IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA LP, AKTIEBOLAGET DRACO, KBI INC. And KBI-E INC., Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	)	C.A. No. 08-305-GMS
ASTRAZENECA LP, AKTIEBOLAGET DRACO, KBI INC. And KBI-E INC., Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., Defendant.	)	C.A. No. 08-453-GMS

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,643,602 AND 6,423,340[1]

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. 5,643,602 (the "'602 patent") and 6,423,340 (the "'340 patent"):

A. The '602 Patent

1. The term "controlled release pellet formulation" in claim 1 of the '602 patent is construed to mean "an oral composition formulated to ensure that the active compound is released

[1] All docket references refer to the docket entries for C.A. No. 08-305-GMS, unless otherwise indicated.

preferentially at the site of the disease to be treated."[2]

2. The term "wherein the pellet, having a size between 0.3 mm and 5 mm diameter" in claim 1 of the '602 patent is construed to mean "wherein the unit is between 0.3 mm and 5 mm in size."[3]

3. The term "a core consisting of a non-pareil seed" in claim 1 of the '602 patent is construed to mean "the innermost part of the pellet consisting of a non-pareil seed and optionally one or more pharmaceutically acceptable excipients."[4]

4. The term "a core consisting of . . . a seed in which a glucocorticosteroid as defined in this claim is homogenously distributed" in claim 1 of the '602 patent is construed to mean "the innermost part of the pellet consisting of a seed of a glucocorticosteroid as defined in this claim

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[2] While the term "preferentially" is never explicitly defined in the specification, the court interprets the term "preferentially" to carry a meaning similar to that conveyed through the description of the formulation in the abstract of the '602 patent, which describes "an oral composition . . . for *targeted slow release* . . . ." (D.I. 55 at JA001.) This is consistent with the description of the release of the active compound provided in the specification:

> Ideally, as long as the dosage form remains in the stomach no release should occur. If Crohn's disease in [the] small intestine is going to be treated the release should continue during about 5 hours after the dosage form has left the stomach. If the large intestine is going to be treated the release should ideally start at caecum, and continue for up to 50 hours.

(*Id.* at JA003.)

[3] The parties agree on the construction of this term. (*See* D.I. 71, Ex. A.)

[4] The court adopts the construction of this term originally proposed by the defendants in D.I. 41, the joint claim construction chart. The court rejects both the plaintiff's proposed construction and the construction proposed by Mylan in its Motion for Leave to File an Amended Joint Claim Construction Chart (D.I. 44).

uniformly distributed in one or more pharmaceutically acceptable materials."[5]

5. The term "a layer surrounding said core" in claim 1 of the '602 patent is construed to mean "a coating enclosing on all sides said core."[6]

6. The term "the layer comprising about 0.5%-30% of the pellet by weight" in claim 1 of the '602 patent is construed to mean "the layer comprising approximately 0.5%-30% of the pellet by weight."[7]

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[5] The court adopts the construction of this term originally proposed by the defendants in D.I. 41, the joint claim construction chart, and adds the words "as defined in this claim." This construction is identical to the construction proposed by Mylan in its Motion for Leave to File an Amended Joint Claim Construction Chart (D.I. 44). The court rejects the plaintiff's proposed construction.

[6] The court finds the terms "coating" and "layer" to be synonymous in the context of this claim term. At the *Markman* hearing, the plaintiffs indicated a willingness to accept a construction of this term that includes "coating" and "enclosing on all sides." (*See* D.I. 67 at 60-61, 158.)

[7] The court rejects the plaintiff's suggestion that this claim could include percentages outside the recited range so long as that percentage "can rate-limit release of the glucocorticosteroid." The court is mindful that the word "about" cannot be read out of a claim that cites a numeric range. *See, e.g., Cohesive Technologies, Inc. v. Waters Corporation*, 543 F.3d 1351, 1368 (Fed. Cir. 2008) ("When 'about' is used as part of a numeric range, 'the use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context.'"). In this case, however, the court finds that any deviation from the recited range must be minimal since the prosecution history affirmatively supports a narrow reading of this term, and since neither the specification nor the prosecution history supports any percentages less than 0.5% or greater than 30%. During the first office action for this claim as it was originally filed in a predecessor application, the Examiner rejected the claim for lack of enablement and noted that no ranges outside 0.5% to 30% were specified (D.I. 55 at JA089), and the Applicant amended the claim to include the "about 0.5%-30%" language in response. (*Id.* at JA313.) Furthermore, the specification of the '602 patent states that the range is "preferably between 1% and 15%" (*Id.* at JA004), and the working examples in patent's specification have first layers of between just 2.05% (Example 2) and 7.56% (Example 4). (*See id.* at JA005-JA007). Given this prosecution history, the court agrees with the defendants that "there is no basis for expanding the range beyond a minimal mathematical variance on either end of the range." (D.I. 51 at 10.)

7. The term "a membrane surrounding both said core and said surrounding layer" in claim 1 of the '602 patent is construed to mean "a coating enclosing on all sides both said core and the layer surrounding said core."[8]

8. The term "which rate corresponds to a release time in vivo of 1 to 50 hours" in claim 1 of the '602 patent is construed to mean "which releases in the body over a period of time that is not less than 1 hour and not more than 50 hours."[9]

B. The '340 Patent

1. The term "Crohn's disease in the small intestine as relapse preventing therapy" in claim 1 of the '340 patent is construed to mean "Crohn's disease of the small intestine, where treatment is used to maintain symptom control once remission has been achieved."[10]

2. The term "controlled release pharmaceutical formulation" in claim 1 of the '340 patent is construed to mean "an oral composition formulated to ensure that the active compound is released preferentially at the site of the disease to be treated."[11]

3. The term "which will release the compound at the site of the disease to be treated" in claim 1 of the '340 patent is construed to have its plain and ordinary meaning.[12]

4. The term "which will release the compound" in claims 1, 12, 13, and 14 of the '340

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[8] *See* footnote 6.

[9] *See* footnote 3.

[10] The court adopts the plaintiff's proposed construction of this term.

[11] *See* footnote 2.

[12] The court finds that no construction of this term is required. Additionally, the parties agree on the construction of this term. (*See* D.I. 71, Ex. A.)

patent is construed to have its plain and ordinary meaning.[13]

5. The term "the condition to be treated is Crohn's disease of the ileum" in claim 12 of the '340 patent is construed to have its plain and ordinary meaning.[14]

6. The term "over a period of from 1-50 hours" in claim 13 of the '340 patent is construed to mean "over a period of time that is not less than 1 hour and not more than 50 hours after oral administration."[15]

7. The term "over a period of from 5-10 hours" in claim 14 of the '340 patent is construed to mean "over a period of time that is not less than 5 hours and not more than 10 hours after oral administration."[16]

Dated: October 5, 2009

CHIEF, UNITED STATES DISTRICT JUDGE

[13] *See* footnote 12.

[14] The parties have stipulated to the construction of the term and agree that the limitation "as relapse preventing therapy" is a limitation of this term in claim 12. (*See* D.I. 71 at 1-2.) The court finds that no further construction is required.

[15] *See* footnote 3.

[16] *See* footnote 3.