IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BAXTER INTERNATIONAL, INC., *Plaintiff* v. CAREFUSION CORPORATION, and BECTON, DICKINSON AND COMPANY, *Defendants*.	)	No. 15 C 9986 Judge Virginia M. Kendall

MEMORANDUM ORDER AND OPINION

Plaintiff Baxter International, Inc. ("Baxter") sued Defendants CareFusion Corporation and Becton, Dickinson and Company (collectively "CareFusion") for infringement of United States Patent No. 5,782,805 ("the '805 Patent'"). CareFusion contends that Baxter engaged in inequitable conduct in obtaining the '805 patent and it is therefore unenforceable. (Dkt. 110 at 21-29). Baxter now moves for partial summary judgment that the '805 patent is not unenforceable due to inequitable conduct and seeks judgment as a matter of law as to Defendants' Fifth Defense under the doctrine of unclean hands, Seventh Defense of unenforceability of the '805 patent due to inequitable conduct, and Seventh Counterclaim for a declaratory judgment of unenforceability of the '805 patent. For the reasons given herein, the Motion (Dkt. 337) is granted.

BACKGROUND

In its Answer, CareFusion's Fifth Defense alleges that the Complaint and its requests for relief are barred by the doctrines of laches, waiver, estoppel, and/or unclean hands. (Dkt. 110 at 21.) Defendants' Seventh Defense alleges that "[t]he '805 Patent is unenforceable due to inequitable conduct by the named inventors and/or their patent counsel during prosecution of U.S.

Patent Application No. 08/631,819, for the reasons set forth in CareFusion's counterclaims." (Dkt. 110 at 21.). CareFusion's Seventh Cause of Action in their Counterclaims is for "Declaratory Judgment of the Unenforceability of the … '805 Patent." (Dkt. 110 at 24-29.) CareFusion's Second Amended Final Unenforceability and Invalidity Contentions Regarding Claims 1-3 and 8-10 of U.S. Patent No. 5,782,805 ("Unenforceability Contentions") allege "Baxter was not only aware of the prior art infusion pumps that included functionality at issue in this case, it compared its own infusion pump to prior art infusion pumps." (Dkt. 339, Ex. BX1 at 21.)

CareFusion's Unenforceability Contentions encompass the "Signature Edition Model 7100 Volumetric Infusion Pump" by IVAC Corporation ("SE I") and the "Gemini PC-4 Volumetric Infusion Pump/Controller" by IMED Corporation ("Gemini PC-4"). (Dkt. 386 ("SOF") ¶ 14). The Contentions also state that "[t]he only material difference between the Model 7100 pump and the Model 7200 pump [("SE II")] is that the Model 7100 pump has one channel, whereas the Model 7200 pump has two channels." (Dkt. 339, BX1 at 38). Grace Esche is the only named inventor identified in CareFusion's Unenforceability Contentions (*Id.* at 22-24).

I. The '805 Patent Prosecution History

U.S. Patent Application No. 08/631,819 (resulting in the '805 patent) was filed April 10, 1996. (Dkt. 414 ("ASOF") ¶ 26). Baxter did not disclose the SE I, SE II, or Gemini PC-4 infusion pumps, or information related to those pumps, to the PTO during the prosecution of the '805 patent. (ASOF ¶ 27). In an Office communication dated April 28, 1997, the examiner rejected the claims including because certain claims were anticipated by prior art reference Rubalcaba, Jr. '578, incorporating Kerns et al '706 by reference. (Dkt. 386-9, Ex. C14 at 2). Baxter subsequently amended claim 1 (*Id.* at 9-14) and represented to the examiner that "claim 1 has been amended to specify that the invention includes 'means for generating a pictoral graphic representation as user

interface information on the main display." (*Id.* at 14). Claim 1 was again rejected by the examiner in September 1997 as anticipated by prior art (*Id.* at 18). The application was again amended and resubmitted in December 1997. (*Id.* at 23). In April 1998, the examiner made an amendment to the record to insert the phrase "removably secured to the main body portion" after "module" in several claims. (Dkt. 339-13 at 2). A Notice of Allowance was subsequently issued. (*Id.*)

