2015 High Technology Summit
Seattle, WA

Biotech Patent Woes - §101

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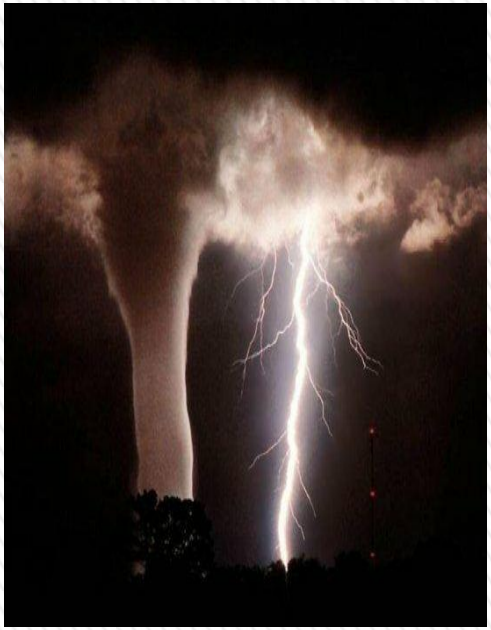
35 U.S.C. § 101

Laws of nature, natural phenomena, abstract ideas, are not eligible.

Neilson v Harford (1841)
LeRoy v Tatham (1853)
O'Reilly v Morse (1854)
Mackay Radio v Radio Corp (1939)
Funk Brothers v Kalo (1948)
1952 Patent Act
Gottschalk v Benson (1972)
Parker v Flook (1978)
Diamond v Chakrabarty (1980)
Diamond v. Diehr (1981)
Bilski v Kappos (2010)
AMP v. Myriad Genetics (2013)
Mayo v. Prometheus (2013)
Alice Corp. v. CLS Bank (2014)
Ariosa v. Sequenom (2015)



35 U.S.C. § 101

Whoever invents or discovers any **new** and **useful**

process, machine, manufacture,

or composition of matter,

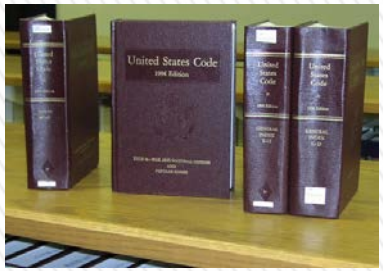
or any new and useful **improvement** thereof,

may obtain a patent therefor,

subject to the conditions and requirements of this title.

Legislative History - § 101

- **Patent Act of 1952**
  - Primary purpose was to codify patent law into Title 35 USC
  - Simplify and clarify the language of the law
- **Changes in the law**
  - Established §§ **101, 102, and 103**
  - In § 101, changed "art" to "process", acknowledging same meaning
  - Defined "process" to mean "process or method, and **includes a new use of a known process, machine, manufacture, composition, or material**"
  - Clarified §101 as setting forth subject matter that can be patented
  - §101 - a **NEW USE of a KNOWN process, machine, manufacture, composition, or material** is **eligible** for patenting, subject to the subject to the conditions and requirements of this title



Legislative History - Section 101

- **1952 Patent Act**
  - **101(a)…** any "new and useful ~~**art**~~ **process**, machine, manufacture, or composition of matter, or any new and useful improvement thereof" may obtain a patent.
  - **100(b) makes clear** that **process or method** is meant…
  - The remainder of the definition **clarifies** the status of processes or methods **which involve merely the new use of a known** process, machine, manufacture, composition or matter, or material;
  - …**they are processes or methods under the statute and may be patented** provided the conditions for patentability are met.

Report of the Committee on the Judiciary Revision of Title 35 USC, May 12, 1952; Journal of the Patent Office Society, August 1952, Vol XXXIV, No. 8, pp. 549-585

LabCorp v Metabolite

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

assaying a body fluid for an elevated level of total homocysteine; and

correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

AMP v. Myriad Genetics

1. A **method** for **identifying a mutant** BRCA2 nucleotide sequence in a suspected mutant BRCA2 allele which comprises

   comparing the nucleotide sequence of the suspected mutant BRCA2 allele with the wild-type BRCA2 nucleotide sequence,

   wherein a difference between the suspected mutant and the wild-type sequences **identifies a mutant** BRCA2 nucleotide sequence.

Mayo v. Prometheus

1. A **method of optimizing therapeutic efficacy** for treatment of an immune-mediated gastrointestinal disorder, comprising:

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

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

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells **indicates a need to increase** the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells **indicates a need to decrease** the amount of said drug subsequently administered to said subject.

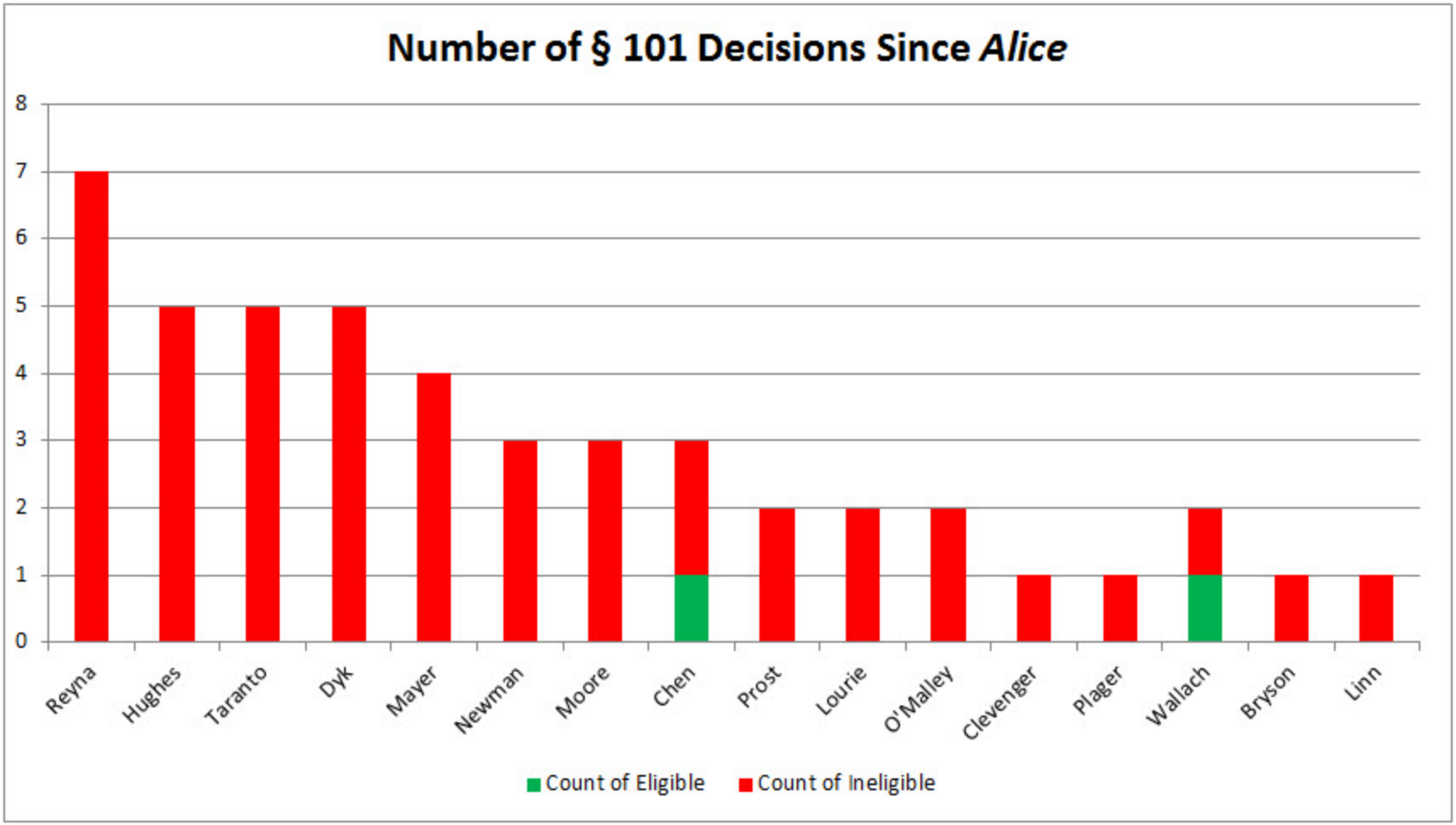
Ariosa v. Sequenom

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 f rom the serum or plasma sample and

detecting the presence of a **paternally inherited** nucleic acid of fetal origin in the sample.

Bilski Blog – Robert Sachs



Bilski Blog – Robert Sachs

Percent of Final Rejections w/ 101 Rejection Before and After Alice

	Before Alice	After Alice
1600 Bio, Gene & O. Chem	**8.1%**	**16.7%**
2100 Computer Architecture	**21.8%**	**16.2%**
2400 Networks and Video	**15.3%**	**11.3%**
2600 Communications	**10.0%**	**7.7%**
3600 Trans., Constr. Biz. Methods		
Business Crypto	38.6%	56.7%
Business Processing & Modeling	44.0%	96.4%
Cost/Price, Reservations	37.6%	72.8%
E-Shopping	37.9%	97.2%
Health Care, Insurance	34.0%	83.5%
Incentive Programs	36.2%	87.4%
Incentives, Oper., Eshopping, Insur., Retail	44.4%	95.0%
Operations Research	46.6%	95.6%
POS, Inventory, Accounting	23.2%	77.7%
3700 Mechanical Eng. & Manuf.		
Amusement & Education	16.5%	30.1%

Solutions?

1. Push back!
2. Encourage Courts to apply the statute as intended
3. Apply the statute in responses to USPTO rejections: **NEW USE OF KNOWN ….**
4. Advise Congress of the problem
5. Lobby for legislative fix

Thank you!