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January 17, 2017

Hon. Paul A. Crotty
United States District Judge
Daniel Patrick Moynihan United States Courthouse
500 Pearl Street, Room 735
New York, NY 10007

Re: *Kowa Company, Ltd. et al. v. Amneal Pharmaceuticals LLC, et al.*,
Case Nos. 14-cv-2758 (PAC); 14-cv-5575 (PAC); 14-cv-7934 (PAC);
and 15-cv-3935 (PAC);

Your Honor:

On behalf of Amneal and Apotex, we write to request a resolution of a dispute regarding (a) the admissibility of a business record of Plaintiff Nissan, and (b) Plaintiffs' delay *until the night before trial* to object to a supplemental expert report served more than a month and a half ago.

The business record is DTX-1422. It is one of two Nissan business records reflecting Nissan's first replication of Example 3 of EP '406, and Nissan's conclusion that it produced Form A. The other Nissan business record is DTX-1332. DTX-1422 is necessary to have a complete record of the first replication. DTX-1422 contains a more detailed record of the science conducted by Nissan.

Only two days before trial, Plaintiff belatedly identified their primary objection to DTX-1422 as being "Untimely." (January 15, 2017 email from K. Carr to Defendants.) We do not believe that is a valid evidentiary objection, especially for a document that Plaintiff Nissan itself

created and has possessed ever since (and throughout this litigation). Nissan's objection to it being a foreign language document is answered by the certified translation Defendants provided back in November. And Nissan's objection for lack of foundation as a business record is contrary to the parties' stipulation in the pretrial order which provides: "Any document produced from the files of Plaintiffs or Defendants shall be deemed: (i) to be authentic under Fed. R. Evid. 901; and (ii) to satisfy the records of a regularly conducted activity exception of Fed. R. Evid. 803(6)(A)-(C)." (Pre-Trial Order, Stipulated Facts at 8, paragraph 47.)

Plaintiffs' position regarding DTX-1422 is especially troubling, because on November 16, 2016, *before* Defendants found the rest of Nissan's business record, Plaintiffs' counsel attempted to force Defendants' expert to speculate on the partial record of DTX-1332 that the first replication did not produce Form A – *while Plaintiffs' counsel withheld from the witness the rest of the record which definitively proved otherwise.* (Roberts Dep. at 101 ("That tells you that the crystalline form that they had obtained was not the target polymorph, correct?") followed by "Why can't you reach that conclusion?").)

When Defendants found the rest of the record in DTX-1422 after the deposition, they obtained a certified translation over the Thanksgiving holiday, and provided it to Plaintiffs as quickly as possible (on November 30, 2016), even though Plaintiffs already had it. And because only the partial record in DTX-1332 had been an exhibit to Dr. Roberts' report, Defendants also provided a 1.5 page supplemental expert report, in which Dr. Roberts explained why DTX-1422 was the rest of Nissan's business record – pointing out the correspondence between the details mentioned in DT-1332 and DTX-1422. A copy of the supplemental report is attached.

Even though Dr. Roberts did not offer any new opinion in introducing the document needed to complete Nissan's business record, Defendants nevertheless offered to make him

available for a deposition if Plaintiffs wished. (November 30, 2016 letter from S. Maddox to K. Carr.) Plaintiffs never responded in any way – until emailing an objection to it *at 8:14 pm the night before trial began*. (November 16, 2016 email from K. Carr to Defendants (referring to “Dr. Rogers’ untimely report”).)

By “going quiet” for a month and a half, until the night before trial and foregoing the offered deposition, Plaintiffs waived any objection to Dr. Robert’s supplemental report and any objection to being confronted with their own document. In any event, the supplemental report was appropriate, because it was necessary to complete the record, and Dr. Roberts did no more than identify a document that Plaintiffs had possessed from the outset.

