1 UNITED STATES PATENT AND TRADEMARK OFFICE 2 BEFORE THE PATENT TRIAL AND APPEAL BOARD 3 4 5 -X AMERIGEN PHARMACEUTICALS LIMITED, : ARGENTUM PHARMACEUTICALS LLC, 6 : Petitioners : 7 VS 8 JANSSEN ONCOLOGY, INC., 9 Patent Owner . -- X 10 Case IPR2016-00286 Patent No. 8,822,438 B2 11 12 13 14 Videotaped deposition of SCOTT R. SERELS, M.D. taken at the offices of Hilton Garden Inn, 560 15 Main Avenue, Norwalk, Connecticut, before Clifford Edwards, LSR, Connecticut License No. SHR.407, a 16 Professional Shorthand Reporter and Notary Public, in and for the State of Connecticut on January 21, 17 2017, at 9:02 a.m. 18 19 20 GOLKOW TECHNOLOGIES, INC. 21 877.370.3377 ph | 917.591.5672 fax deps@golkow.com 22 23 Depor 24

Golkow Technologies, Inc.

Page 1 (1)

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| | SCOLL R. S | ereis, M.D. |
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| | Page 2 | Page 4 |
| | 1 APPEARANCES: | ¹ will now swear in the witness and we may |
| | 2 | ² proceed. |
| | ON BEHALF OF THE PETITIONERS, AMERIGEN | 3 |
| | 3 PHARMACEUTICALS LIMITED, ARGENTUM PHARMACEUTICALS LLC: | 4 SCOTT R. SERELS, M.D. |
| | 4 CHRISTOPHER CASIERI, ESQ. | - |
| | MCNEELY, HARE & WAR LLP | ⁵ residing at 12 Elmcrest Terrace, Norwalk, |
| | 5 12 Roszel Road, Suite C104 | ⁶ Connecticut 06850, having first been duly sworn, |
| | Princeton, NJ 08540 6 609.731.3668 | 7 deposed and testified as follows: |
| | chris@miplaw.com | 8 |
| | 7 | 9 DIRECT EXAMINATION |
| | 8 ON BEHALF OF THE PATENT OWNER, JANSSEN ONCOLOGY | 10 |
| | 9 PAUL J. ZEGGER, ESQ. | ¹¹ BY MR. ZEGGER: |
| | SIDLEY AUSTIN LLP | ¹² Q Good morning. |
| | 10 1501 K STREET, NW | ¹³ A Good morning. |
| | Washington, DC 20005 11 202.736.8060 | ¹⁴ Q Sir, let me put before you a document |
| | pzegger@sidley.com | ¹⁵ that bears exhibit Amerigen 1095. |
| | 12 | - |
| | 13 | |
| | 14 ALSO PRESENT: KEVIN MARTH, VIDEOGRAPHER 15 | ¹⁷ that as your reply declaration in the present IPR |
| | 16 | ¹⁸ proceeding? |
| | 17 | 19 A I do. |
| | 18 | ²⁰ Q Now, is that your signature on the first |
| | 20 | ²¹ page? |
| | 21 | ²² A It is. |
| | 22 | ²³ Q When did you actually sign it? |
| | 23 24 | ²⁴ A The date says January 16. |
| | | Page 5 |
| | Page 3 | Page 5 |
| | THE VIDEOGRAPHER: Good morning. W | ¹ Q Is that when you signed? |
| | ² are now on the record. My name is Kevin | ² A I believe that was when I signed. |
| | ³ Marth. I'm the legal videographer today | ³ Q That was this past Monday? |
| .* | ⁴ representing Golkow Technologies. | 4 A Correct. |
| | ⁵ Today's date is January 21, 2017 and | ⁵ Q You signed a previous declaration in this |
| | ⁶ the time is approximately 9:01 a.m. The | 6 IPR back in December of 2015; do you recall that? |
| | 7 video deposition today is being held in | 7 A I I do recall signing something |
| | ⁸ Norwalk, Connecticut in the matter of | ⁸ previously. |
| | ⁹ Amerigen Pharmaceuticals Limited, | ⁹ Q And do you recall having your deposition |
| | ¹⁰ Argentum Pharmaceuticals LLC vs Janssen | ¹⁰ taken back in August of last year? |
| | ¹¹ Oncology, Inc. for the United States | 11 A Yes. |
| | ¹² Patent and Trademark Office before the | ¹² Q Could you turn to paragraph four of your |
| | ¹³ patent trial and appeal board. Our | ¹³ declaration, the reply declaration? |
| | ¹⁴ deponent today is Dr. Scott Serels. | 14 A Yes. |
| | ¹⁵ At this time, would counsel please | ¹⁵ Q Are you there? |
| | ¹⁶ identify themselves for the record. | 16 A I am. |
| | ¹⁷ MR. ZEGGER: Paul Zegger with Sidley | 17 Q And does that list the materials that you |
| | ¹⁸ Austin for the patent owner Janssen | 18 were asked to review for your reply declaration? |
| | ¹⁹ Oncology, Inc. | 19 A Yes. |
| | ²⁰ MR. CASIERI: Chris Casieri of | 20 Q Okay. In particular, it's the expert |
| | ²¹ McNeely, Hare & War representing the | ²¹ reports of Dr. Chodak, Dr. Auchus and Dr. Velltura? |
| | ²² petitioner. | 22 A Correct. |
| | • | 22 A Contect. 23 Q And also the Amerigen expert declarations |
| | | ²³ Q And also the Amerigen expert declarations²⁴ Dr. Doran and Dr. Rutain (phonetic)? |
| | 24 reporter todav is Mr. Cliff Edwards who | Di. Doran and Di. Rutam (phonetic): |
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| Page 61ACorrect.2QDid you look at any other expert3declarations?34ANot that I recall.5QOkay. Do you recall being provided the6framework's response brief?7ANot in specifies, but yes.8QWell, is that something you reviewed?9AI did, yes.10QYou didn't review is there any reason11why that's not listed in your list of materials12considered in paragraph four?13A14a15it wasn't included.16Q17own's response was dated?18A19Q19Q10Dir, Rettig?11don't. I don't recall.12oorners' response was dated?13A14A15it wasn't included.16Q17own's response was dated?18A19Q20of2016? I'm just trying to find out whether you21recal being provided with that document?22A23document specifically.24Q25Q26Okay. Is there any reason why that3wasn't listed in your list of materials considered22A23document from Dr. Rettig?24A25Q | Page 8 |
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| 2 Q Did you look at any other expert 2 counsel. 3 declarations? 3 Doctor, could I can you to scooch 4 A Not that I recall. 3 Doctor, could I can you to scooch 4 A Not that I recall. 3 Doctor, could I can you to scooch 5 Q Okay. Do you recall being provided the 5 THE WITNESS: Oh, absolutely. 6 A Not in specifics, but yes. 7 bit? 8 Q Well, is that something you reviewed? 9 THE WITNESS: Absolutely. 9 A I did, yes. 9 THE WITNESS: Absolutely. 10 Q You didn't review is there any reason 10 BY MR. ZEGGER: 11 Q In any event, you weren't for purport 12 of your reply declaration, asked to respond to a start included. 14 A Correct. 15 Q Now, in paragraph six of your reply 15 it wasn't included. 16 A Correct. 17 15 Q Okay. That was a brief back in October 16 A Correct. 12 | - |
| 3 declarations? 3 Doctor, could I can you to scooch 4 A Not that I recall. 5 Q Okay. Do you recall being provided the 5 6 patent owner's response brief? 5 THE WITNESS: Oh, absolutely. 7 A Not in specifics, but yes. 7 bit? 8 Q Well, is that something you reviewed? 9 THE WITNESS: Absolutely. 9 A 1 did, yes. 7 bit? 10 Q You didn't review is there any reason 10 BY MR. ZEGGER: 11 Q Ina you you know when the patent 10 Prestrike? 12 considered in paragraph four? 13 A I think this is something that perhaps 14 was reviewed before this document was completed, so 15 10 Q Ina my event, you weren't, for purpor 12 onser's response was dated? 14 A Correct. 15 19 Q Okay. That was a brief back in October 20 0 workin sees to a 21 24 Q Okay. May was up provided a an expert 19 Q And do you agree that a urologist is 24 Q Okay. Is there any reason why that 5 3 20 | e me, |
| A Not that I recall. Q Okay. Do you recall being provided the g and the specifically. A I doint. I don't recall. Q Okay. That was a brief back in October G of 2016? I'm just trying to find out whether you a A I believe I was, but I don't recall the d colaration of a Dr. Rettig? A Correct. BY MR. ZEGGER: A No. A No. A No. A No. | h |
| \$ Q Okay. Do you recall being provided the patent owner's response brie? 5 THE WITNESS: Oh, absolutely. 6 patent owner's response brie? 6 THE VIDEOGRAPHER: just a 7 A Not in specifics, but yes. 7 bit? 8 Q Well, is that something you reviewed? 9 THE WITNESS: Absolutely. 9 A I did, yes. 9 THE VIDEOGRAPHER: Thank ? 10 Q You didn't review is there any reason 11 Q In any event, you weren't, for purpoo 12 considered in paragraph four? 13 Dr. Rettig? 13 A I think this is something that perhaps 14 A Correct. 14 A I don't. I don't recall. 15 Q Now, in paragraph six of your reply 16 Q Okay. That was a brief back in October 19 Q And do you agree that a PHOSITA i 19 Q Okay. That was a brief back in October 19 Q And do you agree that a unologist is 12 document specifically. 22 A I agree. 23 24 Q Okay. Were you provided a an expert 24 G And do you agree that a unologist is 24 G And do you agree that an oncologist is 24 Q Okay. Is there any reason why that 5 38 WR. ZEGGER: 2 A Correct. 2 2 | |
| 6 THE VIDEOGRAPHER: just at 7 A Not in specifics, but yes. 7 8 Q Well, is that something you reviewed? 8 THE WITNESS: Absolutely. 9 A I did, yes. 9 THE VIDEOGRAPHER: Thank is 10 Q You didn't review is there any reason 10 BY MR. ZEGGER: 11 Wy hat's not listed in your list of materials 10 BY MR. ZEGGER: 12 considered in paragraph four? 12 of your reply declaration, asked to respond to a syst included. 12 or morry, do you know when the patent 13 Dr. Rettig? 14 M Correct. 13 A 15 it wasn't included. 16 Correct. 19 Q And do you agree that a PHOSITA is 15 q Okay. That was a brief back in October 19 Q And do you agree that a PHOSITA is 16 correct. 19 Q And do you agree that a PHOSITA is 17 owner's response was dated? 19 Q And do you agree that a urologist is is 17 owner's response was but i don't recall the 22 <td>,</td> | , |
| 7 A Not in specifics, but yes. 7 bit? 8 Q Well, is that something you reviewed? 9 THE WITNESS: Absolutely. 9 A I did, yes. 9 THE WITNESS: Absolutely. 10 Q You didn't review is there any reason 10 BY MR. ZEGGER: 11 Was reviewed before this document was completed, so 12 of your reply declaration, asked to respond to a per the was reviewed before this document was completed, so 14 M any event, you weren't, for purponic of your reply declaration, asked to respond to a per the was reviewed before this document was completed, so 14 A Correct. 15 it was reviewed before this document was completed, so 14 A Correct. 16 Q finany event, you weren't, for purponic da per to ordinary skill in the art or a PHOSITA, for se 16 Q finany sevent and do you agree that a PHOSITA is a correct. 17 A I believe I was, but I don't recall the 18 A I dony. Is to finaterials considered 19 Q Okay. Were you provided a an expert 10 Q kay. Us there any reason why that 15 wasn't listed in your list of materials considered 16 document from Dr. Rettig? 1 A Correct. | |
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| 10 Q You didn't review is there any reason 11 why that's not listed in your list of materials 12 considered in paragraph four? 13 A I think this is something that perhaps 14 Was reviewed before this document was completed, so 15 it wasn't included. 16 Q Tm sorry, do you know when the patent 17 owner's response was dated? 18 A I don't. I don't recall. 19 Q Okay. That was a brief back in October 10 BY MR. ZEGGER: 11 Q In any event, you weren't, for purportiate were most specific to the 20 document from Dr. Rettig? 21 declaration. 22 A I believe I was, but I don't recall the 23 document from Dr. Rettig? 24 Q Okay. Is there any reason why that 5 wasn't listed in your list of materials considered 6 in paragraph four of your reply declaration? 7 A I thought these were most specific to the 8 declaration. 9 Q Okay. Do you know who Dr. Rettig ? 10 A I believe I's a physician, urologist. 11 Q In any event, you weren't, for purportiate with a document? 20 of your reply declaration? 7 A I thought these were most specific to the 8 declaration. 9 Q Okay. Do you know who Dr. Rettig ? 10 A I believe I's a physician, urologist. 11 But, again, I don't recall the specifics of his 12 context in connection with connection with | c vou. sir. |
| 11 Why that's not listed in your list of materials 12 considered in paragraph four? 13 A I think this is something that perhaps 14 Was reviewed before this document was completed, so 15 it wasn't included. 16 Q Fm sorry, do you know when the patent 17 owner's response was dated? 18 A I don't. I don't recall. 19 Q Okay. That was a brief back in October 10 of 2016? Tm just trying to find out whether you 12 A I believe I was, but I don't recall the 14 Q Okay. Were you provided a an expert 17 Page 7 1 declaration of a Dr. Rettig? 14 A Correct. 15 Q Okay. Were you provided a an expert 16 declaration of a Dr. Rettig? 12 A Dr. Rettig? 14 A Correct. 15 Wasn't listed in your list of materials considered 16 declaration. 17 declaration. 18 A Correct. 19 Q And do you agree that a urologist is 20 A Dr. Rettig? | , |
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| 9QOkay. Do you know who Dr. Rettig is?9QAre you an expert in oncology in10AI believe he's a physician, urologist.10endocrinology?11But, again, I don't recall the specifics of his11ANo.12report.12QPrior to your work in connection with | |
