

UNITED STATES PATENT AND TRADEMARK OFFICE

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PAR PHARMACEUTICAL, )  
INC., WOCKHARDT BIO AG )  
and AMNEAL )  
PHARMACEUTICALS LLC, ) No.  
Petitioners, ) IPR 2015-00548  
vs. )  
JAZZ PHARMACEUTICALS, )  
INC., )  
Patent Owner. )  
-----)

DEPOSITION UNDER ORAL EXAMINATION OF

BRYAN BERGERON, MD, FACMI

January 21, 2016

New York, New York

REPORTED BY: DANA N. SREBRENICK, CRR CLR



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1 BRYAN BERGERON, M. D.  
 2 Q. Let me just go over the ground  
 3 rules. Let me know if you don't hear or  
 4 understand a question. If you answer a  
 5 question, we will assume that you heard  
 6 and understood the question, okay?  
 7 A. Okay.  
 8 Q. Let me know if you don't know or  
 9 can't remember the information sought by a  
 10 question. If you answer, we'll assume  
 11 that you know and can remember the  
 12 information sought, okay?  
 13 A. Okay.  
 14 Q. We have a court reporter here  
 15 making a transcript, so be sure to answer  
 16 out loud. The court reporter cannot  
 17 record nodding or shaking of the head.  
 18 Also please say "yes" rather than  
 19 "uh-huh," which sometimes cannot be  
 20 understood by the court reporter, okay?  
 21 A. Understood.  
 22 Q. Let me know if you want to take  
 23 a break for any reason, okay?  
 24 A. Okay.  
 25 Q. And let me know if you realize

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1 BRYAN BERGERON, M. D.  
 2 that an answer that you previously gave is  
 3 inaccurate or incomplete, just say you  
 4 want to correct or supplement the record,  
 5 okay?  
 6 A. Okay.  
 7 Q. Is there any reason you can't  
 8 give full and complete answers today?  
 9 A. No.  
 10 Q. Are you represented by counsel  
 11 today?  
 12 A. Yes, I am.  
 13 Q. Who is that?  
 14 A. Seated here at the table is John  
 15 Biernacki at the end, Frank Calvosa in the  
 16 middle and Evangeline Sue --  
 17 MS. SHIH: Shih.  
 18 A. Sorry, Shih.  
 19 BY MR. BERMAN:  
 20 Q. And you submitted declarations  
 21 in connections with certain inter partes  
 22 re-exam proceedings or IPRs, correct?  
 23 A. That's correct.  
 24 Q. And those IPRs are for six  
 25 different patents owned by Jazz, correct?

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1 BRYAN BERGERON, M. D.  
 2 A. That's my understanding, yes.  
 3 Q. And they were filed by either  
 4 Par Pharmaceutical, Amneal Pharmaceutical  
 5 or Wockhardt, correct?  
 6 A. I'm not sure who actually filed  
 7 them.  
 8 Q. But is it okay if I call the  
 9 filers "petitioners" today?  
 10 A. Sure.  
 11 MR. BERMAN: And just for the  
 12 record, the IPRs are 2015-545, 546,  
 13 547, 548, 551 and 554, joined with  
 14 IPR 2015-1810, 1813, 1814, 1815,  
 15 1816, 1817, 1818 and 1820.  
 16 BY MR. BERMAN:  
 17 Q. So generally, the Jazz patents  
 18 that are the subject of the IPRs deal with  
 19 restricted drug distribution systems,  
 20 correct?  
 21 A. In general, yes.  
 22 Q. And for the purposes of this  
 23 deposition, I'm going to refer to the  
 24 patents by the last three numbers, for  
 25 example, patent 7,668,730 I'll refer to as

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1 BRYAN BERGERON, M. D.  
 2 the '730 patent. Is that okay?  
 3 A. That's fine.  
 4 Q. Okay. And we're going to be  
 5 talking about your knowledge as of certain  
 6 dates. When I ask about your knowledge  
 7 about something in the early 2000s, I mean  
 8 prior to December '2002, okay?  
 9 A. Okay.  
 10 Q. Have you read the six patents  
 11 involved in these IPRs?  
 12 A. I have.  
 13 Q. And you've been named as an  
 14 inventor on several patent and patent  
 15 applications, correct?  
 16 A. That's correct.  
 17 Q. Have you been involved with the  
 18 proceedings at the Patent Office for any  
 19 of those patents or patent applications?  
 20 A. Meaning what?  
 21 Q. Have you had interactions with  
 22 the Patent Office regarding any of those  
 23 patents or patent applications?  
 24 A. Through my patent attorney, but  
 25 not directly.

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1 BRYAN BERGERON, M. D.  
2 Q. Okay. So have you participated  
3 in responses to Office actions?  
4 A. Not directly.  
5 Q. Have you interacted with your  
6 attorney to craft responses to Office  
7 actions?  
8 A. Yes.  
9 Q. Have you ever read an Office  
10 action?  
11 A. Yes.  
12 Q. Have you ever -- have any of the  
13 patent applications that you filed ever  
14 gone to appeal?  
15 A. I believe there's one going to  
16 appeal now.  
17 Q. Do you know whether an appeal  
18 brief was filed in that?  
19 A. I don't know.  
20 Q. Do you know what an appeal brief  
21 is before the Patent and Trademark Office?  
22 A. I'm not positive, but -- I'm not  
23 positive.  
24 Q. Is it your understanding that  
25 that's a request for the board of patent

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1 BRYAN BERGERON, M. D.  
2 appeals to overturn an examiner's  
3 rejection?  
4 A. I'll follow that. It makes  
5 sense.  
6 Q. But you don't recall whether or  
7 not your -- you've filed an appeal brief  
8 in that case?  
9 A. This is early on. This is just  
10 happening. I'm not sure where my attorney  
11 is in that process. It was his decision  
12 to do something within the last week or  
13 two.  
14 Q. When were you asked to be an  
15 expert in this case?  
16 A. I guess a little less than a  
17 year ago.  
18 Q. And what were you told would be  
19 your assignment?  
20 MS. SHIH: Just caution the  
21 witness not to reveal any  
22 attorney/client privileged  
23 communications. If you can answer  
24 without doing so, then you can. If  
25 you cannot answer, then --

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1 BRYAN BERGERON, M. D.  
2 A. This is an IPR case in general  
3 and -- it's an IPR case.  
4 BY MR. BERMAN:  
5 Q. And you've been involved in IPRs  
6 before?  
7 A. Yes, I have. As is on my CV.  
8 Q. Prior to this case, had you ever  
9 heard of XYREM?  
10 A. Yes, I have.  
11 Q. How?  
12 A. I'm not sure. I don't recall  
13 exactly. It could have been the press.  
14 It could have been a lecture or something  
15 I heard in the hospitals. It's been  
16 around for years.  
17 Q. Prior to this case, had you ever  
18 heard of the active pharmaceutical  
19 ingredient known as GHB or sodium oxybate?  
20 A. I've heard of it.  
21 Q. In what capacity?  
22 A. It's also known as the date rape  
23 drug, to put it in that context, at least.  
24 It's -- yeah.  
25 Q. And you've just heard it in --

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1 BRYAN BERGERON, M. D.  
2 in what capacity?  
3 A. I don't recall. Either --  
4 either in the press or in the medical  
5 arena in terms of a notification that  
6 there are drugs that are out there that  
7 are potential drugs for abuse.  
8 Q. And you know that XYREM is an  
9 approved form of GHB, correct?  
10 MS. SHIH: Objection.  
11 A. I don't know. I haven't --  
12 haven't been asked to comment on the  
13 status of the drug or how it was developed  
14 or anything. I don't have an opinion on  
15 that.  
16 BY MR. BERMAN:  
17 Q. Do you know what the active  
18 ingredient in XYREM is?  
19 A. I believe it's a gamma  
20 hydroxybutyrate.  
21 Q. So GHB?  
22 A. Yes.  
23 Q. Do you recall if you heard of  
24 GHB prior to you hearing about XYREM?  
25 A. I don't recall.

1 BRYAN BERGERON, M.D.  
 2 Q. So other than knowing that GHB  
 3 was a date rape drug, what else did you  
 4 know about it?  
 5 A. At some point what it's used  
 6 for, for narcolepsy, for example, for  
 7 treating sleep disorder -- or wakefulness  
 8 or sleep disorders.  
 9 Q. When did you hear about that?  
 10 A. I don't recall.  
 11 Q. Was it after XYREM was approved?  
 12 A. I don't know.  
 13 Q. If you were interested in  
 14 learning more about GHB, how would you  
 15 learn more about it?  
 16 MS. SHIH: Objection. Outside  
 17 the scope.  
 18 A. It's not something I've  
 19 considered.  
 20 BY MR. BERMAN:  
 21 Q. If you were interested in  
 22 learning more about XYREM, how would you  
 23 learn about it?  
 24 MS. SHIH: Same objection.  
 25 A. Same thing. I haven't been

1 BRYAN BERGERON, M.D.  
 2 asked to -- I haven't thought about that.  
 3 It's not why I'm here right now. I  
 4 haven't been asked to evaluate that aspect  
 5 of the drug. I haven't been asked to  
 6 evaluate that part of the pharmacology  
 7 system.  
 8 BY MR. BERMAN:  
 9 Q. So you're not particularly  
 10 interested in XYREM?  
 11 MS. SHIH: Objection.  
 12 A. I'm not saying either way.  
 13 Personally interested in XYREM? I'm not  
 14 sure what you're asking me.  
 15 Q. You're not particularly  
 16 interested in XYREM enough to research it?  
 17 A. I haven't been; in the past I've  
 18 had no -- none that I can recall.  
 19 Q. Would the same be true of GHB in  
 20 general?  
 21 A. Again, as I recall it, yes.  
 22 Q. Prior to this case, have you  
 23 ever heard of restricted drug distribution  
 24 systems?  
 25 A. I'm familiar with the concept.

1 BRYAN BERGERON, M.D.  
 2 Q. How?  
 3 A. I'm a physician.  
 4 Q. Can you --  
 5 A. So as a physician, I can't --  
 6 physicians can't just simply order  
 7 anything they want. So working in a  
 8 hospital you have a formulary and it's an  
 9 approved set of drugs for certain  
 10 purposes. So there are restrictions.  
 11 Q. And that goes to a certain class  
 12 of drugs, correct?  
 13 A. It does do that, yes.  
 14 Q. So aside from -- aside from  
 15 knowing that you can't just simply order a  
 16 drug, what else do you know about  
 17 restricted drug distribution systems?  
 18 MS. SHIH: Objection.  
 19 A. Again we're talking about me as  
 20 a physician or am I talking as a person of  
 21 ordinary skill in the art? How are you  
 22 addressing me?  
 23 BY MR. BERMAN:  
 24 Q. I'm addressing you as Dr.  
 25 Bergeron, the physician.

1 BRYAN BERGERON, M.D.  
 2 A. Okay, so again -- there's --  
 3 you're only allowed to use drugs on a  
 4 formulary working in a hospital and there  
 5 are restrictions on what can be ordered  
 6 for certain types of patients.  
 7 Q. So if you were interested in  
 8 learning more about restricted drug  
 9 distribution systems, how would you learn  
 10 about them?  
 11 MS. SHIH: Objection.  
 12 A. It's not something I've thought  
 13 about.  
 14 BY MR. BERMAN:  
 15 Q. Do you know whether there's  
 16 particular publications that talk about  
 17 restricted drug distribution systems?  
 18 A. Today, through this -- this  
 19 proceeding, I'm aware of what's been  
 20 brought to the table in terms of the  
 21 references here; but before then, no.  
 22 Q. So what about in the early  
 23 2000s, if you wanted to learn more about  
 24 restricted drug distribution systems, how  
 25 would you learn about it?

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