, 47, 48, 514.262, 391, 395

(56) **References Cited**

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Sandborn et al., "Lack of Effect of Intravenous Administration on Time to Respond to Azathioprine for Steroid-Treated Crohn's Disease," *Gastroenterology*, 117(3), 527-535 (Sep., 1999).††

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Black et al., "Thiopurine Methyltransferase Genotype Predicts Therapy-Limiting Severe Toxicity from Azathioprine," *Annals of Internal Medicine*, 129(9):716-718 (1998). (Nov. 1, 1998).

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Cattan et al., "6-Mercaptopurine pharmacokinetics and blood lymphocyte subpopulations in patients with Crohn's disease treated with azathioprine," *Gastroenterol. Clin. Biol.*, 22:160-167 (1998).

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Coleman and Konecny, "The Role of Leukopenia in the 6-Mercaptopurine-Induced Remission of Refractory Crohn's Disease," *Amer. J. Of Gastroenterology*, 89:362-366 (1994). (Mar., 1994).

(List continued on next page.)

Primary Examiner—Gary Geist

Assistant Examiner—L. E. Crane

(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.

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"


US06355623B2

(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 Théoret, Montreal, both of (C) 1999

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

(*) Notice: This patent issued on a continuation application filed under 35 U.S.C. 111(a)(2) and is subject to the patent term provisions of 35 U.S.C. 154(a)(2). Subject to any disclaimer, the 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 1998.

(51) Int. Cl. 7 A61P1/00

(52) U.S. Cl. 514:45; 514:46; 514:262; 514:338

(58) Field of Search 514:45; 514:262

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5,733,915 A * 3/1998 Sandborn

FOREIGN PATENT DOCUMENTS

WO 96/0021 10/1996

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Badavari et al (eds.), *The Merck Index*, 11th Edition & Co., Rahway, NJ, 1989, only p. 916 supplies #918 (Azathioprine)*

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Sandborn et al., "Lack of Effect of Intravenous, Single-Dose Azathioprine on Time to Respond to Azathioprine for Steroid-Resistant Crohn's Disease," *Gastroenterology*, 117(3), 527-531 (1999). ††

Belackbe et al., "Therapeutic Drug Monitoring of Azathioprine and 6-Mercaptopurine Metabolites in Crohn Disease," *Scandinavian Journal of Gastroenterology*, 200(1), 72-76. ††

54 Claims, 3 Drawing Sheets

U.S. Patent

No. 6,355,623

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.

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” (page 4)

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” (page 4)
 - Additional steps can’t “consist of well-understood, routine, conventional activity” (page 6)
 - “[O]rdered combination” can’t add more than what is already present (page 6)

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 *amicus 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 *amicus curiae* were filed by *James W. Geriak* for the American

Parker v. Flook (1978)

→ *In re Application of Flook*

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

CERTIORARI TO THE COURT OF CUSTOMS AND PATENT APPEALS

No. 77-642. Argued April 27, 1977.

Respondent's method for updating alarm limit values in which the formula, held not patentable, identifies a limited class of solution applications of such formulae for patent protection, similar to that in *O'Reilly v. Morse*, art, as it must be, *O'Reilly v. Morse* contains no patentable subject matter. In *Grain Processing v. Procter & Gamble*, 559 F.2d 21, reversed.

STEVENS, J., delivered the opinion, with MR. JUSTICE WHITE, MR. JUSTICE MARSHALL, MR. JUSTICE BLACKMUN, MR. JUSTICE BRENNAN, and MR. JUSTICE STEVENS joined, *post*, p. 598.

Deputy Solicitor General. On the briefs were Solicitor General Shoji, Deputy Solicitor General Nakamura, and Jere W. ...

D. Dennis Allegretti argued for him on the brief were Charles Frank J. Uxa, Jr.*

*John S. Voorhees and Kenneth Business Equipment Manufacturers. Briefs of amici curiae were filed for Applied Data Research, Inc. by Cohen for the Association of ... Briefs of amici curiae were filed by James W. Genak for the American ...

Parker v. Flook (1978)

Application

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 B₁, 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 B₁ + K; and thereafter

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

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 1.1613-4(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.



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-

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. 602,468, 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

penses 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.

Diamond v. Diehr (1981)

→ *In re*
Application
of Diehr

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 1.1613-4(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.

