1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE PATENT TRIAL AND APPEAL BOARD
3 =
4 MYLAN PHARMACEUTICALS, INC.,
et al.,
5
Petitioners,
6
-vs- Case No. IPR2016-01332
7 Patent 8,822,438 B2
8 JANSSEN ONCOLOGY, INC.,
9 Patent Owner.
10 =
11
12 Videotaped Deposition of:
13 JOHN BANTLE, M.D.
14 Madison, Wisconsin
April 24, 2017
15
16
Reported by: Taunia Northouse, RDR, CRR, CRC
17
18
19
20
21
22 Veritext Legal Solutions
23 Mid-Atlantic Region
24 1250 Eye Street NW - Suite 350
25 Washington, D.C. 20005

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1 DEPOSITION of JOHN BANTLE, M.D., a witness
2 of lawful age, taken on behalf of the the patent
3 owner, wherein Mylan Pharmaceuticals, Inc., is
4 Petitioner, and Janssen Oncology, Inc., is the patent
5 owner, before the United States Patent and Trademark
6 Office, pursuant to notice, before Taunia Northouse,
7 a Registered Diplomate Reporter and Notary Public in
8 and for the State of Wisconsin, at the offices of
9 Perkins Coie, Attorneys at Law, One East Main Street,
10 Suite 201, in the City of Madison, County of Dane,
11 and State of Wisconsin, on the 24th day of April
12 2017, commencing at 9 o'clock in the forenoon.
13
14 APPEARANCES
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5
Also present: Connie Hansen, videographer
6
7 ==========================
8
9 THE VIDEOGRAPHER: Good morning.
10 We are now on the record. My name is
11 Connie Hansen. I'm a videographer for
12 Golkow Technologies. Today is April 24th,
13 2017, and the time is 9 a.m. This video
14 deposition is being held in Madison,
15 Wisconsin, in the matter of
16 Mylan Pharmaceuticals, et al., versus
17 Janssen Oncology, Incorporated. The deponent
18 is John Bantle.
19 If counsel would please identify
20 yourselves and then the court reporter,
21 Taunia Northouse, will swear in the witness.
22 MR. KRAUSE: Todd Krause of
23 Sidley Austin for Janssen Oncology, Inc.,
24 patent owner.
25 MS. GREB: Emily Greb of

1 Perkins Coie on behalf of Petitioner Mylan.
2 MR. SWANSON: Robert Swanson on
3 behalf of Mylan as well from Perkins Coie.
4 MR. HAUER: Ryan Hauer from
5 Winston & Strawn for the petitioners.
6
7 JOHN BANTLE, M.D.,
8 called as a witness, being first duly sworn,
9 testified on oath as follows:
10
11 EXAMINATION
12 By Mr. Krause:
13 Q Good morning, Dr. Bantle.
14 A Good morning.
15 Q Can you please state your name and home address
16 for the record.
17 A John Bantle, 1865 Hillcrest Avenue, St. Paul,
18 Minnesota.
19 Q Have you ever been deposed before?
20 A No.
21 Q There are a few points that I'd like to review
22 before we get started. If I ask a question that's
23 not clear or you don't hear me, please let me know
24 so I can ask the question again. If you answer,
25 I'll assume that you understood and heard my

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1 question; okay?
2 A Yes.
3 Q And we have a court reporter taking down your
4 answers to my questions, so please try to give
5 verbal answers to my questions; okay?
6 A Yes.
7 Q We'll try to take breaks about every hour or so.
8 Please let me know if you need a break. I'll
9 finish whatever question I'm on and we can take a
10 break. Is that understood?
11 A Yes.
12 Q Is there any reason you cannot give complete and
13 accurate testimony here today?
14 A No.
15 Q I've handed you a document that's been marked as
16 Mylan Exhibit 1097. Is this your declaration?
17 A It appears to be, yes.
18 Q Is that your signature on the last page of the
19 declaration?
20 A Yes, it is.
21 Q Was the declaration marked as Exhibit 1097 an
22 accurate statement of the opinions that you've
23 reached in this case?
24 A Yes.
25 Q Are there any errors in your declaration or --

