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# 1 2 3 4 5 UNITED STATES DISTRICT COURT 6 NORTHERN DISTRICT OF CALIFORNIA 7 8 MEDTRONIC, INC., et al., No. C-07-0567 MMC (EMC) 9 Plaintiffs, ORDER GRANTING IN PART AND 10 v. DENYING IN PART PLAINTIFFS' OTION TO STRIKE PORTIONS OF 11 AGA MEDICAL CORPORATION. DEFENDANT'S OPENING EXPERT REPORTS 12 Defendant. (Docket No. 238) 13 14

Plaintiffs Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc. (collectively "Medtronic") have moved the Court to strike portions of Defendant AGA Medical Corporation's opening expert reports. The Court held a hearing on the motion on February 25, 2009. Having considered the parties' briefs and accompanying submissions, as well as the oral argument of counsel, the Court hereby **GRANTS** in part and **DENIES** in part Medtronic's motion.

# I. FACTUAL & PROCEDURAL BACKGROUND

Medtronic initiated this lawsuit on January 29, 2007. *See* Docket No. 1 (complaint). AGA answered the complaint on April 4, 2007. *See* Docket No. 9 (answer). In its answer, AGA asserted numerous defenses, including defenses based on invalidity pursuant to 35 U.S.C. § 101; failure to comply with 35 U.S.C. § 112; and unenforceability due to inequitable conduct. *See* Docket No. 9 (Ans. ¶¶ 30-32, 33-35, 36-57).

On July 9, 2007, AGA served its preliminary invalidity contentions. *See* Lawson Decl., Ex. B (preliminary invalidity contentions). Thereafter, AGA served its final invalidity contentions. On

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October 17, 2008, AGA served its supplemental final invalidity contentions. See Yang Decl., Ex. 12 (supplemental final invalidity contentions).

On November 7, 2008, AGA served responses to interrogatories that had been propounded by Medtronic. See Yang Decl., Ex. 6 (interrogatory responses). One of the interrogatories that had been served -- Interrogatory No. 14 -- asked AGA to state all facts supporting each contention that the patents at issue were invalid and unenforceable. See Walsh-Benson Decl., Ex. 2 (interrogatories). At the hearing on the motion to strike, Medtronic conceded that Interrogatory No. 14 was the first interrogatory that it had served on the issue of invalidity and unenforceability.

On November 14, 2008, AGA moved to amend its answer. See Docket No. 129 (motion). More specifically, AGA sought leave to amend (1) to add a new defense not previously pled -- i.e., prosecution laches -- and (2) to add allegations about additional instances of inequitable conduct. (In its original answer, AGA had provided some examples of what it alleged constituted inequitable conduct.) In mid-December 2008, Judge Chesney denied AGA leave to add the prosecution laches defense but granted it leave to add allegations about other examples of inequitable conduct. See Docket No. 158 (order). Judge Chesney gave AGA until January 20, 2009, to file an amended answer.

On December 5, 2008, fact discovery closed, with one exception -- i.e., the parties had until December 19, 2008, to complete fact depositions already noticed. See Docket No. 133 (order).

On December 30, 2008 -- i.e., after the close of fact discovery -- AGA served supplemental responses to several interrogatories, including Interrogatory No. 14. See Lawson Decl., Ex. A (supplemental interrogatory responses).

On January 20, 2009, consistent with Judge Chesney's order, AGA filed and served its amended answer. See Docket No. 208 (amended answer).

On January 23, 2009, AGA served the expert reports now being challenged. See Yang Decl., Exs. 1-4 (expert reports). On February 4, 2009, Medtronic filed the currently pending motion to strike portions of those expert reports.

Expert discovery closed two days after the hearing on the motion to strike (i.e., on February 27, 2009). See Docket No. 133 (order).

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### II. **DISCUSSION**

# Inequitable Conduct Defense (Duerig and Goffney Reports)

Medtronic argues first that certain portions of the Duerig and Goffney reports should be stricken because, although AGA included an inequitable defense in its original answer filed on April 4, 2007, and maintained an inequitable defense in its amended answer filed on January 20, 2009, AGA made no mention of an inequitable conduct based on the actions of Mr. Peterson specifically (an attorney involved with the prosecution of the '852 application), as opposed to Dr. Middleman (an individual involved with the prosecution of the '291 application), until these expert reports were served on January 23, 2009. This request to strike is denied.

Although what is formally before the Court is Medtronic's motion to strike, the situation here may be more aptly characterized in substance as an attempt by AGA to amend its operative answer so as to include additional allegations of inequitable conduct, which, under Federal Rule of Civil Procedure 9(b), must be pled with specificity. So characterized, motions for leave to amend are governed by Federal Rule of Civil Procedure 15(a), which provides in relevant part that leave to amend should be freely given when justice so requires. See Fed. R. Civ. P. 15(a). "Four factors are commonly used to determine the propriety of a motion for leave to amend. These are: bad faith, undue delay, prejudice to the opposing party, and futility of amendment." Ditto v. McCurdy, 510 F.3d 1070, 1079 (9th Cir. 2007). "Delay alone is insufficient to justify denial of leave to amend; the party opposing amendment must also show that the amendment sought is futile, in bad faith or will cause undue prejudice to the opposing party." *Jones v. Bates*, 127 F.3d 839, 847 n.8 (9th Cir. 1997).

In the instant case, the Court acknowledges that, in mid-November 2008, AGA sought leave to amend its original answer to include allegations of additional instances of inequitable conduct. That proposed amended answer – as well as the amended answer actually filed on January 20, 2009, after Judge Chesney granted leave to amend – did not include any allegations about inequitable conduct based specifically on the actions of Mr. Peterson (as opposed to Dr. Middleman). However, AGA has adequately explained why it did not include any such allegations in its proposed and subsequently filed amended answer, or in its response to Interrogatory No. 14 (first provided on November 7, 2008 and then supplemented on December 30, 2008). AGA did not obtain documents

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supporting the particular inequitable conduct allegations involving Mr. Peterson until December 2008, when they were provided by a third party, and AGA was not in a position to show Dr. Duerig the documents until the third party consented to their disclosure, which took place on January 19, 2009. See Hemminger Decl. ¶ 2. At the hearing, Medtronic argued that AGA did not need to have an expert look at the documents in order to know that it had an inequitable conduct defense based on the conduct of Mr. Peterson, but that is not evident from the record. See Yang Decl., Ex. 1 (Duerig Report ¶¶ 125-31). Furthermore, the delay in having Dr. Duerig examine the late produced documents was not substantial.

Moreover, even if there were some undue delay on the part of AGA, Medtronic has failed to establish that it would suffer any prejudice if the operative answer were amended to include allegations of inequitable conduct based on the conduct of Mr. Peterson. Tellingly, at the hearing on the motion to strike, Medtronic stated that the issue here was not one of notice but rather one of pleading. One would expect that, if prejudice were a real concern, then Medtronic would not have given up an argument based on notice. Furthermore, Medtronic does not make any contention that it was not prepared from a factual standpoint to contest the inequitable conduct defense based on the actions of Mr. Peterson. Thus, Medtronic's contention that it was prejudiced because it had only two weeks to prepare a rebuttal report is not persuasive.

Finally, the Court notes that at no point did Medtronic ever object to AGA's answer as insufficient for purposes of Rule 9(b). See Davsko v. Golden Harvest Prods., Inc., 965 F. Supp. 1467, 1474 (D. Kan. 1997).

Accordingly, for the foregoing reasons, the Court denies the motion to strike the portions of the Duerig and Goffney reports at issue herein.

## В. Cragg I Reference (Duerig Report)

Medtronic argues next that portions of Dr. Duerig's report which refer to the Cragg I reference should be stricken because Dr. Duerig relied on the reference to support invalidity under 35 U.S.C. § 102(g) (covering invalidity based on prior invention by another) but the reference was not disclosed as prior art under § 102(g) in AGA's final or supplemental final invalidity contentions or responses to Interrogatory No. 14. This request to strike is denied.

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The issue is, in essence, moot. AGA has disavowed any reliance on the Cragg I reference as a basis for invalidity under § 102(g). It is using the Cragg I reference to establish obviousness under 35 U.S.C. § 103. To the extent Medtronic has expressed concern that AGA will rely on new combinations involving the Cragg I reference not previously identified in its final or supplemental final invalidity contentions, AGA represented at the hearing that it would limit its positions in this litigation to the combinations identified in its final or supplemental final invalidity contentions. See, e.g., Yang Decl., Ex. 12 (supplemental final invalidity contentions).

### C. Combinations of Cragg I, Miyazaki, and Hughes References (Duerig Report)

Medtronic contends that portions of Dr. Duerig's report should be stricken to the extent it is based on new and substantially different combinations that were not specifically identified in AGA's final or supplemental final invalidity contentions. As noted above, this issue is now moot because AGA represented at the hearing that it would limit its positions in this litigation to the combinations identified in its final or supplemental final invalidity contentions. Thus, Medtronic's request to strike is denied as moot.

### D. **Hughes Reference (Bhattacharya Report)**

Medtronic asserts that portions of the Bhattacharya report that discuss the Hughes reference should be stricken because they include an opinion not expressed in AGA's final or supplemental final invalidity contentions, or in its response to Interrogatory No. 14 - i.e., "that the Hughes reference is anticipatory prior art [that] meets every claim limitation." Mot. at 9. In response, AGA asserts that Medtronic has misread the Bhattacharya report. See Opp'n at 10, 16-18. According to AGA, "both AGA and Prof. Bhattacharya do not contend that Hughes is anticipatory prior art, so long as Medtronic pays heed to the Court's claim constructions as to the breadth of the claims." Opp'n at 16 (emphasis added). "Because the Court did not consider stress-induced martensite to be equivalent to thermally-induced martensite, AGA honored the Court's claim construction and omitted Hughes from its invalidity contentions as anticipatory prior art (though Hughes was included as a reference for invalidity due to obviousness)." Opp'n at 18.

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As reflected by the above, AGA is essentially reserving the right to advance a contention that is contingent upon the position taken by Medtronic. The issue here is whether Patent Local Rule<sup>1</sup> 3-3 requires a party to assert a claim of invalidity which is only conditional and contingent on the opposing party's position. Neither party has cited the Court to any authority directly on point. In the absence of such authority, the Court concludes that Rule 3-3 does not require such at least in this case where the contingency is allegedly not clearly anticipated by the Court's claim construction. This conclusion is consistent with Patent Local Rule 3-6, which contemplates that changes to an accused infringer's invalidity contentions may be made under certain circumstances: e.g., the presiding judge's claim construction or for good cause. In short, the contingent contentions in this case are better addressed under Rule 3-6 rather than 3-3. Accordingly, Medtronic's request to strike under Rule 3-3 is denied.

# Obviousness Type Double Patenting Defense (Duerig Report)

An inventor is allowed only one patent for one invention because, "[i]f more than one patent could be obtained on the same invention, an inventor could extend the period of exclusivity that a patent is supposed to provide." Alan L. Durham, Patent Law Essentials 112 (1999). Accordingly, "a claim can be held unpatentable or invalid if it duplicates the subject matter of a claim in an earlier patent to the same inventor. This is referred to as 'double patenting.' Double patenting can also be found where the claims are attributable to different 'inventive entities' but are owned by a common assignee." Id.

There are two different kinds of double patenting: same invention double patenting ("SIDP") and obviousness-type double patenting ("OTDP"). SIDP "means that the later claim is identical in scope to the earlier claim." Id. OTDP "means that the later claim, though not identical, is only an 'obvious variation' of the earlier claim." *Id.* SIDP is covered by 35 U.S.C. § 101. OTDP has its roots based in § 101 but is considered a nonstatutory defense. See Geneva Pharms., Inc. v. GSK, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003). AGA admits that the defense is nonstatutory. See Opp'n at 12 (stating that "OTDP is a judicially-created doctrine").

<sup>&</sup>lt;sup>1</sup> The Court refers to the Patent Local Rules in force for cases filed before March 1, 2008.

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Medtronic argues that because AGA, in its answer, referred only to statutory double patenting (i.e., SIDP) and not nonstatutory double patenting (i.e., OTDP), those portions of the Duerig report that refer to OTDP should be stricken. The Court agrees with Medtronic that, as a formal matter, AGA failed to give notice of OTDP in its answer. The answer referred only to § 101. See Docket No. 9 (Ans. ¶¶ 30-32).

However, the fact that AGA's answer did not specifically identify nonstatutory double patenting as a defense, in addition to statutory double patenting, did not cause any prejudice to Medtronic. Medtronic claims prejudice on the basis that, had it known about the OTDP defense at the outset of the case, it would have conducted discovery any differently from how discovery was actually conducted. But the Court finds this assertion unconvincing as a matter of fact. At the hearing, Medtronic admitted that the first interrogatory it propounded on any of the invalidity and unenforceability defenses was in October 2008 (i.e., Interrogatory No. 14). Nothing indicates it would have propounded discovery any earlier had OTDP been specifically pled.

Moreover, as discussed above, Federal Rule of Civil Procedure 15(a) provides that leave to amend should be freely given when justice so requires. See Fed. R. Civ. P. 15(a). Medtronic was put on notice of the OTDP defense in AGA's response to Interrogatory No. 14, served in November 2008, which stated in relevant part that "the '141 patent is invalid on the basis of statutory and/or obviousness-type double patenting over US Patent No. 4,665,896 and/or US Patent No. 5,067,957." Yang Decl., Ex. 6 (interrogatory responses). While, in its response, AGA mistakenly referred to the '896 patent instead of the '387 patent, that was an obvious error – a fact that Medtronic admitted in its papers as well as at the hearing. See Mot. at 11 n.9 (admitting that the '896 patent has no connection at all to the inventor Jervis, in contrast to the '378 patent and the '957 patent). Given the obviousness of the error, the Court is not persuaded that Medtronic was free to ignore the error simply because AGA has the burden of proving its affirmative defense. Medtronic chose to sit on its rights rather than seeking to discover the basis of the actual OTDP defense. Having failed to exercise its own reasonable diligence, it is in no position to claim undue prejudice. Guided by the factors applicable under Rule 15(a), the Court denies the request to strike.