II. FDA 510(k) Application

The internal project name for Baxter's development of the Colleague infusion pump was the Odyssey Project. (ASOF ¶ 1). Baxter filed an application for Section 510(k) clearance to market the Colleague pump with the FDA around June 30, 1995. (ASOF ¶ 18). The 510(k) Application consists of three volumes containing over 1,200 pages of information. (SOF ¶ 20). At the time Baxter was developing the Colleague infusion pump, infusion pump products were also sold by IVAC and IMED, predecessors to CareFusion. (ASOF ¶ 2). IMED's commercially available products at the time included the "Gemini" line of infusion pumps, including the four-channel Gemini PC-4.(ASOF ¶ 3). IVAC products included the Signature Edition I Model 7100 single pumping channel and Signature Edition II Model 7200 dual pumping channel infusion pump products. (ASOF ¶ 5). The 510(k) application included copies of Operations Manuals for the SE I and Gemini PC-4 pumps, as well as feature comparisons for several infusion pumps, including the Odyssey, SE I, and Gemini PC-4 pumps. (SOF ¶ 16).

One of the requirements for a 510(k) submission is to compare the product to other devices that have already received 510(k) approval. (ASOF ¶ 19). The devices identified as part of a 510(k) submission are "generally speaking" some of the closest competing products. (ASOF ¶ 22). The 510(k) application compares the Colleague pump with other pumps already on the market: the

Gemini PC-4 (IMED), the SE I (IVAC), the LifeCare 175 Breeze Infusion (Abbott), and the Flo-Gard 6201 Volumetric Infusion Pump (Baxter):

> This product is substantially equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to our currently marketed Flo-Gard® 6201 Volumetric Infusion Pump, found to be substantially equivalent for continuous or intermittent infusion of intravenous or drug solutions via intravenous, intra-arterial, subcutaneous or epidural routes of administration under K915522 on February 28, 1992.
>
> It is also substantially equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to:
>
> - The Gemini® PC-4™ Volumetric Infusion Pump/Controller, by Imed, cleared under K921378 on June 9, 1992.
> - The LifeCare 175 Breeze™ Volumetric Infusion System, by Abbott Laboratories, cleared under K923829 on April 7, 1993.
> - The Signature Edition™ I Volumetric Infusion Pump, Model 7100, by IVAC. It is our assumption that this pump was cleared under K930781 on August 19, 1993.

(Dkt. 339-6 at 5, ASOF ¶ 21). At Baxter, the regulatory group was responsible for working on and reviewing the 510(k) application, but a cross-functional team would work on compiling the necessary documents to prepare the file for submission. (ASOF ¶ 24; *see also* Ex. C1 at 88:7-89:15.)

III. The Baxter Inventors

The '805 patent has fourteen named inventors. (SOF ¶ 13). CareFusion deposed five of the named inventors: Grace Esche, Randolph Meinzer, Kenneth Lynn, Gilbert Rivas, and Deb Bello (formerly Deb Gelhar) (collectively, "the Baxter Inventors"). CareFusion also deposed the prosecuting attorney of the '805 patent. (SOF ¶ 32-33).

A. Grace Esche

Esche is a Baxter engineer and a named inventor of the '805 patent. (SOF ¶ 12).

Esche testified she "was not responsible for putting the 510(k) together" but that she "worked on some aspects of documentation that were used to support that [510(k)] application."

(SOF ¶ 22, Dkt. 339, Ex. BX2 at 33:16-23). Esche was also involved in reviewing "[s]ome of the documents that would be part of the submission." (Dkt. 339, Ex. BX2 at 51:19-23).

Esche recalled that Baxter's competitors in the pump market at the time of the Colleague's development included "IMED/IVAC" and Abbott. (*Id.* at 34:20-35:16.) Esche testified that it was not part of her job at the time to look at competing pumps, and she did not know if "IVAC/IMED" were separate companies at the time. (SOF ¶ 28). Esche testified that she "knew who [Baxter's] competitors were, but I don't necessarily know what products were on the market at that time. I can't remember.") (Dkt. 339, Ex. BX2 at 34:20-35:5). When shown the SE I Operation Manual that was submitted as part of the 510(k) Application, Esche testified that she could not recall ever seeing one. (*Id.* at 67:8-21, *see also id.* at 54:24-55:4). When asked if she had "ever seen an IMED Gemini PC-4 infusion pump," Esche responded "I would believe I've seen one." (*Id.* at 53:24-54:12.). She testified she had seen a Gemini PC-4 pump "in the past ten years, probably." When asked if she had "ever seen an IVAC Signature Edition or SE Infusion Pump," Esche stated "I may have." (*Id.* at 54:24-55:7.)

