United States District Court,
D. Delaware.

BIOVAIL LABORATORIES INTERNATIONAL SRL,
Plaintiff.
v.
ANDRX PHARMACEUTICALS, LLC and Andrx Corporation,
Defendants.

C.A. Nos. 05-586(GMS), 05-730(GMS), 06-620(GMS)

June 22, 2007.

Jack B. Blumenfeld, Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, Wilmington, DE, for Plaintiff.

Richard L. Horwitz, Kenneth Laurence Dorsney, Potter Anderson & Corroon, LLP, Wilmington, DE, Douglas H. Carsten, Pro Hac Vice, Jeremy J. Edwards, Pro Hac Vice, Martin P. Endres, Pro Hac Vice, Steven A. Maddox, Pro Hac Vice, Veronica S. Ascarrunz, Pro Hac Vice, for Defendants.

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,529,791 ***AND*** 7,108,866

GREGORY M. SLEET**, District Judge.**

After having considered 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 Nos. 5,529,791 (the "'791 patent") and 7,108,866 (the "'866 patent"):

A. The '791 Patent

1. The term "extended release galenical composition" is construed to mean "a pharmaceutical composition that releases the active ingredient over an extended period of time." FN1

FN1. In making this ruling, the court rejects Andrx's contention that the claims of the '791 patent are limited to the pharmaceutical composition in its dry state. In other words, the court will construe the claims of the '791 patent to extend to both the pharmaceutical composition in its dry state and the pharmaceutical composition *in vivo*. For the parties edification, the court notes that this was a close call and finds that its construction is supported by the specification, the claim language, and the prosecution history of the '791 patent. See '791 Patent col. 2, ll. 10-15 ("it is an object of the present invention to provide galenic forms of Diltiazem with extended release of the active substance.... It is also an object of this invention to provide galenic forms of Diltiazem having excellent bioavailability while avoiding plasmatic concentration peaks."); id. at col. 2., ll. 45-53 (stating same); id. at col. 7, l. 22-col. 8, l. 51 (describing pharmacokinetical testing and results on human subjects, including area under the curve ("AUC") and maximum concentration

("Cmax")); id. at Figure 1 and Figure 2 (illustrating plasma Diltiazem concentration over time after a once daily administration of product administered in the pharmakokinetical studies); id. at Claim 1 (the purpose of the admixture is to "maintain the solubility of Diltiazem in each bead, ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which the composition will meet therein"); see also Joint Appendix ("JA") Ex. 4 Amendment dated April 26, 1993, at A-51-A52 ("In essence, in admixture, the wetting agent appears to control, or strongly influence, the solubility of Diltiazem and does not permit this solubility to be affected by pH or other adverse conditions in the gastrointestinal tract. Further this control appears to occur within the core of the Diltiazem and wetting agent. This control affords a gradual release of Diltiazem in a relatively uniform manner over a period of about 24 hours.... "By combining the wetting agent in admixture with Diltiazem or one or more salts thereof, the solubility of the Diltiazem may be controlled and rendered independent of pH. This is quite important due to the wide variation in pH in the gastrointestinal tract."); id. at A-56 ("The wetting agents claimed in the present invention are substances which are believed to modify the solubility of the Diltiazem inside the coated beads when they are placed in a dissolution medium or when they are ingested by a mammal."). The May 28, 1993 and December 14, 1995 amendments contain language similar to the above-cited excerpts of the '791 patent prosecution history with respect to the admixture and control of the Diltiazem solubility in the gastrointestinal tract and will not be repeated.

2. The term "bead" is construed to mean "the structure containing one or more Diltiazem salts and a wetting agent." FN2

FN2. See footnote 1. The defendant's construction invites the court to import a limitation from the specification into the claims, which is contrary to Federal Circuit precedent. *See* Comarck Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir .1998) (" '[w]hile ... claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.' ").

3. The term "an effective amount of wetting agent" is construed to have its plain and ordinary meaning.FN3

FN3. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir.2005) (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed.Cir.2001)).

4. The term "admixture" is construed to mean "a homogeneous mixture of one or more Diltiazem salts and wetting agent can be found at a point in time during the life of the composition." Further, the term "homogeneous" is construed to mean "the mixture of one or more Diltiazem salts and wetting agent is the same throughout the composition." FN4

FN4. See footnotes 1 and 2.

5. The term "to maintain the solubility of the Diltiazem in each bead" is construed to have its plain and ordinary meaning.FN5 Further, the term "solubility" is construed to mean "an amount of material that is

capable of being dissolved in a given amount of solvent."

FN5. In making its ruling, the court rejects the defendant's proffered construction of the term "maintain."

6. The term "ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract or other adverse conditions which the composition will meet therein" is construed to have its plain and ordinary meaning.FN6

FN6. See footnote 3.

7. The term "said beads being coated with a microporous membrane" is construed to have its plain and ordinary meaning.FN7

FN7. In making its ruling, the court rejects the defendant's proffered construction. See footnote 2.

C. The '866 Patent

1. The term "method of United States Pharmacopiea No. XXIII at 100 rpm in 900 ml of water" is construed to have its plain and ordinary meaning.FN8

FN8. See footnote 3. Additionally, the defendant's construction invites the court to import a limitation from the specification into the claims, which is contrary to Federal Circuit precedent. *See* Comarck Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998) (" '[w]hile ... claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.' ").

2. The term "method of United States Pharmacopiea No. XXIII at 100 rpm in 900 ml of the buffered medium" is construed to have its plain and ordinary meaning. FN9

FN9. See footnote 8.

3. The term "higher bioavailability when given at night compared to when given in the morning without food according to FDA guidelines and criteria" is construed to mean "a formulation administered at night without food exhibits a greater AUC and Cmax than when the same formulation is administered in the morning without food." FN10

FN10. The defendant's construction invites the court to import a limitation from the specification into the claims, which is contrary to Federal Circuit precedent. *See* Comarck Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998) (" '[w]hile ... claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.' ").

4. The term "bioequivalence when given in the morning with our without food according to the same FDA guidelines or criteria" is construed to mean "a formulation administered in the morning with food exhibits a similar bioavailability to a formulation given in the morning without food." FN11

FN11. See footnote 10.

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