

# The Impact of AIA and Alice on Patent Protection on Diagnostic Method: How Much More is Significantly More? 創新、創技、創智、創富

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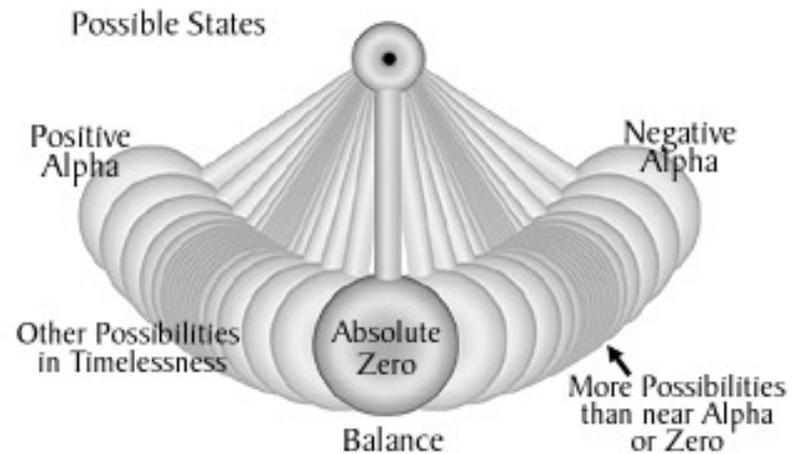
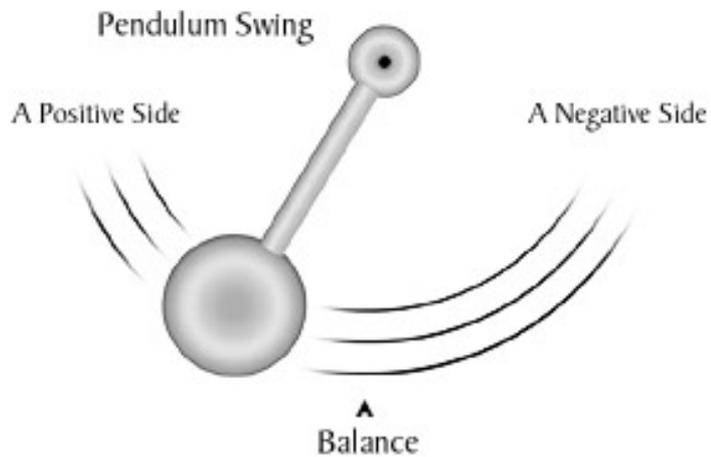
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# Balance and Pendulum



# PTAB and PTAB Troll

The PTAB as a Hedge Fund Tool? Scott A. McKeown, Post-Grant Practice Group, January 15, 2015

- "PTAB Trolls" - manipulate the new administrative trial system of PTAB. "PTAB Trolls" attempt to extract settlements from patentees involved in high value litigation disputes
- Other versions - PTAB Trolls that will take a "short" position in a stock - mere filing of an IPR can spook investors, impacting trading volumes enough to cause a temporary, but significant, price drop (i.e., quick profit for a short seller) - these efforts have mostly failed, but not all.
- Next up, well financed hedge funds taking on key drug patents of the pharmaceutical industry? The founder of Dallas-based Hayman Capital Management, Kyle Bass, announced to the world that he planned to attack 15 drug companies via IPR. "We are going to challenge and invalidate patents through the IPR process ... (and) we are not going to settle . . . The companies that are expanding patents by simply changing the dosage or the way they are packaging something are going to get knee capped. ..This is going to lower drug prices for Medicare and for everyone."

