

Patent Eligible Subject Matter – An Introduction to 35 U.S.C. §101

August 31, 2015



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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 therefore, subject to the conditions and requirements of this title.”

Requirements for Patentability

- Patentable Subject Matter
 - Utility
 - Judicially-recognized exceptions
 - *See Bilski, Myriad, Alice, etc.*
- Novelty
- Non-obviousness
 - *KSR Int'l Co. v. Teleflex Inc.*

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Key Principles of § 101 Patentability

- Invention must be a process, machine, article of manufacture, or composition of matter
- Exceptions: Laws of nature, physical phenomena, and abstract ideas are not patentable
 - But new and useful inventions derived from or that apply these exceptions may be patentable
- Must be an inventive element in addition to any underlying abstract idea
- Literary works, musical compositions, data compilations, and legal documents are not patentable

“Guidepost” § 101 Cases

- *Neilson v. Harford* (1844): English case involving circulation of heated air in a furnace system
 - Held: **patentable**
 - “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”
- *Gottschalk v. Benson*, 409 U.S. 63 (1972): Claims directed to a method for converting binary-coded decimal numbers into true binary numbers
 - Held: **not patentable**
 - “The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”

“Guidepost” § 101 Cases

- *Parker v. Flook*, 437 U.S. 584 (1978): Claims directed to methods for updating alarm limits
 - Held: **not patentable**
 - “The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. . . . The concept of patentable subject matter under § 101 is not ‘like a nose of wax which may be turned and twisted in any direction’”
- *Diamond v. Diehr*, 450 U.S. 175 (1981): Claims directed to a method for curing rubber using a mathematical formula
 - Held: **patentable**
 - “We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”

Funk Brothers Seed Co. v. Kalo Inoculant Co.
333 U.S. 127 (1948)

-
- Fig. 1.
- Fig. 2.
- Fig. 3.
- Fig. 4.
- DAVIDSON,
 Woolly Aconitum
 BY *Small, Chapman & Co.*
 ATTORNEYS.

The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the **storehouse of knowledge of all men. They are manifestations of laws of nature. Free to all men and reserved exclusively to none.**

Diamond v. Chakrabarty

447 U.S. 303 (1980)

- Claims directed to bacteria with foreign genetic material that gave it the capability of breaking down components of crude oil
- Held: **patentable**
 - Contrasted *Funk Brothers* – “Here . . . the patentee has produced a new bacterium with markedly different characteristics from any found in nature.”

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5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U. S. 1, 7-10 (1966). Subsequent patent statutes in 1890, 1870, and 1874 employed this same broad language. In 1932, when the patent laws were recodified, Congress replaced the word “art” with “process,” but otherwise left Jefferson’s language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to “include anything under the sun that is made by man.” S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).⁹

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See *Parker v. Flook*, 437 U. S. 584 (1978); *Gottschalk v. Benson*, 409 U. S. 63, 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 127, 130 (1948); *O’Reilly v. Morse*, 15 How. 62, 112-121 (1854); *Le Roy v. Tatham*, 14 How. 156, 175 (1853). Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.” *Funk*, *supra*, at 130.

Judged in this light, respondent’s micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity “having a distinctive name, character [and]

