

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., et al.,

Plaintiffs,

v.

ACTAVIS ELIZABETH LLC, ET AL,

Defendants.

**C.A. No. 1:16-905-JFB-CJB
(Consolidated)****MEMORANDUM & ORDER**

This matter is before the Court on objections filed by defendant Sawai Pharmaceutical Co., Ltd. (“Sawai”) (D.I. 520) to the Report and Recommendation (“R&R”) of the Magistrate Judge on supplemental claim construction issues (D.I. 515). These are consolidated actions arising under the patent laws of the United States, [35 U.S.C. § 101](#), et seq. as well as the Hatch-Waxman Act, [21 U.S.C. § 355](#).

The actions arise out of filings by multiple generic drug companies, including defendant Sawai, of Abbreviated New Drug Applications (“ANDAs”) with the Food and Drug Administration (“FDA”). The defendants seek to market generic MYRBETRIQ® (mirabegron) extended release tablets prior to the expiration of plaintiff Astellas Pharma Inc.’s¹ Orange Book-listed United States Patent Nos. 7,342,117 (“the ’117 patent”), 7,982,049 (“the ’049 patent”), 8,835,474 (“the ’474 patent”), and United States Reissued patent no. RE44,872 (“the ’872 patent”). MYRBETRIQ is used to treat overactive bladder. The ’117 patent and the ’049 patent, concern mirabegron polymorphs. See

¹ Astellas Pharma Inc. is the record owner and assignee of the patents. Astellas Pharma Global Development, Inc. contracted with Astellas Pharma US, Inc., a subsidiary of Astellas Pharma Inc., to market and sell the drug mirabegron under the trade name MYRBETRIQ®. Plaintiff Astellas Ireland Co., Ltd. is the exclusive licensee of the patents. The plaintiffs will be referred to collectively as “Astellas.”

D.I. 392 at 1 n.2. The other two patents concern methods of treating overactive bladder with mirabegron. *Id.*

In the R&R, the Magistrate Judge addressed supplemental claim construction in connection with the meaning of the term powder x-ray diffraction (“PXRD”)² “peaks,” a term that is found (1) in claim 1 of the ’117 patent and (2) and the meaning of “α-form crystal” as used in claims 1 and 13 of the ’049 patent, as construed by the Court.³

STANDARD OF REVIEW

The standard of review is governed by [28 U.S.C. § 636\(b\)\(1\)\(C\)](#) and [Federal Rule of Civil Procedure 72\(b\)](#). The district court “shall make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made” and “may also receive further evidence or recommit the matter to the Magistrate Judge with instructions.” 28 U.S.C. § 636(b)(1)(C). Similarly, Rule 72(b)(3) requires de novo review of any recommendation that is dispositive of a claim or defense of a party.

The Supreme Court has construed the statutory grant of authority conferred on Magistrate Judges under [28 U.S.C. § 636](#) to mean that nondispositive pretrial matters are governed by § 636(b)(1)(A) and dispositive matters are covered by § 636(b)(1)(B). [Gomez v. United States, 490 U.S. 858, 873-74 \(1989\)](#); see also [Fed. R. Civ. P. 72\(a\)](#). Under subparagraph (B), a district court may refer a dispositive motion to a magistrate judge “to conduct hearings, including evidentiary hearings, and to submit to a judge of

² PXRD is a form of testing. (D.I. 515, R&R at 2)

³ The Court found “α-form crystal” should be construed to mean ‘α-form crystal which is a term of reference for a polymorphic crystal form of (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl] acetanilide that can be distinguished from other forms by characteristic [PXRD] peak(s) and DSC [differential scanning calorimetry] analysis as identified in the specification” (D.I. 259, R&R at 23-24, 39)

the court proposed findings of fact and recommendations for the disposition.” 28 U.S.C. § 636(b)(1)(B); see *EEOC v. City of Long Branch*, 866 F.3d 93, 99–100 (3d Cir. 2017). The product of a Magistrate Judge, following a referral of a dispositive matter, is often called a “report and recommendation.” *Id.* “Parties ‘may serve and file specific written objections to the proposed findings and recommendations’ within 14 days of being served with a copy of the Magistrate Judge’s report and recommendation.” *Id.* (quoting *Fed. R. Civ. P. 72(b)(2)*).

“If a party objects timely to a Magistrate Judge’s report and recommendation, the district court must ‘make a de novo determination of those portions of the report or specified proposed findings or recommendations to which objection is made.’” *EEOC*, 866 F.3d at 99 (quoting 28 U.S.C. § 636(b)(1)).