| 10AI believe he's a physician, urologist.11But, again, I don't recall the specifics of his12report.12Q14Prior to your work in connection with | |
| 11 But, again, I don't recall the specifics of his11ANo.12 report.12QPrior to your work in connection with | |
| ¹² report. ¹² Q Prior to your work in connection with | |
| • | |
| 1 ¹³ Q Okay. Were you asked to review it 1 ¹³ this case, had you ever heard of a condition of | |
| | called |
| 14 specifically? 14 CYP17 deficiency? | |
| 15 A l've seen you know, l've a lot of 16 different de la liferent de la life | |
| ¹⁶ different papers and different, you know, reports ¹⁶ Q And that was prior to your work in | |
| ¹⁷ pertaining to this case. So I recognize the name, ¹⁷ connection with this case? | |
| ¹⁸ but I don't recognize the or remember the or ¹⁹ recall the specifics of what he was describing ¹⁹ O But in terms of your own work, if your own work, if your own work if your | /011 |
| | |
| | - |
| | peruse m |
| A I knew he was a physician. I wasn't sure ²² that area; correct? ²³ exactly what his title was. ²³ A Correct. | |
| 23 exactly what his title was. 24 O Oleve | |

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| | Page 10 | | Page 12 |
| 1 | declaration, you did not fully consider the various | 1 | it says on the front page. |
| 2 | mechanisms by which ketoconazole was known to | 2 | Q Okay. Does that refresh any recollection |
| 3 | inhibit adrenal steroid synthesis beyond inhibiting | 3 | that you have as to when you were first provided the |
| 4 | CYP17 enzyme synthesis; correct? | 4 | Vidal paper? |
| 5 | MR. CASIERI: Object to form. | 5 | A You know, I've seen so many papers, I |
| 6 | A Correct. | 6 | don't recall exactly when. But if that's when he |
| 7 | BY MR. ZEGGER: | 7 | downloaded it, I I really just don't know. I |
| 8 | Q Okay. And particularly, you were | 8 | mean whether his downloading pertains to when I saw |
| 9 | focusing on one particular mechanism of action; is | 9 | the paper, I just don't know. |
| 10 | that right? | 10 | Q Okay. No, I'm just trying to find out |
| 11 | A As it pertained to abiraterone, which was | 11 | how many hours or days before you signed your reply |
| 12 | the compound that we were most interested in. | 12 | declaration on January 16th, you had the Vidal |
| 13 | Q You agree that ketoconazole has | 13 | paper? |
| 14 | | 14 | A I'm not sure. |
| 15 | enzyme synthesis? | 15 | MR. CASIERI: Object to form. |
| 16 | A I do agree. | 16 | BY MR. ZEGGER: |
| 17 | MR. CASIERI: Object to form. | 17 | Q All right. You cite a portion of the |
| 18 | BY MR. ZEGGER: | 18 | Vidal paper in your reply declaration, paragraph |
| 19 | Q Now, in defending the approach that you | 19 | nine; is that right? |
| 20 | took in this case, you cite to an article authored | 20 | I'm sorry, paragraph eight? |
| | by a Vidal and a Dr. De bono; is that right? | 21 | A Correct. |
| 22 | A Correct. | 22 | Q Now, is there any indication in the |
| 23 | Q Let me show you Amerigen Exhibit 1147. | 23 | portion that you cite indicating that ketoconazole |
| 24 | And is this the article that you relied | 24 | is a CYP17 inhibitor? |
| 1 | • | | |
| | Dens 11 | | Dama 12 |
| _ | Page 11 | | Page 13 |
| I | upon? | 1 | A Sorry. Can you repeat the |
| 2 | upon? A Yes. | 2 | A Sorry. Can you repeat theQ Sure. |
| 2 | upon? A Yes. Q When did you first see it? | 2 3 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper |
| 2 3 4 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically | 2 3 4 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a |
| 2 3 4 5 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. | 2 3 4 5 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? |
| 2 3 4 5 6 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of | 2 3 4 5 6 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, |
| 2 3 4 5 6 7 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by | 2 3 4 5 6 7 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. |
| 2 3 4 5 6 7 8 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, | 2 3 4 5 6 7 8 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was |
