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Natural Products and Unnatural Law

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The following remarks are provided for educational purposes and are not intended to address any specific legal matter. They represent the views of the author and not necessarily the views of the firm or any of its members (although I hope they do).

“Markedly Different”

- PTO: A “Marked Difference is a Significant Difference”…
- Between what is claimed and what is a “natural product.”
- Do the identified differences rise to the level of a “marked difference in structure?”
- But before this test can be applied, we must settle on a definition of “natural product” and “non-naturally occurring product.”

What is a "Natural Product"?

- Legally, it is a subgenus of "phenomena of nature" which in turn is a subgenus of "laws of nature". Chakrabarty says "non-naturally occurring …composition of matter" and gives examples.
- Myriad is one of the only recent cases to apply the judicial exception of "natural product".
- Although Chakrabarty defined "composition of matter" very broadly, in Myriad, the Court said the claims were not expressed in terms of "chemical composition" nor did they rely on "chemical changes". (So how can they claim "natural products"?)

The Real Holding: No "Composition of Matter" Claims--Literally.

- Even though the location of the genomic sequences encoding BRACA 1 and 2 had been identified, claiming them ("A that encodes B") focusses only on "the genetic information encoded thereby".
- Myriad simply discovered where the genes were located.
- Myriad did not create any "new compositions of matter."
- Once "discovery" was invoked, Court cited Funk Bros, which treated claims to an "inoculate" mixture of bacteria as barred by the phenomenon of nature exception. In fact, the composition of matter claims were not rejected as directed to "natural products", but as "not the product of invention". (No more than an advance in packaging.)
- Dissent would have found failure to meet today's WDR.

So What is a "Non-Naturally Occurring Product"?

- If Myriad did not involve claims to "new compositions of matter" even if "isolation" was involved, where can we look for guidance?
- In the Fed. Cir.'s Myriad I or II opinions below, Judge Lourie stated: "While purified natural products thus may or may not qualify for patent[s] under s. 101, the isolated DNAs of the present patents [fall under Chakrabarty]". He noted that Parke-Davis involved an unchanged molecule that was for "every practical purpose a new thing…."

Even AMP's Attorney conceded that point(!)

- In the Myriad oral argument, Mr. Hanson was asked by Justice Alito if an anti-cancer chemical in the leaf of an Amazonian tree that needed to be "extracted and reduced to concentrated form" would be patent-ineligible if it was structurally unchanged.
- Mr. Hanson replied that if concentration were needed to make the chemical work as a drug, "[It] well may be patent eligible."

The USPTO Jumps In!

- "What were they thinking?"
- The Guidelines require both that the claimed compound be "non-naturally occurring" and "markedly different in structure from naturally occurring products" to be patent-eligible.
- Neither Myriad, Mayo nor Funk Bros. define "natural product", much less a "markedly structurally different, non-naturally occurring product."

In re Bergy (II)

- 596 F.2d 952 (CCPA 1979)(Pure culture of bacterium producing antibiotic is not a natural product.)
- In the Fed. Cir. Myriad opinions, Judge Lourie did not rely on the "purified natural products" case law including Bergy, but he could have.
- Bergy was vacated by the S. Ct. when it took up Chakrabarty as moot, but the same questions were presented – was the claimed bacterium a patent–eligible manufacture or composition of matter, or was it excluded because it was "living", "naturally occurring", or a "hitherto unknown natural phenomenon"? (444 U.S. 1028).
- Bergy has been extensively cited as precedent ever since.

"Markedly Different"

- Is a term used in Chakrabarty, in a para. contrasting the inoculants in Funk Bros.:

  > "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility."

- These "characteristics" were due to extra plasmids in Chakrabarty's bacterium, but there was no language disparaging Bergy, or requiring structural alterations.
- The Bergy cultures would meet this language.

But the questions remain…

- Is the invention naturally-occurring, e.g., a "natural product" or not?
- If it is not, it still must be markedly different in structure from naturally occurring products.
- While Chakrabarty's oil-eating bacterium was "markedly different", what does that test mean for other inventions?
- Does "markedly different" mean structurally unobvious?
- Are unexpected results relevant in the inquiry?

In re Bergstrom

- 427 F.2d 1394 (CCPA 1970)(Pure prostaglandins patentable in view of impure extracts).
- In Myriad I and II, Judge Lourie dismissed Bergstrom as decided under s. 102., but the court reversed both s. 102 and s. 101 rejections:

"The Board and the solicitor seem to have taken an affirmative view [that a reference disclosing an impure form of a compound can support a rejection both under s. 101 and s. 102]…The sole issue it accurately posed [is] 'whether the claimed pure materials are novel as compared with the less pure materials of the reference' It seems to us that…by definition, pure materials necessarily differ from less pure or impure materials and, if the latter are the only ones existing and available as a standard of reference…perforce the 'pure materials' are new with respect to them."

In summary:

- Myriad and Mayo (much less dicta in Chakrabarty discussing Funk Bros.) do not provide sufficient rationale to depart from about a century of practice that culminated in Bergy.
- "Natural product", "markedly different" and "significantly different" have not been adequately defined by case law or Congress.
- This "Guidance Memorandum" is disruptive, regressive and should be withdrawn.

Thank you for your consideration

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