1 A None of which I'm aware.
2 Q Okay. Doctor, we'll be talking a lot about a
3 person of ordinary skill in the art today. When I
4 refer to person of ordinary skill in the art or
5 POSA, P-O-S-A, I'm referring to a person as you've
6 defined it in your expert report. Is that
7 understood?
8 A Yes.
9 Q And when we talk about the person's knowledge, it
10 refers to that person's knowledge as of
11 August 25th, 2006. Is that also understood?
12 A Yes.
13 Q Your report uses the terms adrenal insufficiency,
14 low adrenal reserve, and mineralocorticoid excess.
15 What do you mean by adrenal insufficiency?
16 A Adrenal insufficiency would be a situation where
17 the adrenal glands have failed or are in the
18 process of failing, where symptoms are produced;
19 and if diagnosis is not made and treatment
20 provided, death can ensue.
21 Q Is it the same as glucocorticoid deficiency?
22 A No. I would view that as somewhat different.
23 With glucocorticoid deficiency one has not enough
24 of a particular kind of adrenal hormone and may
25 have adequate amounts of other things.

1 Q So when you're talking about adrenal
2 insufficiency, you're referring to a deficiency or
3 insufficiency of all of the adrenal steroids; is
4 that correct?
5 A Well, at least the ones that are necessary for
6 health and maintenance of life.
7 Q And which are those?
8 A Those would principally be the glucocorticoids and
9 the mineralocorticoids.
10 Q And what are the necessary glucocorticoids?
11 A The most important is cortisol.
12 Q And are there others?
13 A There are other glucocorticoids, but they're
14 basically precursors to cortisol, such that they
15 occur in the process of developing the cortisol
16 molecule, and they're not usually important in
17 meeting body needs or maintaining normal adrenal
18 function.
19 Q Is it true that other glucocorticoids -- strike
20 that. Is it true that other steroids other than
21 cortisol have glucocorticoid activity?
22 A Yes, that is true.
23 Q And is it true that those steroids contribute to
24 the glucocorticoid activity in the body?
25 A I would have to qualify my yes and say that I

1 don't think they usually do because they're not
2 produced in significant amounts. They're simply
3 precursors to cortisol.
4 Q How is adrenal insufficiency diagnosed?
5 A Well, the definitive test would be something
6 called ACTH stimulation test referred to in this
7 document as a Synacthen test.
8 Q If a person of ordinary skill in the art wanted to
9 determine whether a patient had adrenal
10 insufficiency, what test or tests would that
11 physician want to do?
12 A Well, if one wanted to definitively make the
13 diagnosis, one would do the Synacthen test.
14 Q Are there any other tests that an individual would
15 want to perform or have performed?
16 A Yes. I think occasionally one might simply
17 measure baseline cortisol value, typically first
18 thing in the morning when cortisol values are
19 highest. And if that cortisol value meets the
20 threshold for full adrenal cortisol function, then
21 one doesn't need to do the test.
22 Q Are there any other tests that a physician would
23 want to do in determining whether a patient has
24 adrenal insufficiency?
25 MS. GREB: Objection. Vague as to

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1 time.
2 Q You can go ahead and answer the question.
3 A I'm to answer anyway. Definitely the Synacthen
4 test is the most important. There are other tests
5 that could be done that might provide insight, but
6 to make the diagnosis definitively, one would do
7 the Synacthen test.
8 Q Is that true today?
9 A Yes.
10 Q As it was in August of 2006?
11 A We call it something different, but yes, that is
12 true today.
13 Q Fair enough. To a person of ordinary skill in the
14 art in 2006, would patients' symptoms play any
15 role in the diagnosis of adrenal insufficiency?
16 A Yes. Typically symptoms might be the first clue
17 to testing for the condition. Although I think
18 it's important to say the symptoms are not very
19 specific, things like fatigue, which most of us
20 have, at least from time to time. So it creates a
21 problem in that the diagnosis is often overlooked
22 because the symptoms are nonspecific.
23 Q And do the symptoms become accentuated as the
24 disease progresses?
25 A Yes. As the disease progresses, more symptoms

