

**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 **24th day of October, 2018**.

1. On October 15, 2018, Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively, “Sawai”) filed a Motion for Teleconference to Resolve Discovery Dispute (“Motion”), regarding: (1) Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc.’s (collectively, “Astellas” or “Plaintiffs”) supplemental responses to Defendants’ Interrogatory No. 14 (“Rog. No. 14”) concerning secondary considerations/objective indicia of non-obviousness (“secondary considerations”); and (2) Sawai’s request for the full regulatory record of Plaintiffs’ New Drug Application (“NDA”) (including their supplemental NDA (“sNDA”))— i.e., all correspondence, amendments and supplements. (D.I. 340; *see also* D.I. 342 at 4) The Court has considered the parties’ letter briefs, (D.I. 342, 343), and the parties’ arguments made during the October 23, 2018 discovery dispute teleconference.

2. In September 2017, Sawai served Rog. No. 14, seeking identification of Plaintiffs’ contentions regarding secondary considerations, Plaintiffs’ underlying factual bases for those contentions, related documents, and witnesses with knowledge thereof. (D.I. 342, ex.

A at 2) Plaintiffs' initial response to Rog. No. 14 was, in essence, a non-response. It provided no meaningful information, instead simply listing objections and then vaguely stating:

Astellas may rely on one or more objective indicia of non-obviousness, including but not limited to unexpected results, long-felt need, commercial success, industry recognition and praise, copying, and failure of others. To the extent Astellas will rely on such objective indicia and pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, Astellas will produce documents demonstrating such objective indicia of non-obviousness at the appropriate time.

(*Id.* at 3) Sawai understandably expressed dissatisfaction with this non-answer and pressed for more. (*See, e.g., id.*, ex. B at 15) This eventually led to Plaintiffs providing a supplemental response *eight months later* on May 18, 2018 (the "First Supplement"). (*Id.*, ex. A at 4) Plaintiffs' First Supplement provided barely any more information than did their initial response. In that four-paragraph First Supplement, Plaintiffs confirmed that they would be relying on evidence of secondary considerations, but otherwise, they provided only one substantive statement:

Astellas identifies, *inter alia*, NDA No. 202611, the Myrbetriq® Label, and the '117, '049, '474 and '872 patents as relevant to secondary considerations, *inter alia*, unexpected results. Astellas further identifies the following non-exhaustive list of documents as relevant to, *inter alia*, praise by others and commercial success: [5 Bates-stamped documents totaling 43 pages].

(*Id.*)

3. Secondary considerations can be very important in a case in which obviousness is a defense to patent infringement. *See, e.g., Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010). Plaintiffs themselves acknowledge this, asserting that "objective indicia of non-obviousness are highly relevant to rebutting Defendants' obviousness contentions." (D.I. 343 at 2) When a defendant propounds an interrogatory seeking factual information regarding

this issue, it is entitled to a meaningful response. Unfortunately, as of May 2018—a point by which nearly 19 months had passed since this suit was filed, and at a time when Plaintiffs certainly should have had good handle on their secondary considerations arguments—Sawai still had not gotten such a response.

4. Sawai remained unsatisfied and diligently continued to press Plaintiffs for additional information. (*See* D.I. 342 at 2) Ultimately, on September 10, 2018, Plaintiffs served a 12-page second supplemental response (the “Second Supplement”) in which they finally provided meaningful articulations of their contentions regarding the various objective indicia of non-obviousness (as well as citation to relevant related documents). (*Id.*, ex. A at 5-18) Plaintiffs’ Second Supplement, however, came too late, as it was provided approximately two months after fact discovery had closed. This is so despite the fact that the Second Supplement relied substantially “on information and documents that were available to Plaintiffs months, if not years, earlier.” (D.I. 342 at 3 (emphasis omitted)) Had Plaintiffs instead responded to Rog. No. 14 in a more timely manner, Sawai could have followed up appropriately on the issue during the fact discovery period. Instead, armed with only Plaintiffs’ prior barebones responses, Sawai had no real opportunity to explore and vet Plaintiffs’ positions during fact discovery. That is unfair to Sawai. And it is just not the way the discovery process is supposed to work.

5. With its Motion, Sawai now requests that Plaintiffs’ Second Supplement be stricken. (*Id.* at 4) The problem for Sawai is that, as poor as Plaintiffs’ efforts were in the initial response and the First Supplement, Sawai cannot meet the very high standard for exclusion. The *Pennypack* factors are applicable to this dispute,¹ and they do not support striking Plaintiffs’

¹ Federal Rule of Civil Procedure 37(c)(1) states that “[i]f a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information .

