

Federal Circuit Provides Guidance for Stereochemistry Claim Construction

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On April 16, 2018 in a precedential opinion, the United States Court of Appeals for the Federal Circuit, *Sumitomo Dainippon Pharma v. Emcure Pharms.*, Nos. 2017-1798, -1799, -1800, affirmed the United States District Court for the District of New Jersey by construing the claimed chemical structure diagram to encompass at least the specific enantiomer depicted, refusing to limit the claim to only cover a racemic mixture of the (+) and (-) enantiomers, absent clear indication that the depicted enantiomer should be excluded from the claim.

As a background on stereochemistry, enantiomers are different molecules with the same chemical formula and sequence of atoms but different three-dimensional configurations. Though they often have identical physical properties, enantiomers frequently have different pharmacological properties. Enantiomers may be characterized as (+) and (-) versions based on their ability to rotate polarized light in different directions. Racemates, or racemic mixtures, do not rotate polarized light because they contain equal proportions of (+) and (-) enantiomers of the same compound.

Claim 14 of asserted U.S. Patent No. 5,532,372 recited a structural drawing of the (-) enantiomer of the active ingredient in Appellee's LATUDA® drug. Appellant ANDA filers sought to limit claim 14 to cover only racemic mixtures of the recited structure. But the district court disagreed and construed the claim to cover the specifically depicted (-) enantiomer, as well as the (+) enantiomer and mixtures of the two in any ratio. Because the branded and proposed ANDA drug products include the (-) enantiomer, this construction was dispositive as to infringement.

In affirming the district court's claim construction, the Federal Circuit held that the plain claim language covered, at a minimum, the (-) enantiomer, without opining on whether it also covered the (+) enantiomer or mixtures. The Federal Circuit rejected Appellants' arguments that the claim should be construed to cover only a racemic mixture of the depicted compound because one of skill in the art would understand the claim's structural formula image to specifically depict the (-) enantiomer and nothing in the claim or specification expressly limited the claim to the racemic mixture or disclaimed/disparaged the (-) enantiomer.

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