Published on *The National Law Review* https://natlawreview.com

Patent Claims Are Indefinite Where Claimed "Molecular Weight" Subject to Different Calculations

Article By:

Intellectual Property Practice Group

Addressing the issues of indefiniteness and enablement of pharmaceutical products, the U.S. Court of Appeals for the Federal Circuit upheld judgments of infringement and no validity with respect to one group of claims and reversed judgment of no invalidity with respect to another group of claims. ***Teva Pharmaceuticals USA v. Sandoz Inc.***, Case Nos. 12-1567, -1568, -1569, -1570 (Fed. Cir., July 26, 2013) (Moore, J.).

Teva sued several companies for patent infringement after they submitted Abbreviated New Drug Applications (ANDAs) to market generic versions of Copaxone®. At least seven of the eight Orange Book listed patents were asserted.

The active ingredient is copolymer-1, or glatiramer acetate, which is a polypeptide product that consists of four different amino acids (alanine, glutamic acid, lysine, and tyrosine). Copolymer-1, however, is a mixture of individual polymer molecules with different constituent ratios and different molecular weights (often expressed as "average molecular weight").

The Federal Circuit reaffirmed a principle of patent law by holding that because the claim term "molecular weight" can be calculated at least three different ways—peak average molecular weight (Mp), number average molecular weight (Mn), and weight average molecular weight (Mw)—resulting in three different values, the asserted claims were invalid for indefiniteness. This is because it is not possible to determine whether potential infringing activity will fall within the scope of the claims.

However, the Court also held that at least some of the claims that included this term, but which described in the claim how to calculate "molecular weight," were not indefinite (the Group II claims). In this case, the molecular weight was not expressed as a statistical measure, but rather the percentage of copolymer-1 molecules that fall within a defined range. As a result, the measurement was not dependent on the type of calculation performed because it required a determination of the actual values.

In addition, the Court determined that there was insufficient evidence to overturn the lower court's determinations that the asserted claims were enabled, not obvious, and infringed. Thus Teva's injunction of the various ANDA filers was maintained. However, because one of the seven patents expires after all of the others (in 2015, instead of 2014), the Federal Circuit remanded the case to the

lower court to determine the impact on the length of the injunction.

National Law Review, Volume III, Number 242