Second Supplement. At least four of the *Pennypack* factors redound in Plaintiffs' favor. First, as noted above, it is undisputed that secondary considerations are very important in a patent case like this one. With respect to the third and fourth *Pennypack* factors, trial in this matter is over seven months away, and the Court believes that the prejudice that Sawai faces can be cured in sufficient time so as not to unduly disrupt the order and efficiency of trial. Finally, there is not enough in the record to permit the Court to conclude that Plaintiffs' failure to timely supplement Rog. No. 14 was done in bad faith.

6. Because the exclusion of critical evidence is such an "extreme sanction," *Int'l Bus. Machs. Corp v. Priceline Grp. Inc.*, 271 F. Supp. 3d 667, 694 (D. Del. 2017) (internal quotation marks and citation omitted), it is often hard for movants to show that the *Pennypack* factors militate in favor of exclusion (as is the case here). In a case like this one, where a party utterly fails in its discovery obligations, but where exclusion of evidence is not the right result, the Court is left in a tough spot. How does it follow the law as set out in *Pennypack* and its progeny (i.e., not exclude the evidence), but do so in a way that does not incentivize parties to flout their discovery obligations in the first place? In this Memorandum Order, the Court will try to accomplish both parts of this difficult task.

. . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Even if there is a violation of Rule 26, in order to justify exclusion of the relevant evidence, the movant has to show that application of the "*Pennypack*" factors counsels in favor of that remedy. The *Pennypack* factors include: (1) the importance of the information withheld; (2) the prejudice or surprise to a party against whom the evidence is offered; (3) the likelihood of the disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence. See *Int'l Bus. Machs. Corp v. Priceline Grp. Inc.*, 271 F. Supp. 3d 667, 694 (D. Del. 2017) (citing cases).

7. Accordingly, the Court HEREBY GRANTS-IN-PART Sawai's Motion as follows: (1) Plaintiffs' Second Supplement is not stricken from the case, and in making its secondary considerations case at trial, Plaintiffs and their experts may rely on any evidence/argument fairly raised in the Second Supplement. However, absent further order of the Court, Plaintiffs' reliance on secondary considerations is limited to the content of the Second Supplement.; (2) Sawai may take targeted discovery relating to secondary considerations. The Court expects that the parties will work cooperatively to complete this focused discovery as expeditiously as possible. To that end, by no later than **October 31, 2018**, the parties shall meet and confer, and submit a proposed schedule for such discovery, including the date by which all such discovery shall be completed.; (3) As part of this supplemental discovery, Plaintiffs shall produce all correspondence to and from the FDA regarding their original NDA. Sawai has sufficiently explained the relevance of such documents, (D.I. 342 at 4), and Plaintiffs made no argument regarding burden of production with respect to these documents, (D.I. 343).² (4) In light of Plaintiffs' failure to diligently comply with their discovery obligations regarding Rog. No. 14, the Court will entertain a motion from Sawai for reasonable expenses, including attorney's fees. Such a request should seek recovery for only those expenses relating to Plaintiffs' positions on secondary considerations that Sawai would not have incurred, were

² As for Sawai's request that Plaintiffs be compelled to produce the sNDA, the Court is less certain about the sNDA's relevance to secondary considerations. (*See* D.I. 343 at 3-4 (citing, *e.g.*, *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 998 (Fed. Cir. 2009)). The Court also understands that the request may be related in some way to a brewing discovery dispute regarding Defendants' expert Dr. Michael Chancellor, which the Court may hear shortly. (*See id.* at 3 n.6) The Court will refrain from ruling on this portion of the request until resolution of the issue regarding Dr. Chancellor. It may also request additional short briefing from the parties regarding the sNDA as part of the discovery dispute process relating to Dr. Chancellor.

Plaintiffs to have timely disclosed their positions (e.g., expenses relating to the re-review of discovery documents regarding this issue and/or the costs associated with hereafter deposing or re-deposing a witness relating to this issue). *See* Fed. R. Civ. P. 37(c)(1)(A); *Grote v. Wright Med. Grp., Inc.*, No. 12-CV-2002-LRR, 2013 WL 4670311, at *6 (N.D. Iowa Aug. 30, 2013); *cf.* *Oceans Cuisine, Ltd. v. Fishery Prods., Int'l, Inc.*, No. 05-CV-3613 (DRH)(AKT), 2006 WL 1071578, at *2, *4 (E.D.N.Y. Apr. 21, 2006); *Holden Metal v. Wismarq*, No. 00 C 191, 2004 WL 1498152, at *1 (N.D. Ill. July 1, 2004).

8. 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 **October 29, 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