

TEVA PHARMACEUTICALS USA v. SANDOZ INC., Appeal No. 2012-1567, -1568, -1569 and -1570 (Fed. Cir. June 18, 2015). Before Moore, Mayer and Wallach. Appealed from S.D.N.Y. (Judge Jones).

### Background:

Sandoz submitted an ANDA to the FDA, seeking approval to market generic versions of Teva's drug Copaxon. The district court held that the term "molecular weight" used in Teva's patent was not indefinite, a decision that was later reversed by the Federal Circuit. Teva appealed the Federal Circuit decision to the Supreme Court of the United States, who vacated and remanded the Federal Circuit's decision, holding that the Federal Circuit had not reviewed at least one factual finding (i.e., the meaning of molecular weight) for clear error. Meanwhile, the Supreme Court issued its decision in *Nautilus II*, in which the Supreme Court rejected the Federal Circuit's indefiniteness standard of "not amenable to construction or insolubly ambiguous," and instead modified the indefiniteness standard to be "if [a patent's] claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, *with reasonable certainty*, those skilled in the art about the scope of the invention."

### Issue/Holding:

Is the term "molecular weight" indefinite in light of the new standard for indefiniteness set forth by the Supreme Court in *Nautilus II*? Yes.

### Discussion:

In light of the Supreme Court's new guidance, the Federal Circuit examined the patent record, i.e., the claims, specification and prosecution history, to ascertain if they convey to one skilled in the art with reasonable certainty the scope of the invention claimed. The Federal Circuit first noted that the claim recites "molecular weight" without specifying the meaning of the term. Although the parties agreed that the term "molecular weight" could refer to peak average molecular weight ( $M_p$ ), number average molecular weight ( $M_n$ ) or weight average molecular weight ( $M_w$ ), they also agreed that each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample. Next, the Federal Circuit found that there is also no express definition of "molecular weight" in the specification, and that nowhere in the specification are the terms  $M_p$ ,  $M_n$  or  $M_w$  used.

The Federal Circuit then turned to the prosecution history. Although there was no prosecution history in the patent at issue that was relevant to the construction of the term "molecular weight," the Federal Circuit examined the prosecution history of two related patents that had an identical specification to the patent at issue. During prosecution of one of the related patents, the Examiner rejected the term "molecular weight" as being indefinite, which Teva overcame by arguing the one skilled in the art would understand the term to mean molecular weight ( $M_w$ ). During prosecution of the other related patent, applicants argued that one of ordinary skill in the art would understand the term to mean "peak average molecular weight" ( $M_p$ ). The Federal Circuit considered the district court's fact findings, but pointed out that the skilled artisan would still not be certain as to which type of molecular weight was being considered in light of the claims, specification and prosecution history. Thus, because the patentee failed to inform with *reasonable certainty* those skilled in the art of the scope of the invention, the patent is indefinite.