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

Case IPR2017-00854

Patent 9,187,405 B2

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APOTEX INC., APOTEX CORP., and,  
ARGENTUM PHARMACEUTICALS LLC,  
Petitioners,

- v -

NOVARTIS AG,  
Patent Owner.

-----X

Teleconference  
February 21, 2018  
3:00 p.m.

Transcript of Proceedings

Page 2

1  
2 A P P E A R A N C E S :  
3 Presiding:  
4 The Honorable ROBERT A. POLLOCK,  
Administrative Patent Judge  
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15 ALSO PRESENT:  
16  
17 JUDGE LORA M. GREEN  
18 JUDGE CHRISTOPHER N. KAISER  
19  
20  
21  
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1 TELECONFERENCE  
2 HON. POLLOCK: Good afternoon.  
3 This call is in relation to IPR 2017-00854,  
4 the e-mail from Pat Dolan dated February  
5 20th, 2018. I'm Judge Pollock and I have  
6 with me Judges Green and Kaiser.  
7 Let's start with the roll call.  
8 Who do I have for Petitioner Apotex?  
9 MR. PARMALEE: Steve Parmalee,  
10 your Honor.  
11 HON. POLLOCK: Petitioner  
12 Argemum?  
13 MS. LENTZ: Yes, your Honor, it  
14 is Shannon Lentz.  
15 HON. POLLOCK: Petitioner Teva  
16 Actavis?  
17 MR. SPRINGSTED: Gregory  
18 Springsted, your Honor.  
19 HON. POLLOCK: I'm sorry, I  
20 didn't catch the name.  
21 MR. SPRINGSTED: Gregory  
22 Springsted, your Honor.  
23 HON. POLLOCK: Good afternoon.  
24 Petitioner Sun Pharma?  
25 MR. PARK: Samuel Park on

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1 TELECONFERENCE  
2 behalf of Sun.  
3 HON. POLLOCK: And who is on  
4 the line for Patent Owner Novartis?  
5 MR. TRENCHARD: Good afternoon,  
6 your Honor. It is Robert Trenchard and  
7 Jane Love from Gibson Dunn, and I believe  
8 we should also have a court reporter on for  
9 the benefit of the Board.  
10 HON. POLLOCK: Is the court  
11 reporter there?  
12 THE COURT REPORTER: Yes, sir.  
13 I'm on the line.  
14 HON. POLLOCK: Thank you.  
15 Mr. Trenchard, did you engage the court  
16 reporter today?  
17 MR. TRENCHARD: We did, you  
18 Honor.  
19 HON. POLLOCK: Please submit a  
20 copy of the transcript as an exhibit when  
21 it becomes available.  
22 MR. TRENCHARD: Absolutely,  
23 your Honor.  
24 HON. POLLOCK: Novartis has  
25 requested this call seeking opposition to

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1 TELECONFERENCE  
2 file a motion to strike petitioner's reply  
3 or, in the alternative, submit surreply  
4 arguments in its March 16th, 2018 reply to  
5 Petitioner's Opposition to Motion to Amend  
6 Along With Supporting Evidence.  
7 Mr. Trenchard, I understand  
8 your request stems from Petitioner's  
9 reliance on a new expert, Dr. Benet.  
10 Before explaining why this necessitates any  
11 relief, would you please address whether  
12 you met and conferred with Petitioners in  
13 this matter.  
14 MR. TRENCHARD: We did not meet  
15 and confer, your Honor, given the  
16 timetables involved and given the fact that  
17 only the Board can modify the schedule, we  
18 thought it best to go straight to the  
19 Board. Our understanding also is that  
20 there is no expectation on these sorts of  
21 issues to meet and confer, and if that was  
22 incorrect, we do apologize for that.  
23 HON. POLLOCK: All right, we  
24 will leave it at that.  
25 Would you explain why you think

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1 TELECONFERENCE  
2 relief is necessary.  
3 MR. TRENCHARD: Yes, your  
4 Honor, absolutely, and we appreciate your  
5 Honor setting up the call so promptly.  
6 We really are seeking the  
7 Board's guidance on how to address a  
8 60-page submission from a new witness, as  
9 your Honor pointed out, Dr. Leslie Benet.  
10 The new declaration presents pharmacology  
11 arguments that are new about the references  
12 in the Petition that have been instituted  
13 as well as new arguments about how other  
14 references supposedly support the  
15 instituted grounds, which I will describe  
16 in a moment.  
17 We feel Novartis would be  
18 prejudiced were this material to be  
19 considered by the Board on the current  
20 record. The simplest remedy of course  
21 would be to strike material, and the Trial  
22 Practice Guide of course does say that the  
23 Board normally doesn't parse improper  
24 material in reply and that sort of thing,  
25 but we do understand, of course, that both

