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CLIENT ALERT

Federal Circuit: 'Molecular Weight' Is Still Indefinite

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In a decision applying two recent Supreme Court decisions, the Federal Circuit on Thursday held that the claims to Teva's patents covering the multiple sclerosis drug Copaxone® were invalid for the second time. *Teva Pharm.USA, Inc. v. Sandoz, Inc.*, 2012-1567, slip op. at 18 (Fed. Cir. June 18, 2015). Judge Moore, writing for the court again, found that the claim term "molecular weight" was indefinite because a person of ordinary skill in the art would not understand with reasonable certainty to which type of molecular weight the claim language referred. Prior to remand, the Federal Circuit had reached the same conclusion, which was vacated by the Supreme Court in *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015). There, the Supreme Court held that the appellate court must give deference to subsidiary factual findings made by district courts in construing patent claims and review those findings only for clear error. On remand, the Federal Circuit applied that guidance and reviewed several of the district court's subsidiary factual findings. Despite finding the District Court made no clear error, the Federal Circuit found that the ultimate legal conclusion of indefiniteness remained unchanged.

The patent-in-suit concerns a polymer called copolymer-1, which is made by polymerizing four different amino acids. The claims require a "copolymer-1 having a molecular weight of about 5 to 9 kilodaltons." Because a polymer, such as copolymer-1, is made up of many different chains of monomers of varying length, the molecular weight of the polymer is not as straightforward a calculation as the molecular weight of a molecule such as water. At the district court it was undisputed that molecular weight of copolymer-1 could refer to number average molecular weight (Mn), weight average molecular weight (Mw), or peak average molecular weight (Mp). The district court construed "molecular weight" as "peak average molecular weight," rejecting the defendants' argument that the term was indefinite. In so doing, the district court found that neither the claim language nor the specification provided guidance as to the meaning of "molecular weight" so it relied principally on the following bases:

- Teva's expert's testimony that Example 1 in the patent described Size Exclusion Chromatography for making a polymer with the claimed molecular weight and Figure 1 of the patent shows the molecular weight distribution from this method. The expert further testified that peak average molecular weight is the only type of molecular weight that can be obtained directly from Figure 1. The expert further testified that Figure 1 resulted from the transformation of a chromatogram and that this transformation caused the peaks in Figure 1 to shift slightly.
- Teva's expert's testimony concerning a statement in the prosecution history of a patent in response to an indefiniteness rejection that "average molecular weight" is not indefinite because "[o]ne of ordinary skill in the art would understand that kilodalton units implies a weight average molecular weight." The expert testified that a person of ordinary skill in the art would readily understand this statement to be in error since all of Mn, Mw, and Mp can be expressed in units of kilodaltons. The district court found that given this error a person of ordinary skill in the art would not rely on the statement in determining the meaning of "average molecular weight."
- A later statement in the prosecution history of another related patent in response to an indefiniteness rejection that "'average molecular weight' refers to the molecular weight at the peak of the molecular distribution curve in Figure 1."

After proclaiming the new clearly erroneous standard for subsidiary factual findings, the Supreme Court specifically identified the first factual finding above as such a finding deserving deference. The justices also noted that Teva claimed there was two other such findings but left it for the Federal Circuit to determine. On remand, the Federal Circuit found that the first finding was not clearly erroneous. The panel then looked to the prosecution history and specifically to the second statement listed above. The court found that the district court's finding that all of Mn, Mw, and Mp can be expressed in units of kilodaltons was not clearly erroneous. However, the Federal Circuit held that a "a person of ordinary skill in the art would have understood that the applicants defined the term ‘molecular weight' as Mw to gain allowance of the claims." The Federal Circuit characterized this as a legal conclusion. The Federal Circuit also expressly found that the "determination of the significance of statements made during prosecution to the claim construction is a question of law."

The Federal Circuit thus treated this definition with equal value as the later definition that "average molecular weight" means Mp. Therefore, in the court's eye, the patentee had told a person of skill in the art that "average molecular weight" meant Mw and then told the same "person" that the same term meant Mp. The court found that due to this ambiguity the claims read in light of the specification and prosecution history "fail to inform, with reasonable certainty, those skilled in the art about the scope" of the term "molecular weight." Therefore, the claims are invalid as indefinite under the standard set forth in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014).

In dissent, Judge Mayer took issue with the majority's determination of the significance of the second factual finding above. The dissent argued the district court's finding that a person of ordinary skill in the art would not rely on this facially incorrect statement is a finding of fact that must be reviewed only for clear error. Finding no error, the dissent argued that there is no reasonable basis for finding "molecular weight" to be ambiguous.

Because of the disagreement among the panelists as to what should be considered a factual finding under the Supreme Court's new rule, this decision may be taken up by the *en banc* court. Stay tuned.

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