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IPR2015-00990, Paper No. 67

IPR2015-01093, Paper No. 65

August 23, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II, LLC,
Petitioner,

v.

NPS PHARMACEUTICALS, INC.,
Patent Owner.

Cases IPR2015-00990 and IPR2015-01093
Patent 7,056,886 B2

Held: June 23, 2016

BEFORE: LORA M. GREEN, JACQUELINE WRIGHT
BONILLA, and SHERIDAN K. SNEDDEN, Administrative
Patent Judges.

The above-entitled matter came on for hearing on Thursday, June
23, 2016, commencing at 9:30 a.m., at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

Cases IPR2015-00990 and IPR2015-01093
Patent 7,056,886 B2

APPEARANCES:

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1 P R O C E E D I N G S

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3 JUDGE SNEDDEN: Good morning. This is the final
4 hearing for IPR2015-00990 and consolidated with
5 IPR2015-01093. I'm Judge Snedden. I have with me Judges
6 Bonilla and Green. Who do we have here today for petitioner?

7 MR. FEDOWITZ: On behalf of petitioner, I'm
8 Matthew Fedowitz. This is my partner, Jeff Blake, Mary Bram
9 and Alireza Behrooz.

10 JUDGE SNEDDEN: Welcome. Nice to meet you.
11 And for patent owner?

12 MR. ROBINSON: Joseph Robinson. I'm here with
13 Dustin Weeks, Robert Schaffer and Heather Ettinger. We believe
14 that Margo Furman is in the air somewhere trying to get here
15 today from NPS and Shire.

16 JUDGE SNEDDEN: Thank you. Just briefly, I'll go
17 over our procedure today. Each party will have 60 minutes of
18 total time to present its arguments. Petitioner will open the
19 hearing by presenting its case regarding the challenged claims for
20 which we instituted trial. Patent owner will then respond to
21 petitioner's arguments.

22 Petitioner, you may reserve time to respond to patent
23 owner's presentation. So with that, I'll let you begin. Would you
24 like to reserve any time?

25 MR. FEDOWITZ: I would like to reserve 15 minutes.

1 JUDGE SNEDDEN: I'll start the clock when you
2 begin.

3 MR. FEDOWITZ: In addition, since the cord is a little
4 short, my colleague is going to sit here to operate the slides.

5 Also, I'll be discussing the technical arguments, and my
6 colleague, Jeff Blake, will be discussing commercial success and
7 long-felt need.

8 Your Honors, we have demonstratives. May I approach
9 and give them to you?

10 JUDGE SNEDDEN: Yes.

11 MR. FEDOWITZ: Your Honor, before I get started, I
12 want to briefly preview the items I'm going to discuss today.
13 They include what the prior art discloses and how it can be
14 rationally applied to the claims at issue. I'm going to discuss
15 patent owner's alleged unexpected results. I'm going to address
16 patent owner's arguments regarding the alleged complexities and
17 the new argument that you will hear today about proteins and
18 peptides being different. And I'm also going to discuss the
19 contradiction in Dr. Carpenter's publications.

20 The standard review of review in this inter partes
21 review requires a showing that the facts and the prior art
22 demonstrate the instituted claims are obvious by a preponderance
23 of the evidence. Petitioner, through its petitions and exhibits in
24 the 990 and 1093 IPRs, have met this requirement. We've
25 demonstrated that each of the limitations of the claims at issue are

1 in the prior art. This is set forth in the claim charts, in the
2 petitions and the declarations we have submitted. Based on these
3 disclosures and its institution decision, the Board concluded that
4 there was a reasonable likelihood that the claims at issue are
5 unpatentable.

6 In response to this, patent owner alleged that the
7 instituted claims were novel despite all the limitations being
8 found in the prior art. However, patent owner's grand scheme
9 attempts to argue that the complexity of the formulations at issue
10 and that one of ordinary skill in the art would never arrive at the
11 limitations claimed despite their being suggested in the prior art.

12 This grand scheme, however, is fraught with
13 contradictions of what was well known in the prior art. It also
14 directly contradicts the prior art statements made in the
15 publications by Dr. Carpenter, patent owner's declarant. He
16 discloses in those publications a rational approach to formulation
17 design. Indeed, one of the most pronounced contradictions is the
18 very fact that the complications alleged by patent owner are not
19 even considered in the specification of the '886 patent. In fact,
20 one of the new arguments you'll hear today is that what was
21 known about formulating proteins and peptides cannot be applied
22 to each other. This is a completely new argument by patent
23 owner.

24 JUDGE BONILLA: What do you mean by new
25 argument?

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