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“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. Diehr (1981)

re
application
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" (page 7)
- *Flook*: "doing nothing other than" providing a new formula, with other, conventional steps (page 7)

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

Mayo v. Prometheus

→ **What about the claim in *Rosaire*?**

The method of detecting subterranean deposits from which leakage of emanations occur which comprises taking soil samples from selected points in a predetermined area,
confining the respective soil samples from air contamination,
removing said samples from confinement, and
analyzing the samples with respect to gases contained in the samples directly related to said deposits.

Mayo v. Prometheus

→ **What about the claim in *Rosaire*?**

- **Step 1: Does it implicate a natural law?**

Mayo v. Prometheus

→ What about the claim in *Rosaire*?

The method of detecting subterranean deposits from which leakage of emanations occur which comprises taking soil samples from selected points in a predetermined area, confining the respective soil samples from air contamination, removing said samples from confinement, and analyzing the samples with respect to gases contained in the samples directly related to said deposits.

Mayo v. Prometheus

→ What about the claim in *Rosaire*?

- Step 1: Does it implicate a natural law?
- Natural law: There is a correlation between soil that contains hydrocarbons and soil from areas with oil reserves

Mayo v. Prometheus

- What about the claim in *Rosaire*?
- Step 1: Does it implicate a natural law?
 - Step 2: If so, do the other elements add an inventive concept?

Mayo v. Prometheus

- What about the claim in *Rosaire*?


The method of detecting subterranean deposits from which leakage of emanations occur which comprises taking soil samples from selected points in a predetermined area, confining the respective soil samples from air contamination, removing said samples from confinement, and analyzing the samples with respect to gases contained in the samples directly related to said deposits.

Mayo v. Prometheus

- What about the claim in *Rosaire*?
 - Step 1: Does it implicate a natural law?
 - Step 2: If so, do the other elements add an inventive concept?
 - They add sampling, containing, removing, analyzing steps – standard procedure today; probably standard in 1940?

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.: 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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 9108304 6/1991 (WO) C12Q/1.68
 9506137 3/1995 (WO) C12Q/1.68
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 Database Medline; US National Library of Medicine (NLM); Bethesda, MD, US; Lo et al.; "Presence of Fetal DNA in Maternal Plasma and Serum"; AN (NLM) 97420079; XP002070361; See also *Lancet*, Aug. 1997; 350 (9076) pp. 485-487, England.
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 Lo "Fetal RhD genotyping from maternal plasma" *Annals of Medicine*, vol. 31, No. 5, pp. 308-3012, Oct. 1999.*
 Bianchi "Fetal DNA in Maternal Plasma: The plot thickens and the placental barrier thins" *Am. J. Hum. Genet.* vol. 62, pp. 763-764, Apr. 1998.*
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 * cited by examiner
 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

(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.: 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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 9108304 6/1991 (WO) C12Q/1.68
 9506137 3/1995 (WO) C12Q/1.68
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 Bischoff et al. "Noninvasive Determination of Fetal RhD status using fetal DNA in Maternal Serum and PCR" *J. of the Society for gynecologic investigation*, vol. 6, No. 2, pp. 64-69, Mar-Apr. 2000.*
 Journal of Immunological Methods; vol. 180, No. 1; Fowke et al.; "Genetic Analysis of Human DNA Recovered From Minute Amounts of Serum or Plasma"; Mar. 1995; pp. 45-51; XP004021069.
 Database Medline; US National Library of Medicine (NLM); Bethesda, MD, US; Lo et al.; "Presence of Fetal DNA in Maternal Plasma and Serum"; AN (NLM) 97420079; XP002070361; See also *Lancet*, Aug. 1997; 350 (9076) pp. 485-487, England.
Tsitologia, vol. 37, No. 3; Kazakov et al.; "Extracellular DNA in the Blood of Pregnant Women"; 1995; Institute of Cytology, Russian Academy of Sciences, and Medical Academy of Post Graduate Education, St. Petersburg; pp. 1-8.
 Lo et al. "Presence of fetal DNA in maternal plasma and serum" *Lancet*, vol. 350, pp. 485-487, Aug. 1997.*
 Lo "Fetal RhD genotyping from maternal plasma" *Annals of Medicine*, vol. 31, No. 5, pp. 308-3012, Oct. 1999.*
 Bianchi "Fetal DNA in Maternal Plasma: The plot thickens and the placental barrier thins" *Am. J. Hum. Genet.* vol. 62, pp. 763-764, Apr. 1998.*
 Lo et al. "Prenatal Diagnosis of Fetal RhD status by molecular analysis of maternal plasma" *New England J. of Med.* vol. 339, No. 24, pp. 1734-1738, Dec. 1998.*
 * cited by examiner
 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"

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” (supp. 5)

Ariosa v. Sequenom

- Judge Linn’s concurrence:
- This is different from *Mayo*, and the Court should have been more limited there
 - “[D]octors were already performing in combination all of the claimed steps” in *Mayo*
 - Here, “no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers”
 - So what? What’s the difference?

