UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KOWA COMPANY, LTD., et al.,

Plaintiffs,

-against-

AUROBINDO PHARMA LTD., et al.,

Defendants.

14 Civ. 2497
14 Civ. 2647
14 Civ. 2758
14 Civ. 2759
14 Civ. 2760
14 Civ. 5575
14 Civ. 7934 (PAC)

OPINION & ORDER

HONORABLE PAUL A. CROTTY, United States District Judge:

Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. bring patent infringement claims against seven sets of Defendants.[1] Plaintiffs, manufacturers of the cholesterol-lowering drug Livalo, allege that Defendants are infringing U.S. Patent Nos. 5,856,336 ("the '336 Patent"); 6,465,477 ("the '477 Patent"); and 8,557,993 ("the '993 Patent"). Defendants seek claim construction of the '336 Patent and the '477 Patent; Plaintiffs respond that construction is not necessary for either patent.[2] After the parties briefed the issue, the Court held a *Markman* hearing on October 16, 2015. The Court finds that Defendants have failed to raise an actual dispute regarding the proper scope of either

[1] Defendants are Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively "Aurobindo"); Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively "Mylan"); Amneal Pharmaceuticals, LLC ("Amneal"); Orient Pharma Co., Ltd. ("Orient"); Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively "Zydus"); Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (collectively "Sawai"); and Apotex, Inc. and Apotex Corp. (collectively "Apotex").

[2] The '336 Patent is not at issue in the Apotex case. The '477 Patent is not at issue in the Amneal, Apotex, and Aurobindo cases. There are no construction issues as to the '993 Patent.

patent claim; and accordingly construction is unnecessary.

I. Applicable Law

Claim construction is a matter of law for the Court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). "Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). "When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.2d 1351, 1360 (Fed. Cir. 2008).

II. The '336 Patent

The '336 Patent consists of two claims. Claim 1 describes a chemical compound and Claim 2 states that the compound is used "for reducing hyperlipidemia, hyperlipoproteinemia or atherosclerosis." *See* Pl. Opening Brief ("Pl. Br."), Dkt. 65, Ex. 1 at col. 32, ll. 21-38. Defendants seek construction of Claim 1. As stated at the *Markman* hearing, "[a]ll the defendants want here in their construction is confirmation that all four stereoisomers are included, all mixtures of them are included, and that in no way shape, or form are any of them excluded." Transcript of *Markman* Hearing ("Tr.") at 11. There is no dispute because Plaintiffs agree that the claim covers all four stereoisomers of the compound depicted in Claim 1 and all mixtures thereof. *See* Tr. 6 ("[O]ne of ordinary skill in the art looking at that claim would clearly understand that . . . there are four optical isomers which have the depicted structure. Claim 1 covers each of those."); Tr. 6 ("Where there are mixtures of stereoisomers, each of those stereoisomers in the mixture is covered by claim 1. Clearly such mixtures would also be covered

within the scope of claim 1."); Tr. 7 ("The compound of formula 1 includes all the optical isomers and all the mixtures"); Tr. 7 ("Both parties agree that claim 1 as it's written and as it was allowed by the patent examiner calls the optical isomers and mixtures thereof"); Tr. 10 ("[C]ompound claims [such as this one] which don't include stereochemical terminology or symbols are interpreted as being without limitation as to stereochemical forms.").

Defendants' reliance on *Infosint, S.A. v. H. Lundbeck A/S*, 603 F. Supp. 2d 748 (S.D.N.Y. 2009) in arguing for construction is unavailing. In that case, one party argued that the claim term in dispute covered only a single optical isomer, so construction was necessary to clarify that the claim covered all optical isomers. *Id.* at 756. Here, the parties agree that the claim covers all four optical isomers. Since Defendants have not "raise[d] an actual dispute regarding the proper scope of these claims", *O2 Micro*, 521 F.2d at 1360, claim construction is unnecessary.

III. The '477 Patent

The '477 Patent states that pitavastatin calcium (also known as NK-104), the active ingredient in Livalo, is "unstable at low pH, and many difficulties have been encountered in formulating it into preparations." *See* Pl. Br., Ex. 2 at col. 1, ll. 63-65. The patent describes a method to make a stable form of the compound in the pH range 6.8 to 7.8. Defendants seek construction of Claim 1, which reads in full:

> A pharmaceutical composition comprising (E)-3,5-dihydroxy-7-[4'-4"-flurophenyl-2'-cyclopropyl-quinolin-3'-yl]-6-heptenoic acid, or its salt or ester, and a pharmaceutically acceptable carrier, of which aqueous solution or dispersion of the pharmaceutical composition has pH of from 6.8 to 7.8.

Id. at col. 10, ll. 58-63. Defendants seek construction to clarify the method by which pH is measured. To answer this question, both Plaintiffs and Defendants point to the same explanatory language in the specification:

> The pH as referred to herein indicates the pH value to be determined in such a manner that a unit dose of a solid preparation comprising NK-104 or its salt or ester is sampled and dissolved or dispersed in from 1 to 10 ml of pure water, and the pH of the resulting aqueous solution or dispersion is measured.

Id. at 5. The parties agree that this language explains that pH is to be determined by taking a solid preparation of the pharmaceutical composition (likely a tablet), dissolving the tablet in 1 to 10 ml of pure water, and measuring the pH of the resulting solution. *Compare* Pl. Resp. Br., Dkt. 66 at 7 ("pH is to be measured by dissolving or dispersing a unit dose of the claimed pharmaceutical composition in from 1 to 10 ml of pure water"); and Tr. at 37 (Pl. Counsel: "[Y]ou take a unit dose of the – the thing you are trying to test is the pharmaceutical composition. You take a unit dose of that. You either disperse it or dissolve it in from 1 to 10 milliliters of pure water, and then you measure the pH of the resulting liquid."); *with* Def. Resp. Br., Dkt. 79 at 21 ("Defendants' proposed construction involves taking the 'unit dose of a solid preparation of the pharmaceutical composition'; 'dissolv[ing] or dispers[ing the unit dose] in 1 to 10 mL of pure water'; and then testing for pH"); and Tr. at 40-41 (Def. Counsel: "[Y]ou take a tablet, you're going to dissolve that tablet in 1 to 10 milliliters of pure water, and then a pH monitor is going to measure what the pH of that solution is.") Here too Defendants have not "raise[d] an actual dispute regarding the proper scope of these claims", *O2 Micro*, 521 F.2d at 1360; and claim construction is unnecessary.

CONCLUSION

The Court holds that claim construction is not necessary. The parties are directed to proceed with expert discovery according to the timeline as set forth in the Scheduling Order. *See* Dkt. 93.

Dated: New York, New York
November 4, 2015

SO ORDERED

PAUL A. CROTTY
United States District Judge