UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS HOLDINGS INC., AND APOTEX HOLDINGS, INC., Petitioner,

v.

OSI PHARMACEUTICALS, INC., Patent Owner.

Case IPR2016-01284 Patent 6,900,221 B1

Held: October 3, 2017

Before LORA M. GREEN, RAMA G. ELLURU, and ZHENYU YANG, *Administrative Patent Judges*.



APPEARANCES:

ON BEHALF OF THE PETITIONER:

W. BLAKE COBLENTZ, ESQUIRE ERIC J. CHOI, ESQUIRE Cozen O'Connor 1200 Nineteenth Street, N.W. Washington, D.C. 20036

ON BEHALF OF PATENT OWNER:

AMY WIGMORE, ESQUIRE EMILY R. WHELAN, ESQUIRE KEVIN M. YURKERWICH, Ph.D. Wilmer Cutler Pickering Hale & Dorr, LLP 1875 Pennsylvania Avenue, N.W. Washington, D.C. 20006

The above-entitled matter came on for hearing on Tuesday, October 3, 2017, commencing at 1:00 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia.



1	PROCEEDINGS
2	
3	JUDGE GREEN: Good afternoon. Welcome everyone
4	Please make sure all cell phones are turned off as it can interfere
5	with the microphones. We are on the record. This is the final
6	oral hearing in IPR2016-01284. This proceeding involves U.S.
7	patent number 6,990,221. At this time we would like counsel to
8	introduce yourselves and your colleagues, beginning with
9	petitioner.
10	MR. COBLENTZ: Good afternoon. This is Blake
11	Coblentz, counsel for petitioner, Apotex. With me is Eric Choi,
12	who is also with Cozen.
13	JUDGE GREEN: Thank you. Patent owner?
14	MS. WIGMORE: Good afternoon, Your Honors. My
15	name is Amy Wigmore. I'm here on behalf of patent owner, OSI
16	Pharmaceuticals, Inc. With me here today is lead counsel, Emily
17	Whelan as well as Kevin Yurkerwich.
18	JUDGE GREEN: Thank you. Welcome to the Board.
19	I am joined by Judge Yang and Judge Elluru. Consistent with our
20	previous order, petitioner and patent owner have 45 minutes to
21	present their arguments. Petitioner will proceed first to present its
22	case in chief as to the challenged claims and may reserve rebuttal
23	time to respond to the arguments made by patent owner.
24	Thereafter patent owner will respond to petitioner's case



1	Before we start, I would like to start with a few
2	housekeeping notes. First, we note that the demonstratives are
3	only as an aid to trial and are not evidence of record. That being
4	said, we note that patent owner has objected to a number of
5	petitioner's demonstratives and we will rule on those objections in
6	the final written decision.
7	Counsel for petitioner, you may proceed. Would you
8	like to reserve time for rebuttal?
9	MR. COBLENTZ: Yes. I would like to reserve ten
10	minutes. And we have hard copies of the slides. Would that be
11	helpful?
12	JUDGE GREEN: Yes, please. And you may begin
13	when you are ready.
14	MR. COBLENTZ: Good afternoon. May it please the
15	Board, my name is Blake Coblentz and I'm here on behalf of
16	petitioner, Apotex, along with my colleague, Eric Choi.
17	Now, if we go to slide 2, I think the first place I want to
18	start is kind of give you an overview of where I plan to go today.
19	And the first thing that I would like to handle in this argument is
20	the petitioner's case that claims 44 through 46 and 53 of the '221
21	patent are prima facie obvious. In doing so, I want to go through
22	the references and really show that the primary reference, Schnur
23	really has everything in it, and everything in it from the
24	compound Erlotinib to therapeutically effective amount treating a
25	mammal to treating lung cancer. The one thing that it doesn't



- 1 necessarily have is differentiating that lung cancer is NSCLC.
- 2 And that's where Gibbs and the OSI 10-K come in because Gibbs
- and the OSI 10-K both have Erlotinib. They single out Erlotinib
- 4 specifically, and they also single out the treatment of NSCLC
- 5 specifically as well.
- 6 JUDGE ELLURU: Counsel, what is the disclosure,
- 7 what is the teaching in OSI that's not available in Gibbs relevant
- 8 to the challenged claims?
- 9 MR. COBLENTZ: I think that the teaching in OSI
- 10 10-K is very duplicative of Gibbs. It teaches a very similar thing.
- 11 It's an OSI publication that actually has the fact that NSCLC was
- targeted, actually that it had completed -- OSI had completed
- 13 Phase I trials and was moving into Phase II trials, and it had the
- 14 fact that it was an EGFR inhibitor. So I think they are very
- duplicative. I think Gibbs maybe gives even a little bit more than
- 16 that by calling out that Erlotinib had a good anticancer activity as
- well.
- But I think that the original -- we originally put in the
- 19 OSI 10-K for the situation where they would try to swear behind
- 20 the priority date, which they did not do, which would have
- 21 rendered Gibbs maybe not prior art. But since that was not done
- and it was undisputed that the priority date was March 30th of
- 23 2000, I think the OSI 10-K and Gibbs disclosed very similar type
- of things.



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