

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

MEDTRONIC, INC., et al.,

No. C-07-0567 MMC

Plaintiffs,

**ORDER GRANTING DEFENDANT'S
MOTION FOR LEAVE TO AMEND**

v.

AGA MEDICAL CORPORATION,

Defendant.

Before the Court is defendant AGA Medical Corporation's ("AGA") motion, filed March 18, 2009, for leave to amend its invalidity defense. Plaintiffs Medtronic, Inc., Medtronic USA, Inc., and Medtronic, Vascular, Inc. (collectively, "Medtronic") have filed opposition, to which AGA has replied. Having read and considered the papers filed in support of and in opposition to the motion, the Court deems the matter appropriate for decision thereon, hereby VACATES the hearing scheduled for April 24, 2009, and rules as follows.

BACKGROUND

The instant motion represents AGA's third request to amend its Answer and Counterclaims. Earlier, on November 14, 2008, AGA moved to amend its answer to add a defense of prosecution laches and to add further allegations in support of its defense of inequitable conduct. On December 17, 2008, the Court granted in part and denied in part that motion. (See Order filed Dec. 17, 2008.) On January 21, 2009, AGA moved for leave

1 to assert a false marking counterclaim. On February 18, 2009, the Court denied AGA's
2 motion. (See Order filed Feb. 19, 2009.)

3 By the instant motion, AGA seeks leave to add an affirmative defense alleging
4 United States Patent Number 6,306,141 (“141 patent”) is invalid on the ground of
5 obviousness type double patenting (“OTDP”) in view of United States Patents Numbers
6 5,067,957 (“957 patent”) and 5,597,378 (“378 patent”). OTDP is “a judicially created
7 doctrine grounded in public policy,” the purpose of which “is to prevent the extension of the
8 term of a patent, even where an express statutory basis for [] rejection is missing, by
9 prohibiting the issuance of the claims in a second patent not patentably distinct from the
10 claims of the first patent.” See In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985). The
11 doctrine “preclude[s] a second patent on an invention which would have been obvious from
12 the subject matter of the claims in the first patent, in light of the prior art.” See Ortho
13 Pharm. Corp. v. Smith, 959 F.2d 936, 940 (Fed. Cir. 1992) (internal quotation and citation
14 omitted). OTDP is an “exten[sion]” of “same invention” double patenting, which, pursuant
15 to 35 U.S.C. § 101, “precludes a patentee from obtaining more than one patent on the
16 same invention.” See id. (internal citation omitted); see also Longi, 759 F.2d at 892.

17 LEGAL STANDARD

18 Leave to amend should be freely given when justice so requires. See Fed. R. Civ.
19 P. 15(a)(2). “[F]our factors are commonly used” in determining whether leave to amend is
20 appropriate, specifically, “bad faith, undue delay, prejudice to the opposing party, and futility
21 of amendment.” See DCD Programs, Ltd. v. Leighton, 833 F.2d 183, 186 (9th Cir. 1987).
22 Another factor available for consideration here is whether a party has previously amended
23 its pleading. See id. at 186 n.3. The factors, however, “are not of equal weight in that
24 delay, by itself, is insufficient to justify denial of leave to amend,” see id., and “it is the
25 consideration of prejudice to the opposing party that carries the greatest weight,” see
26 Eminence Capital, LLC v. Aspeon, Inc., 316 F.3d 1048, 1052 (9th Cir. 2003); see also DCD
27 Programs, 833 F.2d at 187 (noting “[t]he party opposing amendment bears the burden of
28 showing prejudice”).

1 **DISCUSSION**

2 **A. Prejudice**

3 Medtronic contends it was not put on notice of AGA's OTDP defense until it received
4 the report of Dr. Thomas W. Duerig ("Duerig"), AGA's expert, on January 23, 2009, and
5 that it will be prejudiced by AGA's assertion of its OTDP defense at this time. Specifically,
6 Medtronic argues that (a) it cannot now engage an expert on the issue of OTDP, (b) it did
7 not have an opportunity to seek construction of the relevant claim terms of the '378 patent,
8 and (c) it cannot now move for summary judgment on AGA's OTDP defense. As set forth
9 below, the Court finds Medtronic's argument unpersuasive.

10 At the outset, the Court notes that AGA first pled the related defense of same
11 invention patenting in its original Answer and Counterclaims, filed April 4, 2007,¹ and that,
12 contrary to Medtronic's argument, Medtronic has been on notice of AGA's OTDP defense
13 since at least November 7, 2008, on which date AGA stated in an interrogatory response
14 that it contended "the '141 patent is invalid on the basis of statutory and/or obviousness
15 type double patenting over US Patent No. 4,655,896 and/or US Patent No. 5,067,957."
16 (See Hemminger Decl. Ex. C (Defendant's Responses and Objections to Plaintiffs' Fourth
17 Set of Interrogatories) at 13:17-20.) Although, as noted, AGA's first reference was to
18 United States Patent Number 4,655,896 ("896 patent") instead of the '378 patent,
19 Medtronic, at the February 25, 2009 hearing on Medtronic's Motion to Strike Portions of
20 AGA's Opening Expert Reports, admitted that it knew such reference was a mistake. (See
21 id. Ex. G (Transcript of Proceedings before Magistrate Judge Edward M. Chen) at 56:9-13.)
22 Rather than objecting to AGA's OTDP defense or seeking to discover the actual basis
23 therefor, Medtronic took no action to either oppose or clarify such defense until February 4,
24 2009, when it filed the above-referenced motion to strike, which motion sought to strike,

25
26 _____
27 ¹AGA states it did not move for leave to amend to assert the defense of OTDP at an
28 earlier date because it believed the allegations in its original Answer and Counterclaims
likewise sufficed to plead the defense of OTDP. Medtronic argues OTDP must be
separately pleaded as a defense. The Court, for the reasons set forth herein, need not
resolve this pleading question.

1 inter alia, the portion of Duerig's report dealing with AGA's OTDP defense.² Medtronic
2 does not assert that, in November 2008, it could not have engaged an expert to address
3 AGA's OTDP defense, nor does Medtronic assert that, at such time, it could not have
4 moved for an order construing any disputed terms contained in the '378 patent and/or for
5 summary judgment on AGA's OTDP defense.

6 Additionally, even assuming, arguendo, Medtronic was not put on notice of AGA's
7 OTDP defense until it received Duerig's expert report on January 23, 2009, Medtronic has
8 failed to demonstrate it will be prejudiced by the timing of AGA's proposed amendment. In
9 particular, Medtronic has failed to explain why, after January 23, 2009, one or more of the
10 experts it had already engaged could not opine on the issue of OTDP; as noted, Medtronic
11 has been aware of AGA's related defense of same invention double patenting since April
12 2007.³ Further, Medtronic has failed to point to any claim term used in the '378 patent that,
13 according to Medtronic, requires construction by the Court, nor has Medtronic identified a
14 ground upon which it would be entitled to summary judgment with respect to AGA's OTDP
15 defense.⁴

16 Accordingly, Medtronic has failed to show it will be prejudiced by the assertion of
17 AGA's OTDP defense.

18 **B. Futility**

19 Medtronic further argues that AGA's proposed amendment to add an OTDP defense
20

21 ²On March 2, 2009, Magistrate Judge Chen denied Medtronic's request to strike this
22 portion of Duerig's report. (See Hemminger Decl. Ex. J (Order Granting in Part and
23 Denying in Part Plaintiffs' Motion to Strike Portions of Defendant's Opening Expert Reports)
at 7.)

24 ³The Court further notes that Duerig, AGA's expert as to OTDP, was not engaged
25 solely with respect to that issue, but, rather, has also offered opinions on numerous other
26 topics. (See generally Decl. Dr. Thomas W. Duerig in Supp. AGA's Opp'n to Medtronic's
27 Mots. Summ. J.)

28 ⁴As discussed, infra, Medtronic does argue the proposed amendment is futile based
on the "the 'safe harbor' provision" (see Opp'n at 17:2) of 35 U.S.C. § 121. If Medtronic
believes it is able to make, based on such ground, a sufficient showing to preclude
introduction of evidence on AGA's OTDP defense, Medtronic may make that showing in the
context of a motion in limine.

1 is futile, on the ground the defense is precluded by “the ‘safe harbor’ provision” (see Opp’n
2 at 17:2) of 35 U.S.C. § 121. Section 121 provides, in relevant part:

3 If two or more independent and distinct inventions are claimed in one application, the
4 Director may require the application to be restricted to one of the inventions. . . . A
5 patent issuing on an application with respect to which a requirement for restriction
6 under this section has been made, or on an application filed as a result of such a
7 requirement, shall not be used as a reference either in the Patent and Trademark
8 Office or in the courts against a divisional application or against the original
9 application or any patent issued on either of them, if the divisional application is filed
10 before the issuance of the patent on the other application.

11 See 35 U.S.C. § 121.

12 Medtronic contends the ‘141 patent is “a divisional patent with claims that were
13 restricted out of the ‘378 patent application” and, consequently, that “the claims of the ‘141
14 patent-in-suit are shielded by § 121’s ‘safe harbor’ from any double patenting defense
15 based on the ‘378 patent.” (See Opp’n at 18:26-19:1.) As AGA points out, however,
16 although Medtronic has presented evidence that a restriction requirement was issued
17 during the prosecution of the ‘378 patent (see Walsh-Benson Decl. Ex. 7 at 2-3), Medtronic
18 has failed to show the asserted claims of the ‘141 patent were the subject of that restriction,
19 see Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1379 (Fed. Cir. 2003)
20 (holding, under § 121, “the earlier application must contain formally entered claims that are
21 restricted and removed, and that claims to the second invention reappear in a separate
22 divisional application after the restriction”); id. at 1381 (placing burden on party seeking to
23 invoke § 121 to show statute applies); see also Miller v. Rykoff-Sexton, Inc., 845 F.2d 209,
24 214 (9th Cir. 1988) (holding “a proposed amendment is futile only if no set of facts can be
25 proved under the amendment to the pleadings that would constitute a valid and sufficient
26 claim or defense”).

27 Accordingly, Medtronic has failed to show AGA’s proposed amendment to add an
28 OTDP defense is futile.⁵

26 ⁵Because Medtronic has failed to show AGA’s proposed amendment will prejudice
27 Medtronic or that the amendment is futile, the Court does not reach Medtronic’s argument
28 that AGA unduly delayed in seeking leave to amend. See DCD Programs, Ltd., 833 F.2d at
186 (noting “delay, by itself, is insufficient to justify denial of leave to amend”); see also
Camarillo v. McCarthy, 998 F.2d 638, 639 (9th Cir. 1993) (noting “[i]n the absence of a

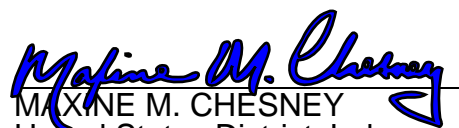
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

CONCLUSION

For the reasons stated above, AGA's motion for leave to amend is hereby GRANTED. AGA's Second Amended Answer and Counterclaims shall be filed no later than May 1, 2009.

IT IS SO ORDERED.

Dated: April 21, 2009


MAXINE M. CHESNEY
United States District Judge

showing of prejudice [], an affirmative defense may be raised for the first time at summary judgment"). Additionally, although a district court's discretion over amendments is "particularly broad" where the court has already given a party one or more opportunities to amend its pleading, see DCD Programs, 833 F.2d at 186 n.3, Medtronic has cited no authority, and the Court is aware of none, suggesting such prior amendment may justify denial of leave to amend where there is no showing of either prejudice or futility.