Ariosa v. Sequenom

- The concurrence: the Supreme Court screwed up
- The *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. last week – we’ll see!

Abstract ideas

United States Patent [19] Patent Number: 5,970,479
Shepherd [45] Date of Patent: Oct. 19, 1999



[54] METHODS AND APPARATUS RELATING TO THE FORMULATION AND TRADING OF RISK MANAGEMENT CONTRACTS
[75] Inventor: Ian K. Shepherd, Toorak, Australia
[73] Assignees: Swycho Infrastructure Services Pty. Ltd., Melbourne, Australia; Swycho Support Services Pty. Ltd., Sydney, Australia
[21] Appl. No.: 08/076,136
[22] Filed: May 28, 1993
[30] Foreign Application Priority Data
May 29, 1992 [AU] Australia PL 2677
Jun. 30, 1992 [AU] Australia PL 3216
[51] Int. Cl.⁵ G06F 17/60
[52] U.S. Cl. 705/37; 705/4
[58] Field of Search 364/408; 705/4, 705/37

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(List continued on next page.)
Primary Examiner—Gail O. Hayes
Assistant Examiner—Barton L. Baitbridge
Attorney, Agent, or Firm—Stein, Kessler, Goldstein & Fox P.L.L.C.

ABSTRACT
[57] Methods and apparatus which deal with the management of risk relating to specified, yet unknown, future events are disclosed.

"Sponsor" stakeholders specify a particular product relating to an event or phenomenon for which there is a range of possible future outcomes.

"Ordering" stakeholders then offer contracts relating to the predetermined phenomenon and corresponding range of outcomes. The offered contracts specify an entitlement or (pay-off) at the future time of maturity for each outcome, and a consideration (or premium) payable, in exchange, to a "counter-party" stakeholder.

Independently of the offered contracts, the "counter-party" stakeholders input data as to their view of the likelihood of occurrence of each outcome in the predetermined range into the future, or specifically at the predetermined date of maturity.

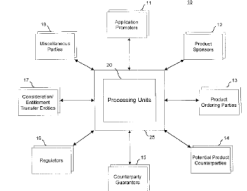
Each offered contract is priced by calculating counter-party premiums from the registered data, and a match attempted by a comparison of the offered premium with the calculated premiums.

Matched contracts can be further traded until maturity, and at-maturity processing handles the exchange of entitlement as between the matched parties to the contract.

39 Claims, 101 Drawing Sheets

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WO 90/11571 10/1990 WIPO
91/14231 9/1991 WIPO
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U.S. Patent No. 5,970,479

→ "Method and apparatus relating to the formulation and trading of risk management contracts"

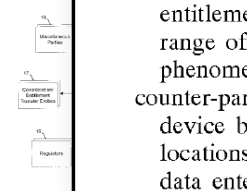
United States Patent [19] Patent Number: 5,970,479
Shepherd [45] Date of Patent: Oct. 19, 1999



[54] METHODS AND APPARATUS RELATING TO THE FORMULATION AND TRADING OF RISK MANAGEMENT CONTRACTS
[75] Inventor: Ian K. Shepherd, Toorak, Australia
[73] Assignees: Swycho Infrastructure Services Pty. Ltd., Melbourne, Australia; Swycho Support Services Pty. Ltd., Sydney, Australia
[21] Appl. No.: 08/076,136
[22] Filed: May 28, 1993
[30] Foreign Application Priority Data
May 29, 1992 [AU] Australia PL 2677
Jun. 30, 1992 [AU] Australia PL 3216
[51] Int. Cl.⁵ G06F 17/60
[52] U.S. Cl. 705/37; 705/4
[58] Field of Search 364/408; 705/4, 705/37

16. A system to enable the formulation of customized multi-party risk management contracts, the system comprising:
a plurality of main data processing devices interconnected by at least one data communications link, each said data processing device running an operating system and applications software;
one or more data storage devices to which each data processing device has access;
a plurality of data input/output channels providing connection to a plurality of stakeholder locations, each said location having data processing means, and the system being programmed for:
regulating input of data, specifying a risk phenomenon, a range of outcomes for the phenomenon, and a time of maturity;
stakeholders inputting to a said data storage device by ones of the stakeholder data processing locations contract data for an offered contract, specifying an entitlement due at maturity for each outcome in the range of outcomes for a one of the predetermined phenomena, and an amount payable to a seller;
counter-party stakeholders inputting to a data storage device by ones of the stakeholder data processing locations registering data, independent of contract data entered by stakeholders, as to a likelihood of occurrence of each outcome in the range of outcomes

References Cited
U.S. PATENT DOCUMENTS
3,573,747 4/1971 Adams et al.
4,346,442 8/1982 Masmano
4,376,978 3/1983 Masmano
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WO 93/15467 8/1993 WIPO
WO 94/20912 9/1994 WIPO



U.S. Patent No. 5,970,479

Method and apparatus relating to the formulation and trading of risk management contracts"

Alice Corp. v. CLS Bank

→ What's the rule in this case?

Alice Corp. v. CLS Bank

→ What's the rule in this case?

- Takes the *Myriad* framework (pp 4-5)
- Look at the claim and see if it sets forth ~~a natural law~~ an abstract idea
- If so, look at the claim without the ~~natural law~~ abstract idea and see if there's an inventive concept
- This is our ~~new~~ now-unified two-step framework

Alice Corp. v. CLS Bank

→ How do we tell if something is an abstract idea?

Alice Corp. v. CLS Bank


→ How do we tell if something is an abstract idea?

- “fundamental economic practice long prevalent in our system of commerce” (page 5)
- “building block of the modern economy” (page 6)
- not a “preexisting, fundamental truth that exists in principle apart from any human action” (page 6)

Alice Corp. v. CLS Bank

→ How do we tell if something is an abstract idea?

- But the reality is, it's hard to know – courts will be sorting this out for a while



US007346545B2

(12) **United States Patent**
Jones

(10) **Patent No.:** US 7,346,545 B2
(45) **Date of Patent:** Mar. 18, 2008

(54) **METHOD AND SYSTEM FOR PAYMENT OF INTELLECTUAL PROPERTY ROYALTIES BY INTERPOSED SPONSOR ON BEHALF OF CONSUMER OVER A TELECOMMUNICATIONS NETWORK**

(75) Inventor: **Dana Howard Jones**, Rancho Palos Verdes, CA (US)

(73) Assignee: **Ultramercial, Inc.**, Palo Verdes, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 624 days.

(21) Appl. No.: **09/867,181**

(22) Filed: **May 29, 2001**

(65) **Prior Publication Data**
US 2001/0047338 A1 Nov. 29, 2001

Related U.S. Application Data

(60) Provisional application No. 60/207,941, filed on May 27, 2000.

(51) **Int. Cl.**
G06Q 30/00 (2006.01)

(52) **U.S. Cl.** 705/26; 705/27

(58) **Field of Classification Search** 705/26-27
See application file for complete search history.

(56) **References Cited**
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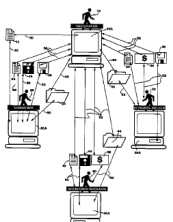
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Alexander, Steve, "FREE... usually carry a cost," *startribune.com*, Jan. 31, 2000. Proquest #98774859, 6 pgs.*

Primary Examiner—Robert M. Poad
(74) *Attorney, Agent, or Firm*—Morrison & Foerster LLP

(57) **ABSTRACT**

The present invention is directed to a method and system for distributing or obtaining products covered by intellectual property over a telecommunications network, whereby a consumer may, rather paying for the products, choose to receive such products after viewing and/or interacting with an interposed sponsor's or advertiser's message, wherein the interposed sponsor or advertiser may pay the owner or assignee of the underlying intellectual property associated with the product through an intermediary such as a facilitator.

