Paper 94

Entered: September 12, 2014

### UNITED STATES PATENT AND TRADEMARK OFFICE

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## BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS, LLC, Petitioner,

v.

## SUPERNUS PHARMACEUTICALS, INC. Patent Owner.

Case Numbers IPR2013-00368, IPR2013-00371 and IPR2013-00372 Patent Numbers 8,206,740, 8,394,405 and 8,394,406

Held: August 12, 2014

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Before: LORA M. GREEN, SCOTT E. KAMHOLZ, and GEORGIANNA WITT BRADEN, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE PETITIONER:

H. KEETO SABHARWAL, ESQUIRE PAUL A. AINSWORTH, ESQUIRE Sterne Kessler Goldstein Fox 1100 New York Avenue, NW Washington, DC 20005



1	ON BEHALF OF PATENT OWNER:
2	GERALD J. FLATTMAN JR., ESQUIRE
3	GREGORY A. MORRIS, ESQUIRE
4	Paul Hastings
5	75 East 55 <sup>th</sup> Street
6	New York, New York
7	-and-
8	STEPHEN B. MAEBIUS, ESQUIRE
9	ANDREW S. BALUCH, ESQUIRE
10	Foley & Lardner, LLP
11	3000 K Street, NW
12	Washington, DC 20007-5109
13	
14	The shave entitled matter come on for bearing on Tuesday
15 16	The above-entitled matter came on for hearing on Tuesday, August 12, 2014, commencing at 1:00 p.m., at the U.S. Patent and
10 17	Trademark Office, 600 Dulany Street, Alexandria, Virginia.
18	Trademark Office, 600 Bularry Street, Alexandria, Virginia.
19	
20	
21	PROCEEDINGS
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23	JUDGE KAMHOLZ: Can everyone in the room hear Judge
24	Braden? Judge Braden, would you speak again, please?
25	JUDGE BRADEN: Yes, I can. Can everyone in the room
26	hear me?
27	JUDGE KAMHOLZ: I think that will suffice.
28	Good afternoon. We will hear argument now in Case
29	Numbers IPR2013-00368, 00371, 00372, Amneal Pharmaceuticals,
30	LLC versus Supernus Pharmaceuticals Incorporated Counsel for the



1	parties, would you please introduce yourselves, starting with the
2	Petitioner?
3	MR. SABHARWAL: Good afternoon, Your Honors. On
4	behalf of Amneal Pharmaceuticals, Keeto Sabharwal of the law firm
5	Sterne, Kessler, Goldstein and Fox.
6	MR. AINSWORTH: Good afternoon, Your Honor, Paul
7	Ainsworth, also with Sterne, Kessler, Goldstein and Fox.
8	JUDGE KAMHOLZ: And Patent Owner?
9	MR. FLATTMANN: Yes, Your Honor. I'm Gerald
10	Flattmann of the law firm of Paul Hastings for the patent holder,
11	Supernus.
12	MR. MORRIS: I'm Greg Morris, Your Honor, from the law
13	firm of Paul Hastings, also for Supernus.
14	MR. MAEBIUS: Also Steve Maebius of Foley and Lardner
15	on behalf of Supernus.
16	JUDGE KAMHOLZ: Welcome, everyone, to the Board.
17	Per our order dated July 18, 204, each side will have one
18	hour to argue during this hearing. The Petitioner will argue first and
19	present all of its arguments concerning all cases and may reserve
20	rebuttal time. You should begin your presentation by indicating how
21	much time you will reserve, if any. The Patent Owner may not
22	reserve rebuttal time.
23	I will remind the parties that the Petitioner bears the burden
24	of proving any proposition of unpatentability by a preponderance of
25	the evidence. I will also remind the parties that this hearing is open to



1 the public and a full transcri	pt of everything	that is said v	will become
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- 2 part of the public record.
- 3 Please bear in mind that the third member of this panel,
- 4 Judge Braden, is attending this hearing by telephone from our office
- 5 in Dallas. Please remember also to mention by number every slide as
- 6 you refer to it. This is especially important to ensure that Judge
- 7 Braden can follow the proceedings.
- 8 With that, I would like to invite Petitioner to begin.
- 9 MR. SABHARWAL: Thank you, Your Honors. Your
- 10 Honor, just a couple of preliminary matters. First of all can you hear
- me? Does this work. Does that work? Hello?
- 12 (Discussion off the record.)
- MR. SABHARWAL: I can speak loud.
- JUDGE KAMHOLZ: Why don't you do that. Someone is
- coming, and we'll deal with it.
- MR. SABHARWAL: Great, thank you. Just a couple
- 17 preliminary matters, Your Honors. First of all, with respect to the
- time allocation, with the Board's permission, we would like to allocate
- 19 40 minutes for our opening presentation and then 20 minutes for
- 20 rebuttal.
- Also, we have hard copies of our demonstratives, if the
- 22 Board would like that.
- JUDGE KAMHOLZ: Yes, please.
- MR. SABHARWAL: Could you hand those out, please.
- 25 Excuse me.



1	(Discussion off the record.)
2	JUDGE KAMHOLZ: Please proceed.
3	MR. SABHARWAL: Thank you. One other thing, Your
4	Honors, in terms of the allocation, I will be addressing the prima facie
5	and secondary consideration issues in part of our opening, and Mr.
6	Ainsworth will be discussing the alternative arguments, the
7	incorporation by reference, the antedation issue and CREATE Act
8	issue.
9	JUDGE KAMHOLZ: Thank you. Please make sure that
10	you speak up and into the microphone so Judge Braden can hear.
11	MR. SABHARWAL: All right. If for any reason you can't
12	hear me, please let me know.
13	JUDGE BRADEN: Thank you. It would be nice.
14	MR. SABHARWAL: Sure. Your Honors, on December 17
15	of 2013, this Board instituted the foregoing IPRs based upon the '932
16	Ashley reference as well as the Sheth reference.
17	In the ensuing eight months, Petitioner's case has been
18	strengthened based upon at least three principal reasons: Number 1,
19	the express disclosures of the '932 reference and the Sheth reference.
20	Your Honors, it doesn't matter what Mr. Flattmann or I say. The
21	references say what they say, and we believe that they strongly
22	demonstrate unpatentability of the alleged invention in this case.
23	Secondly, based upon deposition testimony as well as the
24	pleadings and other exhibits, the Patent Owner, Supernus, has failed
25	to demonstrate that any of the secondary considerations overcome our



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