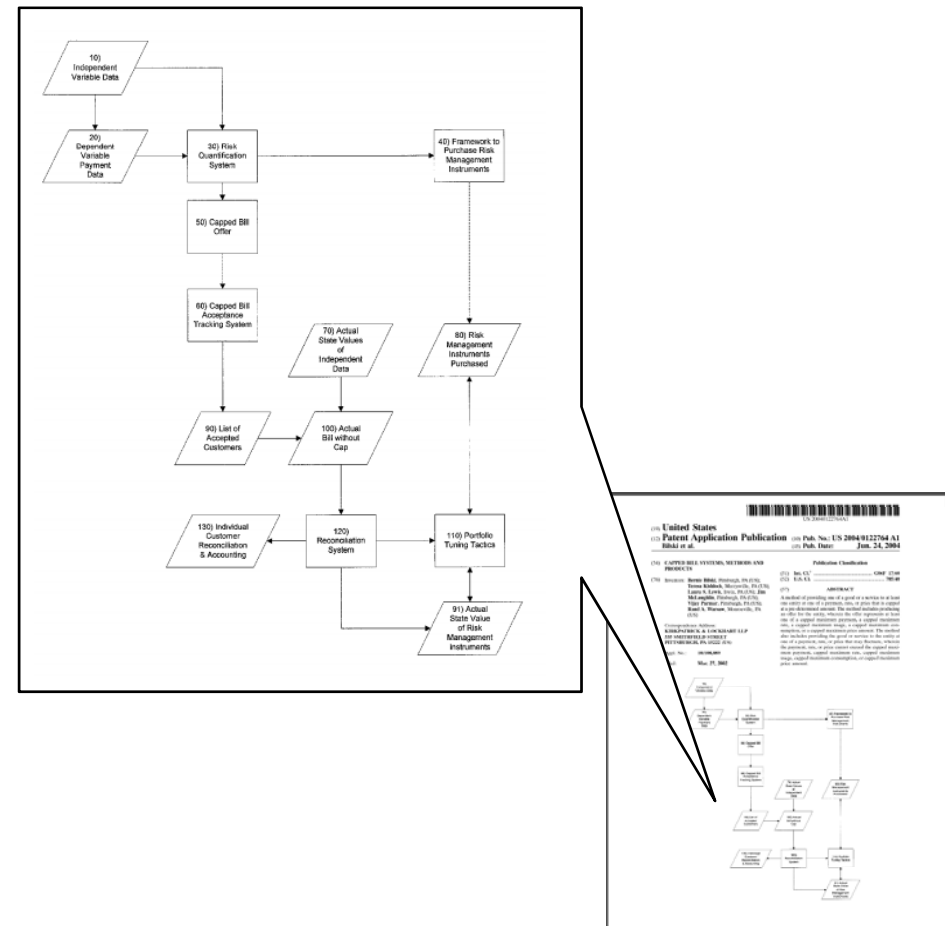
[Claim was] not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity “having a distinctive name, character, [and] use.”

⁹ This same language was employed by P. J. Federico, a principal draftsman of the 1908 recodification, in the testimony regarding that legislation: “[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. . . .” Hearings on H. R. 5700 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951).

Bilski v. Kappos

561 U.S. 593 (2010)

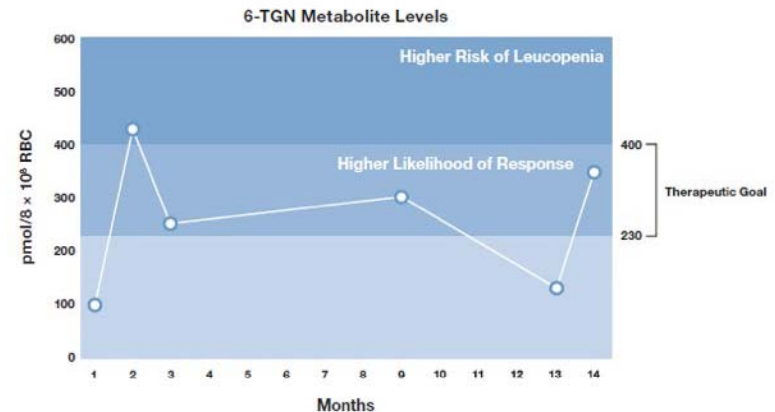
- Claims directed to methods for hedging risks for commodities trading
 - Held: **not patentable**
 - “[T]he machine-or-transformation test is a useful and important clue, an investigative tool, . . . [but] is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”



Mayo Collaborative Servs. v. Prometheus Labs., Inc. 132 S. Ct. 1289 (2012)

- Claims directed to a method of optimizing treatment of a gastrointestinal disorder, involving essentially two steps:

1. Administering a drug to a patient having a gastrointestinal disorder; and
2. Determining the level of the drug in the patient.



