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

Case IPR2015-01117

Case IPR2015-01127

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PAR PHARMACEUTICAL, INC., LUPIN LTD.

and LUPIN PHARMACEUTICALS INC.,

Petitioners,

- against -

HYPERION THERAPEUTICS, INC.,

Patent Owner.  
-----x

November 30, 2015

1:00 p.m.

CONFERENCE CALL

B e f o r e:

TONI R. SCHEINER, Administrative Law Judge

DEBORAH KATZ, Administrative Law Judge

GRACE KARAFFA OBERMANN, Administrative Law

Judge

Page 2

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ALSO PRESENT:  
DAVID SILVERSTEIN, Par Pharmaceutical

Page 3

1 PROCEEDINGS  
2 JUDGE SCHEINER: Why don't we  
3 take a roll call. May I ask who is on the  
4 line for Lupin Pharmaceuticals?  
5 MS. HARDMAN: Cynthia Hardman  
6 and Rob Cerwinski of Goodwin Procter.  
7 JUDGE SCHEINER: And do we have  
8 anyone from Horizon?  
9 MR. PHILLIPS: This is Matthew  
10 Phillips for the Patent Owner.  
11 JUDGE SCHEINER: How about the  
12 original Petitioner, Par Pharmaceutical?  
13 MR. FRENO: Yes, your Honor,  
14 this is Mike Freno from K&L Gates. David  
15 Silverstein from Par is also on as well.  
16 JUDGE SCHEINER: Our  
17 understanding of the purpose of this call  
18 is to discuss Lupin Pharmaceuticals'  
19 proposed motion for joinder. I take it  
20 that is a motion in each of IPR2015-01117  
21 and 011127, is that everybody's  
22 understanding?  
23 MS. HARDMAN: Yes, your Honor.  
24 We would propose to file a motion for  
25 joinder in each of those IPRs.

Page 4

1 PROCEEDINGS  
2 JUDGE SCHEINER: Have the  
3 parties discussed and agreed to any  
4 modifications or alignments of the  
5 schedule?  
6 MS. HARDMAN: The parties did  
7 have an initial meet and confer prior to  
8 this call today. We discussed Lupin's  
9 proposed approach and I think each of the  
10 Patent Owner and Par at least preliminarily  
11 indicated, I will let them speak for  
12 themselves, but as I understand it, based  
13 on our current proposal they are not  
14 planning to oppose our motion for joinder,  
15 and at this time we did not discuss any  
16 changes to the current schedule.  
17 Lupin believes that there would  
18 be no changes necessary, although the one  
19 potential wildcard is whether Patent Owner  
20 plans to file a Patent Owner preliminary  
21 response and, if so, how that might impact  
22 the current schedule.  
23 JUDGE SCHEINER: Why don't you  
24 proceed with explaining the circumstances  
25 surrounding the proposed motion to join, in

Page 5

1 PROCEEDINGS  
2 other words, whether there would be any new  
3 grounds for arguments or evidence raised  
4 and so on.  
5 MS. HARDMAN: Yes, your Honor.  
6 Currently Lupin plans to file  
7 petitions that are essentially identical to  
8 the petitions that Par filed in each of the  
9 IPRs with the exception that we would be  
10 deleting the grounds of unpatentability  
11 that Par proposed that the Board did not  
12 adopt. So the decisions would otherwise be  
13 identical, just shorter, because they would  
14 not include the rejected grounds.  
15 We envision filing the same set  
16 of exhibits, including relying on the  
17 expert testimony or expert declarations  
18 submitted by Par.  
19 JUDGE SCHEINER: Have you  
20 discussed that with Par and secured their  
21 permission to use that expert or their  
22 agreement?  
23 MS. HARDMAN: We have discussed  
24 it with Par, although I believe that Par is  
25 still considering our proposal.

Page 6

1 PROCEEDINGS  
2 JUDGE SCHEINER: I see, okay,  
3 thank you. So at this point you are  
4 anticipating no changes to the schedule and  
5 the same arguments, the same grounds that  
6 were instituted, and the same evidence.  
7 Would you be time barred absent  
8 joinder?  
9 MS. HARDMAN: Not at this  
10 juncture, your Honor. There have been  
11 complaints filed against Lupin as to the  
12 two patents at issue, but to our knowledge  
13 it has not yet been served and, in any  
14 event, it was filed within the last month  
15 or two, so there is no -- so the one-year  
16 bar, if any, has not elapsed.  
17 JUDGE SCHEINER: Thank you.  
18 Let me see. So I guess unless you have  
19 anything else at this moment, why don't we  
20 hear from the other parties and then we can  
21 discuss briefing. I'm sorry, I interrupted  
22 you. Go ahead.  
23 MS. HARDMAN: I'm sorry for  
24 interrupting, your Honor.  
25 There are two issues that we

Page 7

1 PROCEEDINGS  
2 did want to discuss with the Board to see  
3 if the Board has a preference. The first  
4 is that we understand that in other  
5 proceedings the joined party has been  
6 accorded additional pages to briefing,  
7 sometimes it has been seven additional  
8 pages. That would be directed solely to  
9 points of disagreement with the first  
10 petitioner's paper, if any. So we wanted  
11 to see if the Board had a preference as to  
12 whether that would be available to Lupin in  
13 this instance.  
14 JUDGE SCHEINER: What I can  
15 tell you is that the closer you adhere to  
16 the original position the more likely you  
17 are to have your motion granted. So if you  
18 need -- if you anticipate using seven pages  
19 or additional pages we would prefer that  
20 you not need those pages for additional  
21 points. We would prefer the petition to be  
22 essentially identical to the first one, as  
23 you originally indicated.  
24 MS. HARDMAN: Yes, we  
25 anticipate that the petition would be

Page 8

1 PROCEEDINGS  
2 identical. I guess the question for us is  
3 in our motion for joinder whether we  
4 ultimately request the Board consider  
5 giving us seven additional pages for  
6 further, you know, for subsequent filings,  
7 but that's something that we can address  
8 with Lupin as to whether we want to make  
9 that additional request.  
10 JUDGE SCHEINER: At this point  
11 I think what we would -- we would have to  
12 take that under advisement because we don't  
13 know all the circumstances yet and I think  
14 you would have to ask us for  
15 preauthorization if it comes up.  
16 MS. HARDMAN: The second  
17 concern that we have is I understand that  
18 the Board's preference to maximize chances  
19 of joinder is to rely on the same evidence  
20 used by the first Petitioner, but that does  
21 cause a potential issue for Lupin in the  
22 limited circumstance that if Par should  
23 settle out and its expert becomes  
24 unavailable to Lupin and the expert has not  
25 yet been cross-examined on testimony that

Page 9

1 PROCEEDINGS  
2 he has submitted, there is a concern that  
3 Lupin could be left in a position of not  
4 having an expert that it can rely on going  
5 forward. So we wanted to see if the Board  
6 had a preference in that case.  
7 In one previous instance, at  
8 least one or two instances that we are  
9 aware of the Board has permitted the joined  
10 party in such a case to withdraw the  
11 petition without prejudice to allow it an  
12 opportunity to get a new expert on board.  
13 MS. HARDMAN: What we would  
14 prefer is that we cross that bridge when we  
15 come to it, if we do.  
16 MS. HARDMAN: Okay, that is  
17 fine. We hope that we don't get to that  
18 bridge.  
19 JUDGE SCHEINER: We hope so  
20 too.  
21 MS. HARDMAN: Very good, thank  
22 you, your Honor.  
23 JUDGE SCHEINER: Let me go back  
24 and clarify something. We prefer not to  
25 allow extra pages. If you can reach an

