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Sequenom Files Petition for Cert. After Invalidation of Cff Patent

Article By:

Sequenom, the loser in "***Ariosa***," has filed a petition seeking ***Supreme Court*** review of the Fed. Cir.'s invalidation of the claims of US Pat. No. 6,258,540 as an attempt to claim a natural product, cffDNA. While there is no dispute among the commentators that this decision was flat-out wrong, the majority of the panel seemed to agree that it was compelled by the "Mayo/Alice Rule" (after they spotted the natural product, cffDNA, and ignored the other claim steps as conventional). (A copy of the Petition can be found at the end of this post.)

As previously noted by me, this is not a great case to settle the issue of whether or not claims based on biomarkers are patent-eligible. All of the claims on appeal, except for claim 21, are simply directed to methods for detecting cffDNA in a maternal serum or plasma sample. These claims are as patentable as a method of testing transgenic potatoes for the level of the precursor to acrylamide – a carcinogen that you do not want in your chips. The claim is a method claim, even if the precursor enzyme is a natural product. Even the ACLU in Myriad argued that, while a new method of mining gold would be patentable subject matter, a gold nugget is not.

The important claim to those of us trying to get valid diagnostic claims allowed is claim 21, which starts out "A method of performing a pre-natal diagnosis, which method comprises the steps of:…(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the fetal nucleic acid (that is detected in sub-part (iii)). However, even if "a diagnosis" is limited to a pre-natal diagnosis, this is a broad claim. Should the Supreme Court grant cert., would it save a claim that covers all diagnostic uses of an "old" compound, even if this is a new use for a known compound – a claim type the Court endorsed in dictum? The Fed. Cir. did not reproduce or specifically discuss claim 21, but, rather, reproduced claim 25, which starts out "A method for performing a prenatal diagnosis" but has no diagnostic step recited in the body of the claim. The panel did not discuss claim 21 at all but continued to argue that the claims were simple isolation methods.

I would like to see the Court address the patent-eligibility of a diagnostic test for a single condition based on the level of an isolated, purified product-of-nature (e.g., claim 17 of the '540 patent which is not on appeal and, anyway, is a statement of intended use).

Hal Wegner has opined that there is no reason for the Supreme Court to grant cert., since there is no conflict in either the Court's precedent or in that of the lower courts. Whether or not cert. is granted,

Ariosa seems like pretty shaky legal ground to defend at this point.

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