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IPR2016-01582, Paper No. 74
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01582
Patent 8,822,438

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 2:26 p.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

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 ELLURU: Good afternoon. We are here for
4 the final hearing in IPR2016-01582, Wockhardt Bio AG versus
5 Janssen Oncology, Inc. I'm Judge Elluru. To my right is Judge
6 Green. Appearing remotely is Judge Kalan. Let's please begin
7 with appearances of counsel starting with petitioner. Please
8 approach the microphone and state your name.

9 MR. VARUGHESE: Good afternoon, Your Honors.

10 May it please the Board, my name is Dennies Varughese from the
11 law firm of Sterne, Kessler, Goldstein, and Fox on behalf of
12 petitioner, Wockhardt. Joining me today are my colleagues,
13 Deborah Sterling and Lestin Kenton.

14 JUDGE ELLURU: Thank you, counsel. And for patent
15 owner, Janssen.

16 MS. ELDERKIN: Good afternoon. Dianne Elderkin
17 for Janssen Oncology. Presenting argument today for Janssen is
18 David Pritikin from Sidley Austin, and assisting him are his
19 colleagues, Bindu Donovan, Alyssa Monsen and Jeff Kushan.

20 JUDGE ELLURU: Thank you, counsel. I would like to
21 go over how we'll proceed today. Each side will have 35 minutes
22 of total time to present its argument. Please keep in mind that we
23 do have one panel member who is appearing remotely.

24 Typically, again, we can only see -- the remote judge can't see the
25 screen. None of us can today, so please when you are referring to

1 your demonstratives, please refer to them clearly by slide number
2 for our benefit as well as the benefit of the transcript.

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

9 Does counsel have any questions, starting with
10 petitioner?

11 MR. VARUGHESE: No, Your Honor.

12 JUDGE ELLURU: And patent owner?

13 MR. PRITIKIN: No, Your Honor.

14 JUDGE ELLURU: Thank you. Counsel, you may
15 begin when you are ready. And would you like to reserve any
16 time for rebuttal?

17 MR. VARUGHESE: Yes, Your Honor. I would like to
18 reserve ten minutes for rebuttal. Your Honors, we have hard
19 copies of the slides, if we may approach.

20 JUDGE ELLURU: Yes, please.

21 MR. VARUGHESE: Thank you, Your Honor. Once
22 again, Dennies Varughese on behalf of petitioner, Wockhardt.
23 Your Honors, given the prior proceeding today and the *Amerigen*
24 proceeding a few months ago, Your Honors have heard a lot.
25 There's been a lot of papers submitted here. And in putting the

1 Wockhardt proceeding and trial on a fast track and compressed
2 schedule, I presume that the Board recognized that there's some
3 substantial overlap in the technology and the medical issues
4 involved in these multiple proceedings. So to the extent possible,
5 I'm going to try to avoid any redundancy in that regard and try to
6 focus on the Wockhardt-specific issues and specific disputes
7 between Wockhardt and Janssen. However, I am cognizant of the
8 need to have a complete record, so I will touch upon all the major
9 issues. And I'm happy to address any of the questions the Board
10 may have as I do that.

11 Turning to slide 2, this is an overview of our argument.
12 Simply put, Wockhardt submits that claims 1 through 20 of the
13 '438 patent would have been obvious over the combination of
14 Gerber, O'Donnell, and Sartor. I'm going to address some of
15 these points, but in their patent owner response Janssen has
16 advanced a number of arguments that it believes tries to rebut or
17 overcome this *prima facie* case, and for various reasons we
18 submit that they have not done so. Then finally, I'll close by
19 addressing some of the secondary considerations that Janssen has
20 advanced.

21 Turning to slide 4, in instituting the *Amerigen* trial, this
22 Board issued claim constructions for some terms that appear in
23 the claims of the '438 patent, namely "treat," "treating,"
24 "treatment," and "therapeutically effective amount of
25 prednisone." In Wockhardt's petition and in this trial, Janssen and

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