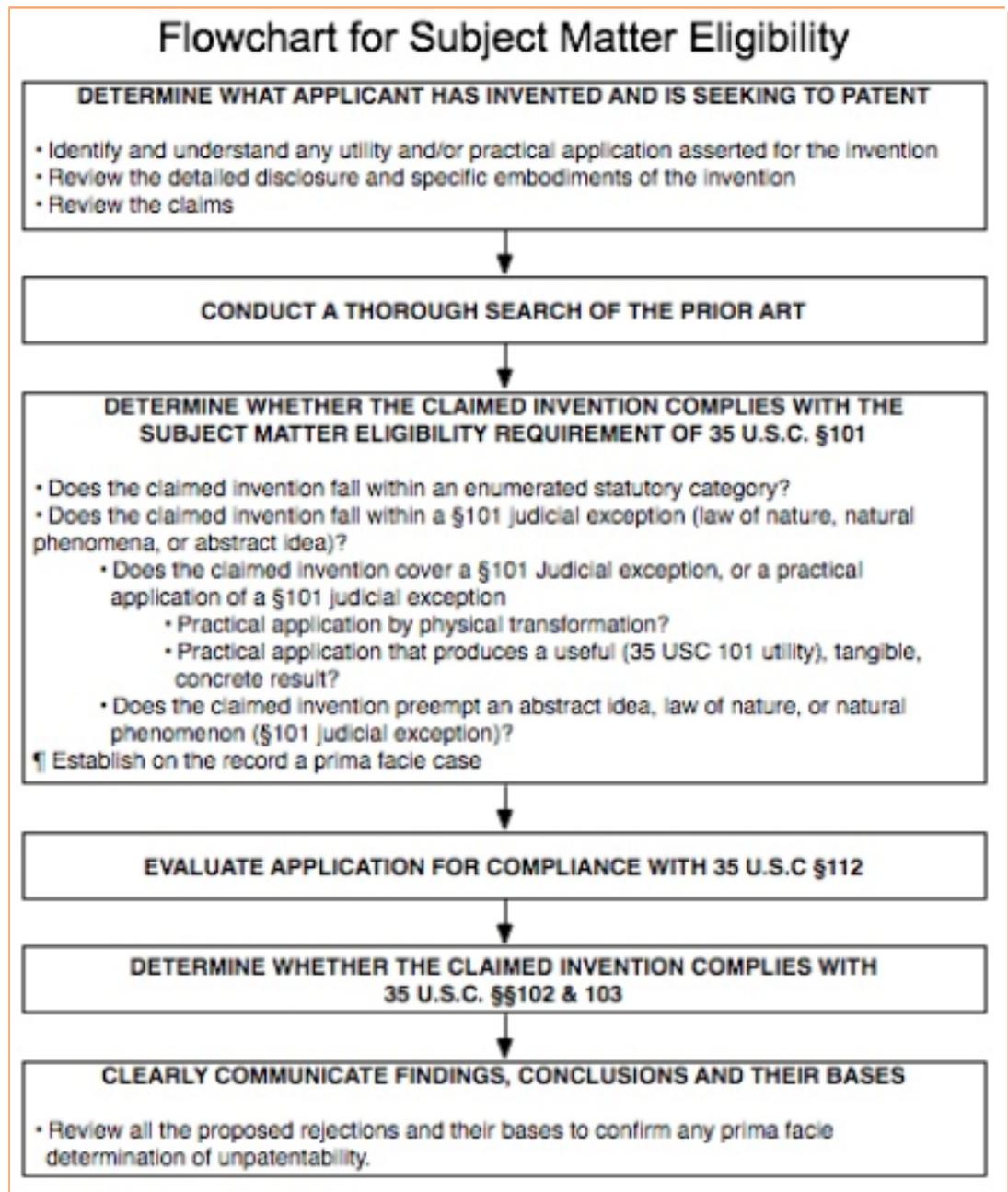
# Legal Requirements for Utility Patent

United States Code/Title 35/Chapter 10/Section XXX

- Statutory Subject Matter (35 USC 101) 法定容許事物
- **Utility (35 USC 101)** 實用性
- **Novelty (35 USC 102)** 新穎性
- **Non-obviousness (35 USC 103)** 非顯而易見 創造性  
[第二十二條 授予專利權的發明和實用新型，應當具備新穎性、創造性和實用性]
- Disclosure - Enablement 可使用 and Best Mode 最佳方法  
(35 USC 112, 1<sup>st</sup> Paragraph in the Specification)
- Inequitable (Illegal) conduct [i.e., inventor, applicant, prior act, transfer of rights,...] (Fraud, Deceptive Intention/Conducts, **35 USC 251**)
- Pay patent fee
- **Litigation** - Claim Construction, interpretation, Indefiniteness, Patent Infringement Literal and Doctrine of Equivalents, Direct and Indirect Infringement

# [Old] Patent Subject Matter Eligibility

- Statutory Subject Matter (101)
- Utility (101)
- Novelty (Prior art)(102)
- Non-obviousness (102/103)
- Enablement/Best mode (112)
- Section 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 there or, subject to the conditions and requirements of this title.
- Judicial exception – law of nature, natural phenomena, or abstract idea, and more...



