United States District Court,
D. Delaware.

AVENTIS PHARMACEUTICALS, INC. and Sanofi-Aventis U.S. LLC,
Plaintiffs.
v.
BARR LABORATORIES, INC,
Defendant.

C.A. No. 06-286 GMS

Dec. 6, 2007.

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

Karen Elizabeth Keller, Karen L. Pascale, Josy W. Ingersoll, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Defendant.

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,976,573 ***and*** 6,143,329

GREGORY M. SLEET**, Chief 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. 5,976,573 (the "'573 patent") and 6,143,329 (the "'329 patent"):

1. The term "pharmaceutically effective amount" is construed to mean "an amount that exerts the pharmacological action of the medicament." FN1

FN1. "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)).

2. The court will limit the term thixotropic to refer to those properties described in specific claims or, in the absence of properties described in a specific claim, those properties described in the specification." FN2

FN2. Usually, it is contrary to Federal Circuit law to import a limitation from the specification into the claim. *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.' "). This case, however, is an exception to that rule, as the patentee limited his invention to specific thixotropic properties both in the

written description and in distinguishing the prior art. See '573 Patent, Abstract ("An aqueous pharmaceutical composition which is capable of being sprayed in the nasal cavity of an individual and which comprises ... (B) a suspending agent in an amount effective ... to impart to the composition the following thixotropic properties: (i) the viscosity of the position [sic] in unsheared form is relatively high, with the composition being in a gel-like form; (ii) as the composition is subjected to shear (shaken) in preparation for spraying, the viscosity of the composition becomes relatively low and such that the composition in the form of a mist flows readily into the nasal passages for deposit on the mucosal surfaces of the nasal cavity; and (iii) in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity ...."); id. at col. 2, ll. 28-38 (same); id. at col. 4, ll, 28-62; D.I. 119, Ex. 3 at A100 ("The ease with which the composition is sprayed into the nasal cavities and its ability to remain in contact with target tissues for relatively long periods of time are attributed to a suspending agent which imparts to the composition thixotropic properties as described in the present application on pages 9, 10, and 11. Applicant's claims include a definition of the thixotropic properties of the composition."); id. at A101 (distinguishing the Settipane et al. and Kobayashi et al. prior art references because they do not disclose several of the claimed elements, including "a suspending agent for dispersing the solid particles of medicament and for imparting to the composition the thixotropic properties which are defined in the applicant's claims"); id at A107 (discussing the s. 112 rejection and directing the examiner's attention "to the present application, pages 9 and 10, wherein there is a detailed discussion of the composition and the thixotropic nature thereof, including the nature of the freely flowable liquid form of the composition and its gel-like form"); id. at A211 (record of the teleconference with the patent examiner explaining that the examiner would allow the claims even though various prior art compositions have thixotropic properties); id. at A215 (reasons for allowance stating: "In addition, the conclusion was made by determining that the claimed composition comprising *unique* thixotropic properties, with specific viscosity traits (sheared and/or unsheared), and further comprising [TAA] as medicant was not explicitly taught or suggested by the prior art of record in this application."). Accordingly, the court concludes that it is proper in this case to limit the invention of the '573 and '329 Patents to those thixotropic properties described in specific claims or, in the absence of properties described in a specific claim, those properties described in the specification.

3. The term "the viscosity of the composition in unsheared form is relatively high, with the composition being a gel having said particles suspended therein" is construed to mean "the viscosity of the composition at rest is higher than the shear viscosity and sufficiently high to hold and maintain the particles of TAA suspended and dispersed substantially uniformly in the composition." FN3

FN3. In making its ruling, the court rejects the plaintiff's construction, which would require "relatively high" viscosities to have a specific range. *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 "in deposited form on the mucosal surfaces, the viscosity of the composition is relatively high and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity" is construed to mean "following deposition on the mucosal surfaces, the composition returns to its unsheared viscosity, which is relatively high and such that it resists being swept away by the mucocillary forces present in the nasal cavity." FN4

FN4. The defendant's construction invites the court to add a limitation to the claim, namely the phrases "extended period of time," and "[t]hat extended period of time must be greater than 30 minutes." The court finds no support in the claim language, the specification, or the prosecution history for reading this limitation into the claim and, therefore, rejects it. See '573 Patent, col. 1, ll. 50-57 (using the term "for example, within 10-30 minutes," which signifies an embodiment, when describing the composition's ability to resist mucocillary forces); see also footnotes 1 and 3.

5. The term "in deposited form on the mucosal surfaces, the viscosity of the composition is about 400 to about 800 cp and such that it resists being cleared from the mucosal surfaces by the inherent mucocillary forces which are present in the nasal cavity" is construed to mean "following deposition on the mucosal surfaces, the composition returns to its unsheared viscosity, which is approximately 400 to 800 cp, when measured according to the method disclosed in the specification, and such that it resists being swept away by the mucocillary forces present in the nasal cavity." FN5

FN5. See footnote 4.

6. The term "the mucosal surfaces of the nasal cavity" is construed to mean "the mucous membranes that line, among other things, the anterior regions of the nose, the turbinates which overlie the concha, the maxillary sinuses, and the frontal sinus." FN6 Further, the terms "for deposit on the on the mucosal surfaces of the nasal cavity" and "in deposited form on the mucosal surfaces" are construed to mean that the medicament is deposited on all of the mucosal surfaces.FN7

FN6. The parties agree as to the construction of the term "the mucosal surfaces of the nasal cavity." Thus, the court adopts the parties' construction. The court's normal practice is not to construe terms on which the parties agree. Here, however, the parties disagree as to whether the medicament must deposit on all of the mucosal surfaces of the nasal cavity. Thus, the court includes the parties' agreed construction for context.

FN7. In making its ruling, the court rejects the plaintiff's proffered construction to the extent that it does not require deposition on all of the mucosal surfaces.

D.Del.,2007.
Adventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.