IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 16-905-JFB-CJB
	)	Consolidated
ACTAVIS ELIZABETH LLC, *et al.*,	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION

At Wilmington this **30th day of July, 2019.**

WHEREAS, having reviewed the briefing of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs") and Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively, "Sawai") regarding two supplemental claim construction issues related to the meaning of the powder x-ray diffraction ("PXRD") "peaks" term that is: (a) found in claim 1 of U.S. Patent No. 7,342,117 (the "'117 patent"); and (2) incorporated by the Court's construction of "α-form crystal" in claims 1 and 13 of U.S. Patent No. 7,982,049 (the "'049 patent") (collectively with the '117 patent, the "PM patents"), (D.I. 475, 486, 495, 500);[1]

NOW, THEREFORE, IT IS HEREBY ORDERED as follows with respect to the parties' two disputes:

1. With respect to Issue #1, the Court recommends that Plaintiffs' proposed construction (i.e., "a signal large enough to be distinguished from the background noise"), (*see* D.I. 486 at v), be adopted. There is no dispute that a "peak" must have a signal that is large

[1] The Court hereby incorporates by reference the summary of the background of this matter set out in its June 18, 2018 Report and Recommendation ("June 18 R&R"). (D.I. 259 at 1-5) It additionally incorporates by reference the legal principles regarding claim construction set out in the June 18 R&R. (*Id.* at 5-9)

enough to be distinguished from the background noise. (D.I. 475 at 1; D.I. 486 at 1; D.I. 487, ex. 5 at ¶ 22) Rather, the parties' dispute centers on "*how* a [person of ordinary skill in the art] would determine if a given signal is indeed sufficiently larger than the noise to be considered a 'peak.'" (D.I. 475 at 1 (emphasis added)) While Sawai's proposed construction would require objective means (e.g., statistical analysis) of making that determination, Plaintiffs' proposal would allow for the use of visual observation alone to make such a determination. (D.I. 475 at 1; *see also* D.I. 486 at 1 (Plaintiffs highlighting that "what appears to be in dispute is whether a POSA must determine a 'peak' using 'substantially and objectively larger' data, or whether a POSA may use all data typically relied upon for PXRD, including visual evaluation"))[2] The Court agrees with Plaintiffs that Sawai's proposed construction (and the impetus behind it) relates to an issue of infringement rather than a true claim construction dispute. (D.I. 486 at 1; D.I. 500 at 3)[3] The patent provides a table relating to the α-form crystal that references 8 characteristic PXRD peaks of that crystal form. ('049 patent, col. 2:29-40; *see also* D.I. 259 at 14) The parties agree that PXRD is a particular form of testing. (D.I. 486 at 3 n.7; D.I. 495 at 2

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[2] Sawai explains that the real crux of the dispute relates to situations where a signal and noise are of similar intensity. (D.I. 475 at 1 n.7; D.I. 495 at 1-2) In such a circumstance, Sawai argues that visual examination alone is insufficient to determine if a given signal constitutes a peak. (D.I. 475 at 1 n.7; D.I. 495 at 1-2) Otherwise, Sawai accepts visual examination as a sufficient methodology to determine if a given signal is a peak. (*See* D.I. 495 at 2 ("[W]hen all PXRD experts can agree there is a peak by visual determination, then it is clear a POSA objectively would consider it one too."))

[3] The patent infringement analysis consists of two steps. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must determine the meaning and scope of the asserted patent claims. *Id.* Claim construction is generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). Second, the trier of fact must compare the properly construed claims to the allegedly infringing device. *Markman*, 52 F.3d at 976. This second step is a question of fact. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012).

n.5) The United States Court of Appeals for the Federal Circuit has explained that "even where the claims require a particular test result, there may be (and often are) disputes between the parties as to the proper application of the test methodology in the circumstances of an individual case. But those disputes are disputes about whether there is infringement, not disputes about whether the patent claims are indefinite." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1377 (Fed. Cir. 2017). Sawai will be free to present its criticisms of Plaintiffs' experts' testing methodology to the District Court via a motion filed pursuant to Federal Rule of Evidence 702[4] and (if necessary) thereafter at trial, all in an effort to argue that Plaintiffs' evidence of infringement is insufficient.[5] *See ADC Telecommc'ns, Inc. v. Switchcraft, Inc.*, 281 F. App'x 989, 992 (Fed. Cir. 2008) (concluding that the parties' dispute over the proper testing method for infringement of the disputed claim limitations was a factual question of infringement rather than a claim construction question, and that a reasonable jury could have