- Federal Circuit twice held (both pre- and post-*Bilski*) that the claims were patentable subject matter:
 - Claims satisfied the machine-or-transformation test
 - Claims did not preempt the use of a natural phenomenon

Prometheus: Supreme Court

- Held: **not patentable**
 - “[T]he claims inform a relevant audience about certain laws of nature”
 - Machine or transformation test doesn’t save the claims:

[I]n stating that the “machine-or-transformation” test is an “*important and useful clue*” to patentability, we have neither said nor implied that the test trumps the “law of nature” exclusion. That being so, **the test fails here.**

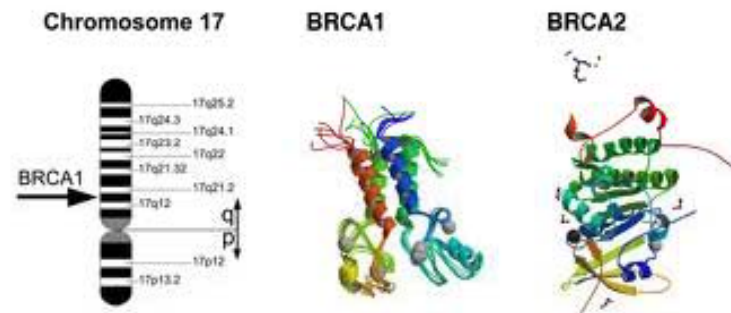
Cite as: 566 U. S. ____ (2012)
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to depart from case law precedent.
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We have considered several further arguments in support of Prometheus’ position. But they do not lead us to adopt a different conclusion. First, the Federal Circuit, in upholding the patent eligibility of the claims before us, relied on this Court’s determination that “[t]ransformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Benson*, *supra*, at 70–71 (emphasis added); see also *Bilski*, *supra*, at ____ (slip op., at 6–7); *Diehr*, 450 U. S., at 184; *Flook*, *supra*, at 588, n. 9; *Cochrane v. Deener*, 94 U. S. 780, 788 (1877). It reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels. 628 F. 3d, at 1356–1357.
The first of these transformations, however, is irrelevant. As we have pointed out, the “administering” step simply helps to pick out the group of individuals who are likely interested in applying the law of nature. See *supra*, at 9. And the second step could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation. See *supra*, at 18. Regardless, in stating that the “machine-or-transformation” test is an “important and useful clue” to patentability, we have neither said nor implied that the test trumps the “law of nature” exclusion. *Bilski*, *supra*, at ____ (slip op., at 6–7) (emphasis added). **That being so, the test fails here.**
Second, Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld. Thus, it encourages us to draw distinctions among laws of nature

Prometheus two-part framework:

1. Do the claims implicate an abstract idea or law of nature?
2. Do the claims add “significantly more” to make them patent-eligible?

Ass'n for Molecular Pathology v. Myriad Genetics, Inc. 133 S. Ct. 2017 (2013)

- Claims directed to two types of composition of matter claims:
 - Isolated DNA molecules encoding BRCA 1 polypeptides
 - Isolated DNA molecules have a specified sequence (cDNA)



- Patents also included claims for methods for screening potential cancer therapeutics and methods for detecting germline alterations in a BRCA 1 gene, but these were not at issue in the Supreme Court

AMP v. Myriad

- District Court found all claims were unpatentable
 - Isolated DNA is not patentable because it is not “markedly different” from native DNA
- The Federal Circuit twice held (both pre- and post-*Prometheus*) that the claims were patentable subject matter:
 - The gene composition of “isolated DNA” claims was patentable because isolated DNA molecules were not found in nature
- Supreme Court agreed to review patentability of composition of matter claims
 - Question presented: **Are human genes patentable?**

