UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC.,
Petitioner,

v.

CHUGAI PHARMACEUTICAL CO. LTD.,
Patent Owner.

Case IPR2017-01357 (Patent 7,332,289 B2)
Case IPR2017-01358 (Patent 7,927,815 B2)

Record of Oral Hearing
Held: August 2, 2018

Before GRACE KARAFFA OBERMANN, RAMA G. ELLURU, and JACQUELINE T. HARLOW, *Administrative Patent Judges.*

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The above-entitled matter came on for hearing on Thursday, August 2, 2018, 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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JUDGE HARLOW: Good afternoon. Please be seated. Today we'll hear argument in IPR2017-01357 and 01358, Pfizer versus Chugai, concerning U.S. patent numbers 7,332,289 and 7,927,815. At this time we would like counsel to introduce yourselves and your colleagues, beginning with petitioner.

MR. SCHEIBELER: Good afternoon, Your Honors. This is John Scheibeler of White & Case, LLP, for petitioner, Pfizer, Inc. With me is Robert Counihan of Fenwick & West, also for petitioner. Robert will be presenting the oral argument on behalf of petitioner today. To Robert's right is Matthew Mezger of Winston & Strawn, also for petitioner. And in the back with me is Jeff Oelke of Fenwick & West.

JUDGE HARLOW: Thank you, Mr. Scheibeler. Patent owner?

MR. BAUGHMAN: Your Honors, Steve Baughman and Megan Raymond from Paul Weiss for patent owner.

JUDGE HARLOW: Thank you very much. Consistent with our prior order, each party will have 45 minutes to present its arguments today. Petitioner will proceed first to present its case as to the challenged claims and may reserve rebuttal time to address any subject matter that's specifically raised during patent owner's argument. Thereafter, patent owner will have the opportunity to respond to petitioner's case. Patent owner may also reserve rebuttal time, but in that instance only to address any arguments raised in petitioner's rebuttal regarding the asserted objective indicia of

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nonobviousness. Rebuttal argument that deviates from those parameters will not be permitted.

We would like to remind the parties that pursuant to Section 316(e), petitioner bears the burden of proving any proposition of unpatentability by a preponderance of the evidence. And we also remind the parties that the hearing is open to the public and that a transcript of the hearing will become part of the record in both proceedings.

For clarity of the record, because I'm participating via remote video link, if the parties could please identify any slide numbers or exhibits and page numbers verbally so that I can hear that and also for the benefit of the court reporter, that would be very much appreciated.

And with that, I invite counsel for petitioner to inform us how much time you would like to reserve for rebuttal and begin your presentation.

MR. COUNIHAN: Thank you, Judge Harlow. I would like to reserve ten minutes, please.

JUDGE OBERMANN: I'm going to be running the clock. So I'm going to set you up with 35 minutes. And when you start speaking, I'll start the clock running.

MR. COUNIHAN: Good afternoon. My name is Robert Counihan speaking on behalf of Pfizer. This case is about inherent anticipation of two patents, which I'll refer to as the Chugai patents, by a patent publication called Shadle. I would first like to turn to slide 3 which sets out the law of inherent anticipation. The law is that merely discovering

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and claiming a new benefit of an old process cannot render the process again patentable. As the Federal Circuit has instructed, that assessment is determined by assessing whether the natural result flowing from the operation of the prior art as taught would result in the performance of the questioned functions or the claimed function.

JUDGE HARLOW: Counsel, petitioner emphasizes the case law concerning the natural result flowing from the operation as taught, but one of the questions that kept arising in my mind when I was thinking about this case is how do we know what the natural result from the operation of Shadle is as taught when Shadle doesn't expressly teach us what its molarity is or whether particles are forming in the other matters for which petitioner is relying on inherency.

MR. COUNIHAN: So that's an excellent question. I want to jump ahead to slide 6. So the two key issues that relate to that question of whether the molarity and conductivity issue requirements are met, there's two disputes. One is patent owner has presented a fifth possible way to make the citrate buffer that is used to elute from the protein affinity column. And the second argument they make is that there's also a wash buffer present when the steps of Shadle are performed in that if you use the fifth method or if there's residual wash buffer present, that that means that the molarity and conductivity requirements are met.

Importantly, if you determine that any of the four methods that we propose for making the citrate buffer, if you determine that those are the

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