IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATIONS and NOVARTIS AG,

Plaintiffs/Counterclaim Defendants

v.

MYLAN PHARMACEUTICALS INC.,

Defendant/Counterclaim Plaintiff.

Civil Action No. 17-389-RGA

MEMORANDUM OPINION

Daniel M. Silver, MCCARTER & ENGLISH LLP, Wilmington, DE; Christina Schwarz (argued), Nicholas N. Kallas, Christopher E. Loh, Charlotte Jacobsen, Jared Stringham (argued), FITZPATRICK, CELLA, HARPER & SCINTO, New York, NY.

Attorneys for Plaintiffs and Counterclaim Defendants.

James M. Lennon, DEVLIN LAW FIRM LLC, Wilmington, DE; Shannon M. Bloodworth, Brandon M. White, PERKINS COIE LLP, Washington, DE; Bryan D. Beel (argued), David Anstaett, PERKINS COIE LLP, Portland, OR.

Attorneys for Defendant and Counterclaim Plaintiff.

June 29, 2018

ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,778,962 ("the '962 patent"), 8,617,598 ("the '598 patent"), and 7,297,703 ("the '703 patent"). I held oral argument on June 14, 2018. (D.I. 71 ("Tr.")).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

II. BACKGROUND

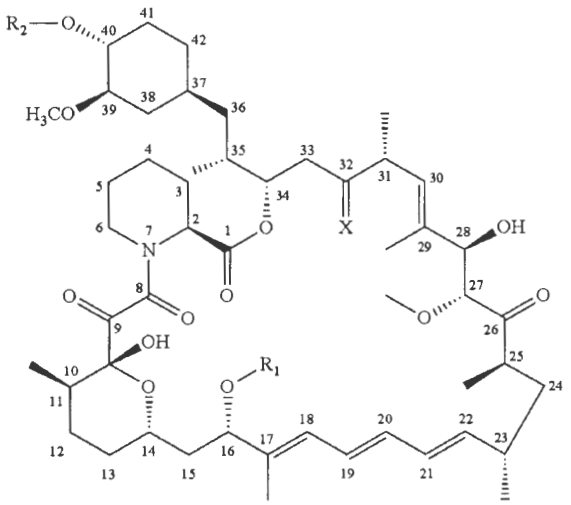
Novartis asserts the '962 and '598 patents against Mylan. (D.I. 1). Mylan seeks declaratory judgments of non-infringement and invalidity of the '962, '598, and '703 patents. (D.I. 15). The '962 patent "claims methods of inhibiting growth of non-malignant solid tumors of the brain . . . by administering therapeutically effective amounts of the active compound everolimus." (D.I. 59 at 1). The '598 patent "claims novel pharmaceutical compositions of

everolimus in the form of dispersible tablets, which tablets are dispersed in an ingestible liquid before consumption." (*Id.* at 32). The '703 patent "discloses and describes mixtures of stabilized pharmaceutical active ingredients, and methods for stabilizing the ingredients," where the "active ingredient is preferably a poly-ene macrolide (a compound with a particular type of ringed structure) having immunosuppressant properties." (*Id.* at 60).

The asserted claims of the '962 patent read as follows:

1. A method for *inhibiting growth* of non-malignant solid tumors of the brain in a subject, said method consisting of administering to said subject *a therapeutically effective amount* of a compound of formula I

I



wherein

R_1 is CH_3,

R_2 is —CH_2—CH_2—OH, and

X is =O.

2. The method of claim 1 wherein the compound of formula I is administered at a daily dose range of from about 0.1 to 25 mg, as a single dose or in divided doses.

3. The method of claim 1 wherein the compound of formula I is administered in a unit dosage form of from about 0.05 to 12.5 mg.

4. The method of claim 1 wherein the compound of formula I is administered in a unit dosage form of from about 0.25 to 10 mg.

6. The method of claim 1 wherein the compound of formula I is administered orally.

('962 patent, claims 1, 2, 3, 4, 6).

The asserted claims of the '598 patent read as follows:

1. A pharmaceutical composition in the form of a dispersible tablet to be dispersed in an ingestible liquid before administration to a patient, comprising a solid dispersion of 40-O-(2-hydroxy)ethyl-rapamycin, a disintegrant comprising cross-linked polyvinylpyrrolidone and *colloidal silicon dioxide*, wherein the composition comprises 1 to 5% *colloidal silicon dioxide* by weight and 10 to 30% of cross-linked polyvinylpyrrolidone by weight, and wherein the tablet has a disintegration time of 3 minutes or less and a hardness of 35 to 80N.

2. The pharmaceutical composition according to claim 1, wherein 250 mg of the composition, when compressed using a force of 8 to 11 kN with a 9 mm die and standard flat punches, forms the dispersible tablet.

3. A method of administering the pharmaceutical composition of claim 1 to a patient in need of said composition which comprises (i) contacting the composition with an aqueous solution (ii) allowing the composition to disperse in the aqueous solution to form a dispersed mixture and (iii) ingesting the dispersed mixture.

4. A composition according to claim 1, wherein the tablet has a disintegration time of 90 seconds or less.

6. A process for producing the pharmaceutical composition according to claim 1, comprising preparing the solid dispersion comprising 40-O-(2-hydroxy)ethyl-rapamycin, mixing the solid dispersion comprising 40-O-(2-hydroxy)ethyl-rapamycin with the disintegrant comprising cross-linked polyvinylpyrrolidone and *colloidal silicon dioxide* to form the pharmaceutical composition and compressing the pharmaceutical composition to form the dispersible tablet.

('598 patent, claims 1, 2, 3, 4, 6).

The asserted claims of the '703 patent read as follows:

1. A solid mixture comprising a poly-ene macrolide and an antioxidant wherein the poly-ene macrolide is selected from the group consisting of rapamycin, a 16-O-substituted rapamycin, and a 40-O-substituted rapamycin and wherein the antioxidant is present in a catalytic amount.

6. A pharmaceutical composition comprising as active ingredient, a mixture according to claim 1 or 2, admixed with one or more pharmaceutically acceptable carriers or diluents.

7. A pharmaceutical composition according to claim 6 for oral administration.

('703 patent, claims 1, 6, 7). The parties agree that the claim term "admixed" in the '703 patent means "together." (D.I. 59 at 1).

Novartis wrote to the Court stating, "Novartis has granted Mylan a covenant not to sue on the '703 patent. As a result, Novartis believes that this Court no longer has jurisdiction over Mylan's counterclaims concerning the '703 patent." (D.I. 64). However, Mylan stated at oral argument, "[T]hat covenant is not sufficient to resolve the declaratory judgment claims and so in our view those two terms are still live." (Tr. 64:22-65:4). The parties indicated that they are "discussing" the covenant, so I will not address the '703 patent terms at this time. (Tr. 65:17-24).

III. TERMS FOR CONSTRUCTION

A. "Therapeutically effective amount" ('962 patent, claims 1, 2, 3, 4, 6)

1. *Novartis's proposed construction*: "an amount that is safe and effective to produce the desired therapeutic effect, i.e., inhibiting growth (slowing the increase in size and/or reducing the size) of non-malignant solid tumors of the brain"

2. *Mylan's proposed construction*: "amount effective for inhibiting growth of non-malignant solid tumors of the brain in a patient"

3. *Court's construction*: "amount effective for inhibiting growth of non-malignant solid tumors of the brain in a patient"

The sole dispute between the parties is whether my construction should include a "safe" amount. (D.I. 59 at 1, 7). Novartis wrote to the Court, indicating that it "agrees to adopt Mylan's construction of 'therapeutically effective amount.'" (D.I. 68). Accordingly, I will adopt Mylan's proposed construction as my own.

B. "Inhibiting growth" ('962 patent, claims 1, 2, 3, 4, 6)

1. *Novartis's proposed construction*: "slowing the increase in size and/or reducing the size, volume, mass, and/or weight"

2. *Mylan's proposed construction*: "plain and ordinary meaning, which is slowing the increase in and/or reducing the growth, including but not limited to measures of volume, mass, or cell proliferation"

3. *Court's construction*: "slowing the increase in and/or reducing the diameter, volume, mass, and/or weight"

Novartis wrote to the Court, indicating that the parties agree to a construction for "inhibiting growth." (D.I. 64). Accordingly, I will adopt that construction as my own.

C. "Colloidal silicon dioxide" ('598 patent, claims 1, 2, 3, 4, 6)

1. *Novartis's proposed construction*:

"colloidal silicon dioxide or colloidal silica"

OR, to the extent further construction is required,

"silicon dioxide forming small, insoluble, nondiffusible particles that remain in suspension"

4. *Mylan's proposed construction*: "fumed silica"

5. *Court's construction*: Plain and ordinary meaning: "colloidal silicon dioxide or colloidal silica"

Mylan contends that I should construe "colloidal silicon dioxide" as "fumed silica." (D.I. 59 at 40). Mylan makes two arguments to support its contention. First, Mylan argues that Novartis made a "disavowal of claim scope, limiting the meaning of 'colloidal silicon dioxide' to the form of silicon dioxide embodied in Aerosil®: fumed silica." (*Id.* at 41). Second, Mylan argues that extrinsic evidence provides that "colloidal silicon dioxide" means "fumed silica." (*Id.* at 41-42).

