IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN PHARMA INTERNATIONAL LTD, Plaintiff, v. ABRAXIS BIOSCIENCE, INC, Defendant.	)	C.A. No. 06-438 GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,399,363 AND 5,834,025

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. 5,399,363 (the "'363 patent") and 5,834,025 (the "'025 patent"):

1. The term "particles consisting essentially of" is construed to mean "the particles, composed of crystalline medicament and surface modifier, may also include other ingredients that do not affect their basic and novel properties, and are essentially free of solvent and other contaminants."[1]

[1] In making this ruling, the court rejects the defendant's construction as being unduly narrow, because a patentee's use of the phrase "consisting essentially of" has "long been understood to permit inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003) (citing *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998); *In re Janakirama-Rao*, 50 C.C.P.A. 1312, 317 F.2d 951, 954 (CCPA 1963)).

2. The term "surface modifier" is construed to mean "a substance that modifies the surface properties of the crystalline medicament."[2]

3. The term "adsorbed on the surface" is construed to mean "a molecule retained at the surface of the crystalline medicament that does not chemically bond with such medicament."[3]

4. The term "crystalline medicament useful in treating cancer" is construed to mean "a medicament suitable for treating cancer that has a regular arrangement of atoms or molecules in a space lattice, as distinguished from amorphous."[4]

5. The term "non-crosslinked" is construed to mean "the individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages."[5]

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[2] "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)). The defendant has proposed a construction for this term, which includes its construction of the term "adsorbed on the surface." The court is not willing to adopt a construction that collapses the claim term "adsorbed on the surface" into the construction of this claim term, because it renders part of the claim redundant. See '353 Patent Claim 1 (claiming "Particles consisting essentially of . . . a crystalline medicament useful in treating cancer . . . said medicament . . . having a non-crosslinked surface modifier adsorbed on the surface thereof . . . .").

[3] In making its ruling, the court rejects the defendant's construction, which would require the surface modifier to "physically adhere" to the surface of the crystalline medicament. *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 plaintiff's construction invites the court to add a limitation to the claim, namely the phrase "a portion." 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 footnote 3.

[5] In making its ruling, the court rejects the plaintiff's proffered construction.

6. The term "in an amount of 0.1-90% by weight and sufficient to maintain an average effective particle size of less than 1000nm" is construed to mean "an amount of surface modifier that maintains the size of the particles such that at least 90% of the particles have a number average particle size of less than about 1000 nanometers."[6]

7. The term "surfactant" is construed to mean "a stabilizing agent that reduces interfacial tension between oil and water."[7]

8. The term "without eliciting adverse hemodynamic effects" is construed to mean "the claimed method of intravenous administration does not elicit undesired effects on the physical aspects of blood circulation (such as reduction in arterial blood pressure and cardiac function) associated with administration of nanoparticles in the mammals to whom the nanoparticles are administered."[8]

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[6] "[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citations omitted); See '363 patent, Col. 4, ll. 65-68 ("By 'an effective average particle size of less than about 1000 nm' it is meant that at least 90% of the particles have a number average particle size of less than about 1000 nm . . . ."). Additionally, the court will apply the same construction to the term "sufficient to maintain an effective average particle size" as used with respect to a particle size of "about 50 nm to 1000 nm" in claim 1 of the '025 patent.

[7] In making its ruling, the court rejects the defendant's proffered construction.

[8] In making its ruling, the court rejects the plaintiff's argument that the term "mammals" should be construed to mean "species of mammals that are sensitive to hemodynamic effects associated with administration of nanoparticles," because this construction invites the court to import the preferred embodiment from the specification into the claims, which is contrary to Federal Circuit precedent. See footnote 3; see also '025 Patent, Col. 2, ll. 66-67 ("Also, as used herein, mammal *preferably* means a dog and other sensitive species including human species.") (emphasis added). The court also rejects the portion of the defendant's construction that incorporates the "claimed compositions," because the plain language of the term makes clear that it is directed at the method of administration, not the compositions.

9. The term "at an infusion rate not exceeding 10 mg/min" is construed to mean "intravenously administering the composition at a rate not exceeding 10 milligrams per minute."[9]

10. The term "organic drug substance" is construed to mean "a crystalline carbon-based therapeutic or diagnostic agent suitable for administration to a mammal."[10]

11. The term "colloidal polymeric material" is construed to mean "a polymer capable of forming a suspension of the organic drug substance."[11]

Dated: August 17, 2007

CHIEF, UNITED STATES DISTRICT JUDGE

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AUG 17 2007
U.S. DISTRICT COURT
DISTRICT OF DELAWARE

[9] In making its ruling, the court concludes that the plain language of the claim states that it is the nanoparticulate drug composition that is administered, not only the nanoparticles.

[10] Usually, it is contrary to Federal Circuit law to import a limitation from the specification into the claim. See footnote 3. This case, however, is an exception to that rule, as the patentees limited their invention to crystalline drugs/therapeutic agents both in the written description and in distinguishing the prior art. See '025 Patent, Col. 7, ll. 28-31 ("The therapeutic or diagnostic agent exists as a discrete, crystalline phase. The crystalline phase differs from a non-crystalline or amorphous phase . . ."); D.I. 144, Ex. 17 at A0236 ("Applicants' specification teaches that the particles of the invention contain the poorly soluble drug substance in a crystalline phase. The crystalline phase differs from non-crystalline and amorphous phases."); id. at A0241 ("The Office Action indicates that Violante teaches a crystalline drug substance. However, Violante teaches a solvent precipitation technique for preparing amorphous, non-crystalline particles. In fact Violante specifically teaches that the crystalline state is to be avoided . . . . Consequently, Violante teaches away from applicants' claimed particles . . . ."). Accordingly, the court concludes that it is proper in this case to limit the invention of the '025 Patent to a "crystalline organic drug substance."

[11] In making its ruling, the court rejects the defendant's proffered construction.