

Comments on Patent Eligibility

BerkeleyLaw

Peter S. Menell

Koret Professor of Law

Director, Berkeley Center for Law & Technology
University of California at Berkeley School of Law



1. Mayo/Alice Flawed { • “invent or discover”
• *Neilson* misreading

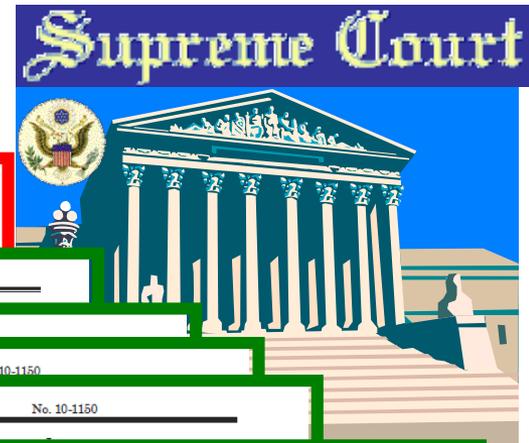
2. Impact of § 101 on Innovation { • diagnostics
• algorithms

3. Need for Legislation/PTO Role



PROMETHEUS[®]
Therapeutics & Diagnostics

v.



No. 10-1150

In The
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES
(d/b/a MAYO MEDICAL LABORATORIES)
and MAYO CLINIC ROCHESTER,

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,

Respondent.

On Writ Of Certiorari To The
United States Court Of Appeals
For The Federal Circuit

BRIEF OF NINE LAW PROFESSORS
AS AMICI CURIAE
IN SUPPORT OF PETITIONERS

JOSHUA D. SARNOFF
Counsel of Record for Amici Curiae
DEPAUL UNIVERSITY
COLLEGE OF LAW
25 E. Jackson
Chicago, IL 60604
(312) 362-6326
jsarnoff@depaul.edu

September 9, 2011

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In the
Supreme Court of the United States

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MAYO COLLABORATIVE SERVICES, DBA MAYO

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IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (d/b/a MAYO MEDICAL

No. 10-1150

In The
Supreme Court of the United States

No. 10-1150

LABORATORIES, INC.,
Respondent.

AMICI CURIAE ASSOCIATION
FOR THE PROTECTION OF LA
INTELLECTUAL AND INTERNATIONAL
PROTECTION OF INTELLECTUAL
PROPERTY OF NEITHER PARTY

PETER C. SCHECHTER
Counsel of Record
EDWARD ANGELA PALMER
& DODGE LLP
750 Lexington Avenue
New York, New York 10022
(212) 912-2834
pschechter@caplaw.com

Association Internationale pour
la Protection de la Propriete
Intellectuelle and International
Association for the Protection of
Intellectual Property (U.S.)

November

No. 10-1150

In The
Supreme Court of the United States

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In The
Supreme Court of the United States

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MAYO COLLABORATIVE SERVICES, DBA MAYO
MEDICAL LABORATORIES, ET AL.,

Petitioners,
v.
PROMETHEUS LABORATORIES INC.,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

BRIEF OF PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA AS AMICI
CURIAE IN SUPPORT OF RESPONDENT

OF COUNSEL
DAVID E. KOEN
PHARMACEUTICAL
RESEARCH AND
MANUFACTURERS OF
AMERICA
800 P St., N.W.
Washington, D.C. 20004
(202) 855-3400

HARRY J. ROYER
Counsel of Record
PAUL D. MARGOLIS
JONES & BLOCK LLP
200 N. WABASH AVENUE
Chicago, IL 60611
(312) 722-9050
hroyer@jones.com

PAUL M. SMITH
FRANZ J. GOLDENBERG
NICOLAUS R. BARNHART
JONES & BLOCK LLP
1099 NEW YORK AVENUE, N.W.
Suite 900
Washington, D.C. 20001
(202) 639-6000

Attorneys for Amicus Curiae

To
The
Clerk
of the
Supreme
Court
of the
United
States
255
Constitution
Avenue
Northwest
Washington,
D.C. 20543

BY
JAY Z. ZHANG
BENJAMIN G.
MYRLAD GENS
320 Wabash
Salt Lake City,
Utah 84103

November 7,



A. Prior Art Treatment of Excluded Discoveries and Creativity in Their Application Are Long-Standing Requirements of the Patent Act.