AMP v. Myriad: Supreme Court

- Supreme Court issued its opinion on June 13, 2013.
 - Held: Claims to isolated segments of naturally occurring DNA (e.g. genes) were **not patent eligible**
 - Unmodified DNA fell within the product of nature exception to § 101
- Important points:
 - Difference between “discovery” and “invention”
 - Severance of chemical bonds during isolation of DNA was irrelevant because it was not claimed
 - Past PTO practice of awarding gene patents received no deference
- But non-naturally occurring synthetic “complementary DNA” (cDNA) *is* patentable
 - Not a product of nature

AMP v. Myriad: Supreme Court

- “Discovery” versus “Invention”
 - Court analogized Myriad’s claims to those in *Funk Brothers* (combination of naturally-occurring bacteria) and distinguished the claims from those in *Chakrabarty* (creation of non-natural bacteria)

In this case . . . Myriad did not create anything. To be sure, it **found** an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. **Groundbreaking, innovative, or even brilliant discovery does not, by itself, satisfy the §101 inquiry.**

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BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad’s principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in *Chakrabarty* is central to this inquiry. Brief for Respondents 14, 23–27. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was “not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Id.*, at 309–310 (quoting *Hartranft v. Wiegmann*, 121 U. S. 609, 615 (1887); alteration in original). The *Chakrabarty* bacterium was new “with markedly different characteristics from any found in nature.” 447 U. S., at 310, due to the additional plasmids and resultant “capacity for degrading oil.” *Id.*, at 305, n. 1. **In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.**

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry. In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U. S. 127 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. *Id.*, at 128–129. The ability of the bacteria to fix nitrogen was well known, and farmers commonly “inoculated” their crops with them to improve soil nitrogen

AMP v. Myriad: Supreme Court

- Breaking the chemical bond to isolate a segment of DNA was not enough to confer patent eligibility on the isolated DNA molecule
 - Not claimed in the composition of matter claims

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subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome 17. See *Ibid.*⁵ The '473 and '492 patents contain similar language as well. See *id.*, at 854, 947. Many of Myriad's patent descriptions simply detail the "iterative process" of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought.⁶ See, e.g., *id.*, at 750. Myriad seeks to import these extensive research efforts into the §101 patent-eligibility inquiry. Brief for Respondents 9–10, 34. But extensive effort alone is insufficient to satisfy the demands of §101.

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims . . . do not rely in any way on the chemical changes that result from the isolation of a particular section of DNA.

Notwithstanding Myriad's repeated use of the phrase "present invention," it is clear from the text of the patent that the various discoveries are the "invention."

⁵Starting from a region on the long arm of human chromosome 17 of the human genome, 17q, which has a size estimated at about 8 million base pairs, a region which contains a genetic locus, BRCA1, which causes susceptibility to cancer, including breast and ovarian cancer, has been identified." *Ibid.*

⁶Myriad first identified groups of relatives with a history of breast cancer (some of whom also had developed ovarian cancer), because these individuals were related, scientists knew that it was more likely that their diseases were the result of genetic predisposition rather than other factors. Myriad compared sections of their chromosomes, looking for shared genetic abnormalities not found in the general population. It was that process which eventually enabled Myriad to determine where in the genetic sequence the BRCA1 and BRCA2 genes reside. See, e.g., *id.*, at 749, 763–775.

AMP v. Myriad: Supreme Court

- No deference to PTO's past practice of awarding gene patents on segments of naturally-occurring DNA
 - Congress had not endorsed this practice in legislation (unlike with certain issues involving plant patents)
 - The United States, as *amicus curiae*, opposed the practice



AMP v. Myriad: Supreme Court

- Claims to non-naturally occurring cDNA molecules are patent eligible
 - cDNA is sufficiently distinct from the DNA from which it is derived
 - Even though the cDNA nucleotide sequence may be “dictated by nature,” cDNA does not naturally occur – it is created by a lab technician

[T]he lab technician unquestionably creates something new when cDNA is made. . . . As a result, cDNA is not a ‘product of nature’ and is patent eligible under §101.