| 2 3 4 5 7 8 9 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." | 2 3 4 5 6 7 8 9 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and |
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| 2 3 4 5 7 8 9 10 11 12 13 14 15 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." Do you see that? A I don't. It's on the bottom of the first page? Q The very first page. A I do. Q Do you have an understanding as to | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and the compound that we are most concerned with, abiraterone, in terms of its mechanism of action, inhibiting the adrenal gland. Q Okay. In well, let's take it step by step here. A Uh-huh. |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." Do you see that? A I don't. It's on the bottom of the first page? Q The very first page. A I do. Q Do you have an understanding as to whether Mr. William Hare is Amerigen's counsel in the present IPR? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and the compound that we are most concerned with, abiraterone, in terms of its mechanism of action, inhibiting the adrenal gland. Q Okay. In well, let's take it step by step here. A Uh-huh. Q Could you look at paragraph eight of your reply declaration? |
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| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." Do you see that? A I don't. It's on the bottom of the first page? Q The very first page. A I do. Q Do you have an understanding as to whether Mr. William Hare is Amerigen's counsel in the present IPR? A He is. I know I know Mr. Hare. Q Okay. And do you see that this indicates that this particular paper by Vidal was downloaded by Mr. Hare on January 12th | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and the compound that we are most concerned with, abiraterone, in terms of its mechanism of action, inhibiting the adrenal gland. Q Okay. In well, let's take it step by step here. A Uh-huh. Q Could you look at paragraph eight of your reply declaration? A Sure. Q Are you there? A I am. Q Okay. And the portion that you cite from |
| 2 3 4 5 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." Do you see that? A I don't. It's on the bottom of the first page? Q The very first page. A I do. Q Do you have an understanding as to whether Mr. William Hare is Amerigen's counsel in the present IPR? A He is. I know I know Mr. Hare. Q Okay. And do you see that this indicates that this particular paper by Vidal was downloaded by Mr. Hare on January 12th A Yes. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and the compound that we are most concerned with, abiraterone, in terms of its mechanism of action, inhibiting the adrenal gland. Q Okay. In well, let's take it step by step here. A Uh-huh. Q Could you look at paragraph eight of your reply declaration? A Sure. Q Are you there? A I am. Q Okay. And the portion that you cite from the Vidal paper states that both ketoconazole and |
| 2 3 4 5 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | upon? A Yes. Q When did you first see it? A This article? I couldn't specifically say. Q All right. Do you see at the bottom of the cover page there is a notation, "Download by Mr. William Hare." And there's a date, "January 12, 2017." Do you see that? A I don't. It's on the bottom of the first page? Q The very first page. A I do. Q Do you have an understanding as to whether Mr. William Hare is Amerigen's counsel in the present IPR? A He is. I know I know Mr. Hare. Q Okay. And do you see that this indicates that this particular paper by Vidal was downloaded by Mr. Hare on January 12th A Yes. Q - 2017? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 | A Sorry. Can you repeat the Q Sure. Is there any portion of the Vidal paper that you cite that indicates that ketoconazole is a CYP17 inhibitor? A Yes. I couldn't exactly find it for you, but yes. I think that, you know, the purpose was that it was describing similarities between it and the compound that we are most concerned with, abiraterone, in terms of its mechanism of action, inhibiting the adrenal gland. Q Okay. In well, let's take it step by step here. A Uh-huh. Q Could you look at paragraph eight of your reply declaration? A Sure. Q Are you there? A I am. Q Okay. And the portion that you cite from |

