

UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Sandoz, Inc., et al.,

Petitioners,

-v-

Case No. IPR2016-00318

Eli Lilly & Company,

Patent Owner.

- - - - -x

Neptune Generics, et al.,

Case No. IPR2016-00237

-v-

Case No. IPR2016-00240

Eli Lilly & Company,

Patent Owner.

- - - - -x

TELEPHONE CONFERENCE

Wednesday, February 22, 2017

Before:

Hon. Lora Green

Reported by:

CHRISTINA CUMMINS, CSR

1                   A P P E A R A N C E S :  
2           BRINKS GILSON & LIONE  
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9           on behalf of the Petitioner Sandoz, Inc. ;  
10          SKIERMONT DERBY LLP  
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16          on behalf of the Petitioner Neptune  
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              Company ;  
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              on behalf of Fresenius Kabi USA.

1 THE COURT: Let's start with our roll call.  
2 Who do we have for patent owner Eli Lilly?

3 MR. KRINSKY: This is David Krinsky, your  
4 Honor, from Williams & Connolly.

5 THE COURT: Okay. Thank you. And then who do  
6 we have for Petitioner Neptune?

7 MS. SPIRES: This is Sarah Spires from  
8 Skiermont Derby for Neptune.

9 THE COURT: And then who do we have for  
10 Petitioner Sandoz?

11 MS. LYDIGSEN: This is Laura Lydigsen of  
12 Brinks, Gilson & Leone for Sandoz.

13 THE COURT: Okay. Thank you. It's my  
14 understanding that Petitioners requested this conference  
15 call. You may begin, and please let me know who's going  
16 to be speaking for Petitioner?

17 MS. SPIRES: Your Honor, this is Sarah Spires.  
18 I will be speaking for Petitioner Neptune.

19 THE COURT: Okay.

20 MS. SPIRES: And then you will probably hear  
21 from Laura Lydigsen, Petitioner for Sandoz, as well.

22 THE COURT: Okay. Thank you. Well, let's  
23 start with the first issue. The first issue is filing a  
24 five-page surrebuttal. And I just wanted to know why

1 Petitioner thinks a rebuttal is necessary at this point  
2 in the proceeding.

3 MS. SPIRES: Your Honor, as you know, the --  
4 this is Sarah Spires for Neptune. As you know, the  
5 Petitioners bear the burden of demonstrating obviousness  
6 in this case. And there are some issues that were  
7 brought up for the first time in sur-reply to which  
8 Petitioners have not had an opportunity to respond.

9 The parties have different records in them, and  
10 so I think there are some issues that Neptune would like  
11 to respond to and some issues that Sandoz would like to  
12 respond to, which is why we're requesting separate  
13 sur-replies. I can speak to the issues that Neptune  
14 would like to respond to.

15 THE COURT: Would this be for the 237 and the  
16 240?

17 MS. SPIRES: Yes, that's correct.

18 THE COURT: Okay. Thank you.

19 MS. SPIRES: And that's largely because the  
20 sur-reply is combined, and so some of the issues are  
21 directed to the Sandoz petition, some are directed to the  
22 Neptune petition.

23 THE COURT: Thanks.

24 MS. SPIRES: And the issues for the Neptune

1 petition that Neptune would like to address are Lilly's  
2 arguments related to the post-priority date statements to  
3 the FDA stating that those are irrelevant and Lilly's  
4 characterization of the Werzal and Hammond studies. In  
5 particular, Lilly made these arguments on February 14th,  
6 but there was new case law that came down that's directly  
7 on point that came down January 30th. And so because of  
8 the date of that case law, Neptune was not able to  
9 address it in its reply, but it was relevant at the time  
10 that Lilly filed its sur-reply. So we would like the  
11 opportunity to respond to Lilly's arguments with the most  
12 up-to-date case law.

13 THE COURT: And what is the case law?

14 MS. SPIRES: It's In Re: Copaxone, consolidated  
15 cases, C-o-p-a-x-o-n-e. It's before Judge Lee in the  
16 District of Delaware. The case number is 1:14-CV-01171.  
17 And that case is document 294.

18 THE COURT: And how is that case law relevant  
19 to this case?

20 MS. SPIRES: In that case Teva was arguing that  
21 there were -- there were FDA documents that Teva -- or  
22 documents that Teva had submitted to the FDA, and Teva  
23 argued that those documents were not relevant. And --  
24 for the same reasons that Lilly argued here saying that

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