# For the Northern District of California

# F. Best Mode Defense (Duerig Report)

Medtronic contends that portions of the Duerig report that refer to a best mode defense should be stricken because, although AGA did refer to 35 U.S.C. § 112<sup>2</sup> in its answer, it never made clear that it was making a best mode defense (as opposed to, *e.g.*, a defense based on indefiniteness or enablement) until after the close of discovery, when it supplemented its response to Interrogatory No. 14. *See* Lawson Decl., Ex. A (supplemental interrogatory responses). AGA made no reference to a best mode defense in its original response to Interrogatory No. 14, which was served on November 7, 2008 -- prior to the close of discovery. *See* Yang Decl., Ex. 6 (interrogatory responses). This request to strike is granted.

The parties agree the best mode defense need not be specifically pled. Nor do the Patent Local Rules require a detailed description of the defense as part of invalidity contentions. *Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431 SBA, 2006 U.S. Dist. LEXIS 90856, at \*15-16 (N.D. Cal. May 15, 2006) (noting that "Patent Local Rule 3-3(d), which governs the disclosure of invalidity contentions based on 35 U.S.C. § 112, only requires disclosure of indefiniteness, enablement, or written description defenses"). However, AGA did not specify and detail this defense in its initial response to Medtronic's interrogatory prior to close of discovery. It should have.

Accordingly, the situation here is analogous to a motion for sanctions, pursuant to Federal Rule of Civil Procedure 37(c)(1), for a failure to disclose timely in response to a valid discovery request. *See Schiller v. City of New York*, No. 04 Civ. 7921 (RJS) (JCF), 2008 U.S. Dist. LEXIS 79620, at \*16 (S.D.N.Y. Oct. 9, 2008) (stating that "[t]here is no doubt that the defendants breached their Rule 26 discovery obligations either by failing to disclose fully at the outset [names of witnesses] or by subsequently failing to supplement in a timely manner" and that, "[e]ither way, the defendants' actions trigger sanctions under Rule 37(c)"). Under Rule 37(c)(1), for such a failure,

<sup>&</sup>lt;sup>2</sup> Section 112 provides: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112.

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preclusion-type sanctions may be issued, see Fed. R. Civ. P. 37(c)(1)(C) (referring to, inter alia, sanctions provided for by Rule 37(b)(2)(A)(ii)-(iii)), unless the party who failed to disclose or timely supplement can establish either that the failure was substantially justified or that the failure to act is harmless. See Fed. R. Civ. P. 37(c)(1); see also Nguyen v. IBP, Inc., 162 F.R.D. 675, 680 (D. Kan. 1995) (stating that "[t]he burden of establishing substantial justification and harmlessness is upon the party who is claimed to have failed to make the required disclosure.").

In the instant case, AGA has failed to show either substantial justification or harmlessness. As to justification, AGA claimed at the hearing that it did not include any information about a best mode defense until its supplemental interrogatory responses because it was only then that fact depositions had taken place, which were necessary in order to flesh out the defense. But AGA has failed to demonstrate why it was not possible, at the time that it served its original response to Interrogatory No. 14, to provide at least its good faith factual basis for asserting the best mode defense, consistent with Federal Rule of Civil Procedure 11. It is not excusable to say nothing until after close of discovery.

As to harmlessness, AGA argued at the hearing that Medtronic knew from the fact depositions that took place in December 2008 that AGA was interested in the issue of best mode. However, as noted above, fact discovery – with the exception of depositions already noticed – closed on December 5, 2008. See Docket No. 133 (order) (providing that fact discovery, except for fact depositions already noticed, was to close on December 5, 2008). It is also too late for Medtronic to retain expert testimony on this issue. Thus, the motion to strike is granted.

### G. Underlying Information for Duerig, Bhattacharya, and Imbeni Reports

Finally, in its brief, Medtronic argued that the Duerig, Bhattacharya, and Imbeni reports should be stricken on the basis that AGA failed to timely provide the underlying information supporting the reports. At the hearing, however, Medtronic essentially stated that it was no longer pressing this argument, other than to note that AGA's conduct was not appropriate. Medtronic specifically stated that it did not want to engage in any additional discovery to cure the prejudice that it claimed it had suffered.

# **United States District Court**

# For the Northern District of California

## III. **CONCLUSION**

For the foregoing reasons, Medtronic's motion to strike is granted in part and denied in part. The Court emphasizes that it is only making rulings regarding the expert reports; it is not making any rulings as to whether, e.g., AGA should be permitted to amend its answer again or AGA should be precluded from asserting any defense.

This order disposes of Docket No. 238.

IT IS SO ORDERED.

Dated: March 2, 2009

EDWARD M. CHEN

United States Magistrate Judge