

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY,
Petitioner,

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Patent Owner.

Case IPR2018-01710 (Patent 8,586,045 B2)
Case IPR2018-01711 (Patent 9,884,907 B2)
Case IPR2018-01712 (Patent 9,884,908 B2)

Record of Oral Hearing
Held: January 8, 2020

Before JENNIFER MEYER CHAGNON, JAMES A. WORTH, and
RICHARD J. SMITH, *Administrative Patent Judges*.

IPR2018-01710 (Patent 8,586,045 B2)
IPR2018-01711 (Patent 9,884,907 B2)
IPR2018-01712 (Patent 9,884,908 B2)

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, January 8, 2020, commencing at 1:20 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

IPR2018-01710 (Patent 8,586,045 B2)
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P R O C E E D I N G S

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2 JUDGE WORTH: Good afternoon. This is an oral hearing in cases
3 Nos. IPR 2018-01710, 1711 and 1712 between Petitioner Eli Lilly and
4 Company and owner of U.S. Patents 8,586,045, 9,884,907 and 9,884,908,
5 Teva Pharmaceuticals International GMBH. My name is Judge Worth. To
6 my right is Judge Chagnon and participating by teleconference from Texas is
7 Judge Smith.

8 As you know per our order each party has 60 minutes to present its
9 argument. Because Petitioner has the burden to show unpatentability of the
10 original claims Petitioner will proceed first followed by Patent Owner.
11 Petitioner may reserve rebuttal time but may only use its time to rebut Patent
12 Owner's arguments. The Patent Owner may also reserve some final time for
13 a surreply.

14 At this time we'd like to ask counsel to introduce yourselves and who
15 you have brought with you, beginning with the Petitioner please.

16 MR. RAICH: Good afternoon, Your Honors. My name is Bill Raich
17 from Finnegan on behalf of Petitioner Eli Lilly and Company. With me
18 today at counsel's table is Pier DeRoo and also here today from Indianapolis
19 are Mark Stewart and Sanjay Jivraj from Eli Lilly.

20 JUDGE WORTH: I believe you may have some people in the
21 overflow room; is that right?

22 MR. RAICH: We do have people in the overflow room, that's correct.
23 Would you like me to introduce everybody?

24 JUDGE WORTH: If you recall who they are.

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1 MR. RAICH: Yes I think Erin Sommers is in the overflow room,
2 Yieyie Yang is counsel also who's here and I believe Yoon Jin Lee is in the
3 overflow room also.

4 JUDGE WORTH: Thank you. For Patent Owner.

5 MS. STERLING: Good afternoon. My name is Deborah Sterling.
6 I'm with Sterne, Kessler, Goldstein & Fox on behalf of Teva
7 Pharmaceuticals. With me at counsel's table is Olga Partington, also from
8 Sterne Kessler. Behind me is Jeremiah Frueauf, and then we have Lori
9 Wolfe and Sharon Hausdorff from Teva and in the overflow room I believe
10 we have David Roadcap and Tyler Liu. Thank you.

11 JUDGE WORTH: Petitioner, would you like to reserve time for
12 rebuttal?

13 MR. RAICH: We would, Your Honor. We'd like to reserve 15
14 minutes.

15 JUDGE WORTH: And Patent Owner.

16 MS. STERLING: We'd like ten please, Your Honor.

17 JUDGE WORTH: Okay. I'm setting the clock for 45 minutes to
18 begin with. Petitioner, you may begin whenever you're ready.

19 MR. RAICH: Okay. Your Honor, we have printed copies of our
20 demonstratives if you'd like. May we approach and provide copies?

21 JUDGE CHAGNON: That's fine.

22 JUDGE WORTH: Yes, please. Thank you. And please recall that
23 Judge Smith is participating by teleconference so you may wish to say what
24 page number you're on and describe for Judge Smith what you're viewing,
25 and that's also for the record.

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1 MR. RAICH: I appreciate that. Thank you, Your Honor. Okay, I'd
2 like to begin. Your Honors, today we're going to explain why Teva's claims
3 are obvious. We're going to focus on actual contemporaneous disclosures,
4 not rhetoric or conclusory expert testimony. My intent is to spend 20 to 25
5 minutes on the prima facie case of obviousness and then to pivot to
6 secondary indicia including Fox Factory.

7 Slide 2. So the challenged method patents are broadly directed to
8 treating headache including migraine by administering a humanized anti-
9 CGRP antagonist antibody and these are incredibly broad claims. There's no
10 requirement for the amino acid sequence of the antibody even though the
11 sequence of an antibody dictates functional parameters like antibody
12 potency, affinity, avidity, specificity, mechanism of action and effector
13 functions. So these challenged claims are also very broad in terms of that
14 they cover either headache or vasomotor symptom. There are 250 different
15 types of headache. There are some dependent claims that are directed to
16 migraine where the strong weight of the evidence establishes motivation and
17 expectation of success.

18 Slide 3. So this shows the combination of references that are asserted
19 in these IPRs. There's Olesen 2004. This is a key publication in 2004 that
20 opened up the field. It definitively provided proof of concept that
21 antagonizing the CGRP pathway effectively treated migraine. After Olesen
22 it was obvious to pursue other CGRP antagonists. Tan 1995, Exhibit 1022,
23 disclosed one of those CGRP antagonists, specifically Tan used an anti-
24 CGRP antibody to antagonize the CGRP pathway in vivo, and Queen,
25 Exhibit 1023, disclosed humanized antibodies for therapeutic use and also

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