

UNITED STATES PATENT AND TRADEMARK OFFICE

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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<p>1 2 3 4 5 Transcript of the deposition of 6 BRYAN BERGERON, MD, FACMI, called for 7 Oral Examination in the 8 above-captioned matter, said 9 deposition taken pursuant to United 10 States Patent and Trademark Office 11 rules and regulations, by and before 12 DANA N. SREBRENICK, a 13 Federally-Approved Certified Realtime 14 Reporter, a New Jersey Certified Court 15 Reporter, a Certified Livenote 16 Reporter, and a Notary Public for the 17 State of New York, at the offices of 18 QUINN EMANUEL URQUHART & SULLIVAN LLP, 19 51 Madison Avenue, New York, New York 20 10010, commencing at 9:30 a.m. 21 22 - - - 23 24 25</p>	<p>1 A P P E A R A N C E S (continued) 2 3 JONES DAY 4 BY: JOHN V. BIERNACKI, ESQ. 5 North Point 6 901 Lakeside Avenue 7 Cleveland, Ohio 44114-1190 8 216.586.7747 9 jvbiernacki@jonesday.com 10 Counsel for the Patent Owner, 11 Jazz Pharmaceuticals 12 13 QUINN EMANUEL URQUHART & 14 SULLIVAN LLP 15 BY: FRANK CALVOSA, ESQ. 16 EVANGELINE SHIH, ESQ. 17 51 Madison Avenue, 52nd Floor 18 New York, New York 10010 19 212.849.7569 20 Evangelineshih@quinnemanuel.com 21 frankcalvosa@quinnemanuel.com 22 Counsel for the Patent Owner, 23 Jazz Pharmaceuticals, Inc. 24 25</p>
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<p>1 A P P E A R A N C E S 2 3 ARENT FOX 4 BY: RICHARD J. BERMAN, ESQ. 5 1717 K Street, NW 6 Washington, DC 20036-5342 7 202.857.6000 8 Richard.berman@arentfox.com 9 Counsel for the Petitioner, 10 Par Pharmaceutical 11 12 MADDOX EDWARDS, PLLC 13 BY: MATTHEW C. RUEDY, ESQ. 14 1900 K Street NW - Suite 725 15 Washington, DC 20006 16 202.830.0779 17 mruedy@meiplaw.com 18 Counsel for the Petitioner, 19 Amneal Pharmaceutical 20 21 22 23 24 25</p>	<p>1 2 - - - 3 BRYAN BERGERON, MD, FACMI, 4 27 Stearns Road, Brookline, 5 Massachusetts 02246, after having been 6 duly sworn, was examined and testified 7 as follows: 8 - - - 9 EXAMINATION BY MR. BERMAN: 10 - - - 11 Q. Good morning, Dr. Bergeron. My 12 name is Rich Berman. I'm counsel for Par 13 Pharmaceutical. I'll be asking you some 14 questions today. 15 A. Good morning. 16 Q. Can you please recite your full 17 name and home address for the record? 18 A. Sure. Bryan Patrick Bergeron. 19 My home address is 27 Stearns Road, 20 Brookline, Mass 02446. 21 Q. And you've been deposed before, 22 correct? 23 A. I have. 24 Q. And that's reflected in your CV? 25 A. Yes, it is.</p>

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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

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 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?

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.

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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 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.

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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 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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