

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.
Petitioners,

v.

SENJU PHARMACEUTICAL CO., LTD.
Patent Owner.

IPR2015-01097 (US Patent No. 8,751,131)
IPR2015-01099 (US Patent No. 8,669,290)
IPR2015-01100 (US Patent No. 8,927,606)
IPR2015-01105 (US Patent No. 8,871,813)¹

**PATENT OWNER'S REPLY IN SUPPORT OF ITS MOTION TO
EXCLUDE EVIDENCE UNDER 37 C.F.R. § 42.64(c)**

¹ The word-for-word identical paper is 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.

TABLE OF CONTENTS

I.	Dr. Lawrence Is Not Qualified to Offer Opinions on Organic or Medicinal Chemistry, and Those Opinions Should Thus Be Excluded.....	1
II.	Dr. Lawrence’s Reply Declaration and Supporting Exhibits Exceed the Proper Scope of Petitioners’ Reply, Lack Relevance and Are Prejudicial	3
III.	Mr. Hofmann is Not Credible Or Qualified to Provide Any Opinions	5
IV.	Conclusion	5

I. Dr. Lawrence Is Not Qualified to Offer Opinions on Organic or Medicinal Chemistry, and Those Opinions Should Thus Be Excluded

On multiple occasions, Dr. Lawrence has candidly admitted that she is not an expert in organic chemistry or medicinal chemistry, *including antioxidant chemistry*. (EX2342, 9:16-11:20; EX2326, 411:7-16.) In a moment of candor, Dr. Lawrence herself characterized her chemistry as “rusty.” (EX2316, 289:3-4.) She was also completely incapable of answering basic chemistry questions regarding the chemical structure of tyloxapol, which was depicted in her own reply declaration. (EX2342, 222:10-21.) Dr. Lawrence’s forthright concessions and inability to answer basic questions eviscerate her credibility and render all her testimony regarding chemistry issues, including her unsupported assertions that tyloxapol is allegedly an antioxidant in the ophthalmic formulations at issue, irrelevant as a matter of law. Her admissions alone should end the inquiry. Yet Dr. Lawrence attempts to testify about matters within these highly complex, specialized chemistry fields, in particular antioxidant chemistry, in which she admits she is not an expert. Accordingly, the Board should exclude Dr. Lawrence’s opinions in these areas or, at the very least, afford them little weight.

Petitioners half-heartedly attempt to salvage Dr. Lawrence’s deficient testimony by arguing that she is a person of ordinary skill in the art of pharmaceutical sciences. Whether she is an expert in pharmaceutical sciences misses the point entirely, because the skilled person encompasses multiple skills,

which also encompasses chemistry, particularly organic and medicinal chemistry. The question thus is whether she is an *expert* in a subject matter directly at issue in these proceedings—medicinal and organic chemistry—not a person of ordinary skill in pharmaceutical sciences. Dr. Lawrence admittedly has no qualifications in the pertinent chemical arts, including antioxidant chemistry, and the holding of *Sundance, Inc. v. DeMonte Fabricating Ltd.* makes clear that her testimony on these issues is thus inadmissible as a matter of law. 550 F.3d 1356, 1364 (Fed. Cir. 2008).

Petitioners falsely assert that Patent Owner made no effort to determine Dr. Lawrence’s understanding of the chemistry issues in these proceedings. To the contrary, Patent Owner extensively questioned Dr. Lawrence on organic and medicinal chemistry issues and, not surprisingly, found that she completely lacks expertise in these areas. (*E.g.*, EX2342, 222:10-21.) She could not even answer simple questions regarding tyloxapol’s chemical structure. (*Id.*) Indeed, it has been *Petitioners*, not Patent Owner, who have repeatedly attempted to shield Dr. Lawrence from organic and medicinal chemistry issues. During cross examination, Petitioners repeatedly objected to questions about these issues as “outside the scope.” (EX2316, 90:5-13; 92:8-14; 101:9-102:3; 169:9-17.) And in the district court trial, Petitioners purposely limited Dr. Lawrence’s testimony to “very, very

basic chemistry”² not organic or medicinal chemistry. (EX2326, 196:19-22; 197:23-198:5.) Dr. Lawrence admittedly has no expertise in medicinal or organic chemistry, including the antioxidant chemistry issues about which she opines. Accordingly, Dr. Lawrence’s opinions involving medicinal and organic chemistry, including antioxidant chemistry, should be excluded or afforded little weight.

II. Dr. Lawrence’s Reply Declaration and Supporting Exhibits Exceed the Proper Scope of Petitioners’ Reply, Lack Relevance and Are Prejudicial

Petitioners devote *eight pages* of their opposition inaccurately contending that Dr. Lawrence’s opinions should be admitted because they allegedly establish that tyloxapol is an antioxidant in ophthalmic formulations. Petitioners are wrong. Notwithstanding Dr. Lawrence’s lack of expertise to offer these new opinions, she acknowledged that partially reduced O₂ species, hydroxyl radicals, and hypochlorous acid are not oxygen and are not present in the ophthalmic formulations claimed in the patents at issue. (EX2342, 234:6-18; 234:20-253:2.) All the references on which Dr. Lawrence now relies for her brand new opinions discuss the use of tyloxapol to prevent biologic injury from these compounds and are therefore completely irrelevant to bromfenac’s oxidative degradation caused by O₂. Dr. Lawrence’s candid concessions wholly undermine her credibility and

² Patent Owner *never* expressed satisfaction with Dr. Lawrence’s qualifications with respect to medicinal and organic chemistry. (EX2326, 197:23-198:1.)

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