UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LIMITED, Petitioner,

V.

VERTEX PHARMACEUTICALS INCORPORATED, Patent Owner.

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Case IPR2016-00558 Patent 6,436,989 B1

Record of Oral Hearing Held: Wednesday, April 5, 2017

BEFORE KRISTINA M. KALAN, ROBERT A. POLLOCK, and MICHELLE N. ANKENBRAND, Administrative Patent Judges

The above-entitled matter came on for hearing on Wednesday, April 5, 2017, commencing at 9:31 a.m. at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.



## APPEARANCES

#### ON BEHALF OF THE PETITIONER:

STEPHEN AUTEN, ESQUIRE JANE S. BERMAN, ESQUIRE TAFT, STETTINIUS & HOLLISTER, LLP 111 East Wacker Drive Suite 2800 Chicago, Illinois 606061 (312) 527-4000

### ON BEHALF OF THE PATENT OWNER:

LISA M. FERRI, ESQUIRE SCOTT A. McMURRY, ESQUIRE BRIAN W. NOLAN, ESQUIRE MAYER BROWN, LLP 1221 Avenue of the Americas New York, New York 10020 (212) 506-2340



1	PROCEEDINGS
2	JUDGE SNEDDEN: Good morning. I'm Judge
3	Snedden, and I have with me on the panel Judge Green
4	and Pollock, and we are here for the final the
5	oral hearing in IPR201600558. I'd like to start with
6	appearances. We'll start with Petitioner. Please
7	stand, introduce yourself, and who you have with you
8	today.
9	MR. AUTEN: Morning, Your Honor. I'm Steve
10	Auten on behalf of Petitioner Lupin Limited.
11	JUDGE SNEDDEN: Thank you. And who did you
12	bring with you today?
13	MR. AUTEN: I'm sorry, I didn't hear that
14	part. That's my colleague, Jane Berman.
15	JUDGE SNEDDEN: Okay, welcome. And Patent
16	Owner?
17	MS. FERRI: Good morning, Your Honor. Lisa
18	Ferri from Mayer Brown, and I'm here on behalf of the
19	Patent Owner, Vertex Pharmaceuticals. I have with me
20	Brian Nolan, also Mayer Brown, and Scott McMurry,
21	also from Mayer Brown.
22	JUDGE SNEDDEN: Okay, welcome. Okay. Each



- 1 party, 45 minutes. We'll begin with Petitioner. You
- 2 can reserve part of your time for rebuttal. Would
- 3 you be reserving time today?
- 4 MR. AUTEN: I'd like to reserve four minutes
- 5 for rebuttal, Your Honor.
- 6 JUDGE SNEDDEN: Four minutes?
- 7 MR. AUTEN: Correct.
- 8 JUDGE SNEDDEN: Okay. All right. With that,
- 9 we'll begin. When you're ready, please stand and
- we'll begin.
- MR. AUTEN: Sure thing. May it please the
- 12 Board, I'm Stephen Auten on behalf of Petitioner
- 13 Lupin Limited. And we're here to talk about
- 14 fosamprenavir and the claims of the '989 patent and
- 15 whether it was obvious to make a prodrug of the
- amprenavir based on a few key certain facts. And
- that is, one, it would have been obvious to use the
- 18 second most common pharmaceutical salt that had been
- 19 used for four decades prior to the relevant date, and
- 20 it would have been obvious to use the number one,
- 21 most common, prodrug moiety for improving solubility
- and thus bioavailability for a prodrug of that type



1	when the prior art completely predicted that such a
2	drug would have the resistance profile and
3	pharmacokinetic profile of amprenavir.
4	So you've seen a lot of content in the papers
5	dedicated to Grobelny and the dog data and that's all
6	a red herring argument. That's all trying to
7	distract you because what a person of ordinary skill
8	in the art would have expected would have been to
9	have the pharmacokinetic profile of amprenavir,
10	because that's the prodrug that's being made of that
11	particular drug. It would not be expected to have a
12	pharmacokinetic profile of a completely different
13	drug in Grobelny's patent application.
14	And even if you accept that argument as true,
15	we'll show you why even Grobelny would have predicted
16	a successful prodrug made of amprenavir. So turning
17	to our deck, starting with slide 3 we just,
18	obviously laid the foundation for amprenavir being
19	the obvious target and being in the prior art as of
20	1994.

Slide 4 actually lays the foundation for what

is key for your decision today; and that is knowing



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