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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS)
CORPORATION, et al.,)
)
Plaintiffs,)
)C.A. No. 13-527-RGA
v.)
)
NOVEN PHARMACEUTICALS, INC.,)
)
Defendant.)

Wednesday, December 3, 2014
2:05 p.m.
Courtroom 4B

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE RICHARD G. ANDREWS
United States District Court Judge

APPEARANCES:

McCARTER & ENGLISH
BY: DANIEL M. SILVER, ESQ.

-and-

FITZPATRICK, CELLA, HARPER & SCINTO
BY: NICHOLAS N. KALLAS, ESQ.
BY: CHARLOTTE JACOBSEN, ESQ.
BY: DOMINICK CONDE, ESQ.
BY: CHRISTOPHER LOH, ESQ.

Counsel for the Plaintiffs

Hawkins Reporting Service
715 N. King Street - Wilmington, Delaware 19801

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APPEARANCES CONTINUED:

PHILLIPS GOLDMAN & SPENCE
BY: JOHN C. PHILLIPS, JR., ESQ.

-and-

KENYON & KENYON
BY: STEVEN J. LEE, ESQ.
BY: MICHAEL K. LEVY, ESQ.
BY: CHRISTOPHER J. COULSON, ESQ.

Counsel for the Defendants

Hawkins Reporting Service
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1 THE CLERK: All rise.

2 THE COURT: All right. Please be
3 seated.

4 Good afternoon. I believe we're
5 going to have some argument now on the trial that
6 we just had. And I take it that the defendants
7 will go first because it's their burden; right?

8 MR. LEE: That's right, Your Honor.

9 THE COURT: All right. Mr. Lee.

10 MR. LEE: May it please the Court.
11 It seems like just yesterday, I was delivering my
12 opening argument.

13 The sole issues in the case are the
14 obviousness or not of Claim 7 and 16 of the '031
15 patent in view of the prior art and whether those
16 claims are obvious variants of the claims of the
17 '176 patent, and therefore, invalid for double
18 patenting.

19 THE COURT: And it's not my
20 intention to interrupt either counsel during
21 closings, notwithstanding what I'm doing now, but
22 I do have one question which -- you know what, I
23 may have some questions when you're done, so --

24 MR. LEE: Okay.

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1 THE COURT: -- don't take my just
2 sitting here as being lack of interest. Okay?

3 MR. LEE: All right. To prove
4 obviousness of these claims, Noven does not have
5 to prove that the use of every antioxidant listed
6 in Claim 16 was obvious, but just that any one of
7 them was. It does not have to prove that every
8 amount of antioxidant within the claim scope of
9 Claim 7 was obvious, but just that some amount of
10 antioxidant falling within the claim of the scope
11 was obvious. It does not have to prove that
12 every transdermal patch or every method of
13 establishing a rivastigmine formulation was
14 obvious, but only that at least one formulation
15 was obvious. And Noven has done that.

16 Plaintiffs have not contested in
17 this case that GB '040 would be a proper starting
18 point for further development of a rivastigmine
19 transdermal patch. Dr. Kydonieus explained why.

20 By 1997, an oral dosage form of
21 rivastigmine taken two or three times a day was
22 already in clinical trials, had been shown to be
23 safe, effective and well tolerated and better
24 than the existing drug. However, it was not

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1 better than the competition, which only required
2 a single dose per day.

3 GB '040 teaches that a transdermal
4 device would be preferable since it could be
5 applied once a day or even less often.
6 Therefore, there was a motivation to develop a
7 transdermal delivery system containing
8 rivastigmine in 1998 and GB '040 was the place to
9 start.

10 I think we have narrowed the issues
11 somewhat. Plaintiffs do not contest, that I have
12 heard, that GB '040 taught a transdermal patch,
13 that it taught a therapeutically effective amount
14 of rivastigmine or that it was routine to
15 determine the amount of antioxidant for use in a
16 particular formulation.

17 They do not contest or they do not
18 contend that GB '040 contained any stability
19 data. They do not contend that the transdermal
20 patch disclosed in GB '040 had a release liner or
21 the typical packaging of a transdermal system.
22 And, therefore, one of ordinary skill in the art
23 would have had to further develop the formulation
24 of GB '040 into a commercial product.

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