

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)¹

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

¹IPR2015-01871 has been joined with this proceeding.

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Dr. Laskar candidly conceded on cross examination that he is not an expert in medicinal or organic chemistry, including antioxidant chemistry. (EX2272 at 20:17-21:5.) Dr. Laskar further conceded that the formulations of the '431 patent (EX1001) as well as the formulations of Yasueda (EX1012) that contain tyloxapol “do not contain any traditional antioxidant or compound that functions in an antioxidant capacity.” (EX2272 at 68:20-69:7.) Dr. Laskar’s candid concessions eviscerate his credibility and render all of his testimony regarding chemistry issues, including his unsupported assertions that tyloxapol allegedly is an antioxidant in the ophthalmic formulations at issue, irrelevant as a matter of law. The Board accordingly should grant Patent Owner’s motion to exclude.

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

Dr. Laskar readily admits that he is not an expert in medicinal or organic chemistry, *including antioxidant chemistry*. (EX2272, 20:17-21:5.) This should end the inquiry. Yet Dr. Laskar nonetheless attempts to testify about matters within these highly complex, specialized chemistry fields in which he admits he is not an expert. The Board thus should exclude Dr. Laskar’s opinions in these areas.

Petitioner half-heartedly attempts to salvage Dr. Laskar’s testimony by relying on dicta in *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008), and arguing that Dr. Laskar is a person of ordinary skill in the

pharmaceutical sciences. This misses the point entirely. Dr. Laskar admittedly has no qualifications in the pertinent chemical arts, including antioxidant chemistry, and the holding of *Sundance* makes clear that his testimony on these issues is thus inadmissible as a matter of law. *Id.* at 1364 (reversing district court and excluding unqualified expert testimony, noting “[n]or may a witness not qualified in the pertinent art testify as an expert on obviousness, or any of the underlying technical questions, such as the nature of the claimed invention, what a prior art reference discloses, or whether the asserted claims read on the prior art reference”).

While the Board has recognized that it “need not find a complete overlap” between an expert’s qualifications and the field of endeavor, *CaptionCall, LLC v. Ultratech, Inc.*, IPR2013-00550, Paper 57 at 11, the Federal Circuit in *Sundance* makes clear that an expert may not offer an opinion in an area in which the expert lacks qualification. Petitioner’s reliance on *Motorola Mobility, LLC v. Intellectual Ventures I, LLC*, CBM2015-00004, Paper 33, is likewise misplaced, because in that case, an expert in electrical engineering having experience in computer programming was found to “align sufficiently” with claims directed to software for use on a user station. *Id.* at 10. Dr. Laskar, in contrast, admittedly has no expertise in medicinal or organic chemistry, including the antioxidant chemistry issues about which he opines. Accordingly, Dr. Laskar’s opinions involving medicinal and organic chemistry, including antioxidant chemistry, should be excluded.

II. Dr. Laskar’s Reply Declaration and Supporting Exhibits Exceed the Proper Scope of Petitioner’s Reply Under 37 C.F.R. § 42.23(b), Lack Relevance Under FRE 402 and Are Prejudicial Under FRE 403

Petitioner spends a full *eight pages* of its opposition inaccurately contending that Dr. Laskar’s opinions should be admitted because they allegedly establish that tyloxapol is an antioxidant in ophthalmic formulations. Petitioner is entirely wrong. Notwithstanding that Dr. Laskar admittedly has no expertise to offer these new opinions, Dr. Laskar candidly conceded on cross examination that these new opinions are not even accurate. Indeed, Dr. Laskar admitted that the formulations of the ’431 patent (EX1001) as well as the formulations of Yasueda (EX1012) that contain tyloxapol “*do not contain any traditional antioxidant or compound that functions in an antioxidant capacity.*” (EX2272 at 68:20-69:7 (emphasis added).) Dr. Laskar’s candid concession wholly undermines his credibility and establishes the irrelevance—and thus inadmissibility—of his opinions to the contrary.

Faced with this fatal concession, Petitioner does not deny that neither its petition nor Dr. Laskar’s opening declaration mentions any alleged antioxidant properties of tyloxapol or any alleged motivation to substitute tyloxapol for polysorbate 80 in Ogawa (EX1004) based on any purported antioxidant properties. Rather, Petitioner wholly mischaracterizes Dr. Laskar’s first cross examination, in which Dr. Laskar only referred to BHT and EDTA as antioxidants and never once referred to tyloxapol as an antioxidant. (EX2114 at 157:2-22, 160:18-162:20.)

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