

Paper No. ____
Filed: April 29, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.
Petitioner,

v.

SENJU PHARMACEUTICAL CO., LTD.
Patent Owner.

Case IPR2015-01099 (Patent 8,669,290 B2)

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

Pursuant to 37 C.F.R. § 42.64(b)(1), Patent Owner objects to Exhibits 1094 and 1122, served with Petitioners' Reply (Paper Nos. 32 & 34 (Confidential Version)). Patent Owner objects to Exhibit 1094 (Reply Declaration of M. Jayne Lawrence, Ph.D.) because portions of the Exhibit lack relevance (FRE 402), as they exceed the proper scope of Petitioners' 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 29, 31-33, 37-38, 40, and 80, as well as footnote 5, of Exhibit 1094 are all directed to new testimony from Dr. Lawrence that tyloxapol is allegedly an antioxidant (§§ 31-33, 37-38, and footnote 5); the specific NSAIDs diclofenac and ketorolac are allegedly subject to oxidative degradation (§ 31); tyloxapol is allegedly less toxic to the ocular membranes (§ 29); and that too much non-ionic surfactant, specifically polysorbate 80, allegedly reduces the effectiveness of benzalkonium chloride (§ 80). That Petitioner knew bromfenac degraded by oxidation and that this new testimony regarding the alleged use of an antioxidant could have been previously presented is

confirmed and recognized in Dr. Lawrence's initial declaration (EX1005), where at ¶ 66(e) it states that stabilizers, such as antioxidants, are added to ophthalmic formulations to decrease the decomposition of the active ingredient and that Ogawa Example 6 uses the stabilizer sodium sulfite (EX1005, ¶186, last sentence), a well-known antioxidant.

Patent Owner further objects to Exhibit 1094 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 29, 31-33, 37-38, 40, 80, and footnote 5, of Exhibit 1094, containing Dr. Lawrence's new testimony, exceed the proper scope of Petitioners' Reply and are thus irrelevant, untimely, prejudicial, and objectionable under FRE 402 and FRE 403.

Patent Owner further objects to Exhibit 1094 under FRE 702 and 37 C.F.R. § 42.65 because the opinions offered by Dr. Lawrence in her reply declaration, specifically at least paragraphs 31, 33, 36-37, 48-49, 51-52, and 73, and footnote 5, evidence a complete lack of expertise in organic or medicinal chemistry and thus Dr. Lawrence is not qualified by knowledge, skill, experience, training or education necessary to form an opinion. Patent Owner further objects to Exhibit 1174 and 1176, upon which Dr. Lawrence relies on for her unqualified opinions in

paragraphs 36 and 48, as irrelevant, untimely, prejudicial and objectionable under FRE 402 and FRE 403.

Patent Owner objects to Exhibit 1122 (Reply Declaration of Ivan Hofmann) under FRE 702 and 37 C.F.R. § 42.65 because the opinions offered by Ivan Hofmann in his reply declaration, specifically at least paragraphs 25-27, 42, 59-60, 62, 69-70, 72-80, 86-87, 99, 102, and 110, discuss subject matter beyond economics for which Mr. Hofmann is not qualified by knowledge, skill, experience, training or education necessary to form an opinion.

Patent Owner also objects to Exhibits 1096, 1097, 1098, 1100, 1101, 1102, 1172, and 1173, which Dr. Lawrence discusses in detail in Exhibit 1094 in paragraphs 31, 33 and 37, and footnote 5, in support of her new testimony that tyloxapol is allegedly an antioxidant. Patent Owner further objects to Exhibit 1169, which Dr. Lawrence discusses in paragraph 29 of Exhibit 1094, in support of her new testimony that tyloxapol is allegedly less toxic to ocular membranes. Patent Owner further objects to Exhibits 1170 and 1171, which Dr. Lawrence discusses in Exhibit 1094 in paragraph 31, in support of her new testimony that the specific NSAIDs diclofenac and ketorolac are allegedly subject to oxidative degradation. Exhibits 1096, 1097, 1098, 1100, 1101, 1102, 1169, 1170, 1171, 1172, and 1173 all lack relevance (FRE 402), as they exceed the proper scope of

Petitioners' 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 1107, 1108, and 1109, which Petitioners use to allegedly support a new argument in Petitioners' Reply (Paper Nos. 32 & 34) that a person of ordinary skill in the art would expect switching polysorbate 80 with tyloxapol to improve preservative efficacy because polysorbate 80 allegedly was known to neutralize BAC. Patent Owner also objects to Exhibits 1179 and 1180, which Dr. Lawrence discusses in Exhibit 1094 in paragraph 80, in support of her new testimony that it was allegedly understood in the art that using too much non-ionic surfactant could reduce the effectiveness of BAC, which would have allegedly informed the person of ordinary skill in the art that lower levels of surfactant would be effective and expected. Exhibits 1107, 1108, 1109, 1179, and 1180 lack relevance (FRE 402), as they exceed the proper scope of Petitioners' 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: April 29, 2016

By: /Bryan C. Diner/
Bryan C. Diner, Lead Counsel
Registration No. 32,409

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.