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1 TELECONFERENCE  
2 the Board and the parties have invested a  
3 lot of time and effort in this case so far  
4 and the Board might be reluctant to strike  
5 that submission.  
6 We are accordingly, as your  
7 Honor pointed out, seeking in the  
8 alternative a permission to submit a  
9 surreply and supporting evidence.  
10 Just to set the background a  
11 bit, in the Institution decision for this  
12 Petition the Board defined a person of  
13 skill as a team of individuals, a physician  
14 with an expertise in multiple sclerosis and  
15 a pharmacologist. We had argued in our  
16 preliminary response that the one expert  
17 that the Petitioners had submitted with the  
18 Petition, Dr. Barbara Giesser, did not  
19 satisfy the obligation to provide the  
20 perspective of a complete person of skill  
21 because she was not a pharmacologist, she  
22 was a physician.  
23 The Board agreed to institute  
24 the Petition on the ground that  
25 Dr. Giesser's training and experience made

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1 TELECONFERENCE  
2 her at least patently familiar with  
3 pharmacology principles, enough to allow  
4 the Petitioners to go forward, and that is  
5 the Institution decision at page 10 is that  
6 reasoning.  
7 We have since cross-examined  
8 Dr. Giesser as well as submitted expert  
9 testimony about the nature of her  
10 expertise, and you can find that in the  
11 Patent Owner's response at 29 to 31 and  
12 also later in the argument section. And we  
13 very strongly and put a lot of pages and a  
14 lot of time with our declarants attacking  
15 Dr. Giesser's pharmacology opinions both as  
16 being issued by somebody who lacked  
17 competence to provide them as well as  
18 substantively incorrect. I think we spent  
19 about six or seven pages in our Patent  
20 Owner's response on that issue and nearly  
21 dozens of paragraphs in the expert  
22 declarations on that issue.  
23 Petitioners filed their reply  
24 papers last Friday, and so far as we could  
25 tell, we have read their brief carefully,

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1 TELECONFERENCE  
2 we have read Dr. Benet's declaration  
3 carefully, and they appear to contest  
4 neither that a person of skill should  
5 include both a physician and a  
6 pharmacologist or that Dr. Giesser lacks  
7 the competence to provide a  
8 pharmacologist's perspective.  
9 Dr. Benet did nothing to try to  
10 rehabilitate Dr. Giesser's opinions on  
11 pharmacology. He did nothing to stand up  
12 for her. There is no additional  
13 declaration from Dr. Giesser herself. Our  
14 brief summarizes her deposition testimony,  
15 which makes plain what it is, she was very  
16 forthright in saying that she was not a  
17 pharmacologist, which is fine. That  
18 doesn't make her a bad person. She was a  
19 very nice person. But it does make her  
20 unqualified to provide the opinions of a  
21 complete person of skill.  
22 Of course the Petitioners have  
23 the burden of doing that with their  
24 Petition, and without a competent  
25 pharmacology expert the Petition on its

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1 TELECONFERENCE  
2 face must fail. But rather than argue or  
3 try to rehabilitate Dr. Giesser's  
4 testimony, they submitted Dr. Benet. He  
5 offers now the perspective of a  
6 pharmacologist for the first time for the  
7 Petitioners on the references that were  
8 instituted. So he argues about the Kovarik  
9 and Thomson references subject to the first  
10 ground, and the Chiba and Budde references  
11 and the Kappos 2005 in the second ground,  
12 that sort of thing.  
13 And this is the first time we  
14 have testimony from a competent witness  
15 from the other side as to at least half of  
16 what a person of skill is in this case  
17 about those references, and of course we  
18 should be entitled to address that  
19 testimony with affirmative evidence on our  
20 part.  
21 In addition to his testimony  
22 about the instituted references, he offers  
23 new opinions about how the references we  
24 say teach away, he says actually point  
25 towards obviousness. That's an argument

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1 TELECONFERENCE  
2 that if they believe that, they could have  
3 put in the Petition. He makes arguments  
4 about an idea called allometric scaling,  
5 about how one could arrive at the dose  
6 claimed in our patent by using certain  
7 algorithms to extrapolate from animal  
8 models to humans; again, new arguments that  
9 we have not had the chance to address.  
10 As I said, we do appreciate  
11 that striking such testimony is a pretty  
12 severe thing and we do think the Board  
13 should think about it, but probably after  
14 the hearing and the Board has become  
15 immersed in the facts at that point.  
16 For present purposes, we think  
17 the most logical way to go is to allow us  
18 to add pages to a filing that is going to  
19 happen anyway on March 16th in order to  
20 address and rebut what is now new evidence  
21 submitted on reply and then the Board will  
22 have a complete record in our quest to get  
23 to the truth of the matter here rather than  
24 a one-sided presentation from their  
25 pharmacologist.

