UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2018-01403
Patent 8,399,514 B2

Record of Oral Hearing
Held: November 13, 2019

Before SHERIDAN K. SNEDDEN, JENNIFER MEYER CHAGNON, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

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APPEARANCES:

ON BEHALF OF THE PETITIONER:

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ON BEHALF OF THE PATENT OWNER:

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The above-entitled matter came on for hearing on Wednesday, November 13, 2019, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

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P R O C E E D I N G S

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BAILIFF: All rise.

JUDGE SNEDDEN: All right. Please be seated. Thank you. Good morning. This is the final hearing in IPR2018-01403. I am Judge Snedden and I have with me on the panel Judge Chagnon and Harlow. Let's begin with appearances, starting with petitioner, please stand, introduce yourself and who you have with you today.

MR. WHITE: Good morning, Your Honor. Brandon White, counsel for Mylan Pharmaceuticals from Perkins Coie and with me today is Nathan Kelley, Courtney Prochnow, Shannon Bloodworth, David Anstaett, Emily Greb and Mike Chajon. And from Mylan Pharmaceuticals, Matt Griner and Tom Jenkins. Mr. Kelley will be handling the argument today.

JUDGE SNEDDEN: Thank you, welcome. Patent owner?

MS. MCCURDY: Good morning, Your Honors. Barbara McCurdy for Biogen. With me at counsel table today is Pier DeRoo, Erin Sommers. Also with me are Mark Feldstein, Cora Holt, Yoonhee Kim and also for Biogen, we have representatives here including the general counsel, Susan Alexander and a number of other representatives. I can introduce them all if you would like. Okay.

JUDGE SNEDDEN: That won't be necessary.

MS. MCCURDY: Okay, thank you.

JUDGE SNEDDEN: Thank you. Per our order granting this oral hearing, each party will have 60 minutes of total time to present its argument. Petitioner will open the hearing presenting its case regarding the challenged claims for which we institute a trial and then patent owner will

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then respond to petitioner's argument. Each party may reserve rebuttal time and patent owner may reserve up to five minutes for rebuttal time per our (inaudible) order.

I also note that Judge Harlow is joining us remotely so I take the opportunity to remind the parties to speak the slide number as you go through your presentation today for both the benefit of the record and also for Judge Harlow. Okay. With that I'll let petitioner being when you're ready.

MR. KELLEY: Thank you. Good morning or good afternoon, Your Honors. I'd like to reserve 20 minutes for rebuttal.

JUDGE SNEDDEN: When you're ready.

MR. KELLEY: So I'd like to begin with a claim in this case. Claim 1 of the 514 patent. And this is on Slide 6 of our presentation which we are getting up now.

So Claim 1 and we will wait for the slide to come up but you have the slides in front of you. Claim 1 is a simple claim. It's the only claim in dispute and it requires three things. It requires a disease, a drug, and a dose.

The disease is multiple sclerosis. The drug is dimethyl fumarate and the dose is 480 milligrams per day. That's what's required by Claim 1. Nothing else is required and no other claim is in dispute in this case.

At the time of the priority date of the 514 patent, the prior art was replete with references directing the skilled artisan right towards that subject matter. DMF was known to treat MS. The claimed 480 milligrams dose was between doses that were known to treat MS in the prior art and GI side effects were also well known at that time.

In the face of that overwhelming evidence, Biogen attempts to side

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step the evidence by presenting distractions. Biogen attempts to say that work by Dr. Kappos was actually work by Dr. O'Neill, that the Kappos study was actually O'Neill's study. That their own press release hasn't been shown to be publicly available when an employee of Westlaw swears it was at the time. That a flaw in the Kappos study that everybody -- that many people skilled in the art recognized in fact was not there and finally by ignoring all the drivers of Tecfidera's commercial success, other than the claim subject matter of the 514 patent.

Now there are four grounds that we presented in our petition and I would like to briefly address ground number four. So it's not displaying but the Board has the slides in front of them so I'm just going to go, oh here we go. Okay.

So the fourth ground the Board is familiar with, that's the ground that relies on Kappos 2006, the clinical trial that showed efficacy of 720 milligram dose as well as an argued efficacy of 360 milligram dose. And clinical trials reference as well as Joshi and the ICH guidelines.

And I would like to start with that because in the previous IPR brought by the coalition, the Board already found that those working in the art would have had sufficient reason to investigate doses between 720 and 360 milligrams in hopes of identifying effective doses with fewer side effects.

And moreover, that those working in the art would also have had a reasonable expectation of success in determining additional therapeutically effective doses.

Now of course we know what the issue was in that case and we know why the final written decision came out the way it was, the way it did, I'm

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