

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

and

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01117¹
Patent 8,642,012

**PETITIONERS' SUPPLEMENTAL REPLY TO
PATENT OWNER'S CORRECTED RESPONSE**

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¹ Case IPR2015-00283, instituted on a petition filed by Lupin Ltd. and Lupin Pharmaceuticals, Inc., has been joined with this proceeding.

I. PATENT OWNER MISCHARACTERIZES DR. SONDHEIMER'S TESTIMONY ABOUT THE '647 PATENT AND OTHER PRIOR ART.

Patent Owner, without the aid of its own expert, attempts to make *Sherwin (Ambrose '33)* relevant by (1) misleadingly citing Dr. Sondheimer's testimony about the '647 patent and (2) arguing that Dr. Sondheimer allegedly failed to objectively consider certain prior art. (Paper 41 at 46, 48 (citing Ex. 2012 10:11-11:2;² 30:11-23; 31:11-17; 103:19-104:7).) Patent Owner's arguments fail for at least two reasons.

First, Petitioners do not rely on the '647 patent to establish a rate of conversion of PAA to UPAGN. (Pet. at 31-32.) As Dr. Sondheimer testified, "the '647 patent . . . teaches the use of ratios of urinary PAGN to creatinine as a convenient measure for an increase in urinary excretion of nitrogen that doesn't require collection of total daily urine." (Ex. 2012 at 105:21-106:18.) Patent Owner, however, cites testimony regarding the conversion of PAA to UPAGN, which neither responds to Petitioners' argument nor addresses what the '647 patent discloses.

Second, Dr. Sondheimer's testimony belies any assertion that he did not "objectively evaluate the prior- art" for the conversion of PAA to UPAGN. (Paper

² Despite filing a corrected Response, Patent Owner now cites incomplete portions of Dr. Sondheimer's testimony. (See, e.g., Paper 41 at 47, 48 (citing Ex. 2012 34:1-35:6, 10:11-11:2).)

41 at 46 (citing Ex. 2012 at 10:11-11:2; 30:11-23; 31:11-17).) The only “limitation” he placed on his consideration of the prior art was the “earliest priority date.” (Ex. 2012 at 265:22-269:14.) Patent Owner therefore has failed to establish the relevance of *Sherwin (Ambrose '33)*.

II. DR. SONDHEIMER TESTIFIED WHY A POSA WOULD READ *BRUSILOW '91* TO TEACH INCOMPLETE CONVERSION.

Without any expert testimony of its own, Patent Owner faults Dr. Sondheimer for both ignoring the conversion of PAA to UPAGN reported in *Brusilow '91* (Paper 41 at 44-45 (citing Ex. 2012 at 49:10-14; 71:24-72:13), and determining that *Brusilow '91* adjusted dosages to account for incomplete conversion (*id.* at 40 (citing Ex. 2012 at 120:7-25)). A POSA would have recognized that the data set in *Brusilow '91* describes the incomplete conversion of PAA to PAGN. (Ex. 1002 at ¶¶ 34-36, 63; Ex. 2012 at 119:3-120:4.) Contrary to Patent Owner’s assertion, Dr. Sondheimer did not ignore that data. Indeed, Dr. Sondheimer’s evaluation of the dosing adjustment in Period III exemplifies his careful consideration of the incomplete conversion reported in Periods I and II. (Ex. 2012 at 119:3-120:19) Moreover, Dr. Sondheimer explained why a POSA would not have relied solely on *Brusilow '91* for information about the rate of conversion of PAA to PAGN. (Ex. 1002 at ¶¶ 40, 43.) Thus, his consideration of other references, including, for example, *Sherwin '19*, is well justified.

III. PATENT OWNER IGNORES TESTIMONY
REGARDING THE URINE COLLECTION TIMES IN COMTE.

Patent Owner seeks to discount *Comte's* disclosure of incomplete conversion (54%) of PAA to UPAGN over eight hours by selectively citing and then embellishing Dr. Sondheimer's testimony regarding collecting urine samples over eight versus twenty-four hours. (Paper 41 at 47, 50 (citing Ex. 2012 at 34:1-35:6; 124:14-21).) Specifically, citing Dr. Sondheimer's testimony, Patent Owner contends that a POSA could not have drawn any conclusions concerning conversion of PAA to PAGN because *Comte* did not provide any data on 24-hour excretion of PAGN. (*Id.*) Contrary to Patent Owner's contention, however, Dr. Sondheimer actually testified that a POSA "might have expected . . . total PAGN, *very slightly* more to have appeared in a 24-hour period than in the eight-hour period." (Ex. 2012 at 34:16-35:8 (emphasis added).) Patent Owner ignores subsequent testimony explaining how a POSA would consider or understand urine collection times, and confirming that urine collected over the two periods may be "equivalent." (Ex. 2012 at 35:9-37:13.) Moreover, Patent Owner ignores both that the '012 patent does not require any specific period for the collection of urine and that *Comte* illustrates a declining rate of conversion. (Ex. 1025 at 589.)

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