1 appear and definitely would indicate something is
2 wrong and would, I think, cause a doctor who has
3 insight and competence to begin to wonder about
4 adrenal insufficiency as the cause of the
5 symptoms. But because the symptoms are so
6 nonspecific, the diagnosis is often overlooked.
7 Q How would a person of ordinary skill in the art in
8 2006 diagnose a patient if they were concerned
9 about CYP17 inhibition?
10 MS. GREB: Objection. Vague.
11 A Yes. Can you restate that?
12 Q Sure. Well, let's back up a little bit. Have you
13 heard the term CYP17?
14 A Yes.
15 Q And what is CYP17?
16 A CYP17 is the short name for 17-alpha-hydroxylase,
17 1720-lyase, L-Y-A-S-E, which is an enzyme that's
18 important in cortisol production by the adrenal
19 glands and also important in the production of
20 adrenal and testicular androgens.
21 Q And so CYP17 is an enzyme; is that correct?
22 A Yes.
23 Q And that enzyme has two activities; is that right?
24 A Correct.
25 Q And those two activities as you recited, one is

1 the 17-alpha-hydroxylase activity?
2 A Hydroxylase at the 17 position on the molecule.
3 Q Okay. And the other is a 1720-lyase activity; is
4 that correct?
5 A Yes, cleaves off two carbon atoms from the
6 molecule.
7 Q If a person of ordinary skill in the art in 2006
8 were concerned about the potential inhibition of
9 the CYP17 enzyme and the potential development of
10 adrenal insufficiency in light of that, what test
11 would that person of ordinary skill want to
12 perform to determine whether or not the patient
13 had adrenal insufficiency or was developing
14 adrenal insufficiency?
15 A Synacthen test would be I think the definitive
16 test.
17 MS. GREB: Objection. Vague. And
18 I'd just remind you to give me a second to
19 object.
20 THE WITNESS: I'm sorry.
21 MS. GREB: That's okay.
22 Q How would a person of ordinary skill in the art
23 diagnose whether or not a patient had inhibited
24 17-alpha-hydroxylase activity?
25 MS. GREB: Objection. Vague.

1 A Well, the Synacthen test would give information as
2 to whether or not cortisol production remained
3 adequate, and if there was inhibition of an
4 enzyme, it should not be adequate. And then
5 someone might look for other things that might be
6 abnormal, like low DHEA or low androstenedione.
7 Q When you say one might, would that be part of what
8 a physician in your view, a person of ordinary
9 skill in the art, would do in his or her
10 diagnosis?
11 A I think it's hard to say for sure what one might
12 do. It's such an uncommon situation that most
13 endocrinologists will never encounter it in their
14 career, but I think that would be what I would do.
15 Q But is it fair to say you don't know what a person
16 of ordinary skill in the art would do?
17 MS. GREB: Objection. Misstates
18 prior testimony.
19 A Should I still answer?
20 Q Yeah. You can go ahead and answer.
21 A Yes. I think -- I think so.
22 Q And how would a person of ordinary skill in the
23 art diagnose a patient if she or he were concerned
24 that that patient had an inhibited 17-lyase
25 activity -- 1720-lyase activity?

