

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MICRO LABS LIMITED AND
MICRO LABS USA INC.,
Petitioners,

v.

SANTEN PHARMACEUTICALS CO., LTD., AND
ASAHI GLASS CO., LTD.,
Patent Owners.

Case IPR2017-01434
Patent 5,886,035

Record of Oral Hearing
Held: September 6, 2018

Before JO-ANNE M. KOKOSKI, CHRISTOPHER G. PAULRAJ, and
DEBRA L. DENNETT, *Administrative Patent Judges*.

Case IPR2017-01434
Patent 5,886,035

APPEARANCES:

ON BEHALF OF THE PETITIONER:

CEDRIC C.Y. TAN, ESQ.
ALTON L. HARE, ESQ.
SOPHIA WEI, ESQ.
KEETO SABHARWAL, ESQ.
Pillsbury Winthrop Shaw Pittman
1300 Seventeenth Street, N.W.
Washington, D.C. 20036

ON BEHALF OF THE PATENT OWNER:

ARLENE L. CHOW, ESQ.
ERNEST YAKOB, Ph.D.
TAKASHI OKUDA, ESQ.
Hogan Lovells US LLP
875 Third Avenue
New York, NY 10022

The above-entitled matter came on for hearing on Thursday, September 6, 2018, commencing at 1:00 p.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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2 JUDGE KOKOSKI: Good afternoon. Today we will hear
3 argument in Case Number IPR2017-01434, concerning U.S. Patent Number
4 5,886,035. I'm Judge Kokoski, and Judge Paulraj is here with me, and Judge
5 Dennett is joining us remotely.

6 Let's start with appearances beginning with Petitioner.

7 MR. TAN: Good afternoon, Your Honor. My name is Cedric Tan
8 for Petitioners. With me is Keeti Sabharwal, Sophia Wei, and Alton L.
9 Hare, all with the law firm Pillsbury.

10 JUDGE KOKOSKI: Thank you.

11 MS. CHOW: Good afternoon, Your Honor. My name is Arlene
12 Chow. I'm with the law firm Hogan Lovells on behalf of Patent Owner.
13 Also with me is Ernest Yakob, Takashi Okuda, as well as representatives
14 from Akorn, Asahi Glass, and Santen Pharmaceutical.

15 JUDGE KOKOSKI: Thank you. Welcome.

16 I do want to remind the parties that Judge Dennett cannot see
17 anything that you put up on the screen, but she does have a copy of the
18 demonstrative exhibits that you provided to us. So during your argument,
19 just make sure that you state what slide or page number you're on so that she
20 can follow along.

21 Speaking of the demonstratives, we did receive objections from
22 both parties with respect to the demonstrative exhibits. We've reviewed all
23 those objections, and we're going to overrule them. We do note that both
24 parties raised a number of objections alleging that there are new arguments
25 in the slides, and while we're not going to limit the use of the slides by either

1 party, we may ask you questions about where support is for arguments that
2 you make in the slides, where we can find that support in the papers.

3 You are also free to argue during your own argument time that the
4 other party is making new arguments here, but please don't interrupt during
5 the other party's argument time. We're aware of your concerns with the
6 demonstratives, and we can deal with that when we're looking at the record,
7 at the close of all of the evidence.

8 So consistent with our hearing order, each party has 60 minutes to
9 present their arguments. Petitioner will proceed first and may reserve
10 rebuttal time. How much time would you like to reserve, if any?

11 MR. TAN: I would like to reserve -- I would like to split it
12 half/half.

13 JUDGE KOKOSKI: Okay. You can begin when you're ready.

14 MR. TAN: Good afternoon again. This is Cedric Tan for the
15 Petitioners. May it please the Board, I would like to start off by referring to
16 paper 11, the Board's institution decision. It is -- in its institution decision,
17 the Board found that the Petitioners have demonstrated a reasonable
18 likelihood on prevailing on its challenge of claims 1 to 14 of the '035 patent,
19 but a genuine issue of material fact existed as to whether Compound C
20 would have been selected as a lead compound due to conflicting expert
21 testimony. The Board indicated in its decision that the parties will have the
22 opportunity to develop the record for trial. Now here we are, nine months
23 later, with a more fully developed record, with additional expert evidence
24 coming primarily from two of the main experts in this case, Dr. deLong for
25 Petitioners and Dr. Macdonald for Patent Owners, but from the time that
26 Patent Owners filed their preliminary response until today, they and their

1 experts, in particular Dr. Macdonald, have been and continue to be flat
2 wrong when they assert that
3 Klimko explicitly teaches away from further development of Compound C
4 due to an unacceptably -- unacceptable therapeutic profile due to the side
5 effects of hyperemia and an initial increase in IOP for Compound C, and in
6 their -- and their experts are wrong, and we will address that, but first I
7 wanted to note very up front that nowhere, nowhere do Patent Owners
8 challenge the undisputed and clear structural similarity between their
9 claimed compound, Tafluprost, and the lead compound, Compound C, from
10 Klimko.

11 Can we go to slide 4, please. Tafluprost differs from the lead
12 compound from Klimko, Compound C, only slightly, in that it has two
13 fluorine substituents at the C-15 carbon, whereas Compound C has a
14 hydroxyl group. In view of the minor differences, the Board's institution
15 decision focused on the issue of selection of the lead compound, Compound
16 C, and were persuaded to institute based on the current record then. The
17 Board instituted on two grounds.

18 Let's go to slide 5. Ground one over Klimko, Kishi, and Ueno, and
19 ground two over Klimko, Kishi, Bezuglov 1982 and/or Bezuglov 1986 and
20 Ueno. Now, I want to touch upon the references very quickly just for
21 background purposes.

22 Let's go to slide 6. Klimko, which is Exhibit 1003, discloses to a
23 person of ordinary skill in the art Compound C, a lead compound that would
24 be a natural choice for further development and as a compound for treatment
25 of elevated IOP or glaucoma.

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