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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CONCEPTUS, INC.,

No. C 09-02280 WHA

Plaintiff,

v.

**ORDER EXCLUDING
REPLY EXPERT
MATERIALS**

HOLOGIC, INC.,

Defendant.

INTRODUCTION

In this patent infringement action, plaintiff's motion in limine no. 2 to exclude evidence, testimony, and argument related to enablement that was not timely disclosed in Thomas Ryan's expert report is partially **GRANTED**.

STATEMENT

Since November 2009, this case has been governed by a case management order. The CMO set August 31, 2010, as the last date for full disclosure of opening expert reports as to any issue on which a party has the burden of proof. The CMO then required any opposing report to be served. It also authorized a reply report by the opening side. The CMO stated, "[r]eply reports must be limited to true rebuttal and should be very brief. They should not add new material that should have been placed in the opening report" The reason for this limitation was obvious, namely to give the opposing side a fair chance to respond to the opening side's panoply of arguments.

1 In this patent action, as the accused, defendant has the burden of proof on invalidity. In
2 June 2010, defendant propounded interrogatories to plaintiff requesting details of “all factual and
3 legal bases for [plaintiff’s] contention that the specifications of the [a]sserted [p]atents enable a
4 person of ordinary skill in the art to make and use the full scope of the invention”
5 (Def. Interrogatory 19). Plaintiff served answers to the interrogatories in July 2010 and then
6 supplemented its answers on August 31, 2010.

7 Also on August 31, defendant served the expert report of Thomas Ryan pursuant to
8 Rule 26. In his report, Ryan stated, “I understand that Conceptus is contending that the affixing
9 step in claim 37 may include the use of energy” but that energy is not contemplated by claim 37.
10 Ryan then briefly dismissed energy as non-enabled even if it is deemed to be in the claim
11 (Ryan Report ¶¶ 149–50). This consumed a total of one paragraph. In response, plaintiff
12 served Dr. John Webster’s expert opposition report wherein Dr. Webster detailed how the use
13 of energy was enabled by the specifications (Webster Rebuttal 9–19). Defendant then served
14 Ryan’s reply report, which included *seventeen pages* related to the non-enablement issue
15 (Ryan Reply ¶¶ 112–149).

16 *In limine*, plaintiff now moves to preclude defendant, its lawyers, and witnesses from
17 “mentioning, suggesting, arguing, or offering any evidence concerning expert opinions by
18 Mr. Thomas Ryan that were not timely and adequately disclosed and on which Hologic bears the
19 burden of proof.” Specifically, plaintiff requests that paragraphs 120, 124, 130, 138, and 148 be
20 stricken from Ryan’s reply report. Plaintiff also asks for an order “excluding any reference or
21 mention by Hologic of opinions by Mr. Ryan that were not disclosed in his opening expert report
22 concerning the enablement of energy.” The motion *in limine* further requests that Ryan’s
23 opinions concerning obviousness be limited to those in the initial report. This order follows full
24 briefing and oral argument on the motion at the final pretrial conference.

25 ANALYSIS

26 All United States patents are presumed to be valid. 35 U.S.C. 282. It is therefore the
27 defendant’s burden to prove invalidity of the patent by clear and convincing evidence.
28 *See Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011). Accordingly, defendant in

1 this case carries the burden of showing that the supposed energy claims of plaintiff’s patent are
2 not enabled. *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1342
3 (Fed. Cir. 2003). Defendant must comply with Rule 26 — and the November 2009 CMO — in
4 discharging its burden.

5 The specification of a patent must enable a person skilled in the art to make and use the
6 claimed invention. 35 U.S.C. 112. Enablement is determined in consideration of the *Wands*
7 factors: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art;
8 (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the existence of
9 working examples; (7) the quantity of experimentation necessary; and (8) the amount of direction
10 provided by the inventor. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

11 Ryan’s initial expert report anticipated that plaintiff would contend that claim 37 included
12 the use of energy. Ryan argued that the use of energy to promote tissue ingrowth was not enabled
13 by the specification. Ryan dismissed some of the *Wands* factors in one to two sentences each and
14 did not address the rest of the factors at all (*see, e.g.*, Ryan Report ¶ 150 (providing one mere
15 sentence discussing the “state of the prior art” *Wands* factor: “[W]hile there have been prior art
16 attempts to use energy as part of a contraceptive method, the use of energy is highly variable and
17 must be matched to the specific method.”)). Dr. Webster, in his opposition report, addressed each
18 of the eight *Wands* factors in detail in his attempt to demonstrate that the patent was enabled.
19 Then — for the first time — defendant addressed each of the *Wands* factors in detail in Ryan’s
20 reply report, including detailed new information relating to each factor that was not in his initial
21 report. The relevant reply passage was seventeen pages long.

