The *AMP v. USPTO* Remand: Déjà Vu as Federal Circuit Majority Reaffirms that Myriad's Isolated DNA Sequences Are Patent-Eligible*

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In a two to one decision, a federal appeals court once again reversed a lower court's ruling in a case challenging patents on isolated DNA sequences from two human genes associated with hereditary breast cancer and ovarian cancer.

So guess what happened in the *AMP* remand? It was a repeat of the first Myriad decision with the same two-to-one majority ruling, for essentially the same reasons. The *AMP* remand decision also held that the 1980 decision in *Diamond v Chakrabarty* (not *Mayo Collaborative Services*) controlled on the patent-eligibility of the claimed isolated DNA sequences. See Chakrabarty Controls on Isolated DNA Sequences, not Mayo* .

With three notable exceptions to be discussed below, what the final outcome was and by what vote is summarized below:

1. Claimed isolated DNA sequences are patent-eligible under 35 U.S.C. § 101. Judges Lourie and Moore said "yea," Judge Bryson again said "nay."

2. Claimed cDNA (i.e., depicting the coding region for the nucleotide sequence of the BRCA1 DNA) are patent-eligible under 35 U.S.C. § 101. Judges Lourie, Moore and Bryson all said "yea."

3. Claimed method for screening potential cancer therapeutics using transformed eukaryotic host cell containing an altered BRCA1 gene are patent-eligible under 35 U.S.C. § 101. Judges Lourie, Moore and Bryson all said "yea."

4. Claimed methods directed to "comparing" or "analyzing" DNA sequences are patent-ineligible under 35 U.S.C. § 101. Judges Lourie, Moore and Bryson all said "yea."

It is important to note what Judge Lourie said the appeal in the *AMP* case was not about, and especially what it really is about:

> "Before reviewing the applicability of the Supreme Court's *Mayo* holding to the claims of the Myriad patents, however, it is important to state what this appeal is not about. It is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the

> patents. The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, *i.e.*, to exclude others from practicing the patented subject matter. It is also not whether the claims at issue are novel or nonobvious or too broad. Those questions are not before us. It is solely whether the claims to isolated BRCA DNA, to methods for comparing DNA sequences, and to a process for screening potential cancer therapeutics meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*. The issue is patent eligibility, not patentability."

How refreshing! After all of the disingenuous rhetorical nonsense spewed by the ACLU, PubPat, and others as to what the *AMP* case is supposedly about, it's good to hear that Judge Lourie hasn't lost sight of what this appeal is really about: patent-eligibility under 35 U.S.C. § 101, not patentability under 35 U.S.C. §§ 102 or 103. It is also not about whether the defendants (i.e., University of Utah or Myriad) should/could have acted differently in "licensing or enforcing" their patent rights, and especially not about whether it's good from a policy standpoint "for one company to hold a patent or license covering a test that may save people's lives."

As Judge Lourie also pointed out, "disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress," not to the courts, be it the Federal Circuit or the Supreme Court. In support, Judge Lourie cited to the recent Obamacare case (*National Federation of Independent Businesses v. Sebelius*) for why isolated DNA which is otherwise a man-made composition of matter should not be treated differently for patent-eligibility purposes under 35 U.S.C. § 101 just because it conveys "genetic information." Indeed, Judge Lourie importantly observed that "Congress is presumed to have been aware of the issue, having enacted a comprehensive patent reform act [i.e., the America Invents Act] during the pendency of this case, and it is ultimately for Congress if it wishes to overturn case law and the long practice of the PTO to determine that isolated DNA must be treated differently from other compositions of matter to account for its perceived special function." That "Congress was aware of the issue and did nothing" when enacting the America Invents Act during the pendency of the *AMP* case is completely consistent with Congress' intent not to change "the longstanding practice of the PTO and the courts" that isolated DNA sequences were patent-eligible under 35 U.S.C. § 101.

A final point that bears repeating (and quoting) from the majority opinion in the *AMP* remand is Judge Lourie's response to the so-called "preemption" question:

> "Plaintiffs argue here that they are preempted from using the patented DNA molecules. The answer to that concern is that permitting patents on isolated genes does not preempt a law of nature. A composition of matter

> is not a law of nature. Moreover, as indicated earlier, a limited preemption is inherent in every patent: the right to exclude for a limited period of time."

Preemption" really isn't a patent-eligibility question under 35 U.S.C. § 101. Instead, "preemption" is really a question of "written description," and especially "enablement," under 35 U.S.C. § 112, first paragraph (and potentially "definiteness" under 35 U.S.C. § 112, second paragraph). As Judge Lourie correctly observes, some "preemption" is inherent in every patent, no matter how broad (or narrow) the patent claim scope is. And unlike trade secret rights which may potentially exist in perpetuity, any such patent "preemption" is further limited in time, i.e., by the 20 year term (from filing date) of the patent.

It can only be hoped that an en banc Federal Circuit, and potentially the Supreme Court, will heed Judge Lourie's warning about leaving "policy questions" to Congress, and not allow the ACLU, PubPat (and others) to further obfuscate what the real question to be decided in the *AMP* case is. It also can only be hoped that these courts will decide that question based on a proper understanding of the claimed subject matter, as well as the applicable law, and not some inapt "plucking a leaf" or "magic microscope" analogy.