

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD., LUPIN PHARMACEUTICALS INC., INNOPHARMA
LICENSING, INC., INNOPHARMA LICENSING LLC, INNOPHARMA
INC., INNOPHARMA LLC, MYLAN PHARMACEUTICALS INC., and
MYLAN INC.
Petitioners

v.

SENJU PHARMACEUTICAL CO., LTD., BAUSCH & LOMB, INC., and
BAUSCH & LOMB PHARMA HOLDINGS CORP.
Patent Owner

IPR2015-01097 (Patent 8,754,131)
IPR2015-01099 (Patent 8,669,290)
IPR2015-01100 (Patent 8,927,606)
IPR2015-01105 (Patent 8,871,813)

**PETITIONERS' REPLY TO
PATENT OWNER'S OPPOSITION TO PETITIONERS'
MOTION TO EXCLUDE¹**

¹ A word-for-word identical paper has been filed in each proceeding identified in the heading. IPR2016-00089 has been joined with IPR2015-01097; IPR2016-00091 has been joined with IPR2015-01100; and IPR2016-00090 has been joined with IPR2015-01105. Each of these joined proceedings includes Petitioners InnoPharma Licensing, Inc., InnoPharma Licensing LLC, InnoPharma Inc., Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively, "InnoPharma") in addition to the parties identified above.

Patent Owner's Opposition fails as it mischaracterizes Mr. Jarosz's redirect testimony as "within the scope" of Petitioners' cross-examination. Opposition at 1. Not only is this incorrect, it is a straw-man argument. The real issue is that the Jarosz redirect testimony set forth opinions that were outside the scope of the Jarosz Declaration, and were disclosed for the first time in this proceeding after Petitioners concluded their cross-examination. Patent Owner had the burden to fully present those opinions in the first instance rather than concealing them until redirect. Therefore, those new opinions (and Exhibit 2323) should be excluded.

I. Mr. Jarosz's Redirect Testimony Was Improper Gamesmanship as It Was Outside the Scope of the Jarosz Declaration

Patent Owner attempts to revise the history of the proceedings here to conceal its deliberate deprivation of Petitioners' cross-examination of Mr. Jarosz. In reality, Mr. Jarosz's February 23, 2016 Declaration gave *no analysis* of lifecycle management of the bromfenac franchise or the effects of such lifecycle management on the commercial success of Prolensa®. *See* EX2130. The Jarosz Declaration also provided no analysis (or very limited analysis) on a number of other issues related to commercial success. It was thus surprising—and prejudicial—when Mr. Jarosz's redirect examination was on matters *not within the scope of Mr. Jarosz's Declaration* and exhibits not entered in the current proceedings. *See, e.g.,* EX1089, 198:12-203:6.

Even worse, Mr. Jarosz's redirect testimony was in rebuttal to an expert

report that was not yet even part of this proceeding; Mr. Hofmann did not submit his Declaration in this proceeding until over one month later. *See* EX1122. Patent Owner effectively granted itself a sur-reply on commercial success without the Board’s permission by shoehorning new Jarosz opinions into the record as “pre-rebuttal” to the Hofmann Declaration. And Patent Owner did it by surprise. With little more than a few moments to prepare probing questions about the Jarosz opinions newly disclosed in these proceedings, Petitioners were deprived a meaningful opportunity to re-cross Mr. Jarosz. Patent Owner’s argument that Petitioners have been aware of Mr. Jarosz’s opinions and Exhibit 2323, Opposition at 6-7, is a red herring. Petitioners’ cross-examination was confined to the opinions actually expressed in the Jarosz Declaration in this proceeding. *See* 37 C.F.R. § 42.53(d)(5)(ii). Petitioners need not be prepared to cross-examine Mr. Jarosz on all declarations submitted in any proceeding. This is the entire reason for requiring Patent Owner to fully present its positions in the Patent Owner Response. *See Medtronic, Inc. v. Nuvasive, Inc.*, IPR2014-00087, Paper 44, at 21.

Patent Owner’s redirect “questions” highlight Patent Owner’s strategy to shovel new opinions into the record that are outside the scope of the Jarosz Declaration entered in this proceeding: “Would you please summarize the bases for your disagreement with Mr. Hoffman’s [sic] conclusions?” and “What opinion do you set forth in paragraph 17 of Senju Exhibit 2323?” EX1089, 180:3-5,

183:14-15. Patent Owner also appears oblivious to its own conduct during the deposition, claiming in its Opposition that it did not “read Exhibit 2323 or instruct Mr. Jarosz to read Exhibit 2323 into the record.” Opposition at 8. Patent Owner did just that. At one point, when Mr. Jarosz asked Patent Owner whether he should “read” various “bullet points” of the text of Exhibit 2323, Patent Owner responded, “Yes. Please.”² EX1089, 198:5-18; *see also, e.g., id.* at 183:14-18 (“Q. What opinion do you set forth in paragraph 17 of Senju Exhibit 2323? A. If you don’t mind I’ll just read instead of paraphrasing. Q. Please do.”).

II. Mr. Jarosz’s Redirect Testimony Was Outside the Scope of Petitioners’ Cross-Examination

Patent Owner’s attempts to characterize Mr. Jarosz’s redirect testimony as “within the scope of Petitioners’ cross-examination,” Opposition at 1-4, also fails even basic scrutiny. For example, the term “lifecycle management” appears nowhere in Mr. Jarosz’s Declaration and was not the subject of cross-examination by Petitioners. EX2130; EX1089, 7:7-172:19. Yet on redirect, Patent Owner and Mr. Jarosz discussed “lifecycle management” nearly ten times. EX1089, 180:21-

² Patent Owner’s allegations of “improper conduct” by Petitioners is no more than projection. Opposition at 4 n.2. Petitioners’ objections were well-founded and the volume necessary; Patent Owner refused to allow a standing objection to the improper questioning during redirect. *See* EX1089, 179:18-180:1.

181:9, 192:22-193:19, 194:7-195:7, 197:12-198:4, 198:5-17, 202:1-203:6.

Therefore Patent Owner's argument that Petitioners opened the door to this improper testimony, Opposition at 1-4, is demonstrably false.

The "hook" that Patent Owner uses to argue Mr. Jarosz's improper testimony was within the scope consists entirely of Petitioners' broad questions about Mr. Jarosz's various declarations *in general*. See Opposition at 1-2. Petitioners did not explore the specific details of those declarations during cross-examination or enter those declarations as exhibits. See, e.g., EX1089, 71:5-17. These high-level questions did not open the door for Patent Owner to explore Mr. Jarosz's specific opinions in those declarations nor enter Mr. Jarosz's declarations in other proceedings as exhibits here. Patent Owner's argument otherwise fails to understand the basic legal construct of "scope."

Patent Owner relies primarily on the "relevance" of Mr. Jarosz's testimony as proving that it is within the scope of cross-examination. Opposition at 3-4, 8-9. This is mistaken; relevance is not the issue here, scope and procedure are. Taking Patent Owner's position to its logical conclusion would mean that a patent owner could submit an expert report containing only one sentence, for example, "commercial success supports the nonobviousness of the patents-at-issue," and be within its rights to provide specific analysis of that broad topic during redirect examination. While that is an absurd conclusion, it follows Patent Owner's

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