IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Biovail Laboratories International SRL,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civ. No. 09-605-JJF-LPS
	:	
Cary Pharmaceuticals Inc.,	:	
	:	
Defendant.	:	

ORDER

At Wilmington this **26th** day of **May, 2010**:

1. In this patent infringement action, the Court has before it a defense motion to strike (D.I. 46) the plaintiff's expert's supplemental declaration (D.I. 43), which the plaintiff submitted in connection with its filing of its answering brief on claim construction. The plaintiff is Biovail Laboratories International SRL ("Biovail"), which holds the patent-in-suit as well as New Drug Application 021515, relating to a drug with the active ingredient bupropion hydrochloride ("Biovail NDA"). (D.I. 1 ¶¶ 1, 5, 6) The Defendant is Cary Pharmaceuticals Inc. ("Cary"), which has filed with the Food and Drug Administration ("FDA") a New Drug Application 22-497, also for a drug with the active ingredient bupropion hydrochloride ("Cary NDA"). (D.I. 1 ¶ 1) Biovail alleges that the Cary NDA infringes the Biovail patent-in-suit. (D.I. 1 ¶ 9)

2. Biovail filed this action on August 13, 2009. (D.I. 1) On January 8, 2010, the parties submitted a status report pursuant to Fed. R. Civ. Proc. 26(f), in which (among other things) Biovail requested a *Markman* hearing in January 2011 while Cary requested a *Markman*

hearing in April 2010. (D.I. 16 at 2) On January 14, 2010, Judge Farnan held a Rule 16 conference and directed the parties to propose suggested dates for a *Markman* hearing in May 2010. The parties conferred and, on February 12, 2010, proposed a schedule – involving dates for: opening claim construction briefs, "[d]epositions of experts who submitted declarations," and responsive claim construction briefs – leading to a requested hearing date of May 27, 2010. (D.I. 24)

3. On February 19, 2010, Judge Farnan entered a Scheduling Order containing the language and dates proposed by the parties, but without setting a *Markman* hearing date. The Scheduling Order provides, in its entirety:

> WHEREAS, a Scheduling Conference was held on January 14, 2010, in the above-captioned matter;
>
> WHEREAS, parties have conferred and agreed to an early Markman schedule;
>
> NOW THEREFORE, IT IS HEREBY ORDERED that parties shall exchange opening claim construction briefs by **April 16, 2010**. Depositions of experts who submitted declarations are to be held **between May 3 and May 7, 2010**. Responsive claim construction briefs shall be filed by **May 14, 2010**.
>
> IT IS FURTHER ORDERED that due to my intended retirement on July 31, 2010, the above-captioned matter is referred to Magistrate Judge Stark to hear and resolve all pretrial matters in the above-captioned matter, up to and including the pretrial conference, subject to 28 U.S.C. § 636(b) and any further Order of the Court.

(D.I. 25) On February 24, 2010, the undersigned magistrate judge scheduled the *Markman* hearing for June 1, 2010. (D.I. 26)

4. Consistent with the Scheduling Order, both parties filed their opening claim

construction briefs on April 16, 2010. (D.I. 31; D.I. 34) At the same time, Biovail filed an expert declaration from Harold B. Hopfenberg ("Hopfenberg Declaration"). (D.I. 33) Cary, in conjunction with its opening brief, filed an expert declaration from Patrick Sinko ("Sinko Declaration"). (D.I. 36)

5. Also consistent with the Scheduling Order, the experts were deposed between May 3 and May 7, 2010. Specifically, Sinko was deposed on May 3 and Hopfenberg on May 5. (D.I. 46 at 1, 3) Hopfenberg attended Sinko's deposition. (D.I. 46 at 3)

6. Consistent with the Scheduling Order, on May 14, 2010, the parties filed their answering claim construction briefs. (D.I. 42; D.I. 44) On the same date, Biovail filed a supplemental declaration of Harold B. Hopfenberg ("Hopfenberg Supplemental Declaration"). (D.I. 43)

7. On May 18, 2010, Cary moved to strike the Hopfenberg Supplemental Declaration as untimely and unauthorized. (D.I. 46) According to Cary, the Hopfenberg Supplemental Declaration contains more than 46 pages and 107 paragraphs of "new opinions" that, pursuant to the Scheduling Order, should have been disclosed in the initial Hopfenberg Declaration or, at the latest, at Hopfenberg's deposition. Cary contends that without striking the Hopfenberg Supplemental Declaration, and the portions of Biovail's answering brief relying on it, Cary will be unduly prejudiced at the *Markman* hearing, as it will not have had an opportunity to cross-examine Hopfenberg on his new opinions, nor an opportunity to prepare its own expert (Sinko) to reply to the new opinions. Moreover, Cary insists that any delay in the June 1, 2010 hearing date will severely prejudice Cary by delaying its ability to launch its new drug product, and by depriving Cary of the early hearing it was granted by Judge Farnan.

8. Biovail answered the motion to strike on May 24, 2010. (D.I. 49) In its response,

Biovail points out that the Scheduling Order does not preclude supplemental expert declarations nor provide a deadline for expert depositions. Moreover, Biovail contends that rebuttal expert declarations are the norm, that Biovail never stated nor suggested that it would not file a supplemental declaration, and that Cary's expert (Sinko) included a statement in his declaration expressly reserving the right to file a rebuttal declaration. Biovail further represents that "[t]here was nothing in the parties' discussions concerning scheduling or the Court's order that precluded expert rebuttal declarations." (D.I. 49 at 2)

9. Exclusion of "critical evidence" in a patent case is an "extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation marks omitted); *see also* D.I. 49-1 Ex. A at 5 (*Dow Chemical Co. v. Nova Chemicals Corp.*, C.A. No. 05-737-JJF (D. Del. May 20, 2010), at 4).

