UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC., ARGENTUM PHARMACEUTICAL LLC, and WEST-WARD PHARMACEUTICALS INTERNATIONAL LIMITED,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2016-01479
Patent 9,006,224 B2

Record of Oral Hearing
Held: November 1, 2017

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE PETITIONER:
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The above-entitled matter came on for hearing on Wednesday, November 1, 2017, commencing at 9:00 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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JUDGE CRUMBLEY: Good morning, everyone. So today we have oral hearing in IPR2016-1479 between Par Pharmaceutical, Argentum Pharmaceutical and West-Ward Pharmaceuticals as petitioners and Novartis as the patent owner. I think I recognize most everyone in the room, so I'm going to dispense with my opening remarks that I typically make, but I would like to get appearances from counsel first.

MS. DANEK: Good morning, Your Honor. My name is Brenda Danek. I will be arguing on behalf of -- I'm counsel for petitioner, Par, and arguing on behalf of all petitioners.

JUDGE CRUMBLEY: Who do you have with you here today?

MS. DANEK: Today I have Daniel Brown, who is counsel for petitioner, Par. Also present are Keith Zullow on behalf of West-Ward, and Tyler Liu on behalf of Argentum.

MS. JACOBSEN: Good morning. Charlotte Jacobsen on behalf of Novartis AG, and with me is Nicholas Kallas.

JUDGE CRUMBLEY: Good morning. So I believe we gave both sides 45 minutes; is that correct?

MS. DANEK: That's correct, Your Honor.

JUDGE CRUMBLEY: So I will note for the record that both parties submitted demonstrative exhibits, and we did receive objections to petitioner's exhibits from the patent owner. There were no objections from petitioner?

MS. DANEK: No, Your Honor.

JUDGE CRUMBLEY: So we've reviewed those objections. They appear primarily addressed to being new arguments and incorporation by reference. I'm just sort of generalizing here. We've considered those. I think for the purposes of the hearing today we are going to go forward with the slides as they are. I think when we review the record as a whole we can determine what's a new argument and dispose of those as necessary. So we are just going to proceed with the slides that were submitted.

All right. Ms. Danek, you can proceed when you are ready. How much time do you want to reserve?

MS. DANEK: I'd like to reserve 15 minutes, Your Honor. I have hard copies of the demonstratives.

JUDGE CRUMBLEY: That would be great.

MS. DANEK: May it please the Court, the prior art on which the Board instituted teaches the use of mTOR inhibitors to treat neuroendocrine tumors. The principal mTOR inhibitors known as of November 2005 were rapamycin and two rapamycin derivatives, everolimus and temsirolimus. The only difference between the prior art and the challenged claims is exchanging one well known rapamycin mTOR inhibitor for another. And that's what I would like to spend much of my time today talking about, the obviousness of that substitution and why a person of ordinary skill in the art would have had a reasonable expectation of success in making that modification.

Let's take a look at slide 2 of the petitioner's demonstratives. This is the claim 1 of the '224 patent. Novartis' '224 patent claims

methods of treating a type of pancreatic tumors called pancreatic neuroendocrine tumors or PNETs. The entire text of the claim is shown on slide 2 of petitioner's demonstratives. The claim includes one step, administering a therapeutically effective amount of everolimus as a monotherapy. The claim also limits the PNETs to those that are advanced, which the Board in its institution decision agreed with petitioners that advanced means metastatic or unresectable. And that's at the institution decision at 7. The claim also identifies that the tumors are after failure of cytotoxic chemotherapy. This is the subject matter that would have been obvious to a person of ordinary skill in the art as of the filing date.

Now I would like to take a look at what Novartis includes in its specification. If we can go to slide 4 of petitioner's demonstratives, Novartis filed its patent application with no clinical data and no preclinical data. All the specification identifies is that certain known experiments could be done. The '224 patent specification from columns 25, line 49 through column 26, line 64, includes a mere one and a half columns of these prophetic examples. The examples say that the utility of the mTOR inhibitors in treating endocrine tumors can be demonstrated in the various in vitro and in vivo assays.

If we look at slide 6 of petitioner's demonstratives, the examples also include several prophetic clinical studies that could be performed at a future time, one of which essentially mirrors the language of the claim, a clinical study of pancreatic neuroendocrine tumors after failure of cytotoxic chemotherapy as a monotherapy. Based on this

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