

Claim Construction-Finding of Subsidiary Facts Reviewed for Clear Error

During patent litigation, the trial court determines the scope of the patent rights by determining what the claims in the patent cover. In making this determination the trial court must ascertain the meaning of words and phrases in a process called “claim construction.” This determination is based on intrinsic evidence (i.e. what is written in the patent or made of record during the patent application process) or extrinsic evidence (e.g. expert testimony, dictionaries, etc.). Intrinsic evidence is a matter of law whereas extrinsic evidence requires the court to make findings based on facts presented by the parties at trial, also known as “subsidiary facts”.

In *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* 574 U.S. ____ (2015), the Supreme Court of the United States held that the district court’s finding of subsidiary facts during claim construction is to be reviewed by the Federal Circuit (“CAFC”) for “clear error” (i.e. with substantial deference to the district court’s findings). Prior to this ruling, the CAFC reviewed findings based on subsidiary facts just like it did questions of law, *de novo* (i.e. with no deference). After *Teva*, the CAFC can now only overturn a finding of subsidiary facts during claim construction if it is certain that the district court made a mistake.

In *Teva*, Teva sued Sandoz for infringing its patent directed to a method of manufacturing Copaxone[®], a multiple sclerosis drug. Sandoz, in turn, moved for a holding that Teva’s patent was invalid (i.e. not enforceable) because the claims were indefinite. To determine if Teva’s claims were indefinite, the district court held a claim construction hearing. Teva’s claims were limited to protecting manufacturing methods where the molecular weight of the active ingredient of Copaxone[®] was between 5 and 9 kilodaltons. Sandoz argued that Teva’s claims were indefinite because “molecular weight” can be calculated by three different methods and Teva did not state in the patent which of the three methods should be used to calculate the molecular weight. The district court found, based on expert testimony, that in the pharmaceutical industry molecular weight is almost always calculated by one method. For that reason, the term “molecular weight” in the Teva patent referred to the molecular weight calculated by a particular method. Thus, the boundaries of the claims were clear and the patent was valid.

On appeal, the CAFC reviewed, *de novo*, all evidence of what methods the pharmaceutical industry uses to calculate molecular weight. The CAFC did not give any deference to the district court’s finding that the pharmaceutical industry almost always uses the same method. Based on its review, the CAFC determined that it was unclear by which method the molecular weight was to be calculated, and thus held that the term “molecular weight” in Teva’s claims was indefinite and therefore, that Teva’s patent was invalid.

The Supreme Court reversed the CAFC's decision after determining that the CAFC must review the district court's findings of fact during claim construction for clear error. The Supreme Court remanded the case to the CAFC to reconsider whether Teva's patent is invalid in light of its ruling.

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