

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD. & ACRUX LIMITED,
Petitioner,

v.

KAKEN PHARMACEUTICAL CO., LTD. and VALEANT
PHARMACEUTICALS INTERNATIONAL, INC.,
Patent Owner.

Case IPR2017-00190
Patent 7,214,506 B2

Record of Oral Hearing
Held: January 26, 2018

Before ERICA A. FRANKLIN, SUSAN L. C. MITCHELL, and
ROBERT A. POLLOCK, *Administrative Patent Judges*.

Case IPR2017-00190
Patent 7,214,506 B2

APPEARANCES:

ON BEHALF OF THE PETITIONER:

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The above-entitled matter came on for hearing on Friday, January 26, 2018, commencing at 9:34 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P R O C E E D I N G S

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3 JUDGE MITCHELL: Well, good morning, everyone. We
4 have a final hearing this morning in IPR2017-00190. I'd like to get
5 appearances on the record starting with Petitioner.

6 MR. FIGG: Good morning, Your Honor. My name is Tony
7 Figg. With me at counsel table is Aydin Harston and my partner, Lisa
8 Phillips, sitting behind me. We're with Rothwell Figg and we're here for
9 the Petitioner Acrux.

10 JUDGE MITCHELL: Great. Thank you.

11 And for Patent Owner.

12 MR. LIVINGSTONE: Good morning, Your Honors. I'm John
13 Livingstone from Finnegan, Henderson, Farabow, Garrett & Dunner on
14 behalf of Patent Owner. At counsel table with me today is my colleague,
15 Jeffrey Jacobstein. I've also got Barbara Rudolph, Tony Hartmann,
16 Ashley Winkler, Naoki Yoshida also from Finnegan, and we've got four
17 representatives from Kaken Pharmaceuticals from Tokyo, Japan.

18 JUDGE MITCHELL: Great. Thank you and welcome.

19 We did set forth the -- oh, go ahead.

20 MR. FIGG: I'm sorry, Your Honor. I neglected to introduce
21 Ms. Shannon Lynch who represents Argentum who was joined as a
22 Petitioner to this case.

23 JUDGE MITCHELL: Great. Thank you and welcome.

1 We did set forth sort of the procedure in our order and I know
2 you gentlemen are familiar with that for how to handle the oral argument,
3 but I'll go over just a few things as reminders.

4 Each party has 45 minutes of time to present the argument for
5 their case. It's important for the clarity of the record -- it's nice that we
6 have everybody on the bench here and we're not -- nobody is remote, but
7 still for the clarity of the record, you know, make sure you refer to the
8 slide number or any exhibits, just so when we go back and look at the
9 hearing transcript we know exactly what you're talking about.

10 Petitioner has the burden of showing unpatentability of the
11 challenged claims and on its Motion to Exclude Evidence, so Petitioner
12 will go first. The Petitioner may reserve time for rebuttal on its main
13 case and on the Motion to Exclude. Patent Owner will then have the
14 opportunity to present its response. You can -- Patent Owner, you do
15 have the burden on your Motion to Exclude, so only for the Motion to
16 Exclude. If you choose to, you can observe some rebuttal time.

17 And I think with that being said, Petitioner, would you like to
18 reserve time for rebuttal?

19 MR. FIGG: Yes, Your Honor. I would like to reserve about 20
20 minutes for rebuttal.

21 JUDGE MITCHELL: Great.

22 MR. FIGG: May I begin?

23 JUDGE MITCHELL: One quick moment while I get your time
24 set up.

1 MR. FIGG: Your Honor, we have paper copies of our
2 demonstratives for members of the Board, if that would be helpful.

3 JUDGE MITCHELL: Great. Yes, I would love it. Thank you.

4 MR. FIGG: And while he's passing them out, I'd like to
5 apologize in advance. Like everyone in America, I'm coming off of a
6 cold, so I'm coughing and my ears are stopped up. I can't -- so I may ask
7 you to repeat things, I apologize.

8 JUDGE MITCHELL: Sure.

9 MR. FIGG: Your Honor, may I begin?

10 JUDGE MITCHELL: Sure. Oh, sure, yes.

11 MR. FIGG: The topical use of efinaconazole for the treatment
12 of fungal infections of the nails was a logical and obvious result of a
13 confluence of technologies in the late 1990s. Oral antifungals were
14 available and were effective with cure rates approaching 40 percent.
15 Those drugs are still today considered the gold standard for
16 onychomycosis therapy, but those drugs were accompanied by
17 undesirable systemic side effects, and so there was a motivation to
18 develop topical treatments for onychomycosis that would avoid those
19 side effects.

20 The prior art described a number of topical formulations that
21 were effective in delivering the active antifungal to the infected site.
22 They included gels and lacquer formulations. Several were approved in
23 Europe and the United States. And as Patent Owner's own expert's
24 contemporaneous publications acknowledged, they were safe and
25 effective. They avoided the systemic side effects of the oral drugs and

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