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1 TELECONFERENCE  
2 HON. POLLOCK: Are you asking  
3 for more pages or only the opportunity to  
4 add your response to the existing reply?  
5 MR. TRENCHARD: Currently we  
6 are entitled to 12 pages to reply on the  
7 Motion to Amend. We ask for an additional  
8 13, essentially the right to submit a  
9 25-page brief with supporting evidence  
10 addressing both the Motion to Amend and  
11 this submission from Dr. Benet. We think  
12 that it is pretty tight. It is also a very  
13 tight timetable to do this. But we think  
14 we can do that in the time and space  
15 provided if we get that sort of  
16 accommodation.  
17 Of course this would not adjust  
18 the schedule at all. It would simply be an  
19 opportunity to respond to really what is  
20 clearly new evidence.  
21 To be sure, Dr. Benet speaks in  
22 terms from time to time of addressing  
23 testimony from our experts, as you would  
24 expect, but that is kind of beside the  
25 point here. The absence of competent

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1 TELECONFERENCE  
2 pharmacology testimony to suppress the  
3 Petition on its face makes all of the  
4 testimony new evidence, as does -- as do  
5 the new theories that he comes up with  
6 based on the references that are in the  
7 case. And this is one of those instances  
8 in which the substance of the testimony  
9 really demands an affirmative evidentiary  
10 response. Cross-examination observations  
11 alone won't do it. We really are entitled  
12 to have a fair shot at this with expert  
13 testimony and the like in response to this  
14 new pharmacology testimony.  
15 That's the sum and substance, I  
16 believe, of our position, your Honor. Once  
17 we're done with this issue, I also would  
18 like to raise an issue about scheduling the  
19 deposition of Dr. Benet. But first I think  
20 we should probably finish up with this one.  
21 HON. POLLOCK: All right,  
22 Mr. Parmalee, why should we not strike  
23 Mr. Benet's testimony?  
24 MR. PARMALEE: Well, thank you,  
25 your Honor. I find it interesting that

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1 TELECONFERENCE  
2 they are asking to strike this testimony  
3 and at the same time asking for his  
4 deposition.  
5 But, anyway, reverting to the  
6 issue on the motion -- the request for a  
7 motion to strike, Patent Owner counsel  
8 referred to the Institution decision from  
9 your Honors and pointed out how the Board  
10 addressed the person of ordinary skill in  
11 the art being part of a multidisciplinary  
12 team, and certainly Dr. Giesser, as the  
13 Board defined it, is part of that  
14 multidisciplinary team because she has an  
15 M.D. with several years of clinical  
16 experience treating multiple sclerosis  
17 patients and is knowledgeable about  
18 multiple sclerosis medical literature, and  
19 I would point out that's on page 9 of the  
20 Institution decision.  
21 Then the Board -- well, first  
22 of all, we really do dispute the argument  
23 in the Patent Owner's mini brief e-mail  
24 that they have submitted and then  
25 Mr. Trenchard's comments here that we

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1 TELECONFERENCE  
2 didn't dispute Patent Owner's attack on the  
3 sufficiency of her background and training.  
4 In fact, I'm quite certain that we  
5 characterized their attack on Dr. Giesser  
6 to be unhinged from the evidence.  
7 But turning to how the  
8 Institution decision addressed the  
9 pharmacokinetic issue, we would point out  
10 that on page 20 of the Institution decision  
11 the Board states that "We do not discern  
12 where this argument" -- that being the  
13 pharmacokinetic argument -- "was raised  
14 during the course of prosecution, nor are  
15 we convinced that this argument is  
16 self-evident based on the art of record.  
17 Accordingly, and contrary to Patent Owner's  
18 contention, we see nothing unfair or  
19 improper in the lack of discussion in the  
20 Petition of the pharmacokinetic data in  
21 Webb, Kahan 2003 and/or Park. We  
22 nevertheless look forward to further  
23 development of this issue at trial," and  
24 that's exactly what the parties have done.  
25 So Patent Owner had its

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1 TELECONFERENCE  
2 opportunity to address the Board's comments  
3 in the Institution decision. They put on  
4 three more expert declarations in addition  
5 to the two that were filed with its  
6 Preliminary Patent Owner -- Patent Owner's  
7 Preliminary -- I'm sorry, POPR, and so they  
8 have had five expert declarations and  
9 basically they have made decisions on how  
10 to proceed in this case with their experts,  
11 and we're not attempting to backfill any  
12 deficiencies in our prima facie case by  
13 including Dr. Benet's testimony, and in  
14 fact, as I just noted, the Board said that  
15 there was no reason that this could have  
16 been raised in the Petition because it was  
17 argument not self-evident based on the art  
18 of record.  
19 So responding to that and to  
20 Patent Owner's expert testimony on the  
21 pharmacokinetic interpretation of the  
22 references, which we had not previously  
23 seen or had a chance to reply to, we  
24 prepared our reply and we also engaged  
25 Dr. Benet to assist via his testimony. Our

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