# Statutory Subject Matter (35 USC 101)

After Alice v CLS Bank 2014 [Machine-or-Transformation Test Not Enough]

Some Recent Examples: [Diamond v. Diehr, 1981][**Bilski** v. Kappos, 2010][**Alice v. CLS Bank, 2014**] [Abstract Idea]

- **Mayo v. Prometheus** [Supreme Court, argued December 7, 2011, decided March 20, 2012]  
Holding: Claims directed to a diagnostic method that involved observing a natural correlation were not patent eligible subject matter [Mayo Test] [cffDNA, Ariosa v Sequenom, 6-12-2015]
- **AMP v. Myriad** [Supreme Court, Argued April 15, 2013, decided June 13, 2013][Nature Product]  
Holding: Naturally occurring DNA sequences, even when isolated from the body, cannot be patented, but artificially created DNA is patent eligible because it is not naturally occurring
- **BB&T v. Maxim** filed 9-16-2013 [DDR Holdings, LLC v. Hotels.com, L.P., Appeal No. 2013-1505 (Fed. Cir. Dec. 5, 2014) confirm eligibility Biz Method, software+computer]  
Covered Business Method Petition (CBM) under AIA of 2012  
Maxim patent 5,949,880 (filed in 1996; issued in 1999) claims “transfer of valuable information between a secure module and another module” and sue BB&T of patent infringement; BB&T counter claim: Maxim patent nothing more than an attempt to patent a well-known and un-patentable abstract idea”

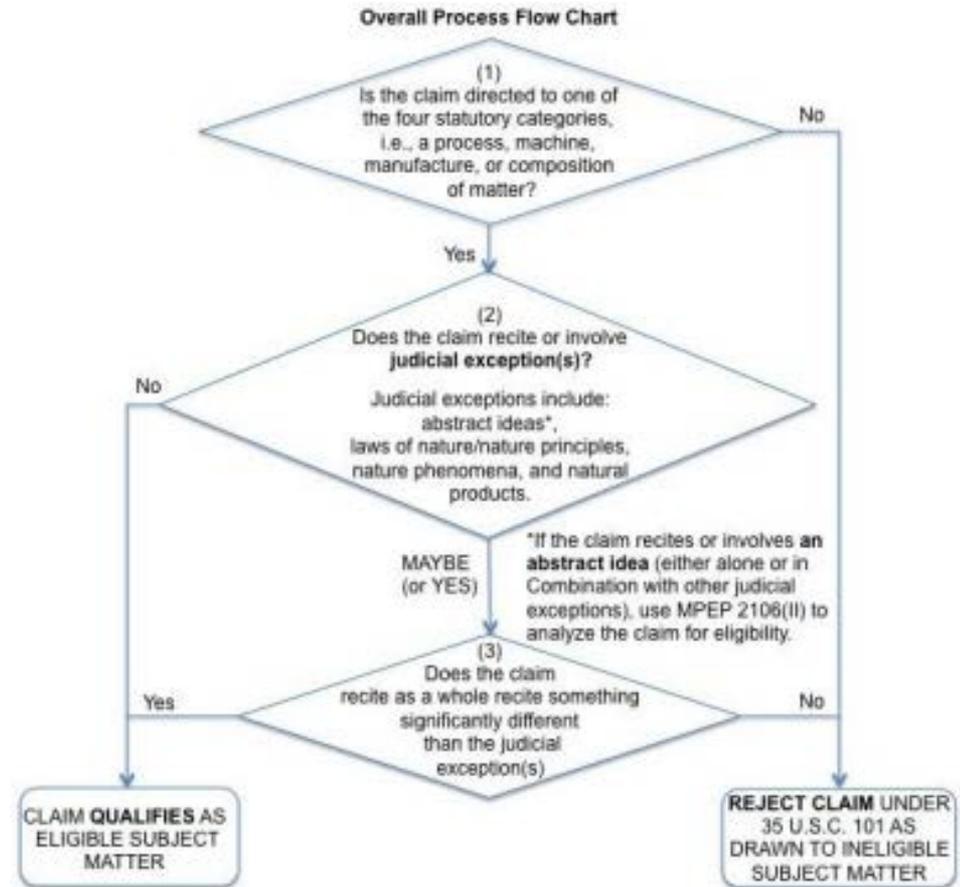
# USPTO Guidance on Patent Subject Matter Eligibility After May-Myriad-Alice Supreme Decision

- Supreme Court's decisions: **Mayo** Collaborative Services v. Prometheus Laboratories, Inc. (2012), Association for Molecular Pathology v. **Myriad** Genetics, Inc. (2013),
- 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature" (see "USPTO Issues Interim Guidance Regarding Mayo v Prometheus").
- Guidance on the Myriad decision that was issued on June 13, 2013 (see "USPTO Issues Memo on AMP v. Myriad to Examining Corps").
- Guidance For Determining Subject Matter Eligibility Of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products," March 4, 2014 (or "Myriad-Mayo Guidance" as the file is named)
- Supreme Court's recent decision: **Alice** v CLS Bank (2014)
- Memorandum to the patent examining corps with the preliminary examination instructions, June 25, 2014; USPTO 2014 Interim Guidance on Patent Subject Matter Eligibility, issued December 16, 2014 [USPTO Releases New Guidance on Patent Subject Matter Eligibility - On **July 30, 2015**, the USPTO released a set of **additional guidance** in respond to comments received from the 2014 Interim Guidance (2014 IEG) on December 26, 2014. The Update responds to "six themes" from the over sixty comments received by the USPTO on its previous Guidance on 35 U.S.C. § 101.]

# New [now Old] Section 101 New Guidance

Subject Matter – Abstract Idea, Laws of Nature, Natural Phenomena & Products of Nature

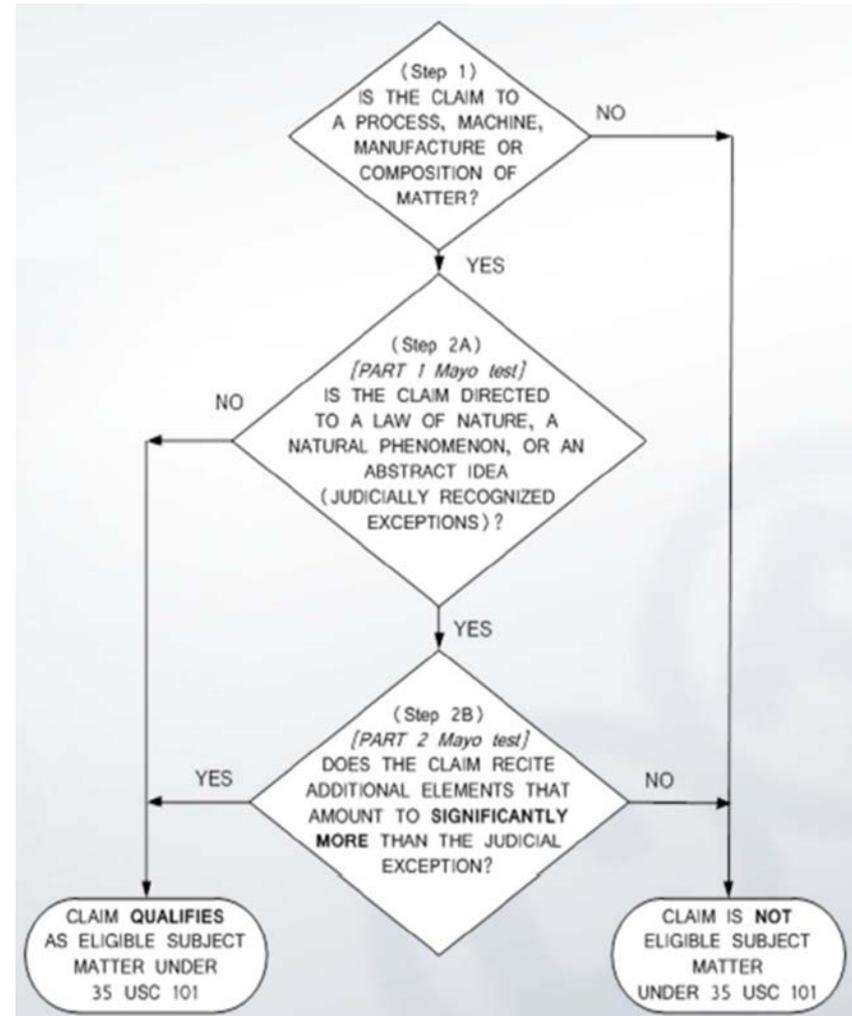
- Old – Machine or Transformation
- The new process [3-2014] to determine patent eligibility under §101 is basically to ask:
  - ✓ Is the claim directed to one of the four categories under §101?
  - ✓ Does the claim recite or involve a judicial exception?
  - ✓ Does the claim as a whole recite something **significantly different** from the judicial exceptions?
- Guidance for Analyzing Subject Matter Eligibility of Claims Reciting Laws of Nature/Natural Principles, Natural Phenomena or Natural Products, **March 4, 2014**