Page 10

1 PROCEEDINGS  
2 agreement with Par to use some of their  
3 pages, that would be fine.  
4 MS. HARDMAN: Understood. We  
5 can raise that further with Par to see if  
6 we can come to an agreement along those  
7 lines. And I guess in terms of letting the  
8 Board know if there have been any  
9 agreements, should we do that within the  
10 body of our joinder motion?  
11 JUDGE SCHEINER: Yes, that  
12 would be helpful.  
13 Shall we move on to hear what  
14 other parties have to say? Let's see,  
15 Mr. Phillips, is it, for Horizon?  
16 MR. PHILLIPS: Yes, your Honor.  
17 JUDGE SCHEINER: I understand,  
18 or at least so far I haven't heard anything  
19 about an opposition to this motion. Do you  
20 have any comment?  
21 MR. PHILLIPS: Very briefly,  
22 yes, your Honor.  
23 In general, the Patent Owner is  
24 not opposed to the proposal that Lupin is  
25 making when we are talking about

Page 11

1 PROCEEDINGS  
2 essentially identical petitions being  
3 filed, the only difference being the  
4 deletion of the non-instituted grounds.  
5 I think that we can work with  
6 the Petitioners to cross the bridge, if it  
7 is necessary, about expert deposition, and  
8 also the Patent Owner has no general  
9 opposition to allowing Lupin to have  
10 additional briefing directed solely to  
11 points of disagreement with Par, but we can  
12 cross that bridge when we get to it as  
13 well.  
14 The only other thing I would  
15 add from the Patent Owner's point of view  
16 is two things, one is we would prefer the  
17 Petitioners to make consolidated filings  
18 other than this additional briefing that is  
19 limited to pointing out the disagreement.  
20 The second thing is that in  
21 terms of time for oral argument or  
22 deposition, we would ask that the  
23 Petitioners jointly share the available  
24 time and not being given any additional  
25 time, that anything additional to what one

Page 12

1 PROCEEDINGS  
2 petitioner would have in this proceeding.  
3 JUDGE SCHEINER: Okay. Hold on  
4 a moment. I know we have a reporter, but  
5 I'm jotting down my own notes.  
6 MR. PHILLIPS: And if you need  
7 me to repeat anything, if I went too fast.  
8 Your Honor, I should also add  
9 that the Patent Owner would not have any  
10 intention to file preliminary responses  
11 against the petitions in this proposal.  
12 JUDGE SCHEINER: So you would  
13 only file against the original petition, in  
14 response to the original petitions, rather?  
15 MR. PHILLIPS: The preliminary  
16 responses were already filed.  
17 JUDGE SCHEINER: That's  
18 correct, sorry. Sorry about that.  
19 MR. PHILLIPS: We will of  
20 course intend to file responses, not  
21 preliminary responses, up-to-date ones.  
22 JUDGE SCHEINER: Right. So can  
23 you go over again briefly what you propose  
24 for points where the Petitioners cannot  
25 agree on a point in dispute?

Page 13

1 PROCEEDINGS  
2 MR. PHILLIPS: Yes.  
3 JUDGE SCHEINER: Where Lupin  
4 and Par cannot agree.  
5 MR. PHILLIPS: Right. If the  
6 two Petitioners cannot agree then the  
7 Patent Owner would not be opposed to having  
8 Lupin have the opportunity to file a  
9 separate paper, a short separate paper  
10 directed solely to the points of  
11 disagreement, and not raising or repeating  
12 or amplifying any arguments that Par has  
13 already made.  
14 JUDGE SCHEINER: Thank you.  
15 That's what I thought I understood. I just  
16 wanted to make sure.  
17 Was there anything else you  
18 would like to say before we hear from Par?  
19 MR. PHILLIPS: No. That's all,  
20 your Honor.  
21 JUDGE SCHEINER: Thank you,  
22 very much.  
23 Mr. Freno or Mr. Silverstein,  
24 do you have any comments?  
25 MR. FRENO: Yes, your Honor.