The requirement for prior art treatment of new discoveries found its first *explicit* statement in American patent law in 1854 in *O'Reilly*, relying on the English precedent of *Nielson v. Harford*, 151 Eng. Rep. 1266 (1841):

Neilson claimed no particular mode of constructing the receptacle, or of heating it. . . . [T]he court at first doubted, whether it was a patent for any thing more than the discovery that hot air would promote the ignition of fuel better than cold. And if this had been the construction, the court, it appears, would have held his patent to be void; *because the discovery of a principle in natural philosophy or physical science, is not patentable.*

But after much consideration, it was finally decided that this principle must be regarded as well known, and that the plaintiff had invented a mechanical mode of applying it to furnaces; and that his invention consisted in interposing a heated receptacle, between the blower and the furnace, and by this means

heating the air after it left the blower, and before it was thrown into the fire. . . .

Undoubtedly, the principle that hot air will promote the ignition of fuel better than cold, was embodied in this machine. *But the patent was not supported because this principle was embodied in it. . . .*

. . . If the Court of Exchequer had said that Neilson's patent was for the discovery, that hot air would promote ignition better than cold, and that he had an exclusive right to use it for that purpose, there might, perhaps, have been some reason to rely upon it. But the court emphatically denied this right to such a patent.

O'Reilly, 56 U.S. (15 How.) at 115-16 (emphasis added). One year earlier, the Court had explicitly stated that scientific, natural, and abstract discoveries are ineligible for patent protection. *See Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853) (“[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.”). But these requirements had a long history, predating the Constitution.

O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1854)

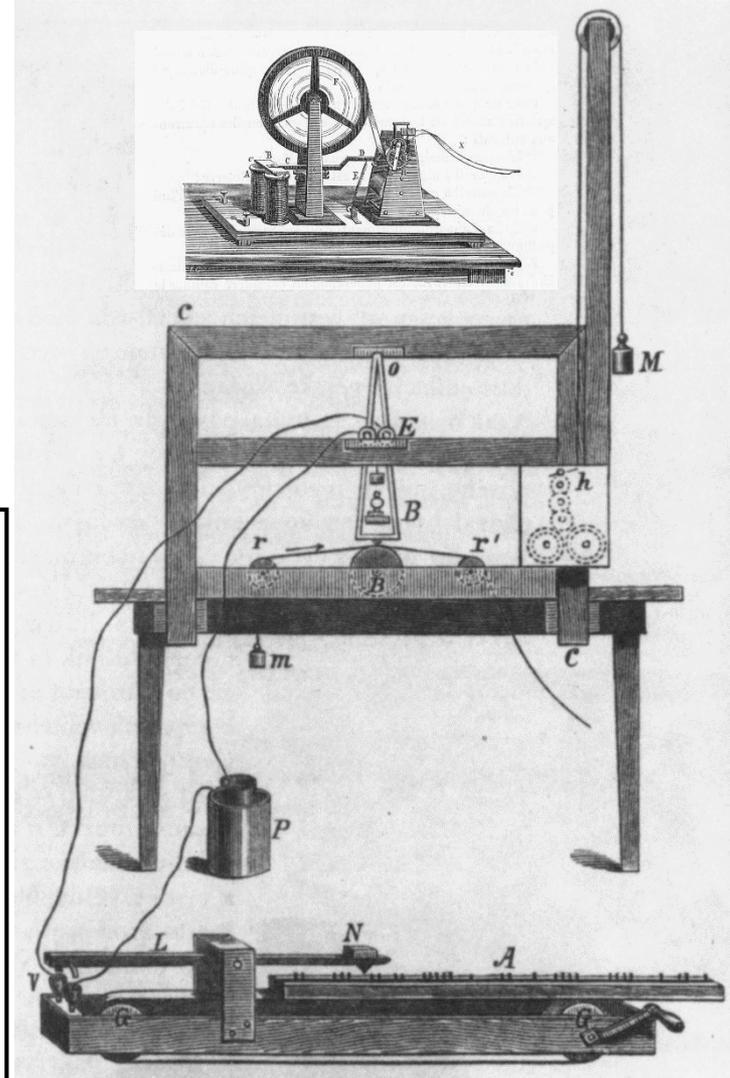
Telegraph



Samuel F.B. Morse

Eighth. I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances . . .

1840 Patent



O'Reilly v. Morse, 56 U.S. (15 How.) 62, 114-15 (1854)

Many cases have been referred to in the argument * * * We shall speak of those only which seem to be considered as leading ones. And those most relied on, and pressed upon the court, in behalf of the patentee, are the cases which arose in England upon **Neilson's patent** for the introduction of heated air between the blowing apparatus and the furnace

Neilson, in his specification, described his invention as one for the improved application of air to produce heat in fires, forges, and furnaces, where a blowing apparatus is required. And it was to be applied as follows: The blast or current of air produced by the blowing apparatus was to be passed from it into an air-vessel or receptacle made sufficiently strong to endure the blast; and through or from that vessel or receptacle by means of a tube, pipe, or aperture into the fire, the receptacle be kept artificially heated to a considerable temperature by heat externally applied.

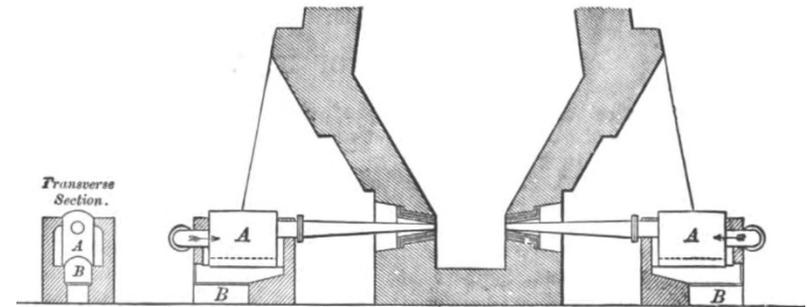


Fig. 5.—Neilson's original hot blast apparatus, 1829.

O'Reilly v. Morse, 56 U.S. (15 How.) 62, 114-15 (1854)

the defendant among other defences insisted- that [1] the machinery for heating the air and throwing it hot into the furnace was **not sufficiently described** in the specification,

and the patent void on that account-and

also, [2] that a patent for throwing hot air into the furnace, instead of cold, and thereby increasing the intensity of the heat, was a patent for a principle, and that **a principle was not patentable**.

[1] Upon the first of these defences, the jury found that a man of ordinary skill and knowledge of the subject, looking at the specification alone, could construct such an apparatus . . .

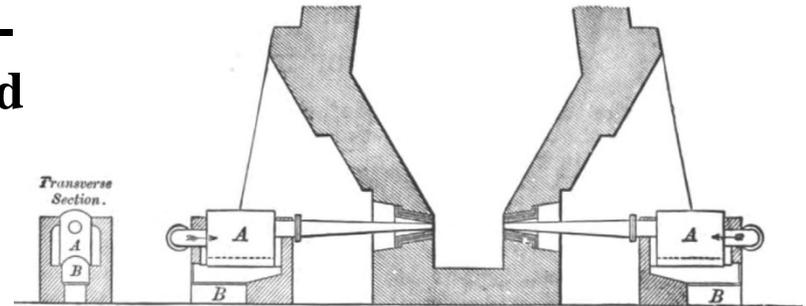


Fig. 5.—Neilson's original hot blast apparatus, 1829.

O'Reilly v. Morse, 56 U.S. (15 How.) 62, 115 (1854)

[2] And upon the second ground of defence, Baron Parke, who delivered the opinion of the court, said:

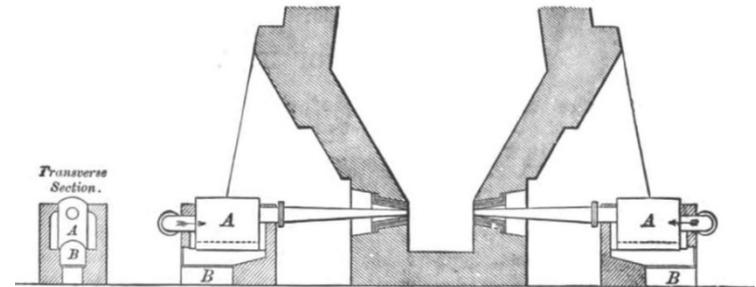


Fig. 5.—Neilson's original hot blast apparatus, 1829.

