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Federal Circuit Patent Bulletin: *Enzo Biochem, Inc. v. Applera Corp.*

March 16, 2015

"[E]ven if we were to consider the district court's finding, which would be subject to review for clear error under Teva, this sole factual finding does not override our [claim construction] analysis of the totality of the specification . . . ."

On March 16, 2015, in *Enzo Biochem, Inc. v. Applera Corp.*, the U.S. Court of Appeals for the Federal Circuit (Prost, Newman, Linn) reversed-in-part, vacated-in-part, and remanded the district court's judgment entering the jury verdict that Applera infringed U.S. Patent 5,449,767, which related to DNA sequencing. The Federal Circuit stated:

While the ultimate construction of a claim term is a legal question reviewed de novo, underlying factual determinations made by the district court are reviewed for clear error. Specifically, "when the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law, and the Court of Appeals will review that construction de novo." However, when the district court looks beyond the intrinsic evidence and consults extrinsic evidence, for example to understand the relevant science, these subsidiary fact findings are reviewed for clear error.

To the extent possible, "the words of a claim are generally given their ordinary and customary meaning." The "ordinary and customary meaning of a claim term" is that meaning that a person of ordinary skill in the art in question, at the time of the invention, would have understood the claim to mean. "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically," the court also looks to "the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." However, when doing so the court must stay ever vigilant to avoid reading limitations from the specification into the claim. . . .

Claim 1 of the '767 patent states that "A" "comprises at least three carbon atoms and represents at least one component of a signaling moiety capable of producing a detectable signal" and is attached to "B" so that it "does not substantially interfere with formation of the signalling moiety." First, the phrase "at least one component of a signalling moiety" indicates that the signalling moiety is composed of multiple parts as the term "component" in and of itself indicates a multipart system. Thus, construing the phrase to allow for a single-component system, as the district court did here, would read out the phrase "component of a signalling moiety" and would thus impermissibly broaden the claim. Second, the claim language requires that "A" be attached either directly or through a linkage group that "does not substantially interfere with formation of the signalling moiety." The plain reading of this phrase is that "A" cannot be the whole signalling moiety, as the claimed compound does not include a formed signalling moiety. In other words, if "A" alone could be the signalling moiety, as the district court found, the requirement that "A" not interfere with the formation of the signalling moiety would be read out of the claim, as the signalling moiety would be formed by the sole presence of "A."

Enzo urges that we should hold that the inventors' inclusion of the term "at least one of" allows for both direct and indirect detection. . . . Here, the dispute is whether "A" can comprise the entirety of "a signalling moiety" despite the claim language that "A" is a "component of a signalling moiety." . . .

The specification provides additional support that claim 1 covers only indirect detection. First, throughout the specification, "A" is described as being capable of forming a signalling moiety only in conjunction with other chemicals, never that "A" alone can be a signalling moiety. Second, the background portion of the specification further describes the invention as a "series of novel nucleotide derivatives that contain biotin, iminobiotin, lipoicacid, and other determinants attached covalently to the pyrimidine or purine ring" and explains that these nucleotides "will interact specifically and uniquely with proteins such as avidin or antibodies." The specification then goes on to describe this interaction as being used "for the detection and localization of nucleic acid components in many of the procedures currently used in biomedical and recombinant-DNA technologies." In other words, the patent describes how "A," a biotin, iminobiotin, or lipoic acid, forms a detectable unit, i.e., a signalling moiety, upon interaction with avidin or antibodies. Third, the specification's only discussion of direct detection, here radioactive labeling, was exclusively in the context of discussing how indirect detection is a superior method. The specification not only discusses the limitations and drawbacks of using radioactive labeling, but states that the claimed compounds can be used "as an alternative to radioisotopes for detection and localization" and that these compounds have "detection capacities equal to or greater than products which utilize radioisotopes and often can be performed more rapidly and with greater resolving power." [N]either section of the '767 patent specification cited by Enzo supports the inclusion of direct detection, even when extrinsic expert testimony is considered.

We have long recognized the "distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." Here, we are using the specification to more fully understand what the patentee claimed. Throughout the '767 patent, the inventors repeatedly emphasized that "A" in combination with other chemicals, forms a signalling moiety not that "A" itself can be a signalling moiety. Therefore, we are persuaded that the inventors were claiming only indirect detection.

The district court concluded, based on expert testimony, that example 9 in the specification was an example of direct detection; however, this argument was not raised by Enzo either in its briefing on appeal or during oral argument. Nevertheless, even if we were to consider the district court's finding, which would be subject to review for clear error under Teva, this sole factual finding does not override our analysis of the totality of the specification, which clearly indicates that the purpose of this invention was directed towards indirect detection, not direct detection.