

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

3  
4 COALITION FOR AFFORDABLE DRUGS V LLC;

5 HAYMAN CREDES MASTER FUND, L.P.;

6 HAYMAN ORANGE FUND SPC - PORTFOLIO A;

7 HAYMAN CAPITAL MASTER FUND, L.P.;

8 HAYMAN OFFSHORE MANAGEMENT, INC.;

9 HAYMAN INVESTMENTS, LLC;

10 NXN PARTNERS, LLC;

11 IP NAVIGATION GROUP, LLC;

12 J KYLE BASS, and ERICH SPANGENBERG,

13 Petitioners,

14 v.

15 BIOGEN MA INC.,

16 Patent Owner

17  
18 Case IPR2015-01993

19 Patent 8,399,514 B2

20  
21 DEPOSITION OF SAMUEL J. PLEASURE, M.D., Ph.D.

22 Washington, D.C.

23 October 20, 2016

24 Reported by: Linda S. Kinkade RDR CRR RMR RPR CSR

25 Job No. 114306

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SAMUEL J. PLEASURE, M.D., Ph.D.  
October 20, 2016  
8:56 a.m.

The following is the transcript of the deposition of SAMUEL J. PLEASURE, M.D., Ph.D. held at the offices of Regus Center, 9711 Washingtonian Boulevard, Suite 550, Gaithersburg, Maryland 20878, and reported by Linda S. Kinkade, RDR, CRR, RMR, RPR, CSR, and Notary Public within and for the state of Maryland.

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1 S. PLEASURE  
 2 P R O C E E D I N G S  
 3  
 4 SAMUEL J. PLEASURE, M.D., Ph.D.,  
 5 having been first duly sworn, was thereafter  
 6 examined and testified as follows:  
 7 EXAMINATION  
 8 BY MR. FLIBBERT:  
 9 **Q. Good morning, Dr. Pleasure.**  
 10 A. Good morning.  
 11 **Q. My name is Mike Flibbert. I'm from the**  
 12 **Finnegan firm, and I'll be asking you questions today.**  
 13 **Could you please state your full name for the**  
 14 **record?**  
 15 A. Sure. It's Samuel Pleasure,  
 16 P-L-E-A-S-U-R-E.  
 17 **Q. Do you understand that you're under oath**  
 18 **today?**  
 19 A. Yes.  
 20 **Q. Do you understand the transcript of your**  
 21 **testimony will be a public record?**  
 22 A. Yes.  
 23 **Q. If you don't understand any questions,**  
 24 **please ask me to repeat, repeat them, and I'll try to**  
 25 **clarify anything you don't understand. Is that okay?**

1 S. PLEASURE  
 2 A. Yes.  
 3 **Q. As you know, the court reporter is**  
 4 **transcribing your testimony, so it's important that**  
 5 **you give verbal answers rather than nodding your head,**  
 6 **for example. Is that okay?**  
 7 A. Yes.  
 8 **Q. And I would ask that if you could just wait**  
 9 **until I finish the question so that we don't talk over**  
 10 **each other so that the transcript is clear. Is that**  
 11 **acceptable?**  
 12 A. I'll try.  
 13 **Q. Me too. If you need a break at any time,**  
 14 **please just ask. All I would request is that, if**  
 15 **there is a question pending, that you would wait until**  
 16 **the question has been answered before we take the**  
 17 **break, if that's acceptable.**  
 18 A. That should be fine.  
 19 **Q. Is there any reason that you can't give**  
 20 **full and truthful testimony today?**  
 21 A. No.  
 22 **Q. Do you understand that I may ask some**  
 23 **hypothetical questions because you're testifying as an**  
 24 **expert witness and that you have to answer those**  
 25 **questions to the best of your ability?**

1 S. PLEASURE  
 2 A. Yes, I understand.  
 3 **Q. Have you been deposed before?**  
 4 A. Yes, I have.  
 5 **Q. On how many times?**  
 6 A. I think total this will make six. In  
 7 patent-related things, I think this will make five.  
 8 **Q. Okay. And were you testifying as an expert**  
 9 **in those cases?**  
 10 A. Yes.  
 11 **Q. In the prior patent cases that you have**  
 12 **worked on, have you ever testified on behalf of the**  
 13 **Patent Owner?**  
 14 A. No.  
 15 **Q. Did you testify at trial in any matter?**  
 16 A. Twice.  
 17 **Q. And which two cases were those?**  
 18 A. There was a case concerning lacosamide in  
 19 federal court in Delaware, and there was a case  
 20 concerning glatiramer acetate in federal court in  
 21 Delaware. I don't remember the case numbers.  
 22 **Q. Do you remember the parties in those two**  
 23 **cases?**  
 24 A. Generally.  
 25 **Q. Well, in the first case, which party did**

S. PLEASURE

you testify on behalf of?

A. It was a joint defense group and I was primarily engaged by Mylan.

**Q. And how about in the second patent case in Delaware?**

A. Again, it was a joint defense group, but I was engaged by Sandoz, I think Sandoz and Momenta.

**Q. Were you qualified as an expert in those cases?**

A. Yes.

**Q. What was your field of expertise that you were qualified in?**

A. For the lacosamide case, I was testifying concerning epilepsy. I have significant expertise in epilepsy during my career, and in addition -- and then in the glatiramer acetate case I was qualified as an expert on multiple sclerosis.

**Q. In any of the cases in which you have been deposed -- well, provided trial testimony, did you provide any opinions regarding clinical trial design?**

A. Yes.

**Q. In which case?**

A. Well, I believe it was in both of them. I mean, I think it depends a little bit on what you mean

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by the -- on what your definition of opinion is. I mean, I discussed clinical trials. I discussed the design of specific clinical trials. I discussed them in a general sense as well. So I think that that's what -- that would fit with what you're saying.

**Q. Okay. Have you provided any testimony previously involving drug dosage design?**

A. You're going to have to clarify what you mean by "design," I think.

**Q. Selection of doses in drug development.**

A. I think that I have, yes. I think I have, given your -- in the construction of your question, yes, particularly concerning glatiramer acetate and also considering concerning -- were you just asking about testifying or were you asking also about a deposition for that question?

**Q. Well, let's start with trial testimony.**

A. So for glatiramer acetate, both in deposition and trial. This was a significant issue of discussion.

**Q. When did you first become aware of this IPR matter involving Biogen's '514 patent?**

A. I'd have to go back into my emails to know exactly. It was not more than a few months ago, I

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don't believe, but, you know, my recollection is a little bit hazy on that just in that I don't recall the specific month, for instance, but it wasn't years ago.

**Q. Do you recall who contacted you?**

A. Mr. Carmichael contacted me initially.

**Q. Do you know whether you had been contacted regarding your availability to provide expert testimony as far back as September 2015?**

A. I'd have to refer to my emails to know. I don't think it was -- I mean, it was -- I don't think it was that long ago, but I'm really not -- I'm really not sure.

**Q. Did you ever discuss this case with anyone from the Neifeld, that's N-E-I-F-E-L-D, IP law firm?**

MS. SPIEGEL: I'm going to caution you not to reveal any privileged attorney-client information; otherwise, you may answer yes or no.

A. I have not.

**Q. Now did you speak with anyone to prepare for your deposition today?**

A. Yes.

**Q. With whom did you speak?**

A. With Carol Spiegel.

S. PLEASURE

**Q. Did you speak with anyone other than counsel?**

A. No. I'm just trying to remember if I spoke with Mr. Carmichael at some point but not really about the deposition per se.

**Q. Did you meet with counsel?**

A. Yes, we met yesterday for some time.

**Q. Do you know for approximately how many hours you met yesterday?**

A. Meeting time was probably about four hours.

**Q. Did you review any documents in preparing for today's deposition?**

A. Yes, I did.

**Q. What documents did you review?**

A. I reviewed documents that I referred to in my -- in my declaration and I have reviewed -- I mean, I'm a neurologist who takes care of patients and uses Tecfidera. I didn't explicitly look at new things concerning that drug for this deposition, but those things I've reviewed in the past they certainly would inform me. So I don't know whether that would fit the criteria of what you're saying, did I review them for the deposition. If you mean by reviewing them in the last couple of days, then no.

1 S. PLEASURE

2 **Q. Did you review any documents that were not**  
3 **cited in your declaration?**

4 A. There may have been one or two other  
5 articles that I -- that I looked over.

6 **Q. Do you recall their titles --**

7 A. Titles ...

8 **Q. -- or any other information on them?**

9 A. I did review a publication by Litjens from  
10 2004, which is a different publication than the one  
11 that's cited in my report. It's a different  
12 pharmacokinetic study.

13 **Q. Do you know which journal that was**  
14 **published in?**

15 A. I don't recall offhand. I'd have to look.

16 **Q. You mentioned maybe another article. Do**  
17 **you recall anything about that?**

18 A. I can't think of any others offhand  
19 actually right now.

20 **Q. Okay.**

21 (Exhibit 1045 marked for  
22 identification: Declaration of Samuel  
23 J. Pleasure, M.D., Ph.D.)

24 **Q. Dr. Pleasure, I'm handing you what's been**  
25 **previously marked as Coalition Exhibit 1045. Could**

1 S. PLEASURE

2 **you please confirm this is a copy of the declaration**  
3 **that you've provided in this case?**

4 A. I believe so, yeah.

5 **Q. Do you have any corrections to the**  
6 **declaration that you'd like to make?**

7 A. I'm not aware of any mistakes at the  
8 moment. I didn't find any.

9 **Q. If you would look at paragraph 2 of your**  
10 **declaration, please. You state there that you made**  
11 **the declaration based on considering the materials**  
12 **that you discuss herein; is that correct?**

13 A. Yes.

14 **Q. The list of materials that you have relied**  
15 **on is in Appendix A of your declaration; is that**  
16 **correct?**

17 A. Yes.

18 **Q. Is that a complete list of materials that**  
19 **you reviewed before completing your declaration?**

20 A. No, I don't believe so. I mean, I have  
21 read many other things about Tecfidera, and, as  
22 paragraph 2 indicates, this is based on my personal  
23 knowledge. I didn't list everything that I've ever  
24 read about this drug or about this compound in this  
25 appendix. The materials that are, I think, necessary

1 S. PLEASURE

2 for my opinion are included here, though.

3 **Q. I understand. I'm asking generally about**  
4 **any materials you would have reviewed in the course of**  
5 **your normal work as a physician or as a professor.**  
6 **I'm simply asking for any other materials that you had**  
7 **reviewed specifically for purposes of preparing your**  
8 **declaration.**

9 A. Oh, yeah. No, there's nothing else that  
10 I'm aware of. No, I can't think of anything.

11 **Q. Did you ask to see any materials to review**  
12 **other than those listed in Appendix A?**

13 A. No.

14 **Q. In developing your expert testimony in this**  
15 **case did you speak with anyone other than counsel?**

16 A. No. I mean, I've spoken with other  
17 neurologists in our MS practice about this drug, but  
18 not having to do with this and not recently.

19 **Q. I understand. Did you perform any research**  
20 **or electronic searches in connection with forming your**  
21 **opinions in your declaration?**

22 A. I'm sure that at some point I did some  
23 PubMed searching, but I don't recall the search terms  
24 per se, and that was -- and it's possible that some of  
25 the documents that I found came through that route,

1 S. PLEASURE

2 some of the documents that I used, but I don't recall  
3 explicitly.

4 **Q. Okay. At any time since you were engaged**  
5 **as a consultant have you reviewed any documents or**  
6 **information not cited in your declaration to increase**  
7 **your knowledge about any topics that are relevant to**  
8 **this case?**

9 A. That's a pretty broad question. I mean, I  
10 would say that my general level of expertise in this  
11 area is relevant to this case. That level of  
12 expertise comes through many, many different sources.  
13 It doesn't come through attempts to explicitly educate  
14 myself about something in this particular case and  
15 those things may inform my opinion.

16 So I don't think that's really possible to give  
17 that a very defined answer. I mean, there are no  
18 specific sources of other information that I can think  
19 of.

20 **Q. Do you know whether the Patent Owner,**  
21 **Biogen, submitted any expert declarations in this**  
22 **proceeding?**

23 A. So I think I was provided with a couple of  
24 those declarations, that I did read at some point, but  
25 I don't think they necessarily informed my opinions

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