16 Claims, 3 Drawing Sheets



U.S. Patent No. 7,346,545

→ “Method and system for payment of intellectual property royalties by interposed sponsor on behalf of consumer over a telecommunications network”

→ Federal Circuit:
Ultramercial v. Hulu



(12) United States Patent
Jones

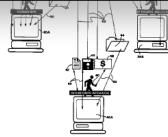
(10) Patent No.: US 7,346,545 B2
(45) Date of Patent: Mar. 18, 2008

U.S. Patent No. 7,346,545

8. A method for distribution of products over the Internet via a facilitator, said method comprising the steps of:

- a first step of providing a product list on an Internet website, wherein at least some of the products are media products covered by intellectual property rights protection and are available for purchase, said media products being provided by content providers, wherein each said media product is comprised of at least one of text data, sound data, and video data;
- a second step of selecting a sponsor message to be associated with at least one of said media products, said sponsor message being selected from a plurality of sponsor messages, said second step including accessing an activity log to verify that the total number of times which the sponsor message has been previously presented is less than the number of transaction cycles contracted by the sponsor of the sponsor message;
- a third step of restricting general public access to said media products;
- a fourth step of offering to a consumer access to a requested media product available for purchase without charge to the consumer on the precondition that the

- consumer views the sponsor message;
- a fifth step of receiving from the consumer a request to view a sponsor message in response to said step of offering;
- a sixth step of facilitating the display of a sponsor message to the consumer in response to receiving the request;
- a seventh step of, if the sponsor message is not an interactive message, allowing said consumer access to said requested media product after said step of facilitating the display of said sponsor message;
- an eighth step of, if the sponsor message is an interactive message, presenting at least one query to the consumer and allowing said consumer access to said media product after receiving a response to said at least one query;
- a ninth step of recording the transaction event to the activity log, said ninth step including updating the total number of times the sponsor message has been presented; and
- a tenth step of receiving payment from the sponsor of the sponsor message displayed.



Ultramercial v. Hulu

“This ordered combination of steps recites an abstraction—an idea, having no particular concrete or tangible form. The process of **receiving copyrighted media, selecting an ad, offering the media in exchange for watching the selected ad, displaying the ad, allowing the consumer access to the media, and receiving payment from the sponsor of the ad** all describe **an abstract idea, devoid of a concrete or tangible application**. Although certain additional limitations, such as consulting an activity log, add a degree of particularity, the concept embodied by the majority of the limitations describes only **the abstract idea of showing an advertisement before delivering free content.**”

Ultramercial v. Hulu, No. 2010-1544 (Fed. Cir. Nov. 14, 2014)



US007818399B1

(12) **United States Patent**
Ross, Jr. et al. (10) **Patent No.:** US 7,818,399 B1
(45) **Date of Patent:** Oct. 19, 2010

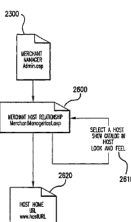
(54) **METHODS OF EXPANDING COMMERCIAL OPPORTUNITIES FOR INTERNET WEBSITES THROUGH COORDINATED OFFSITE MARKETING** 5,515,270 A 5/1996 Weibandt 705/14
5,537,314 A 7/1996 Kanter 705/14
(Continued)

(75) **Inventors:** D. Delano Ross, Jr., Alpharetta, GA (US); Daniel D. Ross, Dunwoody, GA (US); Joseph R. Michaels, Marietta, GA (US); William R. May, Atlanta, GA (US); Richard A. Anderson, Powder Springs, GA (US)
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(73) **Assignee:** **DDR Holdings, LLC**, Dunwoody, GA (US)
(Continued)
Primary Examiner—Patrice L. Winder
(74) *Attorney, Agent, or Firm*—Louis J. Hoffman

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1007 days.
(57) **ABSTRACT**

(21) **Appl. No.:** 11/743,464
(22) **Filed:** Jan. 30, 2006
Related U.S. Application Data
(63) Continuation of application No. 10/461,997, filed on Jan. 11, 2003, now Pat. No. 6,995,572, which is a continuation of application No. 09/358,268, filed on Sep. 17, 1999, now Pat. No. 6,629,135.
(60) Provisional application No. 60/100,697, filed on Sep. 17, 1998.
(51) **Int. Cl. Class.:** G06F 15/16 (2006.01)
(52) **U.S. Cl.:** 709/218; 709/215
(58) **Field of Classification Search:** None
See application file for complete search history.
(56) **References Cited**
U.S. PATENT DOCUMENTS
5,319,542 A 6/1994 King, Jr. et al. 705/27
26 Claims, 24 Drawing Sheets



U.S. Patent No. 7,818,399

→ “Methods of expanding commercial opportunities for internet websites through coordinated offsite marketing”
→ **Federal Circuit: DDR Holdings v. Hotels.com**



