

The Impact of § 101 on Pharmaceutical Patents: Supreme Court and Federal Circuit

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Impact on Pharma: Overview

Historical Perspective

Composition Claims

- Eligible if not naturally-occurring (*Myriad*)

Method Claims – 3 “Buckets”

1. **Diagnostic** (*Mayo; Ariosa*) – ineligible
2. **Treatment** (*Endo*) – often eligible
3. **Preparation** (*Illumina*) – often eligible

Historical Perspective: *Lab Corp.* (2006)

***Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124 (2006)**

- Foreshadowed *Mayo*.
- **Claims:** Method for “detecting” vitamin deficiency, by (1) “assaying a body fluid” to measure a level of an amino acid (homocysteine) and (2) correlating that [elevated] level to a particular vitamin deficiency.
- **Outcome:** Supreme Court granted cert, but later dismissed as improvidently granted. Three-Justice dissent from dismissal (Breyer, J., joined by Stevens and Souter, JJ.) sounds a lot like *Mayo*:
 - Claimed process was “no more than an instruction to read some numbers in light of medical knowledge.”
 - “[A]side from the unpatented test, [claims] embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable natural phenomenon’, and I can find nothing in claim 13 that adds anything more of significance.” *Id.* at 137-38.
 - Section 101 first raised in cert petition, not considered by district court or Federal Circuit.

Composition Claims

Standard:

- Eligible if “markedly different characteristics from any found in nature”—“a product of human ingenuity ‘having a distinctive name, character [and] use.’” *Ass’n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576, 590-91 (2013).

Example: *Ass’n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013)

- **Natural phenomenon:** Myriad discovered location and sequence of two breast cancer genes (BRCA1 and BRCA2), mutations of these naturally occurring genes dramatically increase risk of breast cancer. Myriad developed tests for detecting mutations to assess a patient’s cancer risk.
- **Claims:** Two types of DNA segments: (1) natural DNA isolated from the human genome, and (2) synthetically-created cDNA.
- **Holding:**
 - Isolated DNA not eligible – same genetic information as in naturally-occurring DNA; a product of nature and not a new composition “with markedly different characteristic from any found in nature”
 - cDNA eligible – not naturally-occurring

Bucket #1: Diagnostic Methods

Consistently ineligible.

- “Under *Mayo*, we have consistently held diagnostic claims unpatentable as directed to ineligible subject matter.” *Illumina v. Ariosa Diagnostics*, Slip Op. at 8 (Fed. Cir., August 3, 2020)(“This is not a diagnostic case. . . . It is a method of preparation case.”).
- “Since *Mayo*, we have held every single diagnostic claim in every case before us ineligible.” *Athena Diagnostics v. Mayo, LLC*, 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting from denial of rehearing en banc).

Standards:

- Ineligible if “claimed advance was only in the discovery of the natural law” and additional steps “only apply conventional techniques to detect that natural law.” *Athena Diagnostics v. Mayo*, 915 F.3d 743, *en banc reh’g denied*, 927 F.3d 1333 (Fed. Cir. 2019).
- Ineligible if method amounts to merely “an instruction to doctors to apply the applicable [natural] laws when treating their patients.” *Mayo v. Prometheus*, 566 U.S. 66, 79 (2012).

Bucket #1: Diagnostic Methods

Example: *Athena Diagnostics v. Mayo*, 915 F.3d 743 (Fed. Cir. 2019)

- **Natural law:** Inventors discovered correlation between naturally-occurring protein antibodies and certain neurological disorder.
- **Claims:** Method for diagnosing a neurological disorder by detecting the presence of antibodies to a protein associated with the disorder. No treatment step.
- **Holding:** Ineligible. Even though claims recited “specific” and “concrete” steps for detecting the antibody (immunoprecipitation), these were standard techniques applied in standard ways. Did not matter that they were used to newly detect a natural law.

See also, e.g. (all ineligible):

- *Mayo v. Prometheus*, 566 U.S. 66 (2012)
- *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363 (Fed. Cir. 2018)
- *Cleveland Clinic Found. v. True Health Diagnostics*, 859 F.3d 1352 (Fed. Cir. 2017)
- *Genetic Techs. v. Merial*, 818 F.3d 1369 (Fed. Cir. 2016)
- *Ariosa Diagnostics v. Sequenom*, 788 F.3d 1371, 1373 (Fed. Cir. 2015)

Bucket #1: Diagnostic Methods

***Athena Diagnostics v. Mayo*, 927 F.3d 1333 (Fed. Cir. 2019)(Lourie J., concurring in denial of rehearing *en banc*)**

- Rehearing is denied because court is bound by Supreme Court's decision in *Mayo*.
- . . .” [E]xception to patent eligibility, as respect natural laws, only claims directed to the natural law itself. . . .”
- “The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable.”

Bucket #2: Treatment Methods

Often eligible.

- “[W]e have held that method of treatment claims are patent-eligible.” *Illumina*, 967 F.3d at 1325.

Standards:

- Eligible if “directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome.” *Endo v. Teva*, 919 F.3d 1347, 1354 (Fed. Cir. 2019).
- Must be more than “observation or detection” of a natural phenomena. *Endo*, 919 F.3d at 1356.
- “[C]laiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law.” *Athena*, 915 F.3d at 753.

Bucket #2: Treatment Methods

Example: *Endo v. Teva*, 919 F.3d 1347 (Fed. Cir. 2019)

- **Natural law:** Inventor discovered patients with moderately or severely impaired kidney function need less oxymorphone than usual to achieve a similar level of pain management.
- **Claims:** Method to treat pain in patients with kidney impairment using lower, safer doses of oxymorphone.
- **Holding:** Eligible. The claims do more than just recognize a need to adjust a dosage; they use the natural correlation to prescribe a specific dosage to achieve a specific outcome.

See also, e.g.:

- *Boehringer Ingelheim Pharm. v. Mylan Pharm.*, 803 F. App'x 397 (Fed. Cir. 2020) (eligible)
- *Natural Alternatives Int'l v. Creative Compounds*, 918 F.3d 1338 (Fed. Cir. 2019) (eligible)
- *INO Therapeutics v. Praxair Distribution*, 782 F. App'x 1001 (Fed. Cir. 2019) (ineligible methods for treating respiratory failure by “excluding” certain patients based on natural law), *cert. denied*.
- *Vanda v. West-Ward*, 887 F.3d 1117 (Fed. Cir. 2018) (eligible), *cert denied*.

Bucket #3: Preparation Methods

Often eligible.

Standards:

- Eligible claim includes “specific” preparation steps “not dictated by any natural phenomenon.” *Illumina*, Slip Op. at 10-11.
- Eligible claim includes “physical process steps that change the composition of the mixture,” resulting in something “different from the naturally occurring” properties. *Id.* at 11.
- Mere amplification (“making more”) of a naturally occurring phenomenon is not enough. *Id.* at 12 (distinguishing *Ariosa*).
- Court applied the *Mayo/Alice* test.

Bucket #3: Preparation Methods

Example: *Illumina v. Ariosa Diagnostics*, (Fed. Cir., August 3, 2020)

- **Natural law:** Cell-free fetal DNA tends to be shorter than maternal DNA in mother's blood.
- **Claims:** Method for preparing mixture that increases proportion of fetal DNA to maternal DNA, which is more useful for genetic testing than naturally-occurring proportions. Claims recite physical steps of size discrimination and selectively removing larger DNA fragments.
- **Holding:** Eligible. Method utilizes natural law to prepare a composition that was different from the naturally-occurring composition.

See also, e.g.:

- *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) (eligible method of preparation claiming "improved process of preserving hepatocytes")
- *Am. Axle & Mfg. v. Neapco Holdings*, 939 F.3d 1355 (Fed. Cir. 2019), *opinion modified and superseded on reh'g*, 967 F.3d 1285 (Fed. Cir. 2020) (methods of manufacturing a drive shaft using a natural law to dampen vibrations; some ineligible; others not ineligible for using natural law but possibly abstract)