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| | | Page 14 | | Page 16 |
|---|---------------------|---|----------|---|
| | - | from Vidal "Through the inhibition of key | | something being a CYP17 inhibitor is referring to |
| | - | nes in the adrenal steroid biosynthesis pathways | 1 | the abiraterone acetate not ketoconazole. |
| | | gents such as ketoconazole or the CYP17 | 3 | Correct? |
| | | tor, abiraterone acetate." | 4 | MR. CASIERI: Object to form. |
| | 5 | Do you see that? | 5 | A I think it's subject to interpretation. |
| | 6 A | I do. | 6 | BY MR. ZEGGER: |
| | 7 Q | In the quoted portion that you take from | 7 | Q Well, do you see any express statement in |
| | | , is there any indication that ketoconazole is | 8 | the Vidal paper referring to ketoconazole as a CYP17 |
| | | P17 inhibitor? | | inhibitor? |
| 1 | | Yes. To my recollection, yes. | 10 | A It's it's more a descriptive of |
| 1 | × | Well, either the quoted material refers | 11 | adrenal inhibition. I'd have to reread the article |
| 1 | | oconazole as a | 12 | to be certain if there's anything specifically |
| 1 | | Uh-huh. | 13 | saying, CYP17. |
| 1 | 4 Q | CYP17 inhibitor or it doesn't. | 14 | Q Okay. Well, I don't want you to |
| 1 | 5 | Right? | 15 | A Yup. |
| 1 | | Correct. | 16 | Q to guess. If you could take some time |
| 1 | × | Okay. Now, that's referring to | | looking at the Vidal article |
| 1 | ⁸ abirat | erone acetate as a CYP17 inhibitor; correct? | 18 | A Sure. |
| 1 | | Correct. | 19 | Q that you cite and if you could let us |
| 2 | × | Okay. But it doesn't state that | 20 | know whether you find any express statement in that |
| 2 | ¹ ketoco | onazole is a CYP17 inhibitor. | 21 | article that ketoconazole is a CYP17 inhibitor? |
| 2 | 2 | Correct? | 22 | A Yeah. I think you know, I think what |
| 2 | 3 | MR. CASIERI: Object to form. | | you quoted what I quoted on page eight of the |
| 2 | 4 A | You are saying that quote doesn't? I | 24 | article is the inference that ketoconazole inhibits |
| | | Page 15 | | Page 17 |
| | ¹ mean, | it's subject to interpretation. | 1 | adrenal steroid biosynthesis. And it compares it to |
| 1 | 2 | And, you know, ketoconazole affects the | | abiraterone in terms of being a CYP17 inhibitor. |
| | ³ adrena | al production, the adrenal glands production | 3 | And I think that's where that quote comes from, the |
| | 4 and C | YP17 inhibitors is one of the functions of the | 4 | specific line within page eight which describes it |
| | 5 adrena | al gland. | 5 | as being this inhibitor of biosynthesis and it |
| | 6 BY M | IR. ZEGGER: | 6 | compares it to abiraterone. |
| | 7 Q | Well, my question doesn't go to whether | 7 | Q Okay. So is there any express statement |
| | ⁸ ketoco | onazole | 8 | in the Vidal paper that ketoconazole is a CYP17 |
| | 9 A | Yup. | 9 | inhibitor? |
| 1 | • Q | is a CYP17 inhibitor. | 10 | MR. CASIERI: Object to form. |
| 1 | 1 A | Sure. | 11 | A Yeah. Other than the quote that states |
| 1 | 2 Q | My question goes to whether Vidal | 12 | it comparing it to the other CYP17 inhibitor, there |
| 1 | 3 A | Yes. | 13 | |
| 1 | 4 Q | that publication is referring to | 14 | direct description. |
| 1 | 5 ketoco | onazole as a CYP17 inhibitor. | 15 | |
| 1 | 6 | Do you understand? | 16 | Q Now, could you look at paragraph nine of |
| 1 | 7 A | | 17 | |
| 1 | ⁸ And I | think, you know, that it seems to be fairly | 18 | A Sure. |
| 1 | | from the article that ketoconazole can inhibit | 19 | Q And there you refer to a rebuttal opinion |
| | 9 clear i | | | |
| 2 | | Irenal gland which would encompass the CYP17 | 20 | of Dr. Doran? |
| | o the ad | - | 20 21 | A Uh-huh. |
| | o the ad | nes. So my inference would be that, yes, it | | A Uh-huh. |
| 2 | o the ad | nes. So my inference would be that, yes, it suggest that ketoconazole would inhibit the | 21 | A Uh-huh.Q That's Amerigen's expert? |

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