

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.)
-----)

CONTINUED DEPOSITION UNDER ORAL EXAMINATION

OF

BRYAN BERGERON, MD, FACMI

January 22, 2016

New York, New York

REPORTED BY: DANA N. SREBRENICK, CRR CLR

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<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">Continued Transcript of the deposition of BRYAN BERGERON, MD, FACMI, called for Oral Examination in the above-captioned matter, said deposition taken pursuant to United States Patent and Trademark Office rules and regulations, by and before DANA N. SREBRENICK, a Federally-Approved Certified Realtime Reporter, a New Jersey Certified Court Reporter, a Certified Livenote Reporter, and a Notary Public for the State of New York, at the offices of QUINN EMANUEL URQUHART & SULLIVAN LLP, 51 Madison Avenue, New York, New York 10010, commencing at 9:30 a.m.</p> <p style="text-align: center;">- - -</p>	<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">A P P E A R A N C E S (continued)</p> <p style="text-align: center;">JONES DAY BY: JOHN V. BIERNACKI, ESQ. North Point 901 Lakeside Avenue Cleveland, Ohio 44114-1190 216.586.7747 jvbiernacki@jonesday.com Counsel for the Patent Owner, Jazz Pharmaceuticals</p> <p style="text-align: center;">QUINN EMANUEL URQUHART & SULLIVAN LLP BY: FRANK CALVOSA, ESQ. EVANGELINE SHIH, ESQ. 51 Madison Avenue, 52nd Floor New York, New York 10010 212.849.7569 Evangelineshih@quinnemanuel.com frankcalvosa@quinnemanuel.com Counsel for the Patent Owner, Jazz Pharmaceuticals, Inc.</p>
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<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">A P P E A R A N C E S</p> <p style="text-align: center;">ARENT FOX BY: RICHARD J. BERMAN, ESQ. 1717 K Street, NW Washington, DC 20036-5342 202.857.6000 Richard.berman@arentfox.com Counsel for the Petitioner, Par Pharmaceutical</p> <p style="text-align: center;">MADDOX EDWARDS, PLLC BY: MATTHEW C. RUEDY, ESQ. 1900 K Street NW - Suite 725 Washington, DC 20006 202.830.0779 mruedy@meiplaw.com Counsel for the Petitioner, Amneal Pharmaceutical</p>	<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">- - -</p> <p style="text-align: center;">BRYAN BERGERON, MD, FACMI, 27 Stearns Road, Brookline, Massachusetts 02406, after having been duly sworn, was examined and testified as follows:</p> <p style="text-align: center;">- - -</p> <p style="text-align: center;">CONTINUED EXAMINATION BY MR. BERMAN: - - -</p> <p>Q. Good morning, Dr. Bergeron. A. Good morning. Q. Let's pick up where we left off yesterday in your report, Exhibit 2047 for the '059 IPR. Let's go to page 20 at paragraph 46. Are you there? A. I'm there, yes, yes. Q. The first sentence says, "Based on the ACA disclosures, it is my opinion that a POSA would have understood that generating data for any possible investigations and prosecutions is not the same as generating periodic reports." Do you see that? A. I do.</p>

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1 BRYAN BERGERON, M. D.
 2 Q. And that's because the
 3 information provided in such a manner is
 4 done so upon request; is that right?
 5 A. That's right.
 6 Q. Going on to -- towards the end
 7 of that paragraph, the last sentence, "It
 8 is my opinion that the ACA materials only
 9 disclose generating retrospective ad hoc
 10 reports to aid in diversion investigations
 11 once those investigations have already
 12 been initiated. The ACA materials were
 13 not disclosed, taught or suggested the
 14 claimed prospective periodic reports that
 15 will aid the central pharmacy in
 16 evaluating potential diversion patterns."
 17 Do you see that?
 18 A. I do, yes.
 19 Q. Let's take that second sentence
 20 first. When you say "the claimed
 21 prospective periodic reports," what do you
 22 mean?
 23 A. I think I'm referring to the
 24 claimed reports in the patent, in other
 25 words, the claims.

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1 BRYAN BERGERON, M. D.
 2 Q. Does the word "prospective"
 3 appear in the claims?
 4 A. I don't recall. I can check. I
 5 assume you probably checked.
 6 Q. I submit to you it does not. It
 7 does not appear in the claim.
 8 A. I'll accept that.
 9 Q. Since it does not appear in the
 10 claims, what's your basis that the claims
 11 are limited to prospective periodic
 12 reports?
 13 A. I'm not saying it's limited,
 14 first of all. And I'm talking about
 15 periodic reports, and so by nature,
 16 reports -- a periodic report I talked
 17 about earlier is something that occurs --
 18 the exact wording here -- at regular
 19 frequencies or intervals as opposed to
 20 intermittently or upon request.
 21 So, for example, a weekly report
 22 would be weekly. So it's a preset
 23 frequency. So if I expect a weekly
 24 report, I would see it next week, the
 25 following week, the week after that, the

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1 BRYAN BERGERON, M. D.
 2 week after that.
 3 Q. And so do you --
 4 A. So that's going into the future.
 5 Q. So when you use the term
 6 "prospective," you're just meaning
 7 sometime in the future?
 8 MR. CALVOSA: Objection.
 9 Mischaracterizes.
 10 A. I mean that's part of a periodic
 11 report. So a -- a periodic report is what
 12 is claimed here. So, for example, a
 13 weekly report is a report given every
 14 week, not every -- not once a week and it
 15 skips three weeks, another week and two
 16 weeks and another week. But it's weekly,
 17 so it's prospective.
 18 I can expect that at a set
 19 interval, at regular frequencies or
 20 intervals, as opposed to intermittently or
 21 upon request. So that regular frequency
 22 in that case would be a week, so that's
 23 looking -- I can expect a weekly report
 24 six months from now in the system.
 25 If I'm established -- if I have

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1 BRYAN BERGERON, M. D.
 2 a weekly report, I can look ahead a month
 3 and know there will be a weekly report
 4 there on the week. That's the meaning in
 5 the context of "prospective."
 6 BY MR. BERMAN:
 7 Q. When you're using the term
 8 "prospective," you mean prospective in
 9 time?
 10 A. Yes.
 11 Q. Okay. And in your opinion the
 12 claimed prospective reports aid the
 13 central pharmacy in evaluating potential
 14 diversion patterns, correct?
 15 A. Yes.
 16 Q. So what are some examples of
 17 prospective reports, according to the
 18 patent?
 19 A. So if you look at figure 13-A in
 20 the patent, these reports, for example, on
 21 the figure 13-A, the first report, the
 22 first activity report, RX by zip, new and
 23 total, so the first entry has associated
 24 with it weekly, monthly, and quarterly
 25 reports. And the title of that column in

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1 BRYAN BERGERON, M. D.
 2 the right is "The Report Frequency," so I
 3 would expect that -- the RX by zip, new
 4 and total weekly, monthly and quarterly
 5 reports.
 6 Q. Is a report tracking
 7 prescriptions by physician a prospective
 8 report in your opinion?
 9 A. Can you point to a specific
 10 spot? Are you pointing to the second
 11 entry, what are you asking me?
 12 Q. I'm not pointing to the second
 13 entry. I'm just asking if that would be a
 14 prospective report in your opinion?
 15 A. It would depend.
 16 Q. On what?
 17 A. Is it a weekly report?
 18 Q. I'm asking whether a report
 19 tracking prescriptions by physician would
 20 be a prospective report in your opinion?
 21 MR. CALVOSA: Objection to form.
 22 A. I would need to know more. I
 23 don't have enough information. It
 24 depends, so I cannot make a decision based
 25 on what you've told me.

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1 BRYAN BERGERON, M. D.
 2 BY MR. BERMAN:
 3 Q. So let's look at some of these
 4 other reports on 13-A. One area of
 5 reports listed here is call center. Do
 6 you see that?
 7 A. Call center, yes, middle of the
 8 13-A.
 9 Q. Yeah. And you see that there is
 10 several entries there under the call
 11 center, number of calls received, number
 12 of calls initiated, number of calls
 13 answered in 30 seconds, et cetera,
 14 percentage of calls answered in 30
 15 seconds, number of abandoned calls,
 16 percentage of abandoned calls and average
 17 call length. Do you see all of those?
 18 A. I see those, yes.
 19 Q. And each of those is associated
 20 in figure 13-A with a monthly report,
 21 correct?
 22 A. I see that, yes.
 23 Q. So would that be a prospective
 24 report in your opinion?
 25 MR. CALVOSA: Objection. Form.

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1 BRYAN BERGERON, M. D.
 2 A. Well, I mean, I understand 13-A
 3 to illustrate reports at a -- I'm sorry --
 4 periodic reports, and a period of these
 5 reports would be monthly.
 6 BY MR. BERMAN:
 7 Q. So is that prospective in your
 8 opinion?
 9 A. The reporting is prospective.
 10 Q. Okay. And do the call center
 11 reports aid the central pharmacy in
 12 evaluating potential diversion patterns in
 13 your opinion?
 14 A. It depends.
 15 Q. It depends on what?
 16 A. It depends on the situation. I
 17 haven't -- I haven't studied or opined on
 18 the specific entries in this table and how
 19 they apply to potential use by
 20 third-parties.
 21 Q. So you don't have an opinion as
 22 to whether all the activity reports in
 23 figure 13-A aid the central pharmacy in
 24 evaluating potential diversion patterns?
 25 MR. CALVOSA: Objection.

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1 BRYAN BERGERON, M. D.
 2 Mischaracterizes.
 3 A. What I said is I haven't studied
 4 each individual entry in terms of its
 5 potential for that use. It's not
 6 excluding some of this for that use.
 7 BY MR. BERMAN:
 8 Q. So not all of the activity
 9 reports on 13-A would aid the central
 10 pharmacy in evaluating potential diversion
 11 patterns?
 12 A. Again, I haven't performed that
 13 analysis.
 14 Q. You have no opinion on that?
 15 MR. CALVOSA: Objection.
 16 Mischaracterizes.
 17 A. Well, my opinion is that I
 18 haven't done that analysis. My opinion on
 19 this use -- I offer this 13-A in response
 20 to your question about the nature of these
 21 periodic reports, prospective periodic
 22 reports.
 23 That's -- that's how I'm
 24 offering this. I have not done an
 25 analysis of each entry in this report for

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1 BRYAN BERGERON, M. D.
 2 a particular use.
 3 BY MR. BERMAN:
 4 Q. Turning to the sentence on
 5 retrospective reports, what do you mean by
 6 "retrospective reports" in your opinion on
 7 paragraph 46?
 8 A. I'm sorry, can you point me to
 9 which page?
 10 Q. Sure. It's on page 21, last
 11 sentence -- I'm sorry, second to last
 12 sentence. "It is my opinion that the ACA
 13 materials only disclose generating
 14 retrospective ad hoc reports." Do you see
 15 that?
 16 A. I do.
 17 Q. Okay. What do you mean by
 18 "retrospective reports" in that instance?
 19 A. Well, first of all, the ad hoc
 20 reports are generated or event-driven, so
 21 they are -- there's a need for a report
 22 and then the report is created; and so in
 23 contrast to the prospective reporting,
 24 which occurs every week or every month,
 25 whatever the periodicity is.

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1 BRYAN BERGERON, M. D.
 2 That because the report is ad
 3 hoc, and generated as needed, it
 4 necessarily includes information or data
 5 from things that occurred up to that
 6 current -- up to that point in time and
 7 it's retrospective.
 8 Q. Going back to figure 13-A just
 9 so I can clarify what you mean there. In
 10 the reports, for example, the call center
 11 reports that are reported monthly, doesn't
 12 that include data information or data from
 13 things that occurred up to that point in
 14 time?
 15 A. At what point in time?
 16 Q. At the point in time the report
 17 is generated.
 18 A. I would expect so, yes.
 19 Q. So you said -- in
 20 differentiating between ad hoc and
 21 prospective reporting, you said that the
 22 report, when the report is ad hoc, it
 23 necessarily includes information or data
 24 from things that occurred up to that
 25 current point in time, and you labeled

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1 BRYAN BERGERON, M. D.
 2 that being retrospective.
 3 So I'm trying to understand
 4 what's the difference between the data
 5 that's in a retrospective report in your
 6 opinion and a data that's in a prospective
 7 report?
 8 A. I think you're mixing up two
 9 concepts that we've been talking about, at
 10 least I've been talking about. Right now
 11 you're talking about the data and we were
 12 talking -- I understood we were talking
 13 about -- this conversation about -- we
 14 first start off with prospective periodic
 15 reports, and that's the frequency of the
 16 reports, so I can look forward -- if it's
 17 a weekly report, to a report being
 18 provided next week.
 19 I'm not talking about data in
 20 the report. I'm talking about the report
 21 itself being provided. If it's a weekly
 22 report, every week.
 23 So an ad hoc report occurs at
 24 one point in time. There's no suggestion
 25 in my mind that it's going to occur again.

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1 BRYAN BERGERON, M. D.
 2 It can never occur again ever. So it
 3 cannot be prospective. It's ad hoc. So
 4 it -- by necessity, that report -- I'm not
 5 talking about the data in the report, the
 6 data in the report has to occur -- it
 7 can't have future data in it. It has to
 8 have the data up to that point in time.
 9 Or if it's a periodic report,
 10 say a weekly report or a monthly, I would
 11 expect next month to have another report
 12 and the next month to have another report
 13 and the next month to have another report,
 14 so the reporting is prospective.
 15 At each one of those report
 16 dates, it would then contain data of
 17 course that previously occurred, because
 18 you can't have reports on -- maybe someone
 19 could -- I wouldn't expect data to be from
 20 the future in any of the reports.
 21 So that's what I'm
 22 differentiating in the report itself. I'm
 23 not looking at -- analyzing the data in
 24 the report, characterizing the data in the
 25 report as by necessity being prior to the

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