

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

- - - - -

NEPTUNE GENERICS, LLC

Petitioner

vs.

ELI LILLY & COMPANY

Patent Owner

Case Nos. IPR2016-00237 and 00240

SANDOZ, INC.

Petitioner

vs.

ELI LILLY & COMPANY

Patent Owner

Case No. IPR2016-00318

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Conference Call Held: July 22, 2016

Before: MICHAEL P. TIERNEY and TINA
E. HULSE, Administrative Patent Judges

The above-entitled matter came
on for conference call hearing on Friday,
July 22, 2016 before the U.S. Patent and
Trademark Office, 600 Dulany Street,
Alexandria, Virginia

REPORTED BY:

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6	<p>1 JUDGE TIERNEY: We have a number</p> <p>2 of inter partes reviews. Let me see</p> <p>3 if I have got all the different</p> <p>4 numbers.</p> <p>5 If I have missed one, please</p> <p>6 help me out there. They haven't</p> <p>7 updated our internal dashboard yet to</p> <p>8 assign certain cases.</p> <p>9 But the numbers I have under all</p> <p>10 IPRs 2016-00237, 00240, 00318, also</p> <p>11 01340 and 01429. Those are the</p> <p>12 numbers I have been given. And is</p> <p>13 there any others?</p> <p>14 MS. SPIRES: Yes. For the</p> <p>15 Petitioner, Neptune, there is also</p> <p>16 2016 for both of these, 01190 and</p> <p>17 01341.</p> <p>18 JUDGE TIERNEY: Could you repeat</p> <p>19 the last one, please?</p> <p>20 MS. SPIRES: 0134 -- I'm sorry,</p> <p>21 I gave you the wrong one. Those are</p> <p>22 two others. I think you have already</p> <p>23 got them. Apologies.</p> <p>24 JUDGE TIERNEY: Again, could you</p> <p>25 repeat those two numbers?</p>	8	<p>1 that you mentioned in the beginning --</p> <p>2 JUDGE TIERNEY: Yes.</p> <p>3 MR. GROSSMAN: -- there is also</p> <p>4 1191 and 1343. And there are</p> <p>5 actually, Your Honor, for each of the</p> <p>6 three main proceedings, there is one</p> <p>7 additional petition and motion for</p> <p>8 joinder in each of the proceedings</p> <p>9 from another party of Wockhardt, but</p> <p>10 they are not participating in today's</p> <p>11 call.</p> <p>12 JUDGE TIERNEY: Could you spell</p> <p>13 that party's name, just so I have it?</p> <p>14 MR. GROSSMAN: Sure. It is</p> <p>15 W-o-c-k-h-a-r-d-t.</p> <p>16 JUDGE TIERNEY: Thank you.</p> <p>17 MR. GROSSMAN: Would it be</p> <p>18 useful to give you the IPR numbers for</p> <p>19 those as well or is that --</p> <p>20 JUDGE TIERNEY: If you have</p> <p>21 them, I would like it to all be in the</p> <p>22 transcript so we have an idea of all</p> <p>23 the different parties. And I will see</p> <p>24 if they are going to be assigned to</p> <p>25 the same panel or how they are going</p>
7	<p>1 2016-01190?</p> <p>2 MS. SPIRES: Yes. Those are the</p> <p>3 two joinder motions.</p> <p>4 JUDGE TIERNEY: Okay. I have</p> <p>5 not been given on my docket these</p> <p>6 numbers yet. That's why I am asking</p> <p>7 it.</p> <p>8 MS. SPIRES: Okay.</p> <p>9 JUDGE TIERNEY: So that's the</p> <p>10 first one. The second one is?</p> <p>11 MS. SPIRES: 01341.</p> <p>12 JUDGE TIERNEY: 01341. Okay.</p> <p>13 And apologies, but we -- our --</p> <p>14 we have changed electronic docketing</p> <p>15 systems, and our electronic docketing</p> <p>16 system internally is still being</p> <p>17 updated, as we speak. So not</p> <p>18 everything is available to me at this</p> <p>19 moment.</p> <p>20 MR. GROSSMAN: And, Your Honor,</p> <p>21 Dov Grossman here. And just, I think,</p> <p>22 to completely update this, the numbers</p> <p>23 you were just given, 1190 and 1341, I</p> <p>24 think go with the 237 IPR.</p> <p>25 There is also for the 240 IPR</p>	9	<p>1 to assign the cases.</p> <p>2 MR. GROSSMAN: Sure. So those</p> <p>3 are, again, all IPR-2016. It is 1335,</p> <p>4 1337, and 1393.</p> <p>5 JUDGE TIERNEY: Thank you. Are</p> <p>6 there any additional cases we need to</p> <p>7 be aware of?</p> <p>8 Okay. Hearing nothing, we will</p> <p>9 now move on.</p> <p>10 All right. Thank you for</p> <p>11 everyone joining the conference call</p> <p>12 today. Obviously we have quite a few</p> <p>13 parties today. I would like to start</p> <p>14 off with the Patent Owner.</p> <p>15 And we will start on the cases</p> <p>16 237 and 240, which involve Neptune.</p> <p>17 And apologies in advance if I</p> <p>18 misstate something, please just</p> <p>19 correct me. We have quite a few cases</p> <p>20 and quite a few numbers and quite a</p> <p>21 few parties here. But I would like to</p> <p>22 start with the 237 and 240 and have</p> <p>23 the Patent Owner, Eli Lilly, give us a</p> <p>24 brief background of what needs to be</p> <p>25 taken care of in those particular</p>

