



CareDx v. Natera: Cooked by Boilerplate

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On July 18, the U.S. Court of Appeals for the Federal Circuit issued a precedential decision invalidating yet more patents directed to diagnostic methods.

The case was [CareDx, Inc. v. Natera, Inc.](#), No. 2022-1027 (Fed. Cir. July 18, 2022), and the patents at issue related to methods for diagnosing or predicting organ transplant status using various methods to determine the presence of a donor's cell-free DNA (cfDNA). While there was some variation, all the asserted patents recited the basic steps of:

- "obtaining" or "providing" a "sample" from the recipient that contains cfDNA;
- "genotyping" the transplant donor and/or recipient to develop "polymorphism" or "SNP" "profiles;"
- "sequencing" the cfDNA from the sample using "multiplex" or "high-throughput" sequencing; or performing "digital PCR;" and
- "determining" or "quantifying" the amount of donor cfDNA.

At the trial level, the district court concluded that the patents were directed to the detection of natural phenomena; specifically, the presence of donor cfDNA, and the correlation between donor cfDNA and transplant rejection. The district court further held that the patent specification itself, on numerous occasions, admitted that only *conventional* techniques were recited in the claims. Finding the claims related to nothing more than natural phenomena combined with conventional techniques, the district court found the claims invalid.

On appeal, the Federal Circuit affirmed, relying on the Supreme Court rule in *Mayo* that "[l]aws of nature and natural phenomena are not patentable, but applications and uses of such laws and phenomena may be patentable" and that "adding 'conventional steps, specified at a high level of generality,' to a law of nature of

natural phenomenon does not make a claim to the law or phenomenon patentable.” On this second point, the Federal Circuit rejected CareDx’s arguments that the patents claimed improved measurement methods, referring repeatedly to boilerplate statements from the patents’ specifications that are generally included to help establish compliance with the written description and enablement requirements (e.g., “any technique known in the art may be used”, “method which are well known in the art”, “any suitable method known in the art”) as evidence that, contrary to CareDx’s litigation arguments, the claimed steps were actually conventional and well known.

While it is not surprising that the Federal Circuit would uphold invalidation of a diagnostic method patent, the reasoning in *CareDx* is significant because it highlights areas where it may make sense for patent practitioners to reconsider some practices that are currently commonplace. In particular, it is common in biotechnology patent applications for some techniques to be described as “well-known,” “readily understood by one of ordinary skill in the art,” “known in the art,” or “previously described” as shorthand to convey techniques that may be used to carry out the invention, but which would be understood by the skilled artisan. While this may be a helpful shorthand, *CareDx* makes clear that the use of this type of boilerplate has significant drawbacks, and it can be treated as an admission that claimed steps are conventional and therefore cannot establish subject matter eligibility. In this way, it is reminiscent of *In re Stanford* (discussed [here](#)), where high level recitations of generic computer components – in that case a processor and a memory – played a significant role in the Federal Circuit’s opinion invalidating yet another biotechnology invention. Thus, *CareDx*, especially when considered in combination with *Stanford*, makes clear that for inventions which might be challenged on subject matter eligibility grounds, boilerplate language should be carefully evaluated, and perhaps used more judiciously, if at all.

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