DISCUSSION

The asserted patents claim the α -form of mirabegron, a crystal having certain characteristic peaks in two analytical techniques—powder X-ray diffraction and differential scanning calorimetry. With respect to the term “peaks” in claim 1 of the ’117 patent, the parties’ dispute centers on how a person of ordinary skill in the art (“POSA”) would determine if a signal is sufficiently larger than the noise to be considered a “peak.” D.I. 515, R&R at 2. Astellas contends no construction is necessary, but alternatively proposes “a signal large enough to be distinguished from the background noise,” whereas Sawai proposes “a signal that is substantively and objectively larger than the background noise.”⁴ D.I. 475, Sawai’s Brief at ii. The Magistrate Judge found that defendant Sawai’s proposed construction would require objective means, i.e.,

⁴ “Noise” is the random instrumental fluctuation in signal present in every PXRD experiment (D.I. 475, Sawai’s brief at 1 n.4).

statistical analysis, to make such a determination, whereas the plaintiff's proposal would allow all relevant evidence showing "peak(s)"—including visual observation alone—to be considered. The Magistrate Judge made the factual finding that "[t]here is no dispute that a 'peak' must have a signal that is large enough to be distinguished from background noise" and applied the ordinary meaning of the term. D.I. 515, R&R at 1-2; see *Pfizer Inc. v. Apotex, Inc.*, No. 18-795-RGA, D.I. 58 (D. Del. June 28, 2019). The Magistrate Judge found Sawai's proposed claim construction related to an issue of infringement rather than to a true claim construction dispute. *Id.* The Magistrate Judge agreed with the plaintiff's proposed construction and recommended that the term "peaks" in claim 1 of the '117 patent should be construed as "a signal large enough to be distinguished from background noise." *Id.* at 1.

With respect to the Court's construction of "α-form crystal" in claims 1 and 13 of the '017 patent, Astellas proposed no further limitations, whereas Sawai proposed "generated by a PXRD method on a properly calibrated PXRD instrument with parameters similar to those in the '117 patent, Col. 2:42-47." D.I. 486, Astellas Brief at 5. The referenced parameters are found as examples in the specification. D.I. 487-1, Ex. 3, Michael J. Cima Expert Report at 32; D.I. 1-1, Ex. B, '117 patent, Col. 2:42-47. The Magistrate Judge rejected Sawai's invitation to read the PXRD method parameters from the specification into the claim, noting that "[b]oth parties seem to agree that the POSA could make 'sensitivity adjustments' to such parameters based on the sample to be analyzed." D.I. 515, R&R at 4. The Magistrate Judge was "not persuaded that other parameters may not be used by a POSA[.]" and found no further limitation was required. *Id.*

Sawai objects to the Magistrate Judge's recommendation, arguing the R&R improperly characterizes its arguments as infringement or Daubert arguments, is not supported by the intrinsic evidence, fails to recognize extrinsic evidence and does not reflect basic canons of claim construction. It argues the Magistrate Judge's claim construction is indefinite.

The Court has carefully reviewed the parties' briefs and evidence (D.I. 475, 476-1, 486, 467, 495, 495-1, 500, and 501), defendant Sawai's objections and plaintiff's response (D.I. 520 and 526) and finds no errors of fact or law in the Magistrate Judge's R&R.

The Court agrees that Sawai's proposed construction of "peaks" would deviate substantially from the ordinary meaning by excluding a key tool from the art, visual evaluation. The plaintiff's requested construction is which is commensurate with the ordinary meaning of the term in art. Also, adoption of Sawai's proposed construction of α -form crystals would amount to importing the PXRD method parameters into the claims.

The Court also agrees with the Magistrate Judge's assessment that Sawai's proposed construction relates more to infringement issues than to claim construction. The Magistrate Judge also properly rejected Sawai's attempt to repackage its failed indefiniteness claims. Sawai remains free to criticize the plaintiff's expert testing methodology and to argue that the plaintiffs have failed to produce sufficient evidence of infringement or failed to meet their burden due to plaintiff's experts' utilization of certain PXRD parameters. The Court further finds the Magistrate Judge's R&R is consistent with intrinsic and extrinsic evidence and conforms to canons of claim construction.

The Court finds the Magistrate Judge's analysis is correct as a matter of fact and law.

THEREFORE, IT IS ORDERED THAT:

1. Defendant Sawai's objections (D.I. 520) to the Magistrate Judge's R&R (D.I. 515) are overruled; and
2. The Magistrate Judge's R&R (D.I. 515) is adopted in its entirety.

Dated this 15th day of August 2019.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge