

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOIOS PHARMACEUTICALS LLC,
Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE
SPEZIALPRÄPARATE MBH,
Patent Owner

Case IPR2016-01370
Patent 8,664,231

Record of Oral Hearing
Held: November 7, 2017

Before JACQUELINE WRIGHT BONILLA, *Vice Chief Administrative
Patent Judge*, TONI R. SCHEINER, and ERICA A. FRANKLIN,
Administrative Patent Judges.

Case IPR2016-01370
Patent 8,664,231

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The above-entitled matter came on for hearing Tuesday, November 7, 2017, commencing at 10:00 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia

PROCEEDINGS

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JUDGE BONILLA: Good morning. Please be seated. Just give us a moment to get acclimated.

This is a hearing this morning for IPR2016-01370, between petitioner Koios -- how do you pronounce that?

MR. NOROOZI: Koios.

JUDGE BONILLA: Koios, thank you. Pharmaceuticals LLC, and also the owner of U.S. Patent No. 8,664,231, Medac, I'm just going to say GmbH, rather than pronounce the entire German name. I apologize for that.

Just a few administrator matters before we begin. Just as a reminder, if you are going to talk about any demonstratives today, please describe any slide that you present by slide number. That will make it easier to read along with the transcript and also for us to follow.

I understand that, petitioner, you're the only one that provided slides today; is that correct?

MR. NOROOZI: Actually, patent owner.

JUDGE BONILLA: The patent owner. I'm sorry, my apologies. So there was only you all that brought slides today?

MR. HALEY: That's right, your Honor. Would you like a book of the slides or do you have them with your copies?

JUDGE BONILLA: And the court reporter would like a copy as well.

MR. HALEY: May I approach?

JUDGE BONILLA: Sure. Do you have enough copies for the court reporter?

MR. HALEY: Yes. We've already given her one.

JUDGE BONILLA: As you know, per our hearing order, each party

1 has 45 minutes to present their arguments. Because the petitioner has the
2 burden to show unpatentability of the challenged claims, petitioner will
3 proceed first, followed by patent owner.

4 Petitioner, you may reserve rebuttal time. However, you may only
5 use that time to respond, to rebut patent owner's arguments that are made
6 here.

7 At this time we'd like counsel to introduce themselves, who you have
8 with you, if anybody, beginning with petitioner.

9 MR. NOROOZI: Kayvan Noroozi, on behalf of Koios
10 Pharmaceuticals.

11 MR. HALEY: Jim Haley, on behalf of Medac, and with me arguing
12 today will be Brian Gummow from Haley Guiliano, Henry Huang from
13 Ropes & Gray, and I also have Terry Shoemaker, who is CEO of Medac
14 Pharma, who's the licensee of the patent in dispute, and two of our
15 paralegals from Ropes & Gray.

16 JUDGE BONILLA: Thank you. Petitioner, would you like to reserve
17 any rebuttal time?

18 MR. NOROOZI: Yes, I would, your Honor. I'd like to reserve 15
19 minutes, please.

20 JUDGE BONILLA: All right. You may proceed.

21 MR. NOROOZI: Your Honors, we're here today to talk about the
22 '231 patent, which has 22 claims and only one independent claim. The '231
23 patent is directed to concentrated methotrexate solutions.

24 And based on the institution order and the extensive briefing that you
25 received, it's clear that the board has a firm understanding of the patent and
26 the technology at issue, as well as the prior art. So my goal here is to focus

1 today in this hearing on the core issues that remain in dispute.

2 And the dispute really here only remains with respect to patent owner
3 and its lawyers. Patent owner's expert, Dr. Zizic, gave a deposition in which
4 he ended up in fact agreeing with many of Koios' key positions as articulated
5 by Koios' experts, Dr. Schiff and Dr. Miller.

6 And, in fact, in some instances he even, Dr. Zizic, realized that he had
7 been operating under certain misunderstandings and -- and corrected those
8 during his testimony.

9 And so we began this proceeding with a very powerful evidentiary
10 showing, we believe, in our petition, and now we've come to the conclusion
11 of this proceeding with an even stronger showing.

12 Notably, Medac did not take the deposition of our experts, and we
13 took the deposition of Dr. Zizic, who was the only expert that we needed to
14 depose, in light of the cumulateness of the declarations that patent owner
15 has put forth, as well as the specific testimony that Dr. Zizic offered.

16 Staying true to my promise about focusing this argument, there are 22
17 claims but only four of them are really in any dispute at this point. Those
18 are claims 1 through 3 and claim 22. And you'll see that when you look at
19 patent owner's slides and you open them up, you see in the first or second
20 page they only reference those four claims.

21 Claims 4 through 21 are not materially disputed by patent owner, but
22 we've, of course, made an extensive showing as to each limitation of those
23 claims, and I'm not by any means suggesting that if patent owner doesn't
24 dispute something then you have to assume that it's been sufficiently proven
25 in the record. We have made that showing and that's why patent owner
26 doesn't dispute it.

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