‘It is very difficult to distinguish it from the specification of a patent for a principle, and this at first created in the minds of the court much difficulty; but after full consideration we think that the plaintiff does not merely claim a principle, but a machine, embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces, and his invention then consists in this: by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before cold air, in a heated state to the furnace.’

“invents or discovers”

1790 Patent Act, § 1

grants patents to any person who “invented **or discovered** any useful art, manufacture, engine, machine, or device . . . if they shall deem the invention **or discovery** sufficiently useful and important. . . .”

1793 Patent Act, §§ 1, 3

grant patents to any person who “invented or **discovered** any . . .” requires that “every inventor . . . shall swear . . . he is the true inventor or **discoverer** of the art, machine, or improvement. . . .”

U.S. Constitution

“Writings or **Discoveries**”

1787

1790

1793

“invents or discovers”

1836 Patent Act

§ 1 establishes a Patent Office “to superintend, execute, and perform, all such acts and things touching and respecting the granting and issuing of patents for new and useful **discoveries**, inventions, and improvements.”

§ 6 authorizes “any person . . . having **discovered** or invented any new and useful art, machine, manufacture, or composition of matter” to seek patent protection.

1836



Senate Report: 1836 Act

Whoever imagines that, because so many inventions and so many improvements in machinery have been made, there remains little else to be **discovered**, has but a feeble conception of the infinitude and vastness of mechanical powers, or of the unlimited reach of science. **Much as has been discovered, infinitely more remains unrevealed.** The ingenuity of man is exploring a region without limits, and **delving in a mine whose treasures are exhaustless.** ‘Neither are all the **mysteries of nature unfolded**, nor the mind tired in the pursuit of them.’

The first conceptions of ingenuity, like the first suggestions of science, are theories which require something of experiment and practical exemplification to perfect. . . .

“invents or discovers”

1870 Patent Act

“any person who has invented **or discovered** any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . .” R.S. § 4886.

See also R.S. §§ 4884, 4887, 4888, 4890, 4891, 4892, 4893, 4895, 4896, 4897, 4899, 4902, 4908, 4916, 4917, 4920, 4922, 4923, 4924, 4926, 4927 (referring to “invention **or discovery**” and “inventor **or discoverer**” throughout the statute).

“invents or discovers”

Plant Patent Act of 1930

“Any person who has *invented or discovered* any new and useful art, machine, manufacture, or composition of matter, or who has *invented or discovered* and asexually reproduced any distinct and new variety of plant . . . may, upon payment of the fees required by law, and other due proceeding had, obtain a patent therefor.”

H.R. REP. NO. 71-1129, at 7 (1930) (quoting R.S. § 4886)

Present patent laws apply to “any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . .” **It will be noted that the laws apply both to the acts of inventing and discovery and this alternative application has been true of the patent laws from their beginning.** See, for instance, the Patent Act of 1790 (1 Stat. 109).

“invents or discovers”

1952 Patent Act

§ 101 Whoever invents **or discovers** any new and useful process, machine, manufacture, or composition of matter . . .

§ 100 Definitions:

(a) The term “invention” means invention **or discovery**.

(b) The term “process” means process, art, or method, and **includes a new use of a known process, machine, manufacture, composition of matter, or material**.



- 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 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.

This Court has previously discussed in detail an English case, *Neilson*, which involved a patent claim that posed a legal problem very similar to the problem now before us. * * *

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an **inventive** way. Baron Parke wrote (for the court):

‘It is very difficult to distinguish it from the specification of a patent for a principle, and this at first created in the minds of the court much difficulty; but after full consideration we think that the plaintiff does not merely claim a principle, but a machine, embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces, and his invention then consists in this: by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before cold air, in a heated state to the furnace.’

What is Unconventional or Inventive beyond the Scientific Principle?