10	<p>1 cases. And if there is any motions we</p> <p>2 should be expecting that they would</p> <p>3 like to file.</p> <p>4 So, Eli Lilly, you are up.</p> <p>5 MR. GROSSMAN: Sure. Thank you,</p> <p>6 Your Honor. This is Dov Grossman.</p> <p>7 I think at this point the only</p> <p>8 thing that I would point out is that</p> <p>9 the parties, the Patent Owner and</p> <p>10 Petitioner, Neptune, have filed</p> <p>11 stipulations regarding some of the due</p> <p>12 dates. There was an original one and</p> <p>13 then an updated one that I believe was</p> <p>14 filed yesterday.</p> <p>15 I don't believe at this point as</p> <p>16 between us and Neptune there are any</p> <p>17 issues for the Board. There are, of</p> <p>18 course, the pending motions for</p> <p>19 joinder in those proceedings, which</p> <p>20 our time has not yet run on to respond</p> <p>21 to.</p> <p>22 I don't know whether the Board</p> <p>23 wanted to address any of those today</p> <p>24 or whether that would come later in</p> <p>25 the proceeding, but I think that's --</p>	12	<p>1 discussion.</p> <p>2 JUDGE TIERNEY: For purposes of</p> <p>3 today, you can leave those petitions</p> <p>4 and motions for joinder out of the</p> <p>5 discussion. Just thank you for</p> <p>6 identifying that there is an</p> <p>7 additional set that we need to be</p> <p>8 aware of.</p> <p>9 MR. GROSSMAN: Sure. Not a</p> <p>10 problem.</p> <p>11 It is -- you are correct, Your</p> <p>12 Honor, that they have raised the same</p> <p>13 grounds of patentability. They have</p> <p>14 submitted additional expert</p> <p>15 declarations, in, I believe, perhaps</p> <p>16 not all of them, but in the majority</p> <p>17 of them or I think -- I'm sorry, I</p> <p>18 should say for the Neptune IPRs, I</p> <p>19 believe they have submitted separate</p> <p>20 expert declarations.</p> <p>21 So -- and I am happy to kind of</p> <p>22 address the substantive issue as sort</p> <p>23 of a preview of what our motions would</p> <p>24 be if -- our oppositions would be if</p> <p>25 now is the appropriate time, or if you</p>
11	<p>1 that's the only open issue with</p> <p>2 respect to those two IPRs from our</p> <p>3 perspective.</p> <p>4 JUDGE TIERNEY: Okay. Before --</p> <p>5 before we move on to Neptune, I would</p> <p>6 like to understand the brief I saw</p> <p>7 or -- sorry -- I should say the</p> <p>8 petitions that I have been able to</p> <p>9 identify that have been filed and</p> <p>10 requests for joinder, they appear to</p> <p>11 have the same issues and the same</p> <p>12 exhibits.</p> <p>13 Are there any cases that you can</p> <p>14 identify that have a different set of</p> <p>15 exhibits, different set of challenges</p> <p>16 to your clients before the 237 cases?</p> <p>17 MR. GROSSMAN: Sure. And, Your</p> <p>18 Honor, if I may just, just so it is</p> <p>19 clear, because I don't want to step</p> <p>20 over any bounds here, those motions</p> <p>21 for joinder are from the Wockhardt</p> <p>22 IPRs. And their counsel, of course,</p> <p>23 is not on the line, so I want to flag</p> <p>24 that to the Board to be clear about</p> <p>25 that in terms of the scope of our</p>	13	<p>1 prefer to do that later.</p> <p>2 JUDGE TIERNEY: What I would</p> <p>3 like to at least get a sense of is do</p> <p>4 you need a full three months to go</p> <p>5 ahead and have a Patent Owner</p> <p>6 preliminary response or is there a</p> <p>7 chance we can expedite this and see if</p> <p>8 issues are overlapping with the</p> <p>9 underlying 237 and 240?</p> <p>10 MR. GROSSMAN: Sure. I</p> <p>11 understand, Your Honor.</p> <p>12 I think our view is that to the</p> <p>13 extent that, for these additional</p> <p>14 parties who are on the call and who</p> <p>15 are proposing to join the Neptune</p> <p>16 proceeding, you know, to the extent</p> <p>17 that their joinder would effectively</p> <p>18 be as a silent understudy, meaning</p> <p>19 that there wouldn't be any new issues</p> <p>20 or new evidence that the attorneys for</p> <p>21 Neptune would be handling all the</p> <p>22 examination and deposition defense,</p> <p>23 such that, you know, the parties would</p> <p>24 be joined as a formal matter, but it</p> <p>25 effectively would not change any of</p>