Esche testified that she does not know why documents related to the pumps identified in Baxter's 510(k) submission were not submitted to the USPTO in connection with the application of the '805 patent. (SOF ¶ 29). At the time she was deposed, she testified she had "no knowledge" of why Baxter did not submit documents related to those pumps to the USPTO. (*Id.* ¶ 30). She testified that she "relied on Baxter's lawyers to help with [providing necessary information to the PTO]") (Dkt. 414, Ex. BX18 39:6-23).

B. Randolph Meinzer

Meinzer was a project lead responsible for software development in the Odyssey project and the first named inventor on the '805 patent. (ASOF ¶ 11). The '805 patent was Meinzer's first patent. (Dkt. 386, Ex. C3 at 147:5-10, 148:6-10).

Meinzer testified that he was involved in reviewing pieces of Baxter's 510(k) package (ASOF ¶ 23; Dkt. 386, Ex. C3 at 63:3-64:6, 70:1-71:1) but did not recall reviewing the "comparative device table" in the package. (Ex. C3 at 72:16-18).

Meinzer identified IVAC among Baxter's "primary" or "principal" competitors when asked, along with Abbott and Sabratek. (ASOF ¶ 9, see also Dkt. 386, Ex. C3 at 131:6-18). He testified that he was aware of the pumps "as anybody in the industry would be generally aware of other devices" (ASOF ¶¶ 10, 14; Dkt. 386, Ex. C3 at 141:2- 142:3) and that in general "there were operator's manuals on shelves for other devices" and such manuals for competing products "were around." (ASOF ¶ 14, Dkt. 386, Ex. C3 at 143:5-21; *see also id.* at 157:9-13.) He further testified that he recalled discussing "the salient features of competing pumps with the engineers working" with him, including Esche and Lynn. (ASOF ¶ 15, see also Dkt. 386, Ex. C3 at 144:18-145:13.) He also testified that he "recalled discussing competitors' pumps with Baxter's marketing team and clinical team, including Rivas and Bello. (Dkt. 386, Ex. C3 at 142:19-143:4, 144:2-3.)

When asked "[d]o you know why, as you sit here today, that approximately nine months after Baxter filed its 510(k) petition to the Food and Drug Administration, Baxter did not submit any documentation regarding the substantially equivalent identified predicate devices, the Gemini PC-4, the IVAC SE, or the Abbott Breeze to the Patent Office," Mr. Meinzer testified "I don't understand why they would have to, or why it would have to." (ASOF ¶38; Dkt. 339, Ex. BX8 at 153:19-154:4.) He also testified that he did not know why the documents about the pumps were

not provided to the USPTO. (ASOF ¶ 31, see also Dkt 386, Ex. C3 at 154:6-21, 155:6-21, 158:5-12).

Meinzer testified he understood the pumps were on the market prior to the work he did on the Colleague Pump, and that he understood the devices were identified as substantially equivalent for the purposes of the 510(k), but that "they are not the same intent nor requirement." (Dkt. 386, Ex. C3 at 154:6-21, 155:6-21, 158:5-12). He testified that "the purpose for the 510(k) is different than a filing, so I'm having a hard time drawing a correlation between the two" and that he did not believe that information that Baxter had about the IMED or the IVAC or any other pump already out on the market needed to be disclosed to the Patent Office in relation to the '805 patent "Primarily because the Colleague was novel and unique in relation to the implementation embodiment of the inventions on the device." (*Id.* at 156:21-157:4, 180:10-181:22).

C. Kenneth Lynn

Lynn was the director of the Odyssey Program and a named inventor of the '805 patent. (ASOF ¶ 10). Lynn testified that "it was up to the patent attorney to decide what was listed as prior art on the patent, not the inventor.") (Dkt. 386, Ex. C1 at 36:22-37:16).

