BioPharma Patents Quick Tips and News-May/June 2014

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By: Leanne M. Rakers

QUICK TIPS

35 U.S.C. 112 TIPS:

1) **Does your U.S. Examiner assert that not enough representative species are described in the specification?** MPEP §2163. II.A.3(a)(ii) says that "[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species…" Although the word "may" implies that there are other ways to satisfy the requirement, the quoted portion of the MPEP does not specify any. *AbbVie v. Janssen Biotech*, 2014 WL 2937477 (Fed. Cir. 1 July 2014) helpfully reaffirms that one can also resolve a written description rejection by pointing to a description in the specification of "structural features common to the members of the genus…" (slip op. at 22).

2) **Consider including at least one independent claim that has no functional limitations.** At most, functional claim limitations will only survive challenge if there is a well-known correlation between the claimed function and some structure (addressed in *AbbVie*). Also, where functionally claiming a genus, describe as many species as possible within the genus to show support for achieving the claimed function, per *AbbVie*.

3) **Make sure to fully describe intermediate scope genus claims in addition to broad scope genus claims and species.** Many times an intermediate scope genus is needed and important for protection if the broad scope

QUICK NEWS

1. THREE U.S. SUPREME COURT PATENT CASES!

a) **More on U.S. patent eligibility**: On 19 June 2014, *Alice Corp. v. CLS Bank*, 110 U.S.P.Q.2d 1976 (U.S. 2014) held that the "significantly more" requirement from *Mayo v. Prometheus* applies just as much to "abstract ideas" as to "laws of nature." The USPTO had already issued updated examination guidance (dated 4 Mar 2014) to govern analysis of "natural products" and "laws of nature" *post-Mayo/Myriad*. The USPTO has now issued additional interim guidance (25 June 2014) to extend the Mayo analytical framework to the abstract ideas exception (regardless of whether the claims at issue claim "process" or "apparatus").

b) **A new indefiniteness standard:** On 2 June 2014, *Nautilus Inc. v. BioSig Instruments*, 134 S. Ct. 2120 (2014) held that "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." The test for indefiniteness has changed from "insolubly ambiguous" to "reasonable certainty." The court discussed that definiteness should be assessed from the perspective of one of ordinary skill at the time of application filing—not at the time of litigation.

c) **Joint infringement (and effect on diagnostic method claims)**: On 2 June 2014, *Limelight*

genus is later found invalid. Also, *AbbVie* holds that if a chemical genus claim embraces an allegedly infringing species, but the specification does not describe the structural features of the species, then the claim is not supported by an adequate written description. Intermediate scope genus claims might still survive to be asserted later, however, even if a broad genus is struck down for inadequate written description under *AbbVie*.

4) When claiming properties, give clear, definite instructions in your specification on how to determine the relevant properties.

5) Maximize the value of your dependent claims. Consider adding dependent claims that obviate any potential indefiniteness argument against your independent claim, but also contain meaningful claim limitations.

6) Try to resolve 112 issues in Examiner interviews to control the file history of your U.S. application.

Networks v. Akamai Tech., 134 S. Ct. 2111 (2014) held a method patent is not infringed unless a single actor performs all steps. Inducement (indirect infringement) can occur "if, but only if," there is direct infringement. **Best practice tip:** draft claims from the perspective of a single actor and eliminate steps that can be avoided by the single actor. For a diagnostic method claim, for example, consider using: "obtaining a result from a biomarker assay" and "treating based on the result." Now there is a single actor (*i.e.* the physician) directly infringing. Pursue the diagnostic test lab for induced infringement.

2. **Obviousness-type Double Patenting (OTDP):** On 22 April 2014 the Federal Circuit held that a patent that expires before an earlier-issued patent can still qualify as a double patenting reference for that earlier-issued patent. The new rule is that "the earliest expiration date of all the patents an inventor has on his invention and obvious variants" should be used for the OTDP analysis. *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 110 U.S.P.Q.2d 1551 (Fed. Cir. 2014).