

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NOVEN PHARMACEUTICALS, INC., and MYLAN  
PHARMACEUTICALS, INC.,  
Petitioner,

v.

NOVARTIS AG and LTS LOHMANN THERAPIE-SYSTEME  
AG,  
Patent Owner.

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IPR2014-00549 and IPR2014-00550  
Patents 6,316,023 B1 and 6,335,031 B1

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Held: June 2, 2015

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BEFORE: FRANCISCO C. PRATS, ERICA A. FRANKLIN,  
and CHRISTOPHER G. PAULRAJ, Administrative Patent  
Judges.

The above-entitled matter came on for hearing on Tuesday, June  
2, 2015, commencing at 1:00 p.m., at the U.S. Patent and  
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

IPR2014-00549 and IPR2014-00550  
Patents 6,316,023 B1 and 6,335,031 B1

APPEARANCES:

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P R O C E E D I N G S

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JUDGE PRATS: Good afternoon, everyone. We are here for IPR2014-00549 and IPR2014-00550. This is the final hearing for those cases. Welcome everyone and thank you for coming.

These involve respectively, the 549 involves U.S. patent number 6,316,023 and the 550 involves patent number 6,335,031. The parties are -- Petitioner is Noven Pharmaceuticals and Patent Owner is Novartis and LTS Lohmann Therapie-Systeme.

I would like to point out that the 549 and 550 proceedings have been joined with IPR2015-00265 and 00268 respectively. The Petitioner in those proceedings is Mylan Pharmaceuticals. Mylan will not be presenting argument today.

At this time I would like counsel for the parties to introduce yourselves and your colleagues, beginning with Petitioner, Noven.

MR. LEVY: Good afternoon, Your Honors. Mike Levy from Kenyon & Kenyon on behalf of Petitioner, Noven.

MR. COULSON: I'm Chris Coulson also for Noven, Your Honors.

MS. JACOBSEN: Good afternoon, Your Honors. Charlotte Jacobsen on behalf of Novartis and LTS. And with me

1 is Nicholas Kallas and Raymond Mandra from the firm  
2 Fitzpatrick Cella.

3 MR. ANGER: Your Honors, I'm Ben Anger  
4 representing Mylan Pharmaceuticals, Inc.

5 MR. LEVY: And Your Honor, on behalf of Petitioners,  
6 Steve Lee is also counsel of record and joining us as well.

7 JUDGE PRATS: Thank you. Welcome to the Board.  
8 Consistent with our hearing order, each party has 60 minutes to  
9 present their arguments. Petitioner you may reserve rebuttal time.

10 As to procedure, I note that Patent Owner has made  
11 objections to a number of Petitioner's demonstrative slides.  
12 When we present a particular slide, we are not going to interrupt  
13 the opposition and say, well, I object to that slide. We are just  
14 going to continue through argument. Is that clear?

15 Let me go through and make sure I haven't missed  
16 anything. Okay. Counsel for Petitioner, you may proceed.  
17 Would you like to reserve any rebuttal time?

18 MR. LEVY: Yes, Your Honors, I would like to reserve  
19 20 minutes for rebuttal.

20 Good afternoon, Your Honors, and may it please the  
21 Court. Again, Mike Levy for Petitioner. The main question  
22 posed to the Board is whether a person of ordinary skill in the art  
23 or a POSA would have expected that rivastigmine was  
24 susceptible to oxidation, whether the prior art suggested the  
25 existence of the problem.

1           There's no real dispute, or there shouldn't be, that the  
2 solution to the problem, antioxidant use, is obvious. The  
3 expectation of oxidative degradation provides the motivation to  
4 take the otherwise unremarkable step of adding an antioxidant to  
5 pharmaceutical compositions.

6           The Board is now aware of the Federal Circuit's recent  
7 decision upholding a District Court's finding that other defendants  
8 failed to prove obviousness by clear and convincing evidence  
9 based on the record in that proceeding for the patents here. To be  
10 sure, there is substantially more evidence here and different  
11 evidence than that previous case, and it is particularly evidence  
12 addressing the central issue of whether a POSA would have  
13 suspected rivastigmine's susceptible to oxidation.

14           Petitioner provided expert testimony evidence from two  
15 distinguished individuals. Dr. Christian Schöneich is the chair of  
16 the department of pharmaceutical chemistry at the University of  
17 Kansas. The focus of his professional work, his research since  
18 the early 1990s has been free radical chemistry which includes  
19 the very types of oxidation issues presenting in this case. He is  
20 the only declarant in this case whose expertise is oxidation in  
21 pharmaceutical chemistry.

22           And the other, Dr. Agis Kydonieus, is the president of  
23 Samos Pharmaceuticals, a company serving the pharmaceutical  
24 industry in the field of drug delivery. Dr. Kydonieus has spent  
25 his entire professional career outside of academia in industry and

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