

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

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| 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> |

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

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