14	<p>1 our burden in addressing the main</p> <p>2 Neptune petition, that under those</p> <p>3 circumstances we would be willing to</p> <p>4 waive our POPR for those proceedings</p> <p>5 and proceed with those parties, again,</p> <p>6 joined as a formal matter but sort of</p> <p>7 effectively as if they weren't there</p> <p>8 from a substantive perspective.</p> <p>9 I don't know that the parties</p> <p>10 proposing to join the Apotex petitions</p> <p>11 and the Teva/Fresenius petitions are</p> <p>12 really that -- really in disagreement</p> <p>13 with that position.</p> <p>14 They have tried to sort of</p> <p>15 reserve some potential, if there is a</p> <p>16 unique issue that comes up or reserve</p> <p>17 their own expert, if they sort of need</p> <p>18 it, but I would submit, Your Honor,</p> <p>19 that to the extent that it is the same</p> <p>20 issue, then it is the same grounds of</p> <p>21 patentability, that there wouldn't be</p> <p>22 any need for their expert or any need</p> <p>23 for separate ability on their part to</p> <p>24 address any issues, the fact that they</p> <p>25 are well represented by Neptune in the</p>	16
15	<p>1 case.</p> <p>2 JUDGE TIERNEY: Have you been</p> <p>3 able to reach out and have a</p> <p>4 discussion with the parties seeking</p> <p>5 joinder that you mentioned in</p> <p>6 particular, Apotex and Teva, to see if</p> <p>7 they would be willing to enter into a</p> <p>8 joint stipulation?</p> <p>9 MR. GROSSMAN: We have not had</p> <p>10 that opportunity yet, Your Honor, in</p> <p>11 part because the timing for motions to</p> <p>12 join just ran last week. And so we</p> <p>13 were sort of waiting for everything</p> <p>14 before we could sort of try to address</p> <p>15 any parties' stipulations on this</p> <p>16 issue.</p> <p>17 JUDGE TIERNEY: But I take it</p> <p>18 you are willing to reach out and have</p> <p>19 such a discussion?</p> <p>20 MR. GROSSMAN: We would be happy</p> <p>21 to do so, Your Honor.</p> <p>22 JUDGE TIERNEY: I would</p> <p>23 appreciate it.</p> <p>24 Is there anything else we need</p> <p>25 to discuss from the Patent Owner on</p>	17

1 237 and 240?

2 MR. GROSSMAN: I don't think so,

3 Your Honor.

4 JUDGE TIERNEY: Okay. Now I am

5 going to turn to Neptune on the 237

6 and 240. Counsel for Neptune, are

7 there any motions that you contemplate

8 filing or anything that you need to

9 address?

10 And we understand there is a

11 joinder issue, but let's start with

12 particularly your filing, your case

13 right now, absent joinder, are there

14 any issues we need to discuss?

15 MS. SPIRES: This is Sarah

16 Spires from Skiermont Derby on behalf

17 of Neptune.

18 No, I think counsel for Eli

19 Lilly, we agree with ^ them there

20 that there are no real issues between

21 the parties. The stipulations have

22 been filed. And we will have a pro

23 hac motion or two that we will file

24 coming up here in a little bit. We

25 don't expect that to be any major

1 issue.

2 I will note quickly that the

3 Wockhardt, I believe, IPR joinder

4 motions, we have not been served with

5 those. This is the first I have

6 actually heard of them.

7 So if they are attempting to

8 join the Neptune IPRs, if anyone has

9 information about that, that would be

10 great. I am not able -- I have tried

11 to pull up those three numbers on the

12 portal system, and it is not showing

13 anything. So this one is new to us.

14 JUDGE TIERNEY: Okay. Well, if

15 you can have that conversation

16 off-line because Wockhardt is not

17 actually present and, yeah, I am not

18 even sure I will be assigned those

19 cases at this point in time.

20 MS. SPIRES: Okay.

21 JUDGE TIERNEY: So I would

22 rather not get too far into the

23 substance or any details on those

24 cases.

25 MS. SPIRES: Sure.

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