Respectfully submitted,



Steven A. Maddox

cc: All counsel of record in C.A. Nos.:
14-cv-2758 (PAC);
14-cv-5575 (PAC);
14-cv-7934 (PAC); and
15-cv-3935 (PAC)

Kowa Company, Ltd. et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 14-CV-5575 (PAC)
)	
Sawai USA, Inc. et al.,)	
)	
Defendants.)	

Kowa Company, Ltd. et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 14-cv-7934 (PAC)
)	
Apotex, Inc. et al.,)	
)	
Defendants.)	

Kowa Company, Ltd. et al.,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 15-CV-3935 (PAC)
)	
Lupin Ltd. et al.,)	
)	
Defendants.)	

**SUPPLEMENTAL EXPERT REPORT OF
KEVIN J. ROBERTS, PH.D. REGARDING INVALIDITY**

**THIS ENTIRE REPORT AND ATTACHED EXHIBIT(S) ARE:
HIGHLY CONFIDENTIAL – SUBJECT TO STIPULATION REGARDING
CONFIDENTIALITY AND PROTECTIVE ORDER**

1. I, Kevin J. Roberts, Ph.D., submit this supplemental expert report in this matter. It recently came to my attention that the record with respect to my discussion of Nissan's internal documentation of attempts to reproduce Example 3 from European Publication No. EP 0 520 406 ("EP '406") was incomplete. Within the past few days, I have for the first time become aware of a translation of a Japanese document, which I am told by counsel was produced by plaintiffs in this action but not translated until within the last week.

2. The document is necessary to complete the record with respect to my previously expressed opinion that Nissan obtained Form A of the claimed invention by its faithful reproduction of Example 3 from EP '406.

3. The newly-translated document is attached as Exhibit A to this report. The original Japanese version of the document is appended to the back of the translation.

4. On its face, the translation of Exhibit 28 to my opening report describes a replication of Example 3 of EP '406. (*See* Opening Report at 43, ¶ 104.) However, Exhibit 28 also refers to a previous replication of the example by Nissan – one in which, according to Exhibit 28, Nissan obtained the same polymorphic Form A of the '993 patent-in-suit, according to XRD peak analysis. (*See, e.g.*, Ex. 28 at MYLAN(Pitav)073197 (“{The result of} the powder X-ray diffraction of the samples in this confirmatory test is significantly in agreement with Ciba patent disclosure data basically in the same as the previous test.”).) Exhibit 28 also indicates that the polymorphic Form A produced by the previous replication had a water content of 5.72% “obtained by over-drying.” (*Id.*)

5. The newly-obtained translation at Exhibit A describes a replication of Example 3 of EP '406, and concludes that the product is Form A, based on XRPD analysis. The water content of the product is reported as 5.72%. In addition, the substances tested in both Exhibit 28 and the new document Exhibit A have the same lot prefix – that is, “Lot YT-01354-__.” (Ex. 28 at KN001753854 and MYLAN(Pitav)073199; Ex. A at KN001713738–42.) Exhibit A concludes: “This re-examination of synthetic sample (Lot. YT-01354-019-A) gave the same powder X-ray diffraction data as that of Form A which is described in the Ciba patent implementation example 1.” (Ex. A at KN001713742.) Exhibit A states that the water content of the product was 5.72%. (*Id.*)

6. Exhibit A reflects that Nissan used different drying parameters in its first reproduction as compared to its second reproduction in Exhibit 28. In the first reproduction in Exhibit A, the crystals were “vacuum dried for 5 hours at 40° C” which produced a water content of 5.72%. (Ex. A at KN001713738.) In the second reproduction in Exhibit 28, the crystals were “dried under reduced pressure for 50 minutes at 40 degrees C,” which produced a water content of 10.5%. (Ex. 28 at KN001753851.)

7. This newly-acquired translation of a Nissan document is not the source of a new opinion. It was and remains my opinion that Nissan demonstrated and represented to the European patent authorities that Example 3 of the EP '406 patent produces Form A of the then-pending

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