FEDERAL CIRCUIT SUMMARY FOR WEEK ENDING NOVEMBER 29, 2019

***Merck Sharp & Dohme Corp. v. Wyeth LLC.*, No. 2018-2133 (November 26, 2019) (nonprecedential); Patent No. 8,562,999**

Key point(s):

- The Board must make findings of relevant facts, and present its reasoning in sufficient detail so that the court may conduct a meaningful review of agency action.

Facts/Background: The '999 patent (owned by Wyeth) is directed to formulations for stabilizing polysaccharide-protein conjugate vaccines. The '999 patent claims a formulation that inhibits silicone-induced aggregation by suspending the polysaccharide-protein conjugate in a mixture of (1) a pH buffered saline solution and (2) an aluminum salt. Merck filed two petitions for *inter-parties review* with the Board. In each proceeding, the Board instituted trial and found all the challenged claims in the '999 patent unpatentable except for one – dependent claim 18. Merck then appealed the Board's decision that claim 18 was patentable. Wyeth did not appeal the finding that the other claims were unpatentable.

Holding: Vacated and remanded. Merck agued on appeal that the Board's decisions fail to provide a reasoned basis for upholding claim 18 and the Federal Circuit agreed. Claim 18 depends on claim 1 which recites a solution containing a pH buffered saline solution, an aluminum salt, and polysaccharide-protein conjugates. Claim 18 adds that the protein conjugates comprise 13 different serotype polysaccharides conjugated to a CRM_{197} polypeptide. The Board found that although a prior art reference disclosed the 13 different polysaccharides, Merck did not provide a reason that a person of skill in the art would have modified the formulation in the prior art to comprise the 13 polysaccharides since the prior art reference did not show that such a formulation was even considered, tried and successful. The Federal Circuit held that, standing alone, this finding is insufficient to support a lack of motivation or a reasonable expectation of success since obviousness, unlike anticipation, does not require successful formation, and in this case, there was conflicting evidence as to motivation and reasonable expectation of success that the Board did not address. One of the studies cited in the prior art reference taught a 9-valent version of the vaccine as being conjugated to only the single CRM_{197} carrier. Further, another prior art reference disclosed that the CRM_{197} polypeptide as a particularly preferred carrier protein. Further, the Board declined to rely on a prior art memorandum stating CRM_{197} would be the only carrier protein for the 13-valent version of the vaccine, opining that the memorandum was cumulative to previously submitted evidence. The Federal Circuit held that a better explanation was particularly necessary given the Board's finding that the use of CRM_{197} was obvious with the 7-valent conjugate in claim 17—which also uses CRM_{197} as a sole carrier protein. The Federal Circuit concluded that the Board's decision was too cryptic to survive judicial review.