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1 MS. GREB: Objection. Vague.
2 A An isolated defect in the lyase?
3 Q Yes, Doctor.
4 A I think one would still want to do the Synacthen
5 test to confirm cortisol production is normal.
6 And then one would want to measure DHEA,
7 androstenedione, A-N-D-R-O-S-T-E-N-E-D-I-O-N-E,
8 and in a man testosterone.
9 Q Is it true that just because a patient has a low
10 cortisol level, that does not mean that they have
11 adrenal insufficiency?
12 MS. GREB: Objection. Incomplete
13 hypothetical.
14 A If they have a low cortisol after a Synacthen
15 stimulation test, they have adrenal insufficiency.
16 Q If one were just looking at the cortisol level --
17 A Yes.
18 Q -- would the cortisol -- would a low cortisol
19 level alone mean that a patient has adrenal
20 insufficiency?
21 A If it is low after Synacthen administration, in my
22 opinion, yes.
23 Q And your declaration also refers to low adrenal
24 reserve. What is low adrenal reserve?
25 A Low adrenal reserve might be considered the

1 forerunner to adrenal insufficiency where adrenal
2 function is partially compromised but not yet
3 fully compromised such that a person might be able
4 to meet basic cortisol production needs but could
5 not augment cortisol production at times of great
6 stress.
7 I've been warned that using analogies is
8 probably not a good idea in this proceeding, but I
9 can't help myself in this case to say low adrenal
10 reserve might be like a car whose engine is not
11 working properly and can only go 30 miles an hour.
12 You can get around town okay in that car, but take
13 it out on the freeway and you're likely to have
14 trouble.
15 Q And how is low adrenal reserve diagnosed?
16 A It would usually be diagnosed by the Synacthen
17 test.
18 Q Are there any other methods a person of ordinary
19 skill in the art would use in determining
20 definitively whether or not a patient had low
21 adrenal reserve?
22 A No, I don't think so.
23 Q And when you refer to low adrenal reserve, how do
24 you define low?
25 A Low adrenal reserve would be defined as achieving

1 a cortisol value in the Synacthen test that does
2 not meet the threshold for normal.
3 Q And what is the threshold for normal in your view?
4 MS. GREB: Objection. Vague as to
5 time.
6 A It would be 500 nanomoles per liter or
7 18 micrograms per deciliter, depending on which
8 measure you would like to use.
9 Q Would a person of ordinary skill in the art
10 believe that is the threshold for normal?
11 A Well, there's some debate about what normal is.
12 And the literature would suggest there is some
13 wiggle in that threshold. Some people say it
14 needs to be 20 micrograms per deciliter based on
15 data in the literature. Others say 18 is
16 sufficient. But it's approximately the same.
17 Q What are the symptoms of low adrenal reserve?
18 A The symptoms of low adrenal reserve may be none.
19 In other instances there might be fairly
20 nonspecific symptoms like fatigue, poor appetite,
21 lack of energy, and stamina.
22 Q And why would a person of ordinary skill in the
23 art believe low adrenal reserve could be an issue
24 for patients?
25 A A low adrenal reserve would be an important issue

1 because that individual will probably do fine in
2 day-to-day life as long as nothing stressful
3 happens. But should that person become ill, say
4 develop pneumonia or some significant illness, or
5 should that person require surgery, perhaps urgent
6 surgery, they could quickly decompensate because
7 of the low adrenal reserve and inability to
8 augment cortisol production as would be necessary
9 to meet the stress.
10 Q What illnesses could lead to a decompensation with
11 respect to low adrenal reserve?
12 A All sorts of illnesses. The more serious the
13 illness, the more likely the patient would be
14 compromised. Pneumonia, as I previously
15 mentioned, would be one that comes immediately to
16 mind. Any sort of infectious process would
17 potentially put the person at risk. Numerous
18 other medical conditions that provide major stress
19 for the body would potentially lead to
20 decompensation.
21 Q To your knowledge, does metastatic resistant --
22 (Reporter interrupts)
23 Q To your knowledge, does metastatic resistant --
24 I'm sorry, let me start that again. To your
25 knowledge, does metastatic castrate resistant

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