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

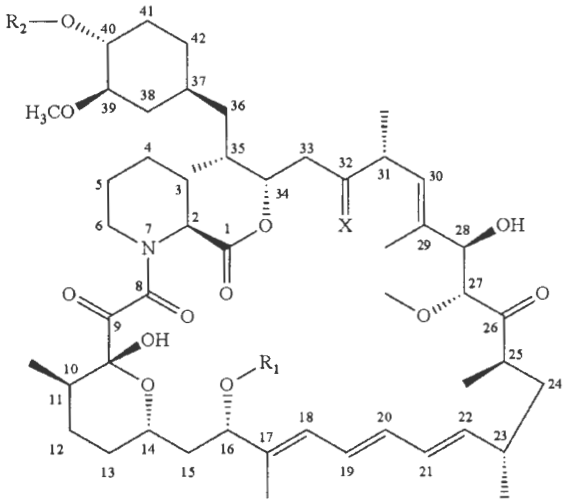
Novartis asserts the '962 and '598 patents against Mylan. (D.I. 1). Mylan seeks declaratory judgments of non-infringement and invalidity of the '962, '598, and '703 patents. (D.I. 15). The '962 patent "claims methods of inhibiting growth of non-malignant solid tumors of the brain . . . by administering 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.

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