

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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INTELIFUSE, INC.,

Plaintiff and Counterclaim-Defendant,

-v-

No. 05 Civ. 8093 (LTS)(DFE)

BIOMEDICAL ENTERPRISES, INC.,

Defendant and Counterclaim-Plaintiff.

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OPINION AND ORDER

Plaintiff and Counterclaim-Defendant InteliFUSE, Inc. (“Plaintiff” or “IFUSE”) brings this action against Defendant and Counterclaim-Plaintiff Biomedical Enterprises, Inc. (“Defendant” or “BME”), alleging infringement of U.S. Patent No. 6,268,589 (the “‘589 Patent”) and U.S. Patent No. 6,323,461 (the “‘461 Patent”) (collectively, the “Patents”). Defendant has asserted a Counterclaim for Declaratory Judgment alleging that it is not infringing, and has not infringed, either the ‘589 or ‘461 Patent, and that the claims of the ‘589 and ‘461 Patents are invalid. The Court has jurisdiction of the instant claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

BME has moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure, asserting that the ‘461 Patent is invalid for certain reasons and that both the ‘589 and ‘461 Patents are unenforceable due to the allegedly inequitable conduct of the Patents’ inventor. The Court has reviewed thoroughly all of the parties’ submissions and, for the reasons explained below, Defendant’s motion for summary judgment is denied.

BACKGROUND

The following material facts are undisputed unless otherwise indicated.¹ The ‘589 Patent was issued on July 31, 2001, from United States Patent Application Serial No. 09/462,862, filed with the United States Patent and Trademark Office (“PTO”) on January 14, 2000. (Def. 56.1 St. ¶¶ 6-7). The ‘461 Patent issued on November 27, 2001, from United States Patent Application Serial No. 09/820,411, filed on March 29, 2001. (Id. at ¶¶ 9-10). As issued, the ‘589 Patent included 23 claims that were directed to a device for heating and thereby closing heat-retractable shape memory clamps. (Id. at ¶ 8.) The ‘461 Patent included 65 claims, with claims 1-50 directed to a heat-retractable shape memory clamp and claims 51-65 directed to a method for closing a heat-retractable shape memory clamp. (Id. at ¶ 11.) The shape memory clamps (staples) in the ‘461 Patent are referred to as “Memograph staples.” (Id. at ¶ 13.) The apparatus used to heat the Memograph staples in the ‘589 Patent is referred to as the “Warmssystem” device. (Id. at ¶¶ 13-14.)

The named inventor for each of the patents-in-suit is Dr. Francis Flot (“Flot”) who is now deceased. (Id. at ¶ 2.) Flot assigned his rights in the ‘589 and ‘461 Patents to M.B.A., S.A. (“MBA”), the company that he had founded and presided over during the prosecution of the patents-in-suit. (Id. at ¶¶ 3-4.) The ‘589 Patent application was prosecuted on behalf of MBA by Mr. Gary Cohen (“Cohen”), a patent attorney. (Id. at ¶ 22.) IFUSE is the current owner of the patents-in-suit. (Pl. 56.1 St. ¶ 5.)

¹ Citations to the parties’ respective S.D.N.Y. Local Civil Rule 56.1 statements (“__ 56.1 St.”) incorporate by reference citations to the underlying evidentiary submissions.

The '589 Patent Prosecution History

On September 12, 2000, during the prosecution of the '589 Patent application, the PTO Examiner issued an Office Action that rejected then-pending claims 1-5 and 7-10, pursuant to 35 U.S.C. § 102, as being anticipated by United States Patent Serial No. 3,868,956 issued to Alfidi et al. (“the Alfidi Patent”), and rejected then-pending claims 1-3, 7-8, and 10 as being anticipated by United States Patent Serial No. 4,485,816 issued to Krumme (“the Krumme Patent”). (Def. 56.1 St. ¶ 23.) In response, Cohen submitted to the PTO a Reply to Office Action on January 12, 2001, in which he cancelled all 12 of the then-pending claims for the '589 Patent and added 30 new claims (numbered as Claims 13-42), which included the 23 claims that were ultimately allowed following certain amendments made by the Examiner. (Id. at ¶¶ 24-25.) Cohen argued for the patentability of the 30 new claims, distinguishing them from the Alfidi and Krumme Patents as follows:

In Alfidi et al. . . . there is no automatic determination or regulation of the suitable amount of heat to be applied to the appliance, to automatically regulate (control) the amount of heat applied by the heating apparatus for reasons of safety . . . The automated apparatus recited in applicant’s claims operates to avoid this potential for damage.

[In] Krumme . . . no controls are provided for regulating the amount of heat which is supplied. Control of the apparatus appears to be left solely to the best judgment of the user. Thus, there is no automatic determination or regulation of the suitable amount of heat to be applied to the staples, to automatically regulate (control) the amount of heat applied by the heating apparatus for reasons of safety.

(Pl. 56.1 St. ¶ 25). Two of the new claims added to the '589 Patent application were independent claims 13 and 31, each of which specified “[a] device for heating and closing heat-retractable shape memory clamps . . . wherein the electronic power and control circuit operates to automatically deliver one of a plurality of different and predetermined quantities of heat to the clamps using the heating unit.” (Def. 56.1 St. ¶ 28) (emphasis added). On March 8, 2001, the

Examiner and Cohen discussed during a phone interview, inter alia, whether the phrase “automatically deliver,” as used in the then newly-added claims 13 and 31, was “new matter” to the ‘589 application. (Id. at ¶¶ 29-31; Pl. 56.1 St. ¶ 31.) The substance of this interview was not entered into the public record of the prosecution of the ‘589 Patent application. (Pl. 56.1 St. ¶ 31.)

In his notes of the interview Cohen wrote that, with respect to claim 13, “‘automatically delivers’ is new matter.” (Declaration of Richard B. Martin (“Martin Decl.”), Ex. I.) Cohen testified in his deposition in this action that, during their conversation, the Examiner had characterized “automatically delivers” as new matter and was inclined to issue the ‘589 Patent if Cohen agreed to remove “automatically” from the phrase “automatically delivers.” (Martin Decl., Ex. J, Cohen Depo., at 164:12-165:14.) MBA did not appeal the Examiner’s position that “automatically deliver” was new matter.² The Examiner reached an agreement with Mr. Cohen by which Mr. Cohen approved amending the “automatically deliver” limitation in claims 13 and 31 so as to delete the word “automatically” and use only the term “deliver.” (Def. 56.1 St. ¶ 33.) The Examiner approved amending these claims to add the limitation “an automatic cut-out circuit coupled with the adjustment circuit.” (Id.) Cohen testified that he agreed to the changes in order to place the application in condition for allowance. (Pl. 56.1 St. ¶ 36.) As amended, claims 13 and 31 of the ‘589 Patent application issued as claims 1 and 13, respectively, of the ‘589 Patent. (Def. 56.1 St. ¶ 37.)

² BME contends that MBA failed to exercise its right to appeal. IFUSE contends that an appeal was neither necessary nor possible because the Examiner never made an explicit written rejection of the amended claims on the basis of new matter. (See Def. 56.1 St. ¶ 41, Pl. 56.1 St. ¶ 41.)

The exact phrase “automatically deliver” is not found within the original claims and specifications of the ‘589 Patent application or Claims 1 and 13 of the ‘589 Patent. (Id. at ¶¶ 38-39.) However, IFUSE proffers expert testimony that, from the text of the ‘589 Patent application and the ‘461 Patent, and in the context of this Court’s claim constructions (see Memorandum Order Following Markman Hearing (docket entry no. 48)), the specification and some of the original claims of the ‘589 Patent application did recite elements and features, such as the “automatic cut-out circuit,” which describe and support the disputed subject matter claimed in Claims 1, 30 and 51 of the ‘461 patent, namely that a quantity of heat is “automatically deliver[ed].” (See Declaration of Cedric Walker (“Walker Decl.”) at ¶¶ 3-4, 6-7, 9-17.)

The ‘461 Patent Prosecution History

On March 29, 2001, three weeks after the March 8, 2001, telephone interview with the Examiner regarding the use of “automatically delivers” in the ‘589 Patent application, Cohen, on behalf of MBA, filed the application that ultimately issued as the ‘461 Patent on November 27, 2001. (Def. 56.1 St. ¶ 42.) The ‘461 Patent application was filed as a “divisional” of the ‘589 Patent application and was examined by the same PTO Examiner who reviewed the ‘589 Patent application. (Id. at ¶¶ 43-44.) On July, 17, 2001, the Examiner allowed all of the pending claims in the ‘461 Patent application, without issuing any office action on the merits. (Id. at ¶ 56). The ‘461 Patent application contained new information that was not found in the ‘589 Patent application. (Id. at ¶ 45.) The originally-filed claims of the ‘461 Patent application included independent Claims 1, 30, and 51, which contain limitations having either the phrase “automatically deliver” (claims 1 and 30) or the phrase “automatically delivering” (claim 51).

(Id. at ¶ 48.) The remaining claims of the ‘461 Patent directly or indirectly depend on one of the independent claims 1, 30, and 51. (Id. at ¶ 50.)

Independent claims 1, 30, and 51 read as follows:

1. A heat-retractable shape memory clamp used in surgery applications which is closed with a device for heating and closing the heat-retractable shape memory clamp . . . wherein the device includes a unit containing an electronic power and control circuit supplied with line current which is coupled with a heating unit . . . and wherein the electronic power and control circuit operates to automatically deliver one of a plurality of different and predetermined quantities of heat to the clamp using the heating unit.
30. A heat-retractable shape memory clamp used in surgery applications . . . wherein the electronic power and control circuit operates to automatically deliver to the clamp, using the heating unit, a predetermined quantity of heat which is determined by said one of the plurality of settings of the device which is matched to the clamp.
51. A method for closing a heat-retractable shape memory clamp in a surgery application using a device for heating and closing the heat-retractable shape memory clamp, wherein the device includes an electronic power and control circuit supplied with line current which is coupled with a heating unit, and wherein the method comprises steps of: . . . automatically delivering to the clamp, using the heating unit, a predetermined quantity of heat produced responsive to the electronic power and control circuit and determined by the selected setting.

(Def. 56.1 St. ¶ 49) (emphasis added). In drafting the disclosure included in the ‘461 Patent application, Cohen added to the original disclosure of the parent ‘589 Patent the following sentence, which was not found in the ‘589 Patent application: “The electronic power and control circuit then operates to automatically determine and regulate the suitable amount of heat which is applied to each clamp.” (Id. at ¶ 51.)

Prior Sales and Public Use

_____ BME alleges the following facts, which are disputed in part by IFUSE, to support its assertion that sales and public use activity occurred more than a year before the operative date

of the '461 application. On April 2, 1999, MBA shipped to BME an operable Warmssystem device and three demonstration Memograph staples. (Id. at ¶ 60.) Dr. Casey Fox (“Fox”), the Chief Executive Officer and Chief Technology Officer of BME, testified that these items were personally provided by Flot to BME. (Id.) In this shipment, MBA further provided BME with twenty brochures and one sales manual (each concerning the Warmssystem device and Memograph staples) and four copies of a video that demonstrated the use of the Warmssystem device and Memograph staples. (Id. at ¶ 61.) A cover letter accompanying the shipment states: “This shipment contains only [demonstration] material for exhibition meeting only.” (Martin Decl., Ex. O-4.) On April 26-28, 1999, BME displayed and demonstrated the Warmssystem device and Memograph staples at the 1999 American Association of Neurological Surgeons meeting (the “1999 AANS meeting”) in New Orleans, Louisiana. (Def. 56.1 St. ¶¶ 68-70.) BME also allowed neurosurgeons attending the conference to use the Warmssystem device to compress Memograph staples. (Id. ¶ 71.)

On March 15, 2000, BME and MBA entered into a Sales and Distribution Licensing Agreement (“the Sales Agreement”) the subject of which was MBA’s Warmssystem devices and Memograph staples. (Def. 56.1 St. ¶¶ 12, 15.) In the Sales Agreement, MBA represented itself as “the author of the patent applications pending in France and the United States relating to the [Memograph] staple and Warmssystem devices.” (Def. 56.1 St. ¶ 16.) The Sales Agreement set forth the terms and conditions of the commercial agreement between MBA and BME; bound both MBA and BME for a five-year term; and included, inter alia, the price of the Memograph staples and Warmssystem devices, the method of delivery, the warranty, and the method of payment. (Id. ¶ 59.)