Page 14

1 PROCEEDINGS  
2 This is Mike Freno from K&L Gates.  
3 In principle, we would not  
4 oppose the joinder that Lupin has proposed  
5 with several caveats; to the extent it is  
6 the same grounds and same petition  
7 arguments, to the extent they are not  
8 extending the schedule, we are fine with  
9 that.  
10 The one point I think where it  
11 is a little bit -- still a little bit foggy  
12 is how they would participate in this IPR.  
13 Based on some of the comments we just heard  
14 with regard to them requesting additional  
15 pages, the opportunity for another expert,  
16 if necessary, and so on, and, you know,  
17 potentially asking questions at  
18 depositions, it appears that they are not  
19 intending to take a complete understudy  
20 role where they would just be there and  
21 then if Par dropped out they would be able  
22 to pick up where Par left off. I think  
23 they are planning something in addition.  
24 Hopefully, we have had a  
25 conversation, and hopefully we can work out

Page 15

1 PROCEEDINGS  
2 some of these differences, but our view is  
3 that to the extent that they want their own  
4 voice, if they want to raise their own  
5 theories, if they want to disagree with  
6 Par, it would be better for them to file  
7 their own IPR petition. So we put in a lot  
8 of work into this IPR and we have our own  
9 theories and we don't want to slow things  
10 down. We don't want added complications,  
11 we just want to go forward with what we  
12 proposed. To the extent Lupin agrees on  
13 those terms, then we have no objection to  
14 them joining.  
15 With regard to the experts, we  
16 have been trying to figure out, because of  
17 the holidays, this only came up last week,  
18 whether or not Neal would be retained by --  
19 or whether or not Lupin would be able to  
20 independently retain Neal Sondheimer, who  
21 is the expert that Par has used. I think  
22 at this point Par would not agree to allow  
23 Lupin to retain Dr. Sondheimer.  
24 JUDGE SCHEINER: In the event  
25 that you drop out?

Page 16

1 PROCEEDINGS  
2 MR. FRENO: Yes.  
3 JUDGE SCHEINER: My  
4 understanding, and we can flesh this out a  
5 little bit, but my understanding was that  
6 the only -- they would use the testimony of  
7 the expert, of Dr. Sondheimer, unless he  
8 becomes unavailable. But this is probably  
9 getting into too much detail for our  
10 purposes right now and I think that the  
11 parties should continue to try to reach an  
12 agreement on this point.  
13 MR. FRENO: And hopefully we  
14 will be able to do that, your Honor.  
15 JUDGE SCHEINER: Okay. So I  
16 think I understand your concerns, mainly  
17 that you are not necessarily persuaded that  
18 Lupin is going to take a back seat position  
19 or, as you called it, an understudy role.  
20 MR. FRENO: Well, your Honor,  
21 this is Mike Freno again, I think they have  
22 every intention of doing that and that is  
23 what they have represented to us is that  
24 they would like to take a back-seat role.  
25 So I don't have any reason to suspect that

Page 17

1 PROCEEDINGS  
2 it would be different. But at the same  
3 time we would like some assurances that it  
4 is truly a back-seat role and that's at the  
5 end of the day Par is calling the shots and  
6 that there will be no delay, there won't be  
7 additional briefing, there won't be  
8 additional questioning.  
9 I mean, for all intents and  
10 purposes we would love to have the insights  
11 of Lupin and to the extent we have  
12 additional time during depositions they can  
13 ask questions of Horizon's experts.  
14 JUDGE SCHEINER: Why don't we  
15 have that, at least not necessarily  
16 memorialized, but let's have Lupin include  
17 in their motion what they envision for  
18 depositions.  
19 MS. HARDMAN: Yes, your Honor.  
20 This is Cynthia Hardman. We will certainly  
21 continue conferring with Par and  
22 memorializing any agreements.  
23 I guess the one outstanding  
24 issue where we feel a little uneasy is what  
25 to do in the event of Par settling out, or

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