# USPTO Guidance: An Algorithm...

See [http://www.uspto.gov/patents/law/exam/jan21forum\\_uspto.pdf](http://www.uspto.gov/patents/law/exam/jan21forum_uspto.pdf)

- 2014 Interim Guidance on Patent Subject Matter Eligibility (issued 12-26-2014)
- Examiners are to:
  1. Determine what the claim is directed to.
  2. Identify the abstract idea recited in the claim (if any).
  3. Determine if the claim as a whole recites **significantly more** than the abstract idea itself.
- Note: USPTO New Guidance on Patent Subject Matter Eligibility – **July 30, 2015**.



# Two-Step Approach

2014 Interim Guidance on Subject Matter Eligibility, USPTO, Issued 12/26/2014

- [Pre-Step1: What is the inventor invented]
- **Step 1** determines whether the claim is directed to a process, machine, manufacture, or composition of matter [not changed and is explained in MPEP 2106(I)]. If the claim is not directed to one of these statutory categories, reject the claim under 35 U.S.C. § 101 as being drawn to non-statutory subject matter. If the claim is directed to a statutory category, proceed to Step 2.
- **Step 2** is the two-part analysis from Alice (also called the Mayo test) for claims directed to laws of nature, natural phenomena, and abstract ideas (the judicially recognized exceptions).
  - ✓ **Step 2A**, determine whether the claim is directed to a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions). If no, the claim is eligible and examination should continue for patentability. If yes, proceed to:
  - ✓ **Step 2B** to determine whether any element, or combination of elements, in the claim is sufficient to ensure that the claim as a whole amounts to **significantly more** than the judicial exception.

To determine the presence of an abstract idea in a claim, examiners are to refer to the court's prior identifications of abstract ideas:



- Mitigating settlement risk
- Hedging
- Creating a contractual relationship
- Using advertising as an exchange or currency
- Processing information through a clearinghouse
- Comparing new and stored information and using rules to identify options
- **Comparing a patient's gene with the wild-type gene, and identifying any differences that arise**
- Using categories to organize, store, and transmit information
- Organizing information through **mathematical correlations**
- Managing a game of Bingo
- The **Arrhenius equation** for calculating the cure time of rubber
- A formula for updating alarm limits
- A **mathematical formula** relating to standing wave phenomena
- A **mathematical procedure** for converting one form of numerical representation to another

# “Significantly More” Analysis

Prior court findings assist in determining whether limitations provide significantly more than an abstract idea in a claim:

## May provide “significantly more”

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- Applying the judicial exception with, or by use of, a particular machine
- Effecting a transformation or reduction of a particular article to a different state or thing
- Adding a specific limitation other than what is well-understood, routine and conventional in the field
- Adding unconventional steps that confine the claim to a particular useful application
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment

## May not provide

- Generic computer performing generic computer function
- Words equivalent to “apply the abstract idea”
- Mere instructions to implement an abstract idea on a computer
- Insignificant extra-solution activity, such as mere data gathering
- Generally linking the use of the abstract idea to a particular technological environment or field of use
- Merely appending well understood, routine, conventional activities previously known to the industry, specified at a high level of generality

# Alice v. CLS - "Abstract Idea"

*Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (2014) (citing *Mayo Collaborative Services. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296-97 (2012)).

