

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

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

MEMORANDUM ORDER

At Wilmington, Delaware this **3rd day of May, 2018**.

1. On April 16, 2018, Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively, “Sawai”) filed a Motion for Teleconference to Resolve Discovery Dispute (“Motion”), regarding Plaintiffs’ objections and responses to Sawai’s Interrogatories Nos. 2-4. (D.I. 182) The Court has considered the parties’ letter briefs, (D.I. 209, 211), and the parties’ arguments made during the May 2, 2018 discovery dispute teleconference.

2. With these Interrogatories, Sawai seeks information regarding:
- For Interrogatory No. 2, “a description of any polymorphic or amorphous or crystalline forms of mirabegron of which Plaintiffs have knowledge . . . and persons with knowledge of these forms[;]”
 - For a revised version of Interrogatory No. 3, “a description of Plaintiffs’ knowledge concerning any amorphous or other non-crystalline form(s) of mirabegron[;]” and
 - For Interrogatory No. 4, “a description of Plaintiffs’ knowledge of any information regarding whether any solid form of mirabegron can convert or change into a crystalline form . . . during manufacturing of a dosage form and/or during the shelf life of a dosage form and persons with knowledge of such conversions or changes.”

(D.I. 209 at 2 (citing *id.*, ex. 3 at 5-6; *see also id.*, ex. 4 at 4, 9, 13))

3. Plaintiffs' supplemental responses, however, are not fully responsive to these Interrogatories. While Sawai's Interrogatories Nos. 2-4 seek information regarding, *inter alia*, non-crystalline forms of mirabegron and Plaintiffs' knowledge of information regarding whether any solid form of mirabegron can convert to a crystalline form, Plaintiffs' supplemental responses mainly refer to crystalline forms of mirabegron and whether the claimed crystalline forms of mirabegron can convert to other forms. (*Id.*, ex. 4 at 8-9, 12-13, 16-17)

4. Sawai expects that the sought-after information will provide support for its non-infringement and invalidity defenses, (D.I. 209 at 1-3), and the Court agrees with Sawai that the information is relevant in this regard, *see* Fed. R. Civ. P. 26(b) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense[.]"). With respect to infringement, for example, the parties currently have disputes about whether Sawai's proposed mirabegron product—which Sawai contends is [REDACTED]—amounts to the claimed form, as well as about what constitutes a claimed form of mirabegron. Accordingly, information in Plaintiffs' possession relating to amorphous forms of mirabegron appears to be relevant to such disputes. Moreover, with respect to invalidity, information about other non-claimed forms of mirabegron could well be relevant to, for instance, whether a piece of prior art inherently anticipates the asserted claims (such as if any such information shows that a claimed form of mirabegron is the "natural result flowing from [an] explicit disclosure of the prior art"). *See Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (internal quotation marks and citations omitted).¹ Indeed, Plaintiffs

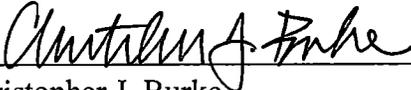
¹ At times, Plaintiffs defend the scope and temporal limits of their responses by pointing to certain of *Sawai's* interrogatory responses. (D.I. 211 at 3) However, there is no discovery dispute before the Court regarding those responses, and therefore the Court does not consider them in the context of resolving the present dispute.

acknowledge that they have produced certain documents relating to amorphous mirabegron, (D.I. 211 at 3 & n.4), which seems to underscore that such information is indeed relevant to this matter.

5. Although Plaintiffs also contend that any sought-after information described above is not relevant if it was generated after the filing of their New Drug Application in 2012, (*id.* at 2-3), the Court does not understand how that is so, particularly with respect to Sawai's potential non-infringement and inherent anticipation defenses.

6. For the reasons set out above, Sawai's Motion is thus GRANTED. By no later than **May 16, 2018**, Plaintiffs shall supplement their responses to Sawai's Interrogatories Nos. 2-4. To the extent that Plaintiffs therein point to documents that they have produced as providing responsive information, pursuant to Federal Rule of Civil Procedure 33(d), Plaintiffs shall identify the Bates number(s) for each responsive document.

7. Because this Memorandum Order 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 Memorandum Order. Any such redacted version shall be submitted no later than **May 8, 2018**, 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 Memorandum Order.



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE