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Section 101: Life Sciences

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Three Lines of Cases

Products of Nature

- *Funk Bros.* (US 1948)
- *Chakrabarty* (US 1980)
- *Myriad* (US 2013)
- *Roslin Inst.* (FC 2014)
- *Bhagat** (FC 2018)
- *Nat'l Alternatives*** (FC 2019)

Laws of Nature

- *Mayo v. Prometheus* (US 2012)
- *Sequenom* (FC 2015)
- *Genetic Tech.* (FC 2016)
- *Cleveland Clinic* (FC 2017)
- *Roche v. Cepheid* (FC 2019)
- *Athena* (FC 2019)

Treatment Methods

- *Vanda* (FC 2018)
- *Nat'l Alternatives*** (FC 2019)
- *Endo v. Teva* (FC 2019)
- *INO Therapeutics** (FC 2019)

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- **Markedly Different Test**
 - structure, function, other properties
 - interaction between components, affect of one on another
 - change in structure, other than isolation/truncation (cDNA vs. fragment)
 - evaluated on what is expressly recited in claims

Products of Nature

- *In re Bhagat* (CAFC 2018) (non-precedential)

65. A lipid-containing formulation, comprising a dosage of omega-6 and omega-3 fatty acids at an omega-6 to omega-3 ratio of 4:1 or greater, **~~contained in one or more complementing casings providing controlled delivery~~** of the formulation to a subject, wherein at least one casing comprises an intermixture of lipids from different sources, and wherein

- (1) omega-6 fatty acids are 4–75% by weight of total lipids and omega-3 fatty acids are 0.1–30% by weight of total lipids; or
- (2) omega-6 fatty acids are not more than 40 grams.

“The Board found, and we agree, that the Applicant has not shown that the claimed mixtures are a “transformation” of the natural products, or that the claimed mixtures have properties not possessed by these products in nature.”

Products of Nature

▪ *Natural Alternatives* (CAFC 2019)

1. A **human dietary supplement**, comprising a beta-alanine in a unit dosage of between about 0.4 grams to 16 grams, wherein the supplement provides a unit dosage of beta-alanine.

D.Ct. had invalidated claims on judgment on the pleadings

CAFC gave weight to *Natural Alternatives*' proposed construction of "dietary supplement" as "an addition to the human diet ... which effectively increases athletic performance and is manufactured to be used over a period of time."

Natural Alternatives (continued)

Moore, Wallach:

"At this stage in the litigation, it has been sufficiently alleged that these characteristics provide significant utility, as the claimed dosage forms can be used to increase athletic performance in a way that naturally occurring beta-alanine cannot."

Reyna (dissenting-in-part):

Majority "relies on a claim construction that improperly imports limitations into the claims and is contradicted by the written description."

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"Section 101: High Tech v. Life Sciences"