US007818399B1

(12) **United States Patent**
Ross, Jr. et al. (10) **Patent No.:** US 7,818,399 B1
(45) **Date of Patent:** Oct. 19, 2010

(54) **METHODS OF EXPANDING COMMERCIAL OPPORTUNITIES FOR INTERNET WEBSITES THROUGH COORDINATED OFFSITE MARKETING** 5,515,270 A 5/1996 Weibandt 705/14
5,537,314 A 7/1996 Kanter 705/14
(Continued)

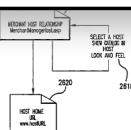
(75) **Inventors:** D. Delano Ross, Jr., Alpharetta, GA (US); Daniel D. Ross, Dunwoody, GA (US)
FOREIGN PATENT DOCUMENTS
WO WO 98/20434 A2 * 5/1998

19. A system useful in an outsource provider serving web pages offering commercial opportunities, the system comprising:

- (a) a computer store containing data, for each of a plurality of first web pages, defining a plurality of visually perceptible elements, which visually perceptible elements correspond to the plurality of first web pages;
 - (i) wherein each of the first web pages belongs to one of a plurality of web page owners;
 - (ii) wherein each of the first web pages displays at least one active link associated with a commerce object associated with a buying opportunity of a selected one of a plurality of merchants; and
 - (iii) wherein the selected merchant, the outsource provider, and the owner of the first web page displaying the associated link are each third parties with respect to one other;

U.S. Patent No. 7,818,399

- (b) a computer server at the outsource provider, which computer server is coupled to the computer store and programmed to:
 - (i) receive from the web browser of a computer user a signal indicating activation of one of the links displayed by one of the first web pages;
 - (ii) automatically identify as the source page the one of the first web pages on which the link has been activated;
 - (iii) in response to identification of the source page, automatically retrieve the stored data corresponding to the source page; and
 - (iv) using the data retrieved, automatically generate and transmit to the web browser a second web page that displays: (A) information associated with the commerce object associated with the link that has been activated, and (B) the plurality of visually perceptible elements visually corresponding to the source page.



Federal Circuit:
DDR Holdings v. Hotels.com

“[T]he ’399 patent’s asserted claims **do not recite a mathematical algorithm**. Nor do they recite a **fundamental economic or longstanding commercial practice**. Although the claims address a business challenge (retaining website visitors), it is a challenge particular to the Internet. * * *

“[T]hese claims stand apart because they do not merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet. Instead, the claimed solution is **necessarily rooted in computer technology** in order to overcome a **problem specifically arising in the realm of computer networks**.”

DDR Holdings v. Hotels.com, No. 2013-1505 (Fed. Cir. Dec. 5, 2014)

“The ’399 patent’s claims are different enough in substance from those in *Ultramercial* because they do not broadly and generically claim ‘use of the Internet’ to perform an abstract business practice (with insignificant added activity). Unlike the claims in *Ultramercial*, the claims at issue here **specify how interactions with the Internet are manipulated to yield a desired result**—a result that **overrides the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink**. * * * When the limitations of the ’399 patent’s asserted claims are **taken together as an ordered combination**, the claims recite an invention that **is not merely the routine or conventional use of the Internet**.”

DDR Holdings v. Hotels.com, No. 2013-1505 (Fed. Cir. Dec. 5, 2014)

Alice Corp. v. CLS Bank

→ Practical effect

- Since *Alice*, *many* software and business-method patents have been invalidated under § 101
- Many have been invalidated on motions to dismiss
- Would you rather win on § 101 or § 102/103?

A unified
framework

A unified framework

→ Before:

- 1. Does a patent claim a “process, machine, manufacture, or composition of matter”?
- 2. If so, does it fall within an exception for laws of nature, natural phenomena, or abstract ideas?

A unified framework

→ Before:

- 1. Does a patent claim a “process, machine, manufacture, or composition of matter”?
- 2. If so, does it fall within an exception for laws of nature, natural phenomena, or abstract ideas?

A unified framework

→ Now:

- 1. Does a patent claim a “process, machine, manufacture, or composition of matter”?
- 2. If so, does it set forth a law of nature, natural phenomenon, or abstract idea?
- 3. If so, do the other elements of the claim add an inventive concept?

Next time

Next time

- **Infringement: claim construction and literal infringement**