

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case No. IPR2016-00829
Patent No. 9,095,559 B2

Record of Oral Hearing
Held: Friday, July 28, 2017

BEFORE: TONI R. SCHEINER, LORA M. GREEN, and DEBORAH
KATZ, *Administrative Patent Judges*.

Case No. IPR2016-00829

Patent No. 9,095,559 B2

APPEARANCES:

ON BEHALF OF THE PETITIONERS, LUPIN LTD. AND
LUPIN PHARMACEUTICALS, INC.:
ELIZABETH J. HOLLAND, ESQUIRE
CYNTHIA LAMBERT HARDMAN, ESQUIRE
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, New York 10018
(212) 813-8800

ON BEHALF OF THE PATENT OWNER, HORIZON
THERAPEUTICS, INC.:
EMER SIMIC, ESQUIRE
ROBERT GREEN, ESQUIRE
GREEN, GRIFFITH & BORG-BREEN, LLP
455 North Cityfront Plaza Drive
Suite 3100
Chicago, Illinois 60611
(312) 883-8000

The above-entitled matter came on for hearing on Friday, July 28, 2017, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia 22314.

1 PROCEEDINGS

2 JUDGE KATZ: Please be seated. Welcome. Good
3 morning. This is an oral argument in inter partes review,
4 2016-00829. Petitioner is Lupin Pharmaceuticals, and Patent
5 Owner is Horizon Therapeutics. I'm Judge Katz, and Judge
6 Scheiner and Judge Green are also on the panel.

7 Before we begin, a few housekeeping things.
8 Hearing is open to the public, and a full transcript will
9 become part of the public record. Each party will have
10 30 minutes for your arguments in total. Petitioner will go
11 first followed by the Patent Owner. And there's no motion to
12 amend at issue in this case, so the burden -- Petitioner
13 carries the burden, and you may reserve rebuttal time.

14 Would you like to reserve rebuttal time?

15 MS. HOLLAND: Yes, your Honor. I'd like to
16 reserve 15 minutes.

17 JUDGE KATZ: 15 minutes. Okay. Thank you.

18 All right. Counsel should not interrupt each
19 other to make objections. Any objections to demonstratives
20 or otherwise should be discussed during your allotted time.
21 When you refer to an exhibit, please state the side, the
22 exhibit, or the page number that you're referring to, for the
23 record so the record is complete and clear.

1 So counsel for Petitioner, can you introduce
2 yourself and those with you, please?

3 MS. HOLLAND: Yes. Good morning. My name is
4 Elizabeth Holland. I'm with the firm of Goodwin Procter here
5 for Petitioner. With me is Cynthia Hordman, also with
6 Goodwin Procter.

7 JUDGE KATZ: Thank you, and for Patent Owner.

8 MS. SIMIC: Good morning. Emer Simic from Green
9 Griffith and Borb-Breen. With me is Robert Green, the
10 counsel for Patent Owner, Horizon Therapeutics.

11 JUDGE KATZ: Okay. All right. I think we're
12 ready to begin.

13 Petitioner, if you'd like to. And -- I'm sorry.
14 I have to figure out how to do this. Okay.

15 When you're ready to begin.

16 MS. HOLLAND: Thank you. Good morning.

17 The claims in the '559 Patent is a prior art drug,
18 Glyceryl Tri-(4-phenylbutyrate), also known as HPN-100, for a
19 prior art purpose -- maintaining normal plasma ammonia levels
20 in patients with urinary cycle disorders.

21 Now, the prior art teaching here is really clear
22 from Patent Owner's own paper.

23 So if we could put up slide 50, please.

1 This is from Patent Owner's response at 39, and
2 Patent Owner says clearly, Using nitrogen-scavenging drugs to
3 maintain plasma ammonia levels within the normal range has
4 therefore been ammonia in the prior art for almost two
5 decades.

6 So how does the Patent Owner say that the claims
7 of this patent, the '559, are different from the prior art?

8 If we go to slide 6, it's really helpful to see
9 this graphically. So what the Patent Owner says is that the
10 prior art taught to adjust the dose of nitrogen-scavenging
11 drugs when the plasma ammonia levels go above the upper limit
12 of normal, which is the solid red line at the top of the
13 chart here -- the graph.

14 They say that the claims in this case cover
15 adjusting the dose when the plasma ammonia levels go
16 somewhere between half the upper limit of normal and the
17 upper limit of normal. In other words, a range that abuts
18 right up against the prior art range -- the admitted prior
19 art range here, above the upper limit of normal. That's it.
20 That's what the claimed invention is.

21 JUDGE KATZ: So -- what -- there are a lot of
22 these sort of words in the claim and in the prior art. What
23 is the difference between, Upper limit of normal, and,

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