

United States District Court,
D. Delaware.

ALZA CORPORATION and McNeil, PPC, Inc,
Plaintiffs.

v.

ANDRX PHARMACEUTICALS, LLC and Andrx Corporation,
Defendants.

Civil Action No. 05-642-JJF

Oct. 5, 2007.

Steven J. Balick, Tiffany Geyer Lydon, John G. Day, Ashby & Geddes, Wilmington, DE, for Plaintiffs.

William J. Cattie, III, George Thomas Lees, III, Rawle & Henderson LLP, Cecil Kyle Musgrove, Douglas T. Lee, John W. Bateman, Robert F. Vroom, Pro Hac Vice, for Defendants.

ORDER

JOSEPH J. FARNAN, JR., District Judge.

WHEREAS, the Court held a Claim Construction Hearing in this matter on December 15, 2006;

WHEREAS, the parties dispute the construction of four phrases: (i) "pharmaceutically acceptable composition" and "dosage form"; (ii) "an ascending release rate over an extended period of time;" (iii) "substantially ascending methylphenidate plasma drug concentration;" and (iv) the term 'about' in the phrase "over a time period of about [x] hours following said administration." The four disputed phrases appear in either or both United States Patent Nos. 6,919,373 (the "'373 patent") and 6,930,129 (the "'129 patent";

WHEREAS, the Court having considered the parties' respective positions;

NOW THEREFORE IT IS HEREBY ORDERED that for the purposes of United States Patent Nos. '373 and '129, the disputed phrases are construed as follows:

1. The phrases "**pharmaceutically acceptable composition**" and "**dosage form**," as used in the claims of the '129 patent and the '373 patent, mean "a pharmaceutical composition that includes a dose of methylphenidate;"

2. The phrase "**an ascending release rate over an extended period of time**," as used in the claims of the '373 patent, means "a release of methylphenidate from the dosage form wherein the amount released in a periodic interval is increased over the amount released during the immediately preceding periodic interval starting at t=0 and continuing through at least the midpoint of the T90 and for at least three hours. The

release rate is as determined by an appropriate in-vitro dissolution test. The ascending release rate does not include release of drug from any immediate-release drug coating that may be applied to the dosage form;"

3. The term 'substantially' in the phrase "**substantially ascending methylphenidate plasma drug concentration**," as used in the claims of the '129 patent and the '373 patent, means "approximately. Thus, a substantially ascending profile is one in which the plasma concentration of methylphenidate generally rises over approximately [x] hours, but may include a slight dip;"

4. The term 'about' in the phrase "**over a time period of about [x] hours following said administration**," as used in the claims of the '129 patent and the '373 patent, means "approximately. Thus, a substantially ascending profile is one in which the plasma concentration of methylphenidate generally rises over approximately [x] hours, but may include a slight dip."

D.Del.,2007.

Alza Corp. v. Andrx Pharmaceuticals, LLC

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