

KING & SPALDING

Subject Matter Eligibility Forum:
Application of March 4, 2014 Guidance to
Small Molecules

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Guidance: Small Molecules – Amazonic Acid

- Claim 1. Purified amazonic acid.
- Claim 2. Purified 5-methyl amazonic acid. (Not Natural)
- Claim 3. A method of treating colon cancer, comprising: administering a daily dose of purified amazonic acid to a patient suffering from colon cancer for a period of time from 10 days to 20 days, wherein said daily dose comprises about 0.75 to about 1.25 teaspoons of amazonic acid.

Guidance Amazonic Acid Example Leaves Large Gaps in Protection

- No Pharmaceutical Composition Claims
 - May be too narrow if pharmaceutically acceptable carrier must impart “significant difference”
 - phosphate buffered saline
- Method claim
 - Limited to single indication
 - Multiple limiting elements
 - 10 to 20 days and 0.75 to 1.25 teaspoons allow for avoidance of infringement with immaterial changes

USPTO Guidance Analysis of Claim 1

- “...the claim as a whole does not recite something significantly different than the natural product, e.g., the claim does not include elements in addition to the judicial exception that add significantly more to the judicial exceptions, and also does not include features that demonstrate that the recited product is markedly different from what exists in nature.”
- “Factor a) is not satisfied, because there is no structural difference between the purified acid in the claim and the acid in the leaves.”
 - But is the claim “as a whole” being analyzed?
 - Claim to “amazonic acid” is different from claim to “purified amazonic acid.”
 - “Purified” is a claim element and must be given plain meaning or its meaning based on the specification
 - Purified amazonic acid does not exist in nature.

Purified Product Claims Provide Best Protection

- 1) Covers product in most purified forms
- 2) Covers any indication including off-label and other approved uses
- 3) Covers product from any source – may be impractical to make commercial amounts from natural source
- 4) Covers product purified from potentially toxic impurities
- 5) Purified form allows for practical formulation and dosage forms
- 6) Allows for patent protection while obtaining data to support method of treatment claims, or possibly pharmaceutical composition claims

USPTO 2001 Utility Guidelines Provides Basis for Purified Natural Product Claims

- *“Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice.* For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming “[y]east, free from organic germs of disease, as an article of manufacture.” Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: *“even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.”* *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).”

Many Examples of Patented Purified Natural Product Therapeutics

- Natural Products obtained from a variety of sources including microorganisms, plants, marine organisms, organ tissue (historical) having activity for oncology, infectious disease, cardiovascular disease, and others. Some historical examples include:
- Adrenaline: U.S. Patent No. 730, 176 (1903)
- Digitalis: U.S. Patent No. 1,898,199 (1933)
- B₁₂: U.S. Patent No. 2,563,794 (1951)
- Vinblastine: U.S. Patent No. 3,097,137 (1963)
- Doxorubicin (adriamycin): U.S. Patent No. 3,590,028 (1971)
- Many more: See, D.J. Newman et al., “Natural Products as Sources of New Drugs over the Period 1981-2002”, *J. Nat. Prod.*, 66:1022-1037 (2003).

Myriad addresses claims to genes and their information

- *“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.”*

“...the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.”

Myriad’s claim *“is concerned primarily with the information contained in the genetic sequence, not with specific chemical composition of a particular molecule.”*

“Judge Lourie found this chemical alteration to be dispositive, because *isolating a particular strand of DNA creates a nonnaturally occurring molecule, even though the chemical alteration does not change the information-transmitting quality of DNA.*”

Myriad holding limited to Genes

- “We merely hold that *genes and the information they encode are not patent eligible under §101* simply because they have been isolated from the surrounding genetic material.”

Past Supreme Court Precedent Allows for Claims to Purified Natural Products - *Chakrabarty*

- *Diamond v. Chakrabarty* - 447 U.S. 303 (1980)
 - Purified natural products have characteristics of a “manufacture or composition of matter”
 - produced from “raw materials”
 - purified product exists in a new form –organism vs purified product
 - Purified product has new properties and uses – useful as therapeutic, available in useful concentrations without other substances

Chakrabarty's Reliance on Funk Brothers Seed Also Applies to Therapeutic Purified Natural Products

- *"No species acquires a different use.* The combination of species produces no new bacteria, no change in the six species of bacteria, and *no enlargement of the range of their utility.* Each species *has the same effect it always had.* The *bacteria perform in their natural way.* Their use in combination does not improve in any way their natural functioning. *They serve the ends nature originally provided, and act quite independently of any effort of the patentee.*"
 - Therapeutic uses of natural products is result of purification
 - Organism often has no or impractical use as therapeutic – may be toxic
 - Purified product administered in new environment achieves new effects having activity/function different from that in its natural environment
 - Function as therapeutic unrelated to function in nature

Supreme Court Argument in *Myriad* Addressed Purified Products Generally, but Limited Decision to Genes

- Colloquy between the Court and counsel repeatedly addressed the hypothetical chemical from a plant that grows in the Amazon that is discovered to treat cancer.
- Counsel for Petitioner stated the purified product may be eligible for a patent:
 - “MR. HANSEN: No, that may well be eligible, because you have now taken what was in nature and you've transformed it in two ways. First of all, you've made it substantially more concentrated than it was in nature; and second, you've given it a function. If it doesn't work in the diluted form but does work in a concentrated form, you've given it a new function. And the -- by both changing its nature and by giving it a new function, you may well have patent – “
- Despite colloquy which could have been basis for broader holding, *Myriad* limits itself to DNA.

THANK YOU