United States District Court,
D. Delaware.

SHIRE LABORATORIES INC,
Plaintiff.
v.
IMPAX LABORATORIES, INC,
Defendant.

Feb. 9, 2005.

Frederick L. Cottrell, III, Richards, Layton & Finger, Wilmington, DE, Nathan Weber, Frommer Lawrence & Haug, New York, NY, for Plaintiff.

Richard K. Herrmann, Mary Matterer, Blank Rome LLP, Wilmington, DE, for Defendant.

ORDER CONSTRUING THE TERMS OF U.S. Patent Nos. 6,322,819 ***and*** 6,605,300

SLEET**, J.**

After considering the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 6,322,819 (the " '819 patent") and U.S. Patent No. 6,605,300 (the " '300 patent"),

1. The term "pharmaceutically active amphetamine salts" in claim 1 of the '819 patent is construed as "amphetamine base, all chemical and chiral derivatives and salts thereof; methylphenidate, all chemical and chiral derivatives and salts thereof; phenylproponalamine and its salts; and all other compounds indicated for the treatment of ADHD;

2. The term "immediate release coating" in claim 1 of the '819 patent is construed as "a coating that allows for the release and absorption of the drug without delay;"

3. The term "enteric release coating" in claim 1 of the '819 patent is construed as "a pH dependent coating that is at least 25(mu) thick and prevents release and absorption of the drug until it reaches the intestines;"

4. The term "delayed pulsed enteric release" in claim 1 of the '819 patent is construed as "the dose of the drug is released in the intestines after a first dose by immediate release and a period of no release;"

5. The term "said component (a) providing for an immediate release of amphetamine salt to provide a first blood level of amphetamine salt" in claim 8 of the '819 patent is construed as "at least one pharmaceutically active amphetamine salt covered with an immediate release coating providing a first blood concentration of amphetamine salt following the immediate release;"

6. The term "component (b) providing a delayed pulse enteric release of amphetamine salt that increases the blood level of amphetamine salt to a second level that is greater than the first level provided by component (a)" in claim 8 of the '819 patent is construed as "at least one pharmaceutically active amphetamine salt covered with an enteric release coating that increases the blood concentration of amphetamine salt following the enteric release to a level that is greater than the first blood concentration;"

7. The term "amphetamine base salts" in claim 1 of the '300 patent is construed as "salts of 1-phenyl-2-aminopropane base formed by the interaction of an acid and a base, or salts of amphetamine base including, but not limited to, dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulphate;"

8. The term "immediate release dosage form" in claim 1 of the '300 patent is construed as "a dosage form that allows for release and absorption of the drug without delay after administration;"

9. The term "immediate release upon oral administration" in claim 1 of the '300 patent is construed as "the dose of drug is released and absorbed without delay after administration;"

10. The term "delayed enteric release dosage form" in claim 1 of the '300 patent is construed as "a dosage form that intentionally delays the release of the drug until it reaches the intestines;"

11. The term "delayed release upon oral administration" in claim 1 of the '300 patent is construed as "the dose of the drug is released in the intestines after a first dose by immediate release and a period of no release;"

12. The term "an area under the curve (AUC) of about 467 to about 714 ng hr/ml" in claim 1 of the '300 patent is construed as "d-amphetamine levels within the specified range (467 to 714 ng hr/ml) (plus-or-minus sign) 20%;"

13. The term "proportional to said 20 mg AUC" in claim 17 of the '300 patent is construed as "an AUC for a total dose different from 20 mg, but having the same or a constant ratio for AUC as to the 20 mg dose;"

14. The term "having a C_{max} proportional to said 20 mg C_{max}" in claim 18 of the '300 patent is construed as "a C_{max} for a total dose different from 20 mg, but having the same or a constant ratio for C_{max} as to the 20 mg dose;"

15. The term "human individual" in claim 8 of the '819 patent and claim 1 of the '300 patent is construed as "a single human;"

16. The terms "and" in claims 1 and 8 of the '819 patent; "releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release" in claim 1 of the '819 patent; "said enteric release coating is a non-pH dependent enteric release coating" in claim 7 of the '819 patent; "the peak plasma concentration of amphetamine base salts reached after release of said delayed enteric release dosage form exceeds the peak plasma concentration previously reached after release of said immediate release dosage form" in claim 1 of the '300 patent; and "when containing about a total dose of 20 mg" in claim 1 of the '300 patent require no construction.

D.Del.,2005.
Shire Laboratories v. IMPAX Laboratories