- Held: Alice's claims to a "intermediated settlement" are directed to "an abstract idea beyond Section 101's scope":
  - ✓ Claimed method similar to "risk hedging" found patent ineligible in *Bilski*
  - ✓ "Simply instruct[s] the practitioner to implement the abstract idea of intermediated settlement on a **generic computer**"
    - "NOT ENOUGH TO TRANSFORM"
    - Supreme Court held both system and method claims invalid

# Alice v. CLS — But When Is “Enough”?

*Alice Corp. v. CLS Bank Int'l*, 134 S.Ct. 2347 (6-19-2014).

“[W]e treat carefully in construing this exclusionary principle lest it swallow all of patent law...”

“At some level, all inventions... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas...”

“Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.”

# Alice v. CLS - What Is an Abstract Idea?

Donald Chisum at <http://patentlyo.com/patent/2014/06/eligibility-implemented-inventions.html>



“I considered but then reconsidered entitling this comment ‘Alice in Wonderland.’”

“[D]oes the Alice opinion provide some meaningful guidance to fill the near void left by the Court in its prior Mayo and Bilski decisions?”

“Those decisions provided no definition of an “abstract idea” (or “law of nature”) and little direction on, precisely, how much “more” was required for the transformation.”

In Alice (June 19, 2014), the Supreme Court held that the two step framework for determining the Section 101 patent-eligibility of a patent claim, which the Court previously articulated in the 2012 Mayo decision on the patentability of a diagnostic method, applied to computer-implemented inventions. Thus, one determines: (1) **does the claim recite an ineligible concept** (natural phenomena, natural law or abstract idea), and (2) if so, **does the claim recite sufficient additional elements to make the claim one to an application of the concept, rather than to the concept itself?**

# Mayo v. Prometheus (Mayo Test)

- Patent application directed to adjusting dosing regimen based on a precise correlation between metabolite levels and likelihood for side effects.
  - ✓ A method of optimizing therapeutic efficacy.....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 .... indicates a need to increase the amount of said drug subsequently administered to said subject the level of 6-thioguanine greater than....indicates a need to decrease the amount of said drug subsequently administered to said subject.

# Court's Analysis (1)



- Law of nature
  - ✓ Correlations between thiopurine metabolite levels and the toxicity and efficacy of the thiopurine drug dosage.
- The administering step, determining step and the wherein clause are not themselves natural laws. However, they failed to transform the nature of the claim.
- The administering step simply refers to the relevant audience, i.e., doctors who treat patients with certain diseases with thiopurine drugs.
  - ✓ Prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of the formula to the relevant audience.

# Court's Analysis (2)

- “Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim set forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law [of nature].”
- In the Court's view the claim amounted to merely stating the law of nature and asking the doctors to apply it.
  - ✓ Has the claimed process transformed unpatentable natural laws into patent eligible applications of those laws?
  - ✓ Is there an “inventive concept?”
  - ✓ Are the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field?
  - ✓ Adding insignificant post-solution activity is said to be not sufficient.

# Ultramercial v Hulu: The Guillotine For Patent Trolls - Is adding "do it on the Internet" enough to make an abstract idea patentable?

- U.S. CAFC's 11-14-2014, decision in Ultramercial v Hulu & Wildtangent, the victims of patent trolls may finally be finding their legal guillotine.
- Issues of fact
  - ✓ Ultramercial's patent related to a business model surrounding a "Method and system for payment of intellectual property royalties by interposed sponsor on behalf of consumer over a telecommunications network". [2010, a trial court held the patent invalid on the grounds it claimed an abstract idea. On appeal, the Federal Circuit reversed, finding the patent non-abstract because it "clearly require[s] specific application to the Internet and a cyber-market environment."]
- The decision of Supreme Court {June 30, 2014 - The petition for a writ of certiorari is granted. The judgment is vacated, and the case is remanded to the US CAFC for further consideration in light of Alice Corp. v. CLS Bank Int'l, 573, U. S. \_\_\_\_ (2014).
  - ✓ The patent is ineligible because the patent constitute nothing more than an abstract idea.
- Note: Abstract idea has never been defined by the Supreme Court nor the CAFC.

