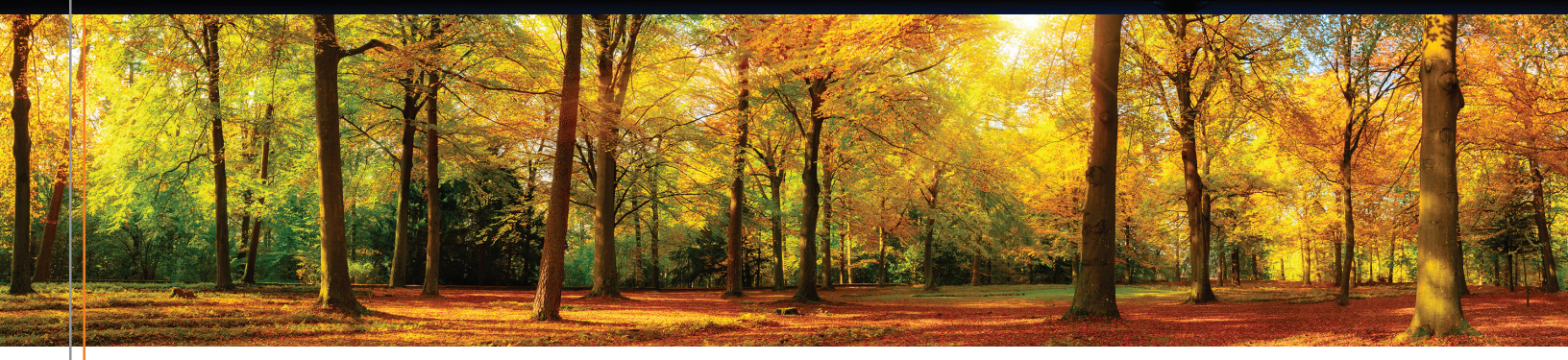
UNITED STATES

BioPharma Patents

QUICK NEWS & PRACTICE TIPS



Diagnostic Method Claims in the U.S.

I. Let's recap the last five years!

- ***Mayo* (2012) =** Supreme Court prohibits patents for diagnostic methods without "significantly more" (essentially, you must not only discover a meaningful diagnostic correlation, but also invent a new detection method, such as a new antibody or array technology).
- ***Myriad* (2013) =** Supreme Court prohibits patents for naturally occurring, "isolated" genes, but human-made DNA (*e.g.*, cDNA) is patent eligible.
- ***Alice* (2014) =** Supreme Court restates Mayo as a 2-part test used now for patent eligibility (step 1, is the claim "directed to" an abstract idea or law of nature?; step 2, if so, is there "something significantly more" than the abstract idea or law of nature?).
- ***Ariosa* (2015) & Genetic Tech. (2016) =** Court of Appeals for the Federal Circuit (CAFC) enforces *Mayo's* prohibition against patents for diagnostic methods, no matter how serious the disease or how significant the advance in diagnostic accuracy or convenience.
- **May 2016:** USPTO releases a new set of training materials that suggest possible ways to claim diagnostic methods that the USPTO will allow (although it remains an open question whether those claims would stand up in court if asserted).
- ***Cleveland Clinic* (June 2017):** CAFC hints that while diagnostic methods are not patentable, a claim to a method of treatment might be eligible, even if the difference between the claimed treatment method and prior art treatment methods lies in a diagnostic method step practiced before administration of the prior art treatment.
- **July 2017:** USPTO releases a report on subject matter eligibility. The report concludes that there is a lot of discontent with the state of the law, but no concrete solutions to resolve the known problems. Legislative change is required in the U.S.

II. Do I have a chance of getting a biomarker/diagnostic method claim to allowance in the U.S.?

1. Avoid words referring to mental processes in the claims (such as "comparing," "diagnosing," or "establishing"). The May 2016 USPTO training materials compare two hypothetical claims, where both claims recite identical method steps, except that one claim has one more step than the other—a "diagnosing" step. The claim with three steps (including the "diagnosing" step) is ineligible, while the claim with only two steps is eligible.

2. Focus the claim on treatment rather than diagnosis. Recite the essential steps of the diagnostic method, and then add a final step of "administer a treatment." Be careful, this strategy may result in a patentable claim, but enforcing it can be complicated if there is one entity that does the diagnosis, and another that does the treatment. *Make sure there is one infringer who performs all steps* (e.g. the doctor), and then pursue induced and/or contributory infringement. *Consider limiting the subject in the claim as one having a certain biomarker level.*

3. Consider claiming a complex or bi-product of detecting the biomarker—not the biomarker itself. For example, if the biomarker is a protein that is detected with a particular antibody, try claiming the complex of protein and antibody together. Similarly, if the biomarker is a nucleotide sequence, consider claiming an amplification product *stained with ethidium bromide, or tagged with biotin.* Think about human-made constructs that will agglomerate to the biomarker during detection, and then claim the complex of *natural* biomarker + *synthetic* detection structure.

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