

Courtenay C.  
Brinckerhoff,  
Partner

Foley & Lardner LLP

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# Section 101: Life Sciences

## Advanced Patent Law Institute



## 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)

# Products of Nature

- *Funk Bros.* (US 1948)
  - *Chakrabarty* (US 1980)
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  - *Bhagat\** (FC 2018)
  - *Nat'l Alternatives\*\** (FC 2019)
- **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- *In re Bhagat* (CAFC 2018) (non-precedential)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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15<sup>th</sup> Annual Advanced Patent Law Institute session

"Section 101: High Tech v. Life Sciences"