10. Here, the Hopfenberg Supplemental Declaration is "critical evidence," as it supports Biovail's position with respect to claim construction, which is the issue to be addressed at the *Markman* hearing. Although expert declarations are extrinsic evidence, and therefore not as reliable as intrinsic evidence, they are among the materials the Court may properly consider in construing the claims of a patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1318-19 (Fed. Cir. 2005). Cary has failed to demonstrate willful deception, as there is no proof (nor even the suggestion) that Biovail affirmatively represented to Cary that it would not file a rebuttal declaration. Nor has Cary demonstrated flagrant disregard of a court order. The limited Scheduling Order entered by Judge Farnan does not address whether the parties are permitted to file rebuttal declarations from experts, nor does it provide a cut-off date for expert depositions. Accordingly, Cary's motion to strike is **DENIED**.

11. This is not to say, however, that Biovail's conduct is laudable – quite the contrary. While Biovail has not engaged in willful deception, its silence as to its intent to file a rebuttal report and its failure to in any way disclose Hopfenberg's rebuttal opinions at a time when Cary could test and/or respond to them appears to have had the consequence of deceiving Cary into believing that the record with respect to the opinions of claim construction experts was complete. Likewise, while Biovail did not flagrantly disregard the Scheduling Order, this is only because the Scheduling Order was truncated, containing only the provisions proposed by the parties themselves in their February 12, 2010 letter. Biovail's filing of a rebuttal expert declaration in connection with its answering claim construction brief, after the period provided for in the Scheduling Order for expert depositions, without prior notice to Cary, was, in the circumstances presented here, inconsistent with the intent of the Scheduling Order. Furthermore, Biovail's conduct, if unaddressed, will unduly prejudice Cary's ability to advocate its position at the *Markman* hearing.

12. Consequently, **IT IS HEREBY ORDERED THAT**:

a. The *Markman* hearing scheduled for June 1, 2010 is **CANCELLED** and **RESCHEDULED** for **June 29, 2010 at 10:00 a.m.**[1]

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[1]The Court is not persuaded that the delay of four weeks between the original date for the *Markman* hearing and the new hearing date will severely prejudice Cary. The *Markman* hearing will still take place relatively early in this litigation, and far closer to the date requested by Cary (April 2010) than the date requested by Biovail (January 2011). Moreover, Cary has yet to receive FDA approval for the Cary NDA. (D.I. 46 at 5 n.4) Also, Cary complains that if the hearing were to take place on June 1, "even if expert testimony is permitted at the *Markman* hearing, Cary could not possibly have its expert prepared to testify at the hearing regarding Dr. Hopfenberg's new and voluminous declaration." (D.I. 50 at 3 n.3) It follows that the short delay in the hearing date will assist Cary in preparing its expert for the hearing. Finally, given the impending retirement of the judge to whom this case is assigned, it cannot have been entirely unforeseeable to the parties that some delay might have occurred, even absent the instant issue that has arisen between the parties.

b. Cary may, **no later than June 4, 2010**, take a second deposition of Biovail's expert, Hopfenberg, solely directed to the Hopfenberg Supplemental Declaration.

c. Cary may, **no later than June 11, 2010**, file a reply brief in support of its proposed claim construction. Any such reply brief shall not exceed **ten (10) pages** in length.

d. Other than provided for by this Order, **no additional claim construction briefing and no additional claim construction expert declarations or reports shall be filed without leave of the Court**.

e. At the claim construction hearing, each side will be allocated **two (2) hours**, in which to present a tutorial, expert testimony, and argument on claim construction.[2]

13. If, following the *Markman* hearing, Cary believes that any unfair prejudice caused by Biovail's conduct has not been adequately ameliorated, Cary may, within 7 days after the *Markman* hearing, file a motion for monetary sanctions. If Cary files such a motion, briefing shall proceed according to the Local Rules.

14. Finally, the Court notes that the last portion of Cary's answering claim construction brief is entitled, "The Declaration of Biovail's Expert Should Be Stricken Under Federal Rule of Evidence 702." (D.I. 44 at 18-20) To the extent Cary intends this to be a motion to strike the initial Hopfenberg Declaration, it is **DENIED**.[3] The Court will consider the

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[2]As a result of the instant Order, by the time of the *Markman* hearing, Biovail will have filed two claim construction briefs and two expert declarations, and taken one deposition of Cary's expert. By that same date, Cary will have filed three claim construction briefs and one expert declaration, and taken two depositions of Biovail's expert. Each party will also have the opportunity to present its expert at the *Markman* hearing. Under the circumstances, the Court considers this an equitable result.

[3] The parties are reminded that "[u]nless otherwise ordered, all requests for relief shall be presented to the Court by motion." D. Del. LR 7.1.2(a).

Hopfenberg Declaration and Hopfenberg Supplemental Declaration, as well as any deposition or hearing testimony of Hopfenberg that is placed in the record, in connection with making recommendations as to the proper construction of the disputed claim terms.

Delaware counsel are reminded of their obligations to inform out-of-state counsel of this Order. To avoid the imposition of sanctions, counsel shall advise the Court immediately of any problems regarding compliance with this Order.

Hon. Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE