

UNITED STATES PATENT AND TRADEMARK OFFICE

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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

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

BEFORE LORA M. GREEN, SHERIDAN K SNEDDEN, and  
ROBERT A. POLLOCK, 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.

Case IPR2016-00558  
Patent 6,436,989 B1

A P P E A R A N C E S

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1                   P R O C E E D I N G S

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.

1 JUDGE SNEDDEN: Okay, welcome. Okay. Each  
2 party, 45 minutes. We'll begin with Petitioner. You  
3 can reserve part of your time for rebuttal. Would  
4 you be reserving time today?

5 MR. AUTEN: I'd like to reserve four minutes  
6 for rebuttal, Your Honor.

7 JUDGE SNEDDEN: Four minutes?

8 MR. AUTEN: Correct.

9 JUDGE SNEDDEN: Okay. All right. With that,  
10 we'll begin. When you're ready, please stand and  
11 we'll begin.

12 MR. AUTEN: Sure thing. May it please the  
13 Board, I'm Stephen Auten on behalf of Petitioner  
14 Lupin Limited. And we're here to talk about  
15 fosamprenavir and the claims of the '989 patent and  
16 whether it was obvious to make a prodrug of the  
17 amprenavir based on a few key certain facts. And  
18 that is, one, it would have been obvious to use the  
19 second most common pharmaceutical salt that had been  
20 used for four decades prior to the relevant date, and  
21 it would have been obvious to use the number one,  
22 most common, prodrug moiety for improving solubility

1 and thus bioavailability for a prodrug of that type  
2 when the prior art completely predicted that such a  
3 drug would have the resistance profile and  
4 pharmacokinetic profile of amprenavir.

5 So you've seen a lot of content in the papers  
6 dedicated to Grobelny and the dog data and that's all  
7 a red herring argument. That's all trying to  
8 distract you because what a person of ordinary skill  
9 in the art would have expected would have been to  
10 have the pharmacokinetic profile of amprenavir,  
11 because that's the prodrug that's being made of that  
12 particular drug. It would not be expected to have a  
13 pharmacokinetic profile of a completely different  
14 drug in Grobelny's patent application.

15 And even if you accept that argument as true,  
16 we'll show you why even Grobelny would have predicted  
17 a successful prodrug made of amprenavir. So turning  
18 to our deck, starting with slide 3 -- we just,  
19 obviously laid the foundation for amprenavir being  
20 the obvious target and being in the prior art as of  
21 1994.

22 Slide 4 actually lays the foundation for what

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