

A Holistic Approach to Complex Medical Diagnostics

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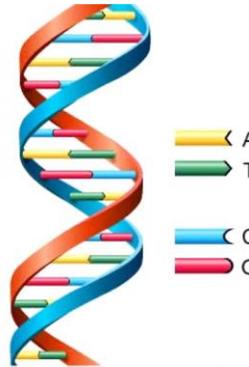
Patentable Subject Matter

§ 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.

Controversial Categories

- **Biotechnology**



- **Computer Software**



- **Business Methods**

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Patentable Subject Matter

Congress intended statutory subject matter to “include anything under the sun that is made by man.”

“This is **not** to suggest that section 101 has **no limits** or that it embraces every discovery. . . . Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.”

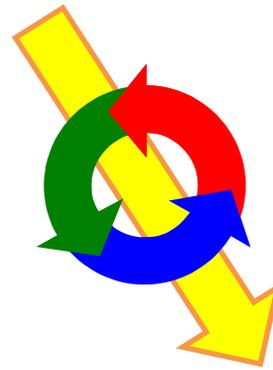
Diamond v. Chakrabarty, 447 U.S. 303 (1980)

Revival of § 101 Exceptions

Patent-Eligible Processes



**Tied to a
Machine**



**Transforms an Article into a
Different State or Thing**

In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc)

Revival of § 101 Exceptions

Held: Method for hedging risk in commodities trading is a patent-ineligible abstract idea

“As numerous amicus briefs argue, the machine-or-transformation test would create **uncertainty** as to the patentability of software, **advanced diagnostic medicine techniques**, and inventions based on linear programming, data compression, and the manipulation of digital signals...”

Bilski v. Kappos, 130 S. Ct. 3218 (2010)

Natural Laws

“Prometheus’ patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm...The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body - **entirely natural processes.”**

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S.Ct. 1239 (2012)

Abstract Ideas

Held: Computer-implemented scheme for mitigating settlement risk in financial transactions is patent-ineligible

“The claimed methods do not, for example, purport to improve the functioning of the computer itself...Nor do they effect an improvement in any other technology or technical field.”

Alice Corp. v. CLS Bank International, 134 S. Ct. 2347 (2014)

Abstract Ideas Or Natural Laws?

“Myriad’s method claims directed to ‘comparing’ or ‘analyzing’ DNA sequences are patent ineligible; such claims include no transformative steps and cover only patent-ineligible, **abstract mental steps**.” 689 F.3d at 1309.

“The Court [in *Mayo*] made clear that such diagnostic methods in that case essentially claim **natural laws** that are not eligible for patent.” 689 F.3d at 1333.

Recent Cases Involving Diagnostic Methods

Held: Non-invasive method of determining fetal risk of Down's syndrome, based on measuring a biomarker and/or an ultrasound screening marker at two different times, is patent-ineligible

“The claims thus recite the **mental process** of comparing data to determine a risk level...Intema also claims a **law of nature**: the relationship between screening marker levels and the risk of fetal Down's syndrome.”

PerkinElmer, Inc. v. Intema Ltd., 496 Fed.Appx 65 (Fed. Cir. 2012) (**unpublished**)

Recent Cases Involving Diagnostic Methods

Held: Non-invasive prenatal test, using cell-free fetal DNA circulating in blood of pregnant women, is patent-ineligible

“[T]he claimed processes at issue – apart from the **natural phenomenon** of paternally inherited cffDNA – involve no more than well-understood, routine, conventional activity.”

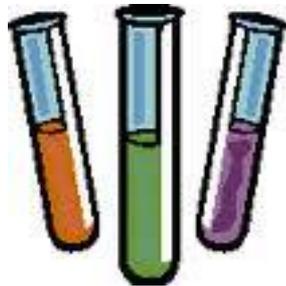
Ariosa Diagnostics, Inc. v. Sequenom, Inc., 2013 WL 5863022 (N.D. Ca. 2013)

Recent Cases Involving Diagnostic Methods

Held: Computer-implemented method for guiding selection of a medical treatment regime is patent-ineligible

“[S]ection 101 covers neither ‘**mental processes**’ – associated with or as part of a category of ‘abstract ideas’ – nor processes that merely invoke a computer and its basic functionality for implementing such mental processes.”

A Turn Toward Secrecy?



Implications for Medical Research



Heightened Regulatory Scrutiny



On July 31, 2014, FDA notified Congress that it would propose a “risk-based, phased-in framework for oversight of LDTs in a manner that is consistent with FDA’s current regulation of *in vitro* diagnostic devices.”

Draft Guidance For LDTs

- Issued on October 3, 2014
- FDA intends to continue to exercise enforcement discretion for “Traditional LDTs”
- Phased-in regulation of complex LDTs that require use of software for interpretation

FDA as Information Intermediary

- **FDA could leverage its gatekeeping authority to reward data production and dissemination**
- **Approval and reimbursement in exchange for disclosure of patent-ineligible information**
- **Structured management of information flows across open and proprietary spaces**

A Holistic Approach