# Ariosa v Sequenom offers Further Clarification on the Scope of Patent-Eligible Subject Matter

WB Raich, AK Lipton and JM Jacobstein, Finnegan, 6-23-2015

- On June 12, 2015, the Federal Circuit issued its eagerly anticipated decision in *Ariosa v. Sequenom*, which assessed the subject matter eligibility of claims directed to a diagnostic method under 35 U.S.C. § 101. [U.S. Patent No. 6,258,540 (“the ‘540 patent”) directed to methods of non-invasively measuring cell-free fetal DNA (“cffDNA”) in maternal plasma and serum.] Despite the discovery of unique diagnostic benefits in what had formerly been considered waste material, the court affirmed the invalidity of the asserted claims of the ‘540 patent, explaining that “[w]here claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent-eligible subject matter if the methods [used to measure a sample] themselves are conventional, routine and well understood applications in the art.” *Ariosa* repeats the Supreme Court’s caution that “[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.” The decision adds to a spate of recent cases marking a shift in the law on patentable subject matter, a trend that started with the Supreme Court decisions in *Mayo v Prometheus*, *AMP v Myriad*, and *Alice v CLS Bank*. [the subject matter eligibility of natural products and phenomena]

# Ariosa v Sequenom offers Further Clarification on the Scope of Patent-Eligible Subject Matter

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- The technology at issue is non-invasive prenatal diagnosis of sex determination, blood typing, other genetic disorders (including Downs Syndrome) and detection of pre-eclampsia, using a simple blood test that reduces or eliminates the need for amniocentesis and chorionic villus sampling (which incur risks to both mother and child). Sequenom is the exclusive licensee of U.S. Patent 6,258,540 originally obtained by Isis Inc.
- Ariosa's argument was simple: the claims at issue **did not "add enough"** to a natural phenomenon (the existence of paternally derived cell-free fetal DNA in maternal blood) to render the claims patent eligible. Because the additional limitations "either apply well-understood, routine, and conventional activity to the natural phenomenon or limit the natural phenomenon to specific types of the natural phenomenon, which are also unpatentable" the claims do not recited patent eligible subject matter according to Ariosa.

# The differences Between Sequenom Case v Mayo Case

- **Like the case in Mayo**, Sequenom claimed methods are **applications of a natural phenomenon**, specifically a method for detecting paternally inherited cffDNA (PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997). The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. **The only subject matter new and useful was the discovery of the presence of cffDNA in maternal plasma or serum.**
- **Unlike the Mayo case**, the Sequenom did something not done before their invention (**detecting cffDNA in maternal blood**). In contrast, every step in the methods claimed in Mayo had been performed in the prior art; the only inventive aspect in those claims was the therapeutic ratio, which the Court found to be a "natural law." Accordingly, the Mayo claims did nothing more than recite the natural law. That is not the case here. **Tragically, the remainder of this portion of the opinion recites the tedious evidence from the specification regarding known amplification and detection methods while ignoring that these methods had never been used to detect cffDNA in maternal blood.**

# Take Home Messages

## The Court Tried to Strike a Balance?

- Too broad an interpretation of this exclusionary principle could eviscerate [remove the gut of] patent law. (Mayo v. Prometheus)
- All inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.
- A process is not unpatentable simply because it contains a law of nature or a mathematical algorithm. (Parker v. Flook)
- An application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection. (Diamond v. Diehr)
- The general rejection theme is “did not say/add enough” on things which is important as a patent – novel, useful to the humankind, non-obvious, unexpected, benefit to human discovery/invention (Ariosa v Sequenom)
- At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. (Alice v CLS Bank)

# The Confusion Continue...



- Ineligible Subject Matter + “Something”
- → “Different” → “Significantly Different”  
→ “Significantly More”
- Very similar to obvious determination [KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)]: TSM v GM Factors – scope, level of ordinary skill in the art, differences between the claimed invention and the current invention, “objective evidence” such as commercial success, long-felt but unsolved needs and failure of others, etc.
- Questions?
- Answers?
- Discussion?