

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA USA, INC.,
Petitioner,

v.

ANDRX CORPORATION,
ANDRX LABORATORIES, INC.,
ANDRX LABORATORIES (NJ), INC.,
ANDRX EU LTD.,
ANDRX PHARMACEUTICALS, LLC,
TEVA PHARMACEUTICAL INDUSTRIES LTD.,
Patent Owners.

Case IPR2017-01648
Patent 6,866,866 B1

Record of Oral Hearing
Held: September 24, 2018

Before SUSAN L.C. MITCHELL, JO-ANNE M. KOKOSKI, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

Case IPR2017-01648
Patent 6,866,866 B1

APPEARANCES:

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The above-entitled matter came on for hearing on Monday, September 24, 2018, commencing at 1:01 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

PROCEEDINGS

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JUDGE MITCHELL: Please be seated. Well, good afternoon, everyone. We have a final hearing this afternoon in IPR 2017-01648. I am Judge Mitchell and seated to my right is Judge Kokoski and appearing remotely is Judge Zastrow Newman. And Judge Hulse was -- good morning. Judge Hulse was unavailable to be here today and we did put in a panel change order but I am guessing you all probably might not have seen it since it was, you know, in transit. So anyway, I would like to get appearances for the parties on the record so let me start with petitioner.

MR. MOORE: My name is Stephen Moore with Withers Bergman. We are representing Aurobindo USA. I am here with my colleague Lalindra Sanichar.

JUDGE MITCHELL: Great, thank you, and welcome. And for patent owner?

MR. ROSES: Jonathan Roses of Wilmer Hale on behalf of Shionogi. With me also at counsel table is David Cavanaugh of Wilmer Hale, David Yin of Wilmer Hale and also David Chaves of Chaves IP Law on behalf of Andrx and Teva Pharmaceuticals USA.

JUDGE MITCHELL: Great, thank you and welcome. We did receive objections to demonstratives from both sides and we have reviewed those objections from both petitioner and patent owner. We have decided that we will not exclude any particular demonstrative exhibits based on those objections. But certainly in each party's respective arguments, you can raise those objections and talk to us about why a particular demonstrative is not accurate or whatever the objection is.

1 We certainly don't want either side to interrupt the other so certainly
2 do that in your argument. And, patent owner, you're certainly free to do,
3 you know, raise it whether or not petitioner has raised it in the opening. You
4 can make your objection.

5 We did set forth our procedure for how we are going to handle the
6 oral argument in our oral hearing order but I like to just go over some of the
7 logistics as reminders. Each party has 45 minutes of total time to present
8 argument. It's certainly important for the clarity of the record that if you
9 refer to a particular exhibit or a particular demonstrative that you list the
10 slide number and the number of the exhibit. And that way our record is
11 clear and certainly for Judge Zastrow Newman who is our remote judge, she
12 can't see what you have got up here on the screen so she is following along
13 with her own copy so please make sure you refer to the exhibit and slide
14 number.

15 Petitioner has the burden of showing unpatentability of the challenged
16 claims so the petitioner will go first. And then the patent owner will have an
17 opportunity to present its response. So with that, we can get started and
18 petitioner, would you like to reserve some of your 45 minutes for a rebuttal?

19 MR. MOORE: Yes, I would like to reserve 20 minutes.

20 JUDGE MITCHELL: 20 minutes, okay.

21 MR. MOORE: If you could just give us one second to get the slides
22 set up, I'm sorry.

23 JUDGE MITCHELL: Sure, sure.

24 MR. MOORE: I'm sorry.

25 JUDGE MITCHELL: No, that's fine.

26 MR. MOORE: While we are getting that set up, would anyone like a

1 hard copy of this?

2 JUDGE MITCHELL: Oh, I would like one. Thank you.

3 (Recess)

4 MR. MOORE: Well, if we start at Slide 2, what this is is just a
5 summary from the Federal Circuit opinion in Sciele v. Lupin which dealt
6 with this exact same patent in another case.

7 JUDGE MITCHELL: I would like to ask you, I'm sorry to interrupt.
8 Can you speak directly into the mic just so --

9 MR. MOORE: Oh, I'm sorry.

10 JUDGE MITCHELL: That's all right.

11 MR. MOORE: I'm not sure it's even on.

12 SPEAKER: It might not be on.

13 MR. MOORE: No, it's not on. There we go.

14 JUDGE MITCHELL: There you go.

15 MR. MOORE: Okay. So what the Sciele court defined this patent as
16 so that's why I'm not saying it, they said it is that basically it deals with
17 dosage forms with a mean time to maximum plasma concentration or the
18 quote Tmax of the drug which occurs at 5.5 to 7.5 hours after oral
19 administration when given on a once a day basis to human patients.

20 As far as the other claims, they're all narrower. They either give
21 narrower Tmax ranges or they add additional pharmacokinetic parameters
22 that are being claimed.

23 Now in Slide 3, I'm just saying that just to make it clear on the record
24 that we are challenging all Claims 1 through 25.

25 Now if we go to Slide 4, this is actually a very important slide because
26 Claim 1 is the only independent claim in this patent, only one. And if you

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