22 Per the operative CMO, “[r]eply reports must be limited to true rebuttal and should be
23 very brief. They should not add new material that should have been placed in the opening
24 report.” Plaintiff identifies paragraphs 120, 124, 130, 138, and 148 as paragraphs that contain
25 new material that should be stricken. This order agrees.

26 Paragraph 120 in Ryan’s reply report discussed the availability of electro-surgical
27 equipment including the state of the technology at the time of the patent, but he omitted this in his
28 initial report. In paragraph 130, Ryan’s reply demonstrated in detail why the use of energy was

1 unpredictable in the fallopian tube. In his initial report, Ryan merely said “the use of energy is
2 highly variable and must be matched to a specific method.” Finally, paragraphs 124, 138,
3 and 148 of the reply report detailed burdensome experimentation that allegedly would be required
4 in order to develop a device under the patent. In contrast, the opening report merely alleged the
5 conclusion that undue experimentation would be required and provided no details. The
6 information in these reply paragraphs was not included in Ryan’s expert report and should have
7 been. It must now be stricken for failure to comply with the CMO.

8 Plaintiff further requests to “exclude any reference or mention by Hologic of opinions by
9 Mr. Ryan that were not disclosed in his opening expert report concerning the enablement of
10 energy.” This request is vague, and relief will be limited to the information that is stricken by this
11 order. In addition to the paragraphs cited by plaintiff, paragraphs 129, 136, 144, and 146 also
12 presented new material that should have been included in the initial report had a comprehensive
13 examination of the issues been done at that time.

14 Paragraphs 129 and 136 relied on the deposition testimony of one of the inventors of
15 the ’361 patent to form an opinion on the prior state of the art and the guidance provided by the
16 inventor. A proper analysis of the *Wands* factors in the initial report should have included this
17 information. Moreover, instead of detailing the reasons for coming to the conclusion that undue
18 experimentation would be required in his initial report, Ryan waited until paragraphs 144 and 146
19 in his reply report to explain the difficulty of translating animal experiments to humans.

20 Defendant now contends that the detailed reply report is merely a rebuttal to Dr.
21 Webster’s report. This is a truism, for all replies will be responsive to opposition arguments.
22 This begs the question. The question is whether the “reply” material should have been in the
23 opening from the outset. The new material was foreseeable and should have been provided at the
24 outset so that Dr. Webster would have a fair opportunity to oppose and to rebut. To allow this
25 voluminous new material now would bless sandbagging.

26 Defendant further blames the appearance of new material in the reply report on late and
27 inadequate answers to defendant’s interrogatory number nineteen. The interrogatory, however,
28 did not specifically inquire about “RF energy” or “energy” and defendant had not placed plaintiff

1 on notice that defendant would contend that “RF energy” or “energy” was not enabled. At all
2 events, even if plaintiff failed to provide timely responses, that would not relieve defendant of *its*
3 *burden* to show that the inclusion of energy in the claim was not enabled. Defendant cannot “sit
4 back and wait and see what the other side came up with and then rebut that limited universe.”
5 *Atmel Corp. v. Info. Storage Devices, Inc.*, 189 F.R.D. 410, 416 (N.D. Cal. 1999) (Alsup, J.).
6 Defendant’s expert should have put forth *his argument* regarding non-enablement in order to
7 carry the defense burden.

8 **CONCLUSION**

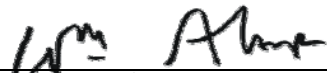
9 For the foregoing reasons, the motion *in limine* is partially **GRANTED**. This order strikes
10 paragraphs 120, 124, 129, 130, 136, 138, 144, 146, and 148 from Thomas Ryan’s reply report.

11 Importantly, this order *in limine* is without prejudice to defense expert Thomas Ryan
12 testifying to the excluded items in the event the door is opened on cross-examination or on
13 redirect in the event cross-examination opens the door. Nor does this order bar the points made in
14 the excluded evidence from being made via other witnesses or exhibits if such testimony or
15 exhibits are admitted. Nor does this order bar defendant from making the same points on
16 cross-examination of plaintiff’s expert. Nor does this order rule out the possibility that the judge
17 himself will decide that the specification fails to enable the accused method.

18 As for the obviousness issue, defense expert Ryan will be limited on direct examination to
19 the specific combinations of references laid out in his opening report and limited to the specific
20 grounds given in the report.

21
22 **IT IS SO ORDERED.**

23
24 Dated: September 27, 2011.

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26 _____
27 WILLIAM ALSUP
28 UNITED STATES DISTRICT JUDGE