Thus, the claimed process included not only a law of nature but also several **unconventional** steps (such as inserting the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.

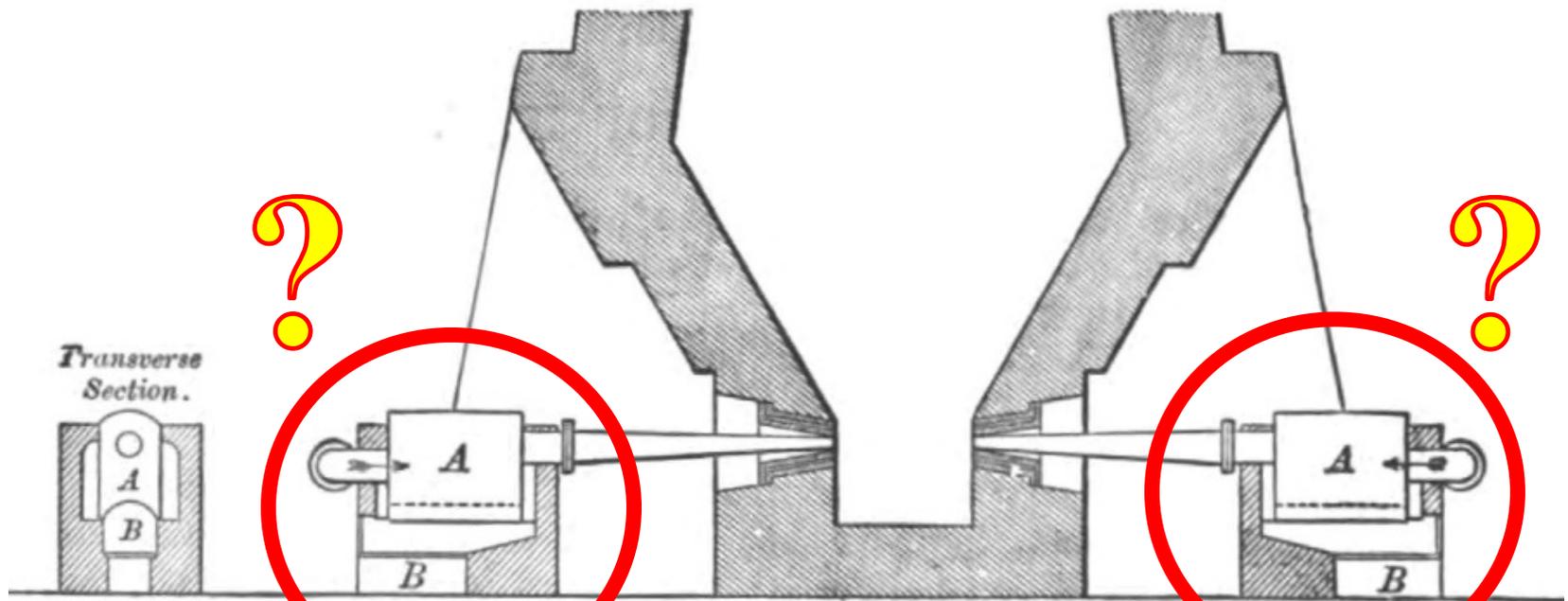


Fig. 5.—Neilson's original hot blast apparatus, 1829.

Mayo: Thus, the claimed process included not only a law of nature but also several **unconventional** steps (such as inserting the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.

Neilson: the patentee argued that:

[t]he mode of heating air **was perfectly well known**; it was no discovery of Mr. Neilson's, every body knew it. Air had been heated, and there had been different shaped vessels employed for heating the air; for heating the air economically, and for heating it to a higher or lesser degree of temperature; **all that was perfectly well known.**

Neilson, 1 Web. P.C. at 344.

Proper Interpretation of *Mayo's* Quotation

‘It is very difficult to distinguish it from the specification of a patent for a principle, and this at first created in the minds of the court much difficulty; but after full consideration we think that the plaintiff does not merely claim a principle, but a machine, embodying a principle, and a very valuable one. **We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces**, and his invention then consists in this: by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before cold air, in a heated state to the furnace.’

Is Neilson's Invention a Machine?

Reference to *Minter v. Wells*

Minter v. Wells

[I]t was the application of a well-known principle, but for the first time applied to a chair. . . . Lord Lyndhurst and the rest of the court held, that this was not a claim to a principle, but to the construction of a chair on this principle, in whatever shape or form it may be constructed. Just so as to the hot blast, *only the principle is also new.*

Househill Coal & Iron Co. v. Neilson, 1 Web. P.C. 673, 686 (1843) (emphasis added).





v. SEQUENOM®

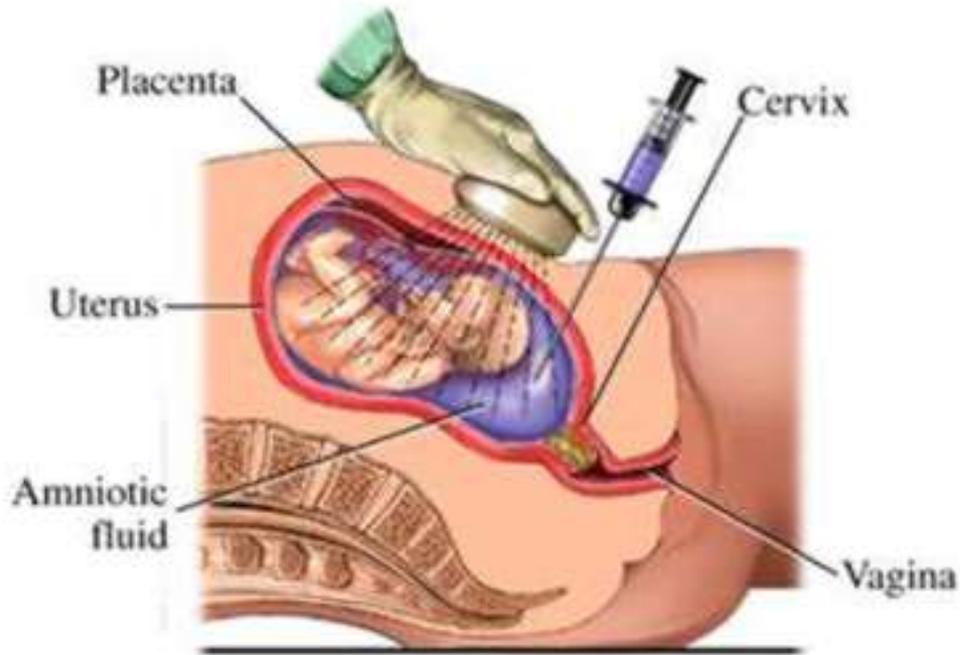
U.S. Patent No. 6,258,540 (Jul. 10, 2001)

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

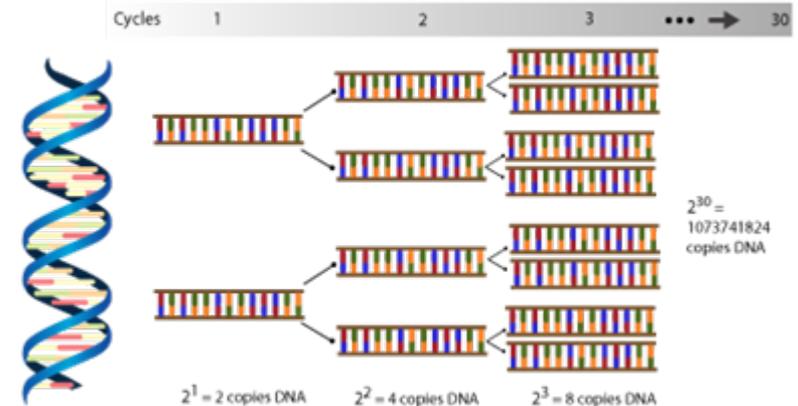


Amniocentesis

Blood Test



PCR amplification



Chain Reaction, copies from copies produced

Condition**MaterniT21 PLUS test ^{3,4,5,6}
detection rate/samples detected**

Trisomy 21	Down Syndrome	>99% (210 of 212)
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Trisomy 18	Edwards Syndrome	>99% (59 of 59)
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Trisomy 13	Patau Syndrome	>91% (11 of 12)
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Fetal sex aneuploidies	>96% (25 of 26 combined)
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Select microdeletions	>94% (17 of 18)
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**In The
Supreme Court of the United States**

—◆—
SEQUENOM, INC.,

Petitioner,

v.

ARIOSA DIAGNOSTICS, INC., NATERA, INC.,
AND DNA DIAGNOSTICS CENTER, INC.,

Respondents.

—◆—
**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit**

—◆—
**BRIEF OF PROFESSORS JEFFREY A. LEFSTIN AND
PETER S. MENELL AS *AMICI CURIAE* IN SUPPORT
OF PETITION FOR A WRIT OF CERTIORARI**

—◆—
JEFFREY A. LEFSTIN
Professor of Law
UNIVERSITY OF CALIFORNIA,
HASTINGS COLLEGE OF LAW
200 McAllister Street
San Francisco, CA 94102
(415) 565-4658
lefstinj@uchastings.edu

PETER S. MENELL
Koret Professor of Law
Counsel of Record
UNIVERSITY OF CALIFORNIA,
AT BERKELEY SCHOOL OF LAW
2240 Piedmont Avenue
Berkeley, CA 94720
(510) 642-5489
pmenell@law.berkeley.edu

April 20, 2016

**In The
Supreme Court of the United States**

SEQUENOM, INC.,

II.	A Requirement for Inventive Application Fundamentally Misreads the Precedential Basis for the Inventive Application Concept	15
A.	<i>Neilson</i> Did Not Treat Discoveries as “Being Well Known”	16
B.	Foundational Precedent Required Only Conventional Application, Not Inventive Application.....	20
III.	Engrafting “Inventiveness” or “Undue Preemption” onto § 101 Short-Circuits the 1952 Act Patentability Framework.....	23

THE EMPEROR HAS NO CLOTHES



THE EMPEROR HAS NO CLOTHES



Gottschalk v. Benson, 409 U.S. 63 (1972)

BCD  Binary
53 = 0101 0011  110101

8. The method of converting signals from binary coded decimal into binary which comprises the steps of
- (1) storing the binary coded signals in a reentrant shift register,
 - (2) shifting the signals to the right at least three places, until there is a binary “1” in the second position of said register,
 - (3) masking out said binary “1” in said register position of said register,
 - (4) adding a binary “1” to the first position of said register,
 - (5) shifting the signals to the left by two positions,
 - (6) adding a “1” to said first position, and
 - (7) shifting the signals to the right by at least three positions in preparation for a succeeding binary “1” in the second position of said register.

“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”

- “[T]he process claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion.”
- “the patent would **wholly pre-empt the mathematical formula** and in practical effect would be a patent on the algorithm itself.”

If these programs are to be patentable, considerable problems are raised which only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain. The technological problems tendered in the many briefs before us indicate to us that considered action by the Congress is needed.

Gottschalk v. Benson, 409 U.S. 63, 73 (1972)
(Douglas, J.) (footnotes omitted)

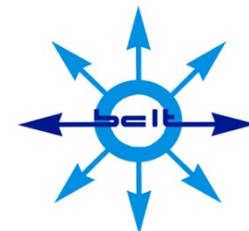
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Koret Professor of Law

Director, Berkeley Center for Law & Technology
University of California at Berkeley School of Law



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• *Neilson* misreading

2. Impact of § 101 on Innovation { • diagnostics
• algorithms

3. Need for Legislation/PTO Role



White Paper on Remixes, First Sale, and Statutory Damages

Copyright Policy, Creativity, and Innovation
in the Digital Economy

THE DEPARTMENT OF COMMERCE
INTERNET POLICY TASK FORCE

January 2016

UNITED STATES COPYRIGHT OFFICE



THE MAKING AVAILABLE RIGHT IN THE UNITED STATES

A REPORT OF THE REGISTER OF COPYRIGHTS

FEBRUARY 2016



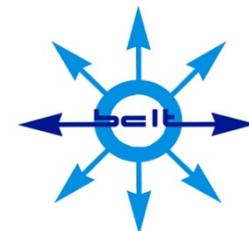
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