

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMERIGEN PHARMACEUTICALS LIMITED and  
ARGENTUM PHARMACEUTICALS LLC,  
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner.

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Case IPR2016-00286  
Patent 8,822,438 B2

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Held: February 16, 2017

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BEFORE: LORA M. GREEN, RAMA G. ELLURU, and  
KRISTINA M. KALAN, Administrative Patent Judges.

The above-entitled matter came on for hearing on Thursday,  
February 16, 2017, commencing at 1:00 p.m., at the U.S.  
Patent and Trademark Office, 600 Dulany Street, Alexandria,  
Virginia.

Case IPR2016-00286  
Patent 8,822,438 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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1 P R O C E E D I N G S

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3 JUDGE GREEN: This is the final oral hearing in  
4 IPR2016-00286 involving patent number 8,822,438.  
5 IPR2016-01317 has been joined with this proceeding. I am Judge  
6 Green. Beside me is Rama Elluru. And Judge Kalan is joining us  
7 from Denver. As set forth in our hearing order, each side will  
8 have 45 minutes. Petitioner will go first to present its case in  
9 chief followed by patent owner. Petitioner may reserve time for  
10 rebuttal.

11 I would like to ask the parties to introduce yourselves  
12 starting with petitioner.

13 MR. HARE: Hello. My name is Bill Hare for  
14 Amerigen Pharmaceuticals and Argentum Pharmaceuticals here  
15 with my co-counsel, Chris Casieri, Renita Rathinam, and Teresa  
16 Rea and Shannon Lentz for Argentum Pharmaceuticals.

17 JUDGE GREEN: Thank you very much. Patent  
18 owner?

19 MS. ELDERKIN: Good afternoon, members of the  
20 Board. I'm Dianne Elderkin, lead counsel for the patent owner.  
21 And I would like to introduce David Pritikin, who will be doing  
22 the arguments, and his colleagues, Alyssa Monsen and Bindu  
23 Donovan.

24 JUDGE GREEN: Thank you. I would like to remind  
25 the parties that this hearing is open to the public and a full

1 transcript of the hearing will be made part of the record. In  
2 addition, when discussing any particular demonstrative or slide,  
3 please refer to it by slide or page number to help us maintain a  
4 clear transcript. In addition, we have a colleague joining us from  
5 Denver who cannot see the demonstratives. So if you don't say  
6 what slide or demonstrative you are using, she cannot follow the  
7 argument very well.

8           Petitioner, you have the burden of showing  
9 unpatentability of the challenged claims. You may begin. Would  
10 you like to reserve rebuttal time?

11           MR. HARE: I would like to reserve ten minutes for  
12 rebuttal.

13           JUDGE GREEN: Thank you. You may start when you  
14 are ready.

15           MR. HARE: If we can jump to slide 2, so this IPR is  
16 about the '438 patent, which is directed towards a method of  
17 treating prostate cancer by administering therapeutically effective  
18 amount of abiraterone acetate and a therapeutically effective  
19 amount of prednisone. So the prior art shows all the elements of  
20 claim 1.

21           If we can go to slide 3, it's undisputed that the prior art  
22 teaches the treatment of prostate cancer with abiraterone acetate.  
23 That's shown in O'Donnell and Barrie. The prior art teaches  
24 abiraterone acetate is a selective CYP17 inhibitor -- CYP17 is an  
25 enzyme -- that's shown in O'Donnell and Barrie, and that

1 ketoconazole, another compound that inhibits the CYP17  
2 enzyme, was administered in combination with prednisolone in  
3 treating hormone refractory prostate cancer. And that's shown in  
4 Gerber.

5           So I would like to move to slide 4 and talk a little bit  
6 about O'Donnell and Gerber. So O'Donnell teaches that  
7 abiraterone acetate treats prostate cancer, and O'Donnell teaches  
8 that abiraterone acetate is a selective CYP17 inhibitor and that it's  
9 more effective in suppressing testosterone levels than is  
10 ketoconazole. Then we have Gerber which teaches that  
11 ketoconazole was being administered to treat prostate cancer in  
12 combination with prednisone. And again, ketoconazole is a  
13 compound that inhibits the CYP17 enzyme.

14           Now, Barrie and Gerber, that's the other grounds for  
15 institution, and this is on slide 5. So Barrie is also known as a  
16 '213 patent. This is in the Orange Book for Zytiga. This patent  
17 teaches that abiraterone acetate treats prostate cancer. Barrie, the  
18 '213 patent, also teaches that abiraterone acetate is a CYP17  
19 inhibitor that is more effective at suppressing testosterone levels  
20 than ketoconazole, another CYP17 inhibitor. And then you have  
21 again Gerber which we spoke about earlier, in which  
22 ketoconazole being a CYP17 inhibitor was administered in  
23 combination with prednisone to treat hormone refractory prostate  
24 cancer.

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