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[4] Indeed, Sawai has separately moved to exclude, under Rule 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), Plaintiffs' experts' infringement opinions for "us[ing] subjective, visual methods to determine whether 'peaks' were present" in Sawai's accused product. (D.I. 491 at 9)

[5] At times, Sawai seems to acknowledge that its proposal is only "typically" utilized by the person of ordinary skill in the art, which seems to cut against construing "peaks" as Sawai proposes (i.e., to *require* statistical analysis). (*See* D.I. 475 at 2 ("[A] POSA *typically* uses an objective standard to determine whether the number of counts for a given signal has statistically exceeded the 'noise' over several steps before identifying a signal as a 'peak,' especially when the signals and the noise are of similar intensity.") (emphasis added); *id.* at 1-2 n.7 ("Statistical analyses of a signal can be used with visual interpretation to determine if a signal rises sufficiently above the noise to be a 'peak,' but *typically*, a POSA does not rely on visual interpretation alone to determine if a peak is present or not[.]") (emphasis added)) Indeed, even Sawai appears to have utilized only the visual evaluation methodology in determining whether the α-form crystal peaks were present in its own samples. (D.I. 500 at 3)

accepted defendant's criticisms of plaintiff's testing methodology and concluded that plaintiff had failed to introduce preponderant evidence of infringement).

2. With respect to Issue #2, the Court recommends that Plaintiffs' proposal (i.e., that no further limitations are required), (D.I. 486 at v), be adopted. Sawai asserts that claim terms directed to a measured quantity should be defined with respect to a particular method of measurement "when (a) the applicable method is apparent from the intrinsic record of the patent and (b) different methods give significantly different results." (D.I. 475 at 4) It is undisputed that the patent specification provides a description of the parameters under which "measurement of [PXRD as described in the patent] was carried out[.]" ('117 patent, col. 2:42-47; D.I. 475 at 5; D.I. 486 at 5) It is also undisputed that the asserted claims do not recite PXRD testing parameters that must be utilized. (D.I. 475 at 5; D.I. 500 at 3-4) Both parties seem to agree that the POSA could make "sensitivity adjustments" to such parameters based on the sample to be analyzed. (D.I. 495 at 4; *see also* D.I. 486 at 5-6) While Sawai's expert speculates that changing the PXRD parameters could result in peaks with different 2θ values, (D.I. 476, ex. 3 at ¶ 208), he does not provide evidence of circumstances where, after using different parameters, the peak positions differed. Moreover, Plaintiffs' expert explains that the 2θ values are related to the physical d-spacings in the crystals, which are characteristic of the crystal form. (D.I. 487, ex. 5 at ¶ 14) In other words, if the α-form crystal is present but the characteristic peaks are not observed, that means that the PXRD parameters were not sensitive enough to observe the 2θ values; in such a case, the parameters could be adjusted. (*Id.*) Accordingly, a scenario where there are peaks with *different* 2θ values depending on the parameters utilized seems to be a different scenario than one where a sample has particular 2θ values that *may not be able to be observed* based on the parameters used. Therefore, the Court agrees with Plaintiffs that Sawai

has not shown that "'different methods give significantly different results.'" (D.I. 486 at 5 (quoting D.I. 475 at 5-6)) The Court is not persuaded that other parameters may not be utilized by a POSA. *See, e.g.*, *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, C.A. No. 17-374-LPS (Consolidated), 2018 WL 5077895, at *6 (D. Del. Oct. 18, 2018) (rejecting defendant's argument that claim should be construed as needing to be measured solely and exclusively by a certain technique where: (1) the claims were silent as to a method of measurement; and (2) while the specification explained that the particle sizes were determined using a particular technique, this explanation did not, as a matter of claim construction law, exclude the possibility that other methods of measurement might alternatively be used). Sawai is of course still free to argue that, with regard to the matter of infringement, Plaintiffs have failed to meet their burden due to Plaintiffs' experts' utilization of certain PXRD parameters.[6]

3. This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within seven (7) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2), and responses to any objections within seven (7) days after any objections are filed. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006). The parties are otherwise directed to the Court's Standing Order for Objections Filed

[6] Relatedly, Plaintiffs' experts' testing, including their purported "alterations of" well-known PXRD methods, is a subject of Sawai's pending *Daubert* motion (wherein Sawai argues that these alterations amount to the use of unreliable techniques). (*See* D.I. 491 at 7-8)

Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

4. Because this Report and Recommendation may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the Report and Recommendation. Any such redacted version shall be submitted no later than **August 2, 2019**, for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Report and Recommendation.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE