IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| SANOFI and SANOFI-AVENTIS U.S. LLC,<br><br>Plaintiffs,<br><br>v.<br><br>LUPIN ATLANTIS HOLDINGS S.A., et al.,<br><br>Defendants. | Civil Action No. 15-415-RGA<br>**CONSOLIDATED** |

MEMORANDUM OPINION

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October 3, 2016

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is claim construction of multiple terms in U.S. Patent No. 9,107,900 B2 ("the '900 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 123). The Court heard oral argument on September 21, 2016. (D.I. 139).

## I. BACKGROUND

On May 21, 2015, Plaintiffs brought this patent infringement action alleging infringement of the '900 patent. (D.I. 1). The '900 patent is directed to methods of using dronedarone for the prevention of cardiovascular hospitalization. The '900 patent is similar to, but not identical to, U.S. Patent 8,410,167 B2, which I construed in the prior case *Sanofi, et. al. v. Glenmark Pharmaceuticals, et. al.*, 2015 WL 5092631 (D. Del. Aug. 28, 2015).

## II. 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 (internal quotation marks omitted). 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 and internal quotation marks omitted).

## III. PATENTS AT ISSUE

Claim 6 of the '900 patent is representative of asserted claims 1 and 6 in the relevant parts. It reads:

> 6. A method of reducing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and evening meal, (i) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation or flutter; and (ii) wherein said patient has congestive heart failure defined as NYHA class III; and (iii) wherein said patient has not been hospitalized for heart failure within the last month.

('900 patent, col. 29, ll. 1–10).

Claim 9 of the '900 patent reads:

> 9. A method of reducing a risk of cardiovascular hospitalization for atrial fibrillation in a patient, said method comprising administering dronedarone, or a pharmaceutically acceptable salt thereof, twice a day

with a morning and an evening meal to a patient in need of reduction of said risk, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent non-permanent atrial fibrillation; and (iii) wherein said patient has structural heart disease, wherein said structural heart disease is coronary heart disease; and (iv) wherein said patient has (a) an age greater than or equal to 75 or (b) an age greater than or equal to 70 and at least one cardiovascular risk factor selected from the group consisting of:

i. hypertension;

ii. diabetes;

iii. a history of cerebral stroke or of systemic embolism;

iv. a left atrial diameter greater than or equal to 50 mm; and

v. a left ventricular ejection fraction less than 40%.

('900 patent, col. 29, l. 19–col. 30, l. 12).

## IV. CONSTRUCTION OF DISPUTED TERMS

1. "a method of reducing a risk of cardiovascular hospitalization in a patient"; "a method of reducing a risk of hospitalization for atrial fibrillation in a patient"

   a. *Plaintiffs' proposed construction*: limiting preamble

   b. *Defendants' proposed construction*: non-limiting preamble

   c. *Court's construction*: limiting preamble

"While it is true that preamble language is often treated as nonlimiting in nature, it is not unusual ... to treat preamble language as limiting, as it is in this case." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). A preamble is limiting if it is "necessary to give meaning to the claim." *Id.*; *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). One way for a preamble to "give meaning" to a claim is to provide an antecedent basis for a term in the body of the claim. *Bicon, Inc.*, 441 F.3d at 952 ("[W]hen the limitations in the body of the

claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention." (internal quotation marks omitted)). That is the case here; in claims 1, 6, and 9 of the '900 patent the preamble gives meaning to terms in the claim body.

For claims 1 and 6, the preamble gives meaning to the term "effective amount" in the claim body. The need for the preamble is apparent when reading the body of the claims without it: "administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof...." Such a reading begs the question, effective for what?

Defendants primarily rely on three Federal Circuit cases to argue that the preamble is non-limiting: *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001); *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); and *American Medical Systems, Inc, et. al. v. Biolitec, Inc.*, 618 F.3d 1354 (Fed. Cir. 2010). As I explain, these cases are inapposite because the preambles in the relevant claims do not provide an antecedent basis.

At first blush, *Bristol-Myers* appears to govern the analysis here. *Bristol-Myers*, however, is distinguishable because in that claim the definition of effective amount was provided in the claim body. The claim read: "anti-neoplastically effective amount of about 135–175 mg/m2 taxol...." *Bristol-Myers*, 246 F.3d at 1371. Because there was no need for the preamble as an antecedent basis to understand what an effective amount was, the preamble did not "explain a claim limitation."

*See id.* at 1373, 1375 (explaining that the claim language belies the plaintiff's argument that the preamble is necessary to understand the claims).

Similarly in *Embrex* the preamble was not necessary to define "effective" because the body of the claim did the job itself. 216 F.3d at 1346. There the claim language read: "A method ... comprising injecting a vaccine effective *for inducing immunity* against said disease...." *Id.* (emphasis added). The desired effect—inducing immunity—was stated in the claim body and reference back to the preamble was not necessary.

In *American Medical Systems*, the Federal Circuit rejected the argument that the preamble term "photoselective vaporization of tissue" provided an antecedent basis for "the tissue." 618 F.3d at 1359. The preamble did "not specify a particular type or location of tissue being treated." *Id.* In the '900 patent though, the preamble to claims 1 and 6 does specify a particular type of effect—the reduction of cardiovascular hospitalization—giving meaning to the term effective.

In claim 9, the preamble provides an antecedent basis for the term "patient in need of reduction of said risk." Plaintiffs rely on *Rapoport v. Dement* to argue that the preamble is limiting here. 254 F.3d 1053 (Fed. Cir. 2001). I find this argument persuasive because the analysis in *Rapoport* lays over the claim language here. In *Rapoport*, the claim language read: "A method for treatment of sleep apneas comprising administration of a therapeutically effective amount of [the claimed compound] to a patient in need of such treatment...." *Id.* at 1056. The court explained that "without treating the phrase 'treatment of sleep apneas' as a claim

limitation, the phrase 'to a patient in need of such treatment' would not have a proper antecedent basis." *Id.* at 1059. Without the phrase "reducing a risk of cardiovascular hospitalization," the phrase "a patient in need of reduction of said risk" would not have a proper antecedent basis.

2. "effective amount"

   a. *Plaintiffs' proposed construction*: an amount effective to reduce a risk of cardiovascular hospitalization

   b. *Defendants' proposed construction*: plain and ordinary meaning

   c. *Court's construction*: an amount effective to reduce a risk of cardiovascular hospitalization

Having found that the preamble is limiting because it provides an antecedent basis for effective amount, I necessarily find that the term effective amount takes meaning from the preamble. In claims 1 and 6, effective amount means "an amount effective to reduce a risk of cardiovascular hospitalization."

"Effective amount" has a customary usage: the amount that is effective to accomplish the purpose of the claim. *Abbott Labs. v. Baxter Pharm. Products, Inc.*, 334 F.3d 1274, 1277-78 (Fed. Cir. 2003). In this case, the claims are addressed to reducing a risk of cardiovascular hospitalization. The proper construction of "effective amount" is therefore the amount that achieves that goal.

## V. CONCLUSION

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