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ALERT

Intellectual Property Practice

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CareDx v. Natera – Extrinsic Evidence Fails to Nullify Applicant's Prior Admissions

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The case concerns three Stanford patents licensed and asserted by CareDx: U.S. Patent Numbers 8,703,652 (asserted against Natera and Eurofins), and 9,845,497 and 10,329,607 (asserted against Natera). Natera and Eurofins each filed motions for summary judgment of invalidity of the asserted patents under 35 U.S.C. § 101, which the Court initially denied in December 2020. The Court then later denied certification motions for interlocutory appeal and instead ruled *sua sponte* to reconsider its denial of summary judgment. Following an evidentiary hearing, the Court reversed its previous ruling to find all claims of the asserted patents invalid under §101.

What You Need to Know:

- Patent-eligible subject matter is defined by 35 U.S.C. § 101 as any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. Judicially-created limitations of § 101 exclude laws of nature, natural phenomena, and abstract ideas.
- Under Mayo and Alice, the Supreme Court created a two-part eligibility test (*i.e.*, "the Alice test") which asks: (i) are the claims in question directed to a patent-ineligible concept (*i.e.*, a law of nature, natural phenomenon, or abstract idea), and if so, (ii) do the individual or combined elements of the asserted claims set forth an inventive concept? In Athena, the Federal Circuit held that at step one of the Alice inquiry, claims are directed to a natural law if they "recite only [a] natural law together with standard techniques for observing it."
- The idea that a patentee is bound by the words it uses in its patent - whether in the claims or elsewhere in the specification - is a fundamental tenet of patent law.

The asserted patents share a single written description entitled "Non-invasive Diagnosis of Graft Rejection in Organ Transplant Patients." The methods disclosed in the representative claims are summarized by the Court as having four steps for detecting an organ donor's cell-free DNA (cfDNA) in a transplant recipient:

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

The patents' written description expressly states that the techniques referred to in these steps are, "unless otherwise indicated, conventional techniques of immunology, biochemistry, chemistry, molecular biology, microbiology, cell biology, genomics, and recombinant DNA, which are within the skill of the art."[1] But, according to the Court, "nowhere in the written description do the patents "otherwise indicate" that any of these techniques are nonconventional," and instead, "the written description is replete with characterizations of the techniques in terms that confirm their conventionality." This position was shared by Defendants and their shared expert witness, Dr. John Quackenbush.

CareDx unsuccessfully argued (i) that the admission in the written description that the claimed techniques are routine is highly ubiquitous in patent applications, and that to interpret it to be a supposed voluntary confession that there is no inventive concept in the specification would be unfair; (ii) that the patents do, in fact, "otherwise indicate" that some of the individual techniques (*i.e.*, digital PCR and next generation sequencing) are nonconventional; (iii) that the invention applies a never-before used combination of techniques for the claimed purpose (*i.e.*, that the novelty of the application of the recited techniques makes the techniques nonconventional); (iv) that the combination of the recited techniques is itself nonconventional; and (v) that extrinsic evidence establishes that the recited techniques were not conventional, citing opinions of its own expert, Dr. Brian Van Ness, as well as six scientific articles that discussed the nascent nature of some of the specifically disclosed techniques.

Regarding CareDx's argument (v), the Court admonished that "[p]ermitting CareDx to now nullify with extrinsic evidence an unambiguous representation it made to the PTO to secure its patents and exclude competitors like Defendants from making or using the claimed invention would be fundamentally at odds with the basic principles underlying our patent system," that it "would make Defendants' right to design around meaningless," and that it "would also reward CareDx for being dishonest – either when it told the PTO that the recited techniques were conventional or when it insisted before this Court that they were not."

This case highlights the need for patent applicants pursuing diagnostic methods claims to expressly disclose in their applications (*i.e.*, to "otherwise indicate") the specific ways in which their techniques are not routine or conventional.

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1. The '652 patent at 5 :36-40.

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