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INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC.,
WEST-WARD PHARMACEUTICAL CORP., and HIKMA
PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332
Patent 8,822,438 B2

Held: May 24, 2017

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

The above-entitled matter came on for hearing on Wednesday,
May 24, 2017, commencing at 1:00 p.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

Case IPR2016-01332
Patent 8,822,438 B2

APPEARANCES:

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

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3 JUDGE ELLURU: Good afternoon. We are here for
4 the hearing in IPR2016-01332, Mylan Pharmaceuticals, Inc.,
5 versus Janssen Oncology, Inc. I'm Judge Elluru. To my right is
6 Judge Green. Appearing remotely is Judge Kalan.

7 Could we start with appearances of counsel, please.
8 May counsel for Mylan approach and introduce counsel.

9 MR. WHITE: Good afternoon, Your Honor. Brandon
10 White from Perkins Coie for petitioner, Mylan. Also with me are
11 my colleagues, Rob Swanson, Shannon Bloodworth, Bryan Beel,
12 Maria Stubbings and Matt Reiner from Mylan.

13 JUDGE ELLURU: Thank you. Welcome. And for
14 patent owner, Janssen.

15 MS. ELDERKIN: Good afternoon. I'm Dianne
16 Elderkin for Janssen Oncology. Presenting argument today for
17 Janssen is David Pritikin from Sidley & Austin. And assisting
18 him at counsel table from Sidley are Bindu Donovan and Alyssa
19 Monsen.

20 JUDGE ELLURU: Thank you and welcome. I would
21 like to go over how we'll proceed today. Each side will have
22 35 minutes of total time to present its arguments. Please keep in
23 mind that we have one panel member who is appearing remotely.
24 Typically she is the only one who can't see the screen in the
25 hearing, but I have heard that none of us are going to be able to

1 see the screen today, so please be sure to refer to demonstratives
2 by slide number.

3 Petitioner has the burden to show that the challenged
4 claims are unpatentable and will thus present its case first. Patent
5 owner will then argue its opposition to petitioner's case. If
6 petitioner has reserved any time, petitioner can use that time for
7 rebuttal. I will give you a warning when you are reaching the end
8 of your argument time.

9 Do counsel have any questions, starting with petitioner?

10 MR. WHITE: No.

11 JUDGE ELLURU: And patent owner?

12 MR. PRITIKIN: No, Your Honor.

13 JUDGE ELLURU: Thank you. Mr. White, you may
14 proceed when you are ready.

15 MR. WHITE: Your Honor, since we are doing this the
16 old-fashioned way, would you like hard copies of the slides?

17 JUDGE ELLURU: That would be great, thank you.

18 Would counsel like to reserve any time for rebuttal?

19 MR. WHITE: Yes, ten minutes, please. So good
20 afternoon, Your Honors. Once we get through the large volume
21 of paper in this case, the petitioners would submit that the only
22 question in this proceeding that we really need to decide is
23 whether the person of ordinary skill in the art, a practicing
24 oncologist treating patients with prostate cancer, would be

1 motivated to combine abiraterone acetate with prednisone. We
2 believe the answer to that question is yes.

3 So why do we believe the answer to that question is
4 yes? Well, if we turn to slide 37, we can start with the
5 proposition that this was a patent that was allowed to issue only
6 on the basis of commercial success. The patent owner never
7 overcame the prior art or the merits during prosecution. The
8 examiner allowed the claims based on the Examiner's conclusion
9 on the record before him that Zytiga was a commercial success.
10 So we believe during prosecution and shown in the proceeding the
11 patent owner never overcame the prior art. All of the elements of
12 claim 1 are in the prior art.

13 JUDGE GREEN: Just to be clear, commercial success
14 itself does not carry a day. We assume that the Examiner
15 weighed that with the evidence of obviousness and just thought
16 that when weighing all the evidence it supported the patentability
17 of claims, correct?

18 MR. WHITE: Certainly the Examiner, I'm sure,
19 conducted the proper analysis and considered all of the evidence
20 before him and allowed the claims to issue, as stated in his
21 reasons for allowance based on commercial success, but we do
22 think there are some issues with the evidence before him, and
23 we'll get to that later.

24 So the authors of the prior art here, particularly the
25 O'Donnell reference and the Attard 2005 reference, Exhibits 1003

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