

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC; HAYMAN
CREDES MASTER FUND, L.P.; HAYMAN ORANGE FUND
SPC - PORTFOLIO A; HAYMAN CAPITAL MASTER FUND,
L.P.; HAYMAN CAPITAL MANAGEMENT, L.P.; HAYMAN
OFFSHORE INVESTMENTS, LLC; NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC; KYLE BASS and ERICH
SPANGENBERG,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

Held: November 30, 2016

BEFORE: SALLY G. LANE, RICHARD E. SCHAFER, and
DEBORAH KATZ, Administrative Patent Judges.

The above-entitled matter came on for hearing on Wednesday,
November 30, 2016, commencing at 9:31 a.m., at the U.S. Patent
and Trademark Office, 600 Dulany Street, Alexandria, Virginia.

Case IPR2015-01993
Patent 8,399,514 B2

APPEARANCES:

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1 PROCEEDINGS

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3 JUDGE SCHAFER: Good morning. We have two oral
4 arguments this morning. The first is for IPR2015-01993,
5 Coalition For Affordable Drugs, et al., versus Biogen MA. The
6 second argument is for interference 106,023, Biogen MA versus
7 Forward Pharma. We'll take a short recess after the first
8 argument so the parties can set up for the interference argument.

9 The time for the argument in the IPR has been set for
10 20 minutes on each side. Who will be arguing for Coalition?

11 MR. CARMICHAEL: James Carmichael.

12 JUDGE SCHAFER: How much time would you like to
13 reserve for rebuttal?

14 MR. CARMICHAEL: Five minutes, please.

15 JUDGE SCHAFER: Who will be arguing for Biogen?

16 MR. FLIBBERT: Mike Flibbert from Finnegan, Your
17 Honor.

18 JUDGE SCHAFER: How much time would you like to
19 reserve?

20 MR. FLIBBERT: One minute, please, Your Honor.

21 JUDGE SCHAFER: Do the parties have
22 demonstratives that they want to bring up to us?

23 MR. CARMICHAEL: We do, sure.

24 JUDGE SCHAFER: And if you could give one set to
25 the court reporter. I'm going to have the court reporter attach the

1 demonstratives to the transcript. That's how we'll get them into
2 the record. Okay, Mr. Carmichael, if you want to go ahead.

3 MR. CARMICHAEL: Thank you. And may it please
4 the Board, claims 1 through 20 of the '514 patent should be
5 cancelled as obvious over the prior art. There are two main issues
6 I would like to address. One is that the references have not been
7 disqualified as prior art. And the other is that the claims are
8 obvious over the references.

9 Taking the first issue first, the Kappos 2006 qualifies as
10 prior art under Section 102(b) and Joshi '999 qualifies as prior art
11 under 102(a) both for the same reason that the provisional
12 application does not provide 112 support for the claims in the
13 later application.

14 JUDGE SCHAFER: Why isn't the Kappos published
15 application -- not the Kappos. The Joshi '999 published
16 application, why isn't that being relied on as prior art? It would
17 be 102(b) prior art, I think it issued. It was published in 2003 or
18 '4.

19 MR. CARMICHAEL: That's a good question. It was
20 not part of the petition.

21 JUDGE SCHAFER: Okay. Go ahead.

22 MR. CARMICHAEL: So the claimed invention
23 involves administering 480 milligrams of DMF on a daily basis to
24 a patient in need of treatment for MS. The provisional
25 application includes many different diseases. Not just MS. I

1 show you on the first slide here just a small example of the many
2 diseases discussed, but you can see that they used the phrase "a
3 variety of neurodegenerative diseases." They list here ALS,
4 Alzheimer's and Parkinson's. Now, to be sure, MS is sprinkled
5 throughout the application as well among dozens of other
6 conditions, but by the time that we get to the section on dosage,
7 it's not specific to any particular condition.

8 Dr. Pleasure has testified that the paragraph relied on,
9 the dosage section, which is Section 10 of the provisional
10 application, in a particular paragraph 116, does not refer to MS or
11 any other indication. He also testified that the dosing that's
12 discussed blazes a trail only to 720 and to no other dosages.

13 We can see that in the paragraph 116, that's the only
14 mention of 480 milligrams. I have colored in red four amounts
15 that represent the lower end of various ranges. The first one is
16 0.1 grams, which is 100 milligrams up to 1,000 milligrams a day.
17 The second range is 200 milligrams to 800 milligrams a day.
18 And then in parentheses there are examples of ranges within the
19 200 to 800 range, including 240 to 720, 485 to 720 and about
20 720.

21 What is especially interesting here is that the lower ends
22 of these ranges, some of them were known to be ineffective to
23 people of skill in the art at the time of the provisional. So a
24 person of ordinary skill in the art would not see this and think that

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