

Paper No. \_\_\_\_\_  
Filed: March 25, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

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

v.

SENJU PHARMACEUTICAL CO., LTD.,  
Patent Owner

---

Case IPR2015-00903 (Patent 8,129,431 B2)<sup>1</sup>

---

**PATENT OWNER'S OBJECTIONS  
UNDER 37 C.F.R. § 42.64(B)(1)**

---

1. IPR2015-01871 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner objects to Exhibit 1104, served with Petitioner's Reply (Paper No. 56). Patent Owner objects to Exhibit 1104 (Reply Declaration of Paul Laskar) because portions of the Exhibit lack relevance (FRE 402), as they exceed the proper scope of Petitioner's Reply. 37 C.F.R. § 42.23(b) states "[a] reply may only respond to arguments raised in the corresponding . . . patent owner response." As explained in the Trial Practice Guide, "new evidence necessary to make out a prima facie case for [] unpatentability" and "new evidence that could have been presented in a prior filing" are improper. 77 Fed. Reg. 48767. "[A] reply that raises a new issue or belatedly presents evidence will not be considered and may be returned." *Id.* For instance, paragraphs 4-34 of Exhibit 1104 are all directed to new testimony from Dr. Laskar that tyloxapol is allegedly an antioxidant.

Patent Owner further objects to Exhibit 1104 because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence and arguments therein (FRE 403). As explained above, at least paragraphs 4-34 of Exhibit 1104 containing Dr. Laskar's new testimony exceed the proper scope of Petitioner's Reply and are thus irrelevant, untimely, prejudicial, and objectionable under FRE 402 and FRE 403.

Patent Owner further objects to Exhibit 1104 under FRE 702 and 37 C.F.R. § 42.65 because the opinions offered by Dr. Laskar in his reply declaration,

specifically at least paragraphs 8, 10-13, and 17-19, evidence a complete lack of expertise in organic or medicinal chemistry and thus Dr. Laskar is not qualified by knowledge, skill, experience, training or education necessary to form an opinion.

Patent Owner also objects to Exhibits 1089, 1092, 1093, 1105, 1106, 1091, 1094, and 1148, which Dr. Laskar discusses in detail in Exhibit 1104 in paragraphs 19 and 23-29, in support of his new testimony that tyloxapol is allegedly an antioxidant, because these Exhibits lack relevance (FRE 402), as they exceed the proper scope of Petitioner's Reply. *See* 37 C.F.R. § 42.23(b); 77 Fed. Reg. 48767. Patent Owner further objects to these Exhibits because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence therein (FRE 403).

Patent Owner objects to Exhibits 1075, 1098, and 1076, which Petitioners use to allegedly support a new argument in Petitioner's Reply (Paper 56) that a person of ordinary skill in the art would expect that switching polysorbate 80 with tyloxapol would improve preservative efficacy because polysorbate 80 allegedly was known to neutralize BAC. Exhibits 1075, 1098, and 1076 lack relevance (FRE 402), as they exceed the proper scope of Petitioner's Reply. *See* 37 C.F.R. § 42.23(b); 77 Fed. Reg. 48767. Patent Owner further objects to these Exhibits because of the prejudice resulting from Patent Owner's inability to respond to the untimely evidence therein (FRE 403).

Date: March 25, 2016

By: /Bryan C. Diner/  
Bryan C. Diner, Lead Counsel  
Registration No. 32,409  
Justin J. Hasford, Backup Counsel  
Registration No. 62,180  
**Finnegan, Henderson, Farabow, Garrett  
& Dunner, LLP**  
901 New York Avenue NW  
Washington, DC 20001

*Attorneys for Patent Owner Senju  
Pharmaceutical Co., Ltd.*

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the foregoing **PATENT OWNER'S OBJECTIONS UNDER 37 C.F.R. § 42.64(B)(1)** was filed on March 25, 2016, and served via email directed to counsel of record for the Petitioner at the following:

Jitendra Malik, Ph.D  
[Jitty.malik@alston.com](mailto:Jitty.malik@alston.com)

Bryan Skelton, Ph.D.  
[Bryan.skelton@alston.com](mailto:Bryan.skelton@alston.com)

Lance Soderstrom  
[Lance.soderstrom@alson.com](mailto:Lance.soderstrom@alson.com)

Hitetada James Abe  
[James.abe@alston.com](mailto:James.abe@alston.com)

Joseph M. Janusz  
[Joe.janusz@alston.com](mailto:Joe.janusz@alston.com)

Deborah Yellin  
[dyellin@crowell.com](mailto:dyellin@crowell.com)

Jonathan Lindsay  
[jlindsay@crowell.com](mailto:jlindsay@crowell.com)

Shannon Lentz  
[slentz@crowell.com](mailto:slentz@crowell.com)

Dated: March 25, 2016

/Ashley F. Cheung/

Ashley F. Cheung

Case Manager

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, LLP