As to Mylan's disavowal argument, Mylan points to both the '598 patent specification and prosecution history.[1] First, the specification states, "Colloidal silicon dioxide may be obtained commercially . . . as Aerosil®." ('598 patent, 3:30-31). Aerosil® is a fumed silica product. (D.I. 59 at 40) (citing D.I. 60-2, Exh. 20 at 3:56-59)). But this provision in the specification merely provides that "fumed silica" is "colloidal silicon dioxide." It does not limit "colloidal silicon dioxide" to "fumed silica." Second, during prosecution, the patentee responded to the Examiner's rejection of the pending claims, stating the "problem" of poor disintegration times for the manufactured composition "was solved by adding Aerosil (silicon dioxide)." (D.I. 60-6, Exh. 56 at 7). The patentee also referred to Aerosil® as "Aerosil: Colloidal silicon dioxide." (*Id.* at 9). However, "for prosecution disclaimer to attach . . . the alleged disavowing actions or statements made during prosecution must be both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). The patentee's statements do not amount to "clear and unmistakable" disclaimer. The patentee's statements can be interpreted to mean that colloidal silicon dioxide provides a benefit, and Aerosil® is but one form of colloidal silicon dioxide. Accordingly, I do not find any disavowal based on the intrinsic record.

As to Mylan's extrinsic evidence argument, Mylan points to definitions of "colloidal silicon dioxide" from two references, which it deems "authoritative."[2] (D.I. 59 at 41-42). First, the United States Pharmacopoeia defines "Colloidal Silicon Dioxide" as "a submicroscopic fumed silica prepared by the vapor-phase hydrolysis of a silicon compound." (D.I. 60-5, Exh. 44 at 2514). Similarly, the Handbook of Pharmaceutical Excipients defines "colloidal silicon

[1] As Novartis notes, the words "fumed silica" appear nowhere in the intrinsic record. (D.I. 59 at 45). As Mylan notes, the intrinsic record never provides a definition for "colloidal silicon dioxide." (*Id.* at 40, 45).

[2] Mylan's expert describes the United States Pharmacopoeia as "the leading resource in the formulations industry for Food and Drug Administration-enforceable standards for drugs." (D.I. 60-6, Exh. 58 at 13).

dioxide" as "*Aerosil*; *Cab-O Sil*; colloidal silica; fumed silica; light anhydrous silicic acid; silicic anhydridic; silicon dioxide fumed; *Wacker HDK*." (D.I. 60-5, Exh. 46 at 143).

However, Novartis responds with other extrinsic evidence, which it cites in support of its own construction. (D.I. 59 at 48-50). For example, a chapter in a booked entitled *Adsorption on New and Modified Inorganic Sorbents* states, "There are numerous industrial products of colloidal silicas in various forms," including fumed silica like "aerosil" and non-fumed silica like "precipitated silicas," "silica sol," "silica hydrogels," and "porous silica."[3] (D.I. 60-2, Exh. 17 at 93-94). *Merriam Webster's Medical Desk Dictionary* defines "silica gel," which is non-fumed, as "colloidal silica." (D.I. 60-2, Exh. 12 at 654). Novartis cites numerous United States patents, which refer to "colloidal silica" as including "Syloid 44," which is non-fumed. (D.I. 60-2, Exh. 22 at 6:17-18; D.I. 60-2, Exh. 23 at 8:24-25; D.I. 60-2, Exh. 24 at 8:49-50; D.I. 60-2, Exh. 25 at 6:14-15; D.I. 60-2, Exh. 26 at 5:52; D.I. 60-2, Exh. 27 at 15:43; D.I. 60-2, Exh. 28 at 6:17-18). Novartis's expert argues, "A POSA would have understood that each of" these products, including silica gels, porous silica, and Syloid 44, "was a 'colloidal silica' or 'colloidal silicon dioxide.'" (D.I. 60-1, Exh. 10 at 11-13).

Mylan does not disagree that these references are inconsistent with the definition from the United States Pharmacopoeia, stating that the references use language that "confuses the issue." (Tr. at 52:2-8). However, Mylan's expert opines that the references cited by Novartis are not "extrinsic sources that a person in the art would ordinarily review." (D.I. 60-6, Exh. 56 at 15).

I agree with Mylan that the United States Pharmacopoeia is an authoritative reference. However, I also agree with Novartis's expert that several other pieces of extrinsic evidence

[3] The parties agree that "colloidal silica" is synonymous with "colloidal silicon dioxide." (D.I. 59 at 31, 33).

provide that "colloidal silicon dioxide" includes more products than just "fumed silica," and that a skilled artisan would have relied on those pieces of extrinsic evidence. Accordingly, I find that a skilled artisan would understand "colloidal silicon dioxide" to be broader than "fumed silica," based on the extrinsic evidence as a whole. I decline to adopt Mylan's proposed construction.

I also decline to adopt Novartis's additional proposed language, "silicon dioxide forming small, insoluble nondiffusible particles that remain in suspension."[4] As discussed at oral argument, I find Novartis's proposed language to be non-scientific and unhelpful in illuminating the meaning of "colloidal silicon dioxide." (Tr. at 46:21-47:12). Novartis agrees that the language is not necessary. (D.I. 59 at 35).

Instead, I adopt a plain and ordinary meaning construction, and specify that "colloidal silicon dioxide" and "colloidal silica" are synonyms. Colloidal silicon dioxide is not limited to fumed silica.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.

[4] Mylan argues that adopting this language would "create indefiniteness." (D.I. 59 at 42). Because I decline to adopt the language, I need not evaluate Mylan's argument.