Prior to executing the Sales Agreement, Flot furnished BME with an operable Warmssystem device and samples of Memograph staples. (Id. ¶¶ 74-75.) The Warmssystem device and Memograph staples received by BME were fully functional and intended for BME’s use at the 2000 American Association of Orthopedic Surgeons meeting (the “AAOS meeting”) in Orlando, Florida. (Id. at ¶ 76.) Between March 15 and March 17, 2000, in BME’s exhibit booth at the AAOS meeting, BME openly used the Warmssystem device to compress Memograph staples in demonstrations, allowed surgeons in attendance to personally use the Warmssystem device to close particular Memograph staples, and continuously displayed a video demonstrating the use of the Warmssystem device to close particular Memograph staples. (Id. at ¶¶ 82-84, 86.) Both the 1999 AANS meeting and the 2000 AAOS meeting were open to the public, provided attendees paid an admission fee. (Id. at ¶ 88.) During prosecution of the patents-in-suit, Cohen asked Flot, through a French patent agent for Flot and MBA (Cabinet Michael Poupon), to provide him with the date on which MBA had first supplied BME with Memograph staples in order to assess the patentability of the ‘589 and ‘461 Patent applications. (Id. at ¶ 126; Pl. 56.1 St. at ¶ 126.) In response, Poupon issued a response that “the first delivery of MBA staples took place around May 2000.” (Def. 56.1 St. ¶ 127.)

The Beynet Thesis

Around June 1994, Patrick Beynet (“Beynet”) authored an academic thesis (“the Beynet Thesis”) for his masters degree in mechanical engineering at the University of Nancy, in Nancy, France (id. at ¶ 89), titled “Production of a Fracture-Reducing Staple using TiNi Shape-

Memory Alloys.”³ (Martin Decl., Exs. W, W-1.) The Beynet Thesis is a printed publication that has been available to the general public since 1994. (Id., Ex. W.) The Beynet Thesis considers the use of shape memory staples made of nickel alloy and contemplates a “tool [that] must be able to permit the surgeon to place the staple easily without possibility of error . . . [and that] must satisfy technological demands such as the rise in temperature.” (Id. at ¶ 92.)

Flot was aware of the Beynet Thesis from the time it was written: he was Beynet’s surgical advisor; he provided Beynet with answers to questions about the use of the shape memory staples in patients; and his name appears on the Beynet Thesis’ cover page. (Def. 56.1 St. ¶¶ 94-95.) Beynet testified that Flot had asked him questions about the Beynet Thesis while Beynet researched and wrote it and that Flot continued to ask questions about the heating device for a month after the thesis was completed. (Id. at ¶ 96.) Around 1996, excerpts of the Beynet Thesis appeared in a document published under the names of P. Diebold, P. Beynet, and F. Flot, entitled “The New Use of Shape Memory Staple in Foot Surgery” (the “Flot paper”). (Id. at ¶ 98.) BME asserts that the Flot paper described a clinical study using the Warmsystem device and Memograph staples and that Flot provided a copy of this document to BME. (Id. at ¶ 99.)

In 1998, MBA utilized documents referencing the Beynet Thesis to obtain Conformité Européenne (“CE”) certification for its Memograph staples, a credential required for the sale of devices in the European Community. (Def. 56.1 St. ¶¶ 101-02.) These documents were specifically relied upon in the Checklist of Compliance with Essential Requirements of

³ Beynet wrote the thesis in French and the Court has been provided with an English- language translation. (Martin Decl., Ex. M-3.) IFUSE contends that the actual English-language title of the Beynet Thesis is “Mechanics of Fluids and Thermal Energy.” (Pl. 56.1 St. ¶ 89.) Determination of the proper English-language title is not necessary to resolve the instant motion.

Medical Devices Directive 93/42/EEC, under sections concerned with design and manufacturing methods to ensure patient safety; minimizing the risk associated with exposure to external electrical influences, electrostatic discharge, pressure or temperature; and addressing risk arising where maintenance and calibration are not possible. (Id. at ¶ 105.) Fox testified that, during the time that Flot was seeking to enter into the Sales Agreement with BME, Flot provided a portion of the English-language translation of the Beynet Thesis to BME and told Fox that the Beynet Thesis was “the basic design input document concerning the Warmssystem device and Memograph staples.” (Id. at ¶ 110.) Fox also testified that Flot indicated that BME should utilize the Beynet Thesis and other technical documents as support for the filing of the premarket notification with the Food and Drug Administration (“FDA”), for European CE and Underwriters Laboratories (“UL”) certifications, and for quality system development efforts. (Id. at ¶ 113.) BME used these technical documents, including the Beynet Thesis, to obtain FDA approval, European CE certification, and UL certification. (Def. 56.1 St. ¶ 116.)

During the prosecution of the ‘589 Patent application and the ‘461 Patent application, neither Flot nor anyone else provided the Beynet Thesis to Cohen or the PTO. (Id. at ¶¶ 123-24.) In connection with the filing of both patent applications, Flot signed a “Combined Declaration for Patent Application and Power of Attorney” in which he acknowledged his duty of disclosure as required by 37 C.F.R. § 1.56. (Id. at ¶ 125.)

DISCUSSION

Summary judgment is to be granted in favor of a moving party where the “pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears

the burden of establishing that there is no genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). A fact is considered material “if it ‘might affect the outcome of the suit under the governing law,’” and an issue of fact is a genuine one where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” Holtz v. Rockefeller & Co. Inc., 258 F.3d 62, 69 (2d Cir. 2001) (quoting Anderson, 477 U.S. at 248). The Second Circuit has explained, however, that “[t]he party against whom summary judgment is sought . . . ‘must do more than simply show that there is some metaphysical doubt as to the material facts. . . . [T]he nonmoving party must come forward with specific facts showing that there is a genuine issue for trial.’” Caldarola v. Calabrese, 298 F.3d 156, 160 (2d Cir. 2002) (quoting Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986)).

The patent challenger bears the burden of proving that a patent is invalid or unenforceable. 35 U.S.C. § 282; Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1569-70 (Fed. Cir. 1987) (invalidity); Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001) (unenforceability). With respect to challenges of invalidity and unenforceability, the burden is one of clear and convincing evidence. See, e.g., Buildex Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1463 (Fed. Cir. 1988) (invalidity); Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362 (Fed. Cir. 2003) (unenforceability due to inequitable conduct). “[I]n ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254 (1986). BME must thus present clear and convincing evidence that establishes prima facie cases of invalidity and inequitable conduct. If BME satisfies this burden, IFUSE must come forward with competent evidence that demonstrates the existence of one or more genuine issues of material fact to defeat BME’s summary judgment motion. Id. at 256.

Validity of the '461 Patent

BME's argument for the invalidity of the '461 Patent depends on a predicate determination of the operative filing date. 35 U.S.C. § 102(b) provides that an applicant is entitled to a patent unless "the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C.A. § 102(b) (West 2001). The prior use and sales activities alleged by BME to establish the invalidity of the claims of the '461 Patent occurred less than one year before January 14, 2000 (the filing date of the '589 Patent application) but more than one year before March 29, 2001 (the actual filing date of the '461 Patent application). The parties dispute whether the '461 Patent, which was filed as a "divisional" of the '589 Patent application, is entitled to the earlier filing date of the '589 Patent application or to its actual filing date.

BME asserts that the '461 Patent is only entitled to the March 29, 2001, filing date rather than the earlier January 14, 2000, filing date of the '589 application. A patent application will be entitled to the filing date of an earlier-filed application if it fulfills four requirements: (1) the application must have been filed before the earlier application issued to patent; (2) the application has an inventor in common with the earlier-filed application; (3) the application has a specific reference to the earlier application; and (4) the application is "disclosed in the manner provided for by the first paragraph of section 112 of this title in an application previously filed in the United States." 35 U.S.C.A. § 120 (West 2001). BME does not dispute that the first three of these requirements have been fulfilled.⁴ BME asserts that IFUSE is estopped from arguing that it

⁴ The record indicates that Flot was named as the inventor on both the '461 and '589 Patent applications; that the March 29, 2001, filing of the '461 Patent application occurred before the '589 Patent was issued on July 31, 2001; and that the '461 Patent application contains a specific reference to the '589 Patent

is entitled to the earlier filing date due to an amendment to the “automatically deliver” terminology in the ‘589 Patent application. BME also argues that the claims of the ‘461 Patent are not entitled to the January 14, 2000, filing date of the ‘589 Patent application because the phrases “automatically deliver” (claims 1 and 30 of the ‘461 Patent) and “automatically delivering” (in claim 51 of the ‘461 Patent) constitute “new matter” that is not supported by the disclosure of the ‘589 Patent application. BME thus contends that it is entitled to summary judgment as a matter of law because the later filing date renders the ‘461 Patent invalid due to prior sales and public use that allegedly occurred more than one year before it was filed.

Estoppel

BME argues that IFUSE is precluded from asserting that the ‘589 Patent application contains an adequate written description of the independent claims of the ‘461 Patent due to estoppel resulting from the amendment of the “automatically deliver” terminology during the prosecution of the ‘589 Patent application. As previously noted, the only evidentiary proffers as to the circumstances of this amendment are Cohen’s deposition testimony and handwritten notes. The Examiner did not issue an Office Action or any written rejection of the purported new matter. In Waldemar Link v. Osteonics Corp., the court explained that:

Estoppel does not occur . . . in the absence of an explicit final rejection under 35 U.S.C. § 112, first paragraph Absent a clear rejection, estoppel does not apply In the absence of a clear and unambiguous rejection under 35 U.S.C. § 112, estoppel does not bar [Plaintiff] from obtaining an earlier filing date for the disputed claims.

Id., 32 F.3d 556, 559-60 (Fed. Cir. 1994). The official record of the ‘589 Patent application proceedings in this case does not reveal a rejection within the meaning of the first paragraph of section 112. The PTO rules governing claim rejection specify that, when an examiner rejects a

application insofar as it was filed as a divisional of the ‘589 Patent application.

claim “[t]he reasons for any adverse action or any objection or requirement will be stated in an Office Action[.]” 37 C.F.R. § 1.104(a)(2)(2005). Thus, a rejection could not have been made by the Examiner in a phone interview, as such a rejection must be explicitly stated in an Office Action. Cohen’s testimony and the notes of his phone interview with the Examiner are insufficient to establish a prima facie case that the Examiner rejected any claims.⁵

New Matter in the ‘461 Application

BME’s non-disclosure argument turns on whether the claims of the ‘461 Patent were adequately disclosed in the ‘589 Patent application or, to the contrary, whether they constituted “new matter.” As a term of art in United States patent law, “new matter” is defined as subject matter not included in the original specification, claims, or drawings of a filed patent application. Manual of Patent Examining Procedure (“M.P.E.P.”) § 608.04(a). 35 U.S.C. § 132(a) provides that “[n]o amendment shall introduce new matter into the disclosure,” and the basis for evaluation of whether an amendment contains new matter is the written description requirement in paragraph 1 of section 112. In re Rasmussen, 650 F.2d 1212, 1214 (C.C.P.A. 1981).⁶ Where the issue is whether an earlier-filed (“parent”) application provides adequate

⁵ In support of its contentions, BME cites cases in which the PTO rejected the amended claims of a parent application on the basis that they contained new matter not adequately disclosed in the original specification as filed and the applicant, in turn, did not pursue the claims in the parent application and instead filed a continuing application containing the previously-rejected new matter. See, e.g., Litton Systems, Inc. v. Whirlpool Corp., 728 F.2d 1423 (Fed. Cir. 1984); Pennwalt Corp v. Akzona, Inc., 740 F.2d 1573 (Fed. Cir. 1984). However, the ‘461 Patent application was not filed instead of the ‘589 Patent application; MBA did not abandon the ‘589 Patent application. Rather, the ‘589 Patent application issued to the ‘589 Patent.

⁶ “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

disclosure for an invention named in a subsequent (“child”) application, the inquiry into the “sufficiency of support in a parent application is whether the disclosure of the [parent] application . . . ‘reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.’” Ralston-Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) (citations omitted). This “written description” requirement does not necessitate that the claims in the child application match the specification of the parent application word for word. In re Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983). For written description inquiries, “[t]he primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure.” In re Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976). Thus, to determine whether the invention described by the independent claims of the ‘461 Patent was adequately disclosed by the ‘589 Patent application, the Court must examine whether there was a sufficient “written description” of an invention characterized by limitations including the phrase “automatically deliver” or “automatically delivering” in the ‘589 Patent application. See Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

IFUSE has proffered an expert declaration opining that the relevant language of the ‘589 Patent, construed in light of this Court’s earlier claim construction determinations, was adequate to enable a person skilled in the art to determine that the inventor was at that time in possession of the invention later defined in the independent claims of the ‘461 Patent application.

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.A. § 112, ¶ 1 (West 2001).

(See Declaration of Cedric Walker (“Walker Decl.”) at ¶¶ 3-4, 6-7, 9-17.) On this record, construed in the light most favorable to IFUSE as the non-moving party, it cannot be said that a reasonable fact finder could not determine that the ‘461 Patent is entitled to claim the same filing date as the ‘589 Patent. Thus, there is a genuine issue of material fact precluding summary judgment of invalidity based on the the ‘461 Patent’s actual filing date and MBA’s activities prior to March 29, 2000.

Validity of ‘589 and ‘461 Patents – Alleged Inequitable Conduct

BME argues that the ‘589 and ‘461 Patents are unenforceable due to Flot’s allegedly inequitable conduct during the prosecution of the Patents. BME alleges that Flot withheld prior art that was material to the patentability of the claims (the Beynet Thesis) with the intent to deceive the PTO. BME also alleges that the ‘461 Patent is unenforceable because Flot, intending to deceive the PTO, did not disclose material information relating to pre-March 2001 prior sales and public use activities.

To meet its burden of demonstrating that a patent is unenforceable due to inequitable conduct, BME must proffer clear and convincing evidence of “affirmative misrepresentations of material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.” Alza Corp. v. Mylan Labs, Inc., 391 F.3d 1365, 1373 (Fed. Cir. 2004) (citations omitted). PTO Rule 56 provides:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R. § 1.56(b) (2006). Under a previous version of the rule, inequitable conduct was evaluated according to a “reasonable examiner” standard, in which “information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” 37 C.F.R. § 1.56(a) (1991); Cargill, 476 F.3d at 1364. The Federal Circuit has held that the standard currently set forth in PTO Rule 56 does not supplant the earlier “reasonable examiner” standard. Cargill, Inc. v. Canabra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). That is, materiality can be established under either standard. Id. However, information is not material under either standard if it is “merely cumulative or less material than other references already before the examiner.” GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001).

To establish the intent element of inequitable conduct, “the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” Id. Intent to deceive does not have to be proven by direct evidence but rather may be inferred from the circumstances surrounding the alleged misconduct. Id. However, a showing of materiality does not create a presumption of intent, which is a separate and essential component of inequitable conduct. Allen Eng’g Corp. v. Bartell Inds., Inc., 299 F.3d 1336, 1351-52 (Fed. Cir. 2002).

If the elements of materiality and intent have been proven by clear and convincing

evidence, the Court must then “balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable.” Impax Labs. v. Aventis Pharm., Inc., 468 F.3d 1366, 1375 (Fed. Cir. 2006). Under the balancing test, a stronger showing of one of the elements, materiality or intent, lowers the showing required as to the other element to establish inequitable conduct. Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997).

Materiality

_____ BME argues that the Beynet Thesis was material prior art and that a reasonable examiner would have considered it important in deciding whether to issue the ‘589 and ‘461 Patents. In support of its contention, BME proffers Fox’s assertion in his affidavit that “Flot referenced [the Beynet] Thesis many times and told me that it was the definitive technical description of the Warmssystem device and Memograph staples and the subject matter of the patents-in-suit.”⁷ (Fox Aff. ¶ 42.) BME also proffers evidence that Flot used this document to obtain regulatory approvals for MBA’s Warmssystem device and Memograph staples. IFUSE contends that the “Warmssystem” device described in the paper is not the same as that later patented and commercialized by MBA and BME. (Pl. 56.1 St. ¶ 99.) In support of its contention, IFUSE distinguishes the use of Joule effect (electrical current) heating in the patented

⁷ IFUSE moved to exclude and/or strike Flot’s statements recited in Fox’s Affidavit “on the grounds that the proffered evidence is inadmissible hearsay.” (Docket entry no. 88.) However, BME contends that the statements “are not being offered to prove the truth of the matters asserted,” while arguing in the alternative that the statements are admissible as non-hearsay or under exceptions to the hearsay rule. (Docket entry no. 114.) In light of IFUSE’s proffers, the statements would be insufficient to establish BME’s entitlement to a judgment of invalidity as a matter of law even if they were taken into account for all purposes. IFUSE’s motion to strike is therefore denied without prejudice to its right to renew its objection to any later proffer of same or similar material.

Warmssystem device from language in the Flot paper that states that “the joule effect . . . was difficult to use to heat the staple, the conduction technic [sic] being easier to use.” (*Id.*) IFUSE has proffered Walker’s expert testimony as evidence that the Beynet Thesis investigated the use of Joule effect heating to close shape memory staples yet had concluded that such use would not be possible. (Second Declaration of Cedric F. Walker (“Second Walker Decl.”) at ¶¶ 10-11, 16.) Walker further asserts that the Beynet Thesis did not contain any description of the heating device described by the patents-in-suit, stating:

[T]he Beynet Thesis is not relevant to the claimed inventions of the Flot ‘589 and ‘461 Patents for the simple reason that those patents claim inventions that are nowhere described or suggested by the Beynet Thesis. The Flot ‘589 Patent claims an electrical current (Joule effect) heating device having a number of elements, including “an electronic power and control circuit” which in turn includes a “current supplying circuit,” a “system controller,” an “adjustment circuit,” and “an automatic cut-out circuit,” and further specifies that the electronic power and control circuit “operates to deliver one of a plurality of different and predetermined quantities of heat” to the clamps (staples). The Beynet Thesis contains no disclosure of any such device or the elements of them for the simple reasons that (1) the Beynet Thesis describes no actual heating devices at all, all his work in regard to heating being in the form of “calculations” or “simulations” (which the Beynet Thesis in any event states “cannot be taken as reliable”), and (2) the Beynet Thesis especially does not describe any Joule effect heating device, inasmuch as Beynet had concluded that Joule effect heating was “not viable” and abandons any efforts to design, let alone build, any such heating device. The same is true for the claimed inventions of the ‘461 Patent[.]

(Second Walker Decl. ¶ 18.) On this record, construed in the light most favorable to the non-moving party, the Court cannot conclude that BME has carried its burden of demonstrating that it is entitled to summary judgment that the Beynet Thesis was material as a matter of law.

BME also alleges that Flot, with the intent to deceive the PTO, withheld evidence of prior sales and public use activities occurring more than one year before the filing date of the ‘461 Patent application. If the ‘461 Patent is entitled to the January 14, 2000, filing date of the ‘589 Patent, then the prior sales and public use activities Flot is alleged to have concealed will

not have occurred more than one year before the filing date of the '461 Patent. As explained above, there are genuine issues of material fact precluding the determination of the operative date of the '461 application. Accordingly, the materiality of the pre-March 29, 2001, activities cannot be determined as a matter of law.

Intent

The second element of BME's allegation of inequitable conduct requires clear and convincing proof that Flot intentionally deceived the PTO by withholding the Beynet Thesis from the PTO while using it to obtain commercial advantage and regulatory approvals. However, as explained above, the evidentiary proffers on the record create competing inferences regarding Flot's intent that preclude determinations as a matter of law as to both the materiality of the Beynet Thesis and Flot's intent. See, e.g., Grain Processing Corp. v. American Maize-Products Co., 840 F.2d 902, 907 (Fed. Cir. 1988). Furthermore, the lack of a good faith explanation from the now-deceased inventor, Flot, does not amount to clear and convincing evidence of intent on a summary judgment motion. M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335, 1342-43 (Fed. Cir. 2006).

CONCLUSION

For the foregoing reasons, BME's motion for summary judgment is denied. IFUSE's motion to strike the affidavit of Cedric Fox is denied without prejudice to its right to renew its objection to any later proffer of the same or similar material.

SO ORDERED.

Dated: New York, New York
September 25, 2009



LAURA TAYLOR SWAIN
United States District Judge