Cite as: 569 U.S. ____ (2013)
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been removed.” Brief for Petitioners 49. They nevertheless argue that cDNA is not patent eligible because “[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician.” *Id.*, at 51. That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a “product of nature” and is patent eligible under §101, except insofar as “very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.”

III

It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad’s patents “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.” 702 F. Supp. 2d, at 202–203, and are not at issue in this case.

Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that “[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are

⁹We express no opinion whether cDNA satisfies the other statutory requirements of patentability. See, e.g., 35 U.S.C. §§102, 103, and 112; Brief for United States as Amicus Curiae 19, n. 5.

AMP v. Myriad: Supreme Court

- Several potential issues not implicated by this case:
 - Method claims
 - For example: Innovative method of manipulating genes while searching for and isolating BRCA genes
 - New applications of knowledge gained about genes
 - For example: Process or system that uses a mutated BRCA gene to transform cell to make an improved cancer therapeutic screening tool
 - Patentability of DNA where the order of naturally occurring nucleotides has been altered
 - Possibly patentable because the specific order of these nucleotides would not occur in nature

CLS Bank v. Alice Corp.

- Claims directed to computerized methods and apparatuses for mitigating “settlement risk” by using a third-party intermediary
 - Both system and method claims were asserted



- District court invalidated both asserted system and method claims under § 101
 - Abstract idea of “employing an intermediary to facilitate simultaneous exchange of obligations in order to minimize risk”

CLS Bank v. Alice Corp. (Federal Circuit)

- Federal Circuit held in July 2012 that all claims are patentable (Linn, O'Malley) (Prost dissented)
 - “[I]t is not manifestly evident that a claim is directed to patent ineligible subject matter.”
 - Must be “the single most reasonable understanding”
 - Expressed concerns regarding the “abstractness...of the abstract ideas test”
 - In October 2012, Federal Circuit ordered *en banc* review
- In May 2013, a very divided *en banc* court found claims **not** patent-eligible
 - Court issued seven different opinions
- Supreme Court granted review in December 2013

Alice Corp. v. CLS Bank: Supreme Court

13-298 ALICE CORPORATION PTY. LTD. V. CLS BANK INTERNATIONAL

DECISION BELOW: 717 F.3d 1269

LOWER COURT CASE NUMBER: 2011-1301

QUESTION PRESENTED:

Whether claims to computer-implemented inventions-including claims to systems and machines, processes, and items of manufacture-are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by this Court?

CERT. GRANTED 12/6/2013

Alice Corp. v. CLS Bank

134 S. Ct. 2347 (2014)

- Supreme Court agreed with the Federal Circuit.
 - Claims relating to a computerized scheme for mitigating “settlement risk” were **not patent eligible** under §101
- Invalid based on two-part *Prometheus* test
 - (1) claims at issue were drawn to an abstract idea
 - (2) nothing in the claims included an inventive concept sufficient to transform the abstract idea into a patent eligible invention
- Generic computer implementation of the claims was insufficient to supply the necessary inventive concept
 - Both system and method claims were treated the same way

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

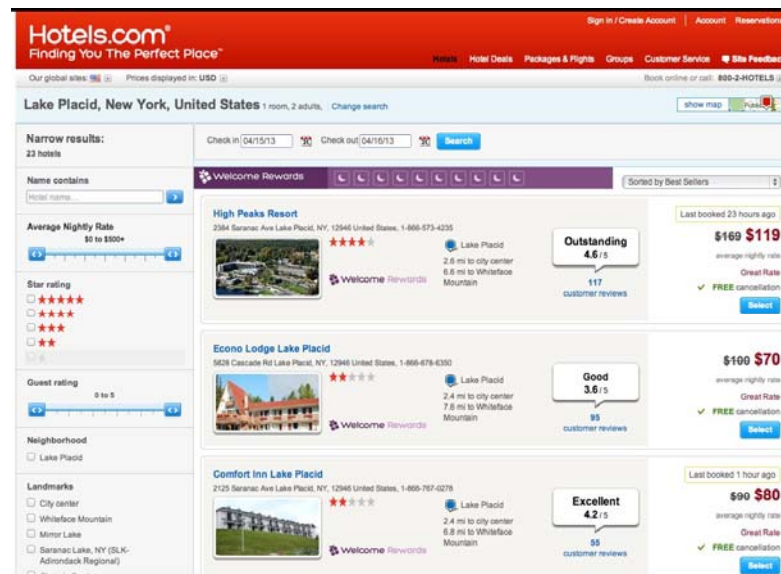
Takeaways:

- Software still patentable, but only barely
 - Non-preemptive, innovative detail must narrow claim scope
 - Claims directed to solving problems unique or inherent to computing more likely to be held patentable
- Pure business method patents using well-known, conventional technology likely ineligible
- Overlap in analysis between § 101 and §§ 102/103
 - But § 101 issues more easily resolved on summary judgment (or before)
- Two-part *Prometheus* test remains the standard



Subsequent Decisions

- Post-*Alice* Federal Circuit Decisions:
 - Almost all post-*Alice* Federal Circuit decisions have found claims at issue unpatentable under § 101
 - Only one Federal Circuit case held claims patentable
 - *DDR Holdings v. Hotels.com*, 773 F.3d 1245 (Fed. Cir. 2014)



Subsequent Decisions

- Post-Alice Federal Circuit Decisions:

- ✗ – Methods and systems for managing a game of Bingo
 - *Planet Bingo, LLC v. VKGS LLC*, 576 F. App'x 1005 (Fed. Cir. 2014)
- ✗ – Organizing information through mathematical relationships
 - *Digitech Image Techs., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344 (Fed. Cir. 2014)
- ✗ – Guaranteeing performance of online transaction
 - *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350 (Fed. Cir. 2014)
- ✗ – Computerized method for using advertising as an exchange or currency
 - *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014)
- ✗ – Composition of BRCA primers and Diagnostic methods for BRCA
 - *Univ. of Utah Res. Found. v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014)
- ✗ – Extracting/recognizing data from hard copy documents
 - *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343 (Fed. Cir. 2014)

Subsequent Decisions

- Post-Alice Federal Circuit Decisions:

- ✗ – Speech recognition interface

- *Allvoice Devs. US, LLC v. Microsoft Corp.*, No. 2014-1258, 2015 U.S. App. LEXIS 8476 (Fed. Cir. May 22, 2015)

- ✗ – Offer-based price optimization

- *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1358 (Fed. Cir. 2015)

- ✗ – Methods for detecting cffDNA to diagnose certain fetal characteristics

- *Ariosa Diagnostics v. Sequenom*, 788 F.3d 1371 (Fed. Cir. 2015)

- ✗ – Methods for retaining information lost in the navigation of online forms

- *Internet Patents Corp. v. Active Network, Inc.*, Nos. 2014-1048, 2014-1061, 2014-1062, 2014-1063, 2015 U.S. App. LEXIS 10536 (Fed. Cir. June 23, 2015)

- ✗ – Methods of tracking financial transactions and providing customized web page content

- *Intellectual Ventures I LLC v. Capital One Bank (USA)*, No. 2014-1506, 2015 U.S. App. LEXIS 11537 (Fed. Cir. July 6, 2015)

DDR Holdings v. Hotels.com

773 F.3d 1245 (Fed. Cir. 2014)

- Claims directed to a computerized method of generating composite web page with visual elements of host and third party
 - Similar to a “store within a store” concept
- Holding: **patentable**
 - “the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks”
 - The asserted claims “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.”

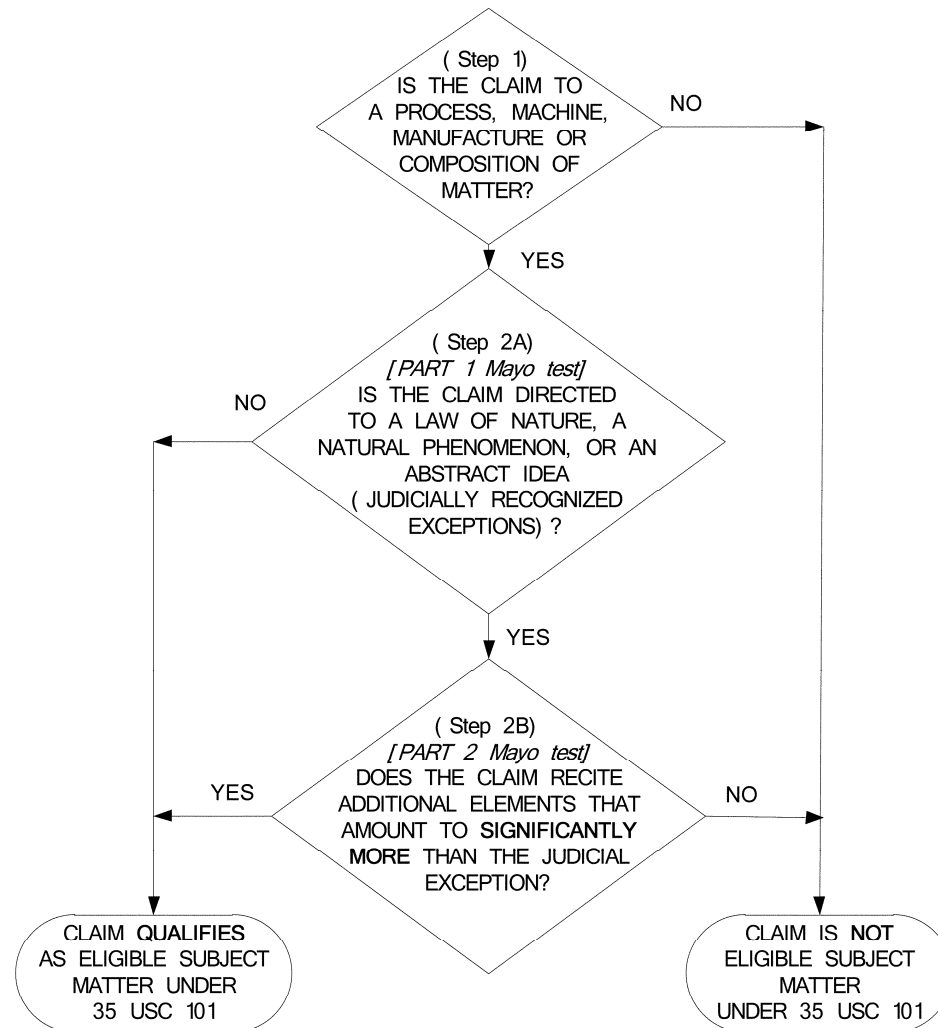
DDR Holdings v. Hotels.com 773 F.3d 1245 (Fed. Cir. 2014)

- Court was careful to warn that not all patents addressing “Internet-centric challenges” are patent-eligible
 - Contrasted *Ulramercial’s* advertising and content-distribution claims because the asserted *DDR* claims “do not broadly and generically claim ‘use of the Internet’ to perform an abstract business practice (with insignificant added activity).”
- **Takeaway:** Claims need not be incredibly technologically complex, but cannot merely recite commonplace business methods or processes
 - Many Federal Circuit and district court cases have cited and distinguished *DDR Holdings*
 - But a handful of district court cases have relied on it to uphold claims as patent-eligible

Drafting Patent Eligible Method Claims

- Drafters of method claims using a law of nature, natural phenomenon, or abstract idea must consider:
 - Applying routine and conventional methods – even to a pioneering discovery of a natural phenomenon – is likely not enough under step two of *Mayo*
 - What “new and useful” process steps would be sufficient to satisfy step two of *Mayo*?
- Consider December 16, 2014 USPTO Interim Guidance
 - Updated July 2015

PTO Framework For Claim Analysis



Applies to all claims
(product and process)
with a judicial
exception (any type).