Lynn was part of the cross-functional team that compiled the necessary documents to prepare the 510(k) application for submission to the FDA. (*Id.* at 88:7-23). Lynn testified that when submitting a 510(k), Baxter had to "demonstrate substantial equivalence to existing devices on the market, not that their technologies are identical or their novelties are identical, but that they are supporting the same therapies that you are claiming with your device that you're applying for." (ASOF ¶ 22, Dkt. 386, Ex. C1 at 92:19-93:16).

Lynn identified IVAC and IMED among Baxter's "primary" or "principal" competitors when asked, along with Abbott and Braun. (ASOF ¶ 9, see also Dkt. 386, Ex. C1 at 16:23-17:6).

Lynn testified that it was not a core requirement of his job to be aware of the products offered by Baxter's competitors, but "we were aware of things that – because in the industry, you have, obviously, knowledge of other companies." (ASOF ¶ 12, *see also* Dkt. 386, Ex. C1 at 18:17-19:25). Lynn was aware of the IVAC SE and Gemini PC-4 pumps. (ASOF ¶10). Lynn further testified he had no firsthand knowledge of whether the clinical team would be aware of competing products, although "they would probably be aware" even though it was "not a requirement for the[ir] job." (*Id.*). Lynn testified that it was common practice to collect competing pump manuals, but there was no standard procedure to do so, and the manuals were never widely distributed. (ASOF ¶13, *see also* Dkt. 386, Ex. C1 at 101:8-11). Lynn did not recollect having copies of the SE II pump manual. (*Id.*)

Lynn testified that he does not know why documents related to the competitor pumps were not provided to the USPTO. (ASOF ¶ 33, *see also* Dkt. 386, Ex. C1 at 39:11-16).

D. Gilbert Rivas

Rivas is a former member of Baxter's marketing team and a named inventor of the '805 patent. (ASOF ¶ 16). Rivas testified he was "not involved with [the '805 patent application] after it was submitted." (Dkt. 414, Ex. BX14 197:6-10).

Rivas testified that he "prepared certain project-related documents, but I was not involved in the preparation and submission of the 510(k)" (ASOF ¶23, Dkt. 386, Ex. C4 at 44:22-45:3, 45:19-24, 46:2-6; 47:4-10,114:22-115:11). He testified he thought he might have "worked on the product user interface documents, and that's probably the extent of my involvement with it." (*Id.* at 116:3-11, 136:22-137:14, 161:17-162:21). Rivas testified he would expect he was involved in a "Market Evaluation Plan" (ASOF ¶ 16) but that he had no recollection of whether he was actually involved in a Marketing Evaluation Plan for the Colleague pump. (Dkt. 386, Ex. C4 at 52:15-

53:11). Rivas also testified that had no recollection of the "comparative device table" in the 510(k) application. (*Id.* at 47:4-10, 49:2-6, 136:22-137:14; Dkt. 414, Ex. BX14 at 150:18-151:13, 181:20-182:2.)

Rivas was aware that IMED had a "Gemini" pump (ASOF ¶ 10). He testified that he did not remember who was responsible for collecting information regarding comparisons against the competition, but believed that "Randy Meinzer, Ken Lynn, Jan Stewart, Deb Gelhar [Ballo]" were "the four that I remember" that "potentially" were involved in the comparisons against competition. (ASOF ¶ 17, Dkt. 386, Ex. C4 at 136:7-138:21).

When asked if he knew "why Baxter did not provide any information related to the IMED PC infusion pump to Baxter's attorneys prosecuting the '805 patent application," Mr. Rivas testified "[m]y belief is that our device was different and was a new invention that provided a flexible user interface that provided our clinical users with the opportunity for specific settings for their particular clinical needs." (SOF ¶ 36). He further testified that he could not recall specifically why Baxter did not provide information to its prosecuting attorneys regarding the IMED PC infusion pump at the time the '805 patent application was being submitted. (Dkt. 339, Ex. BX9 at 208:24-209:10). When asked if he knew "of a reason why Baxter did not submit any information regarding any of the Gemini PC products to the Patent Office," Mr. Rivas testified "[m]y belief is that we believed that our user interface was a fairly new invention. We thought that our flexible user interface platform that allowed us to configure the features by user for different clinical settings, we thought that was a pretty new and novel item. So if we didn't include anybody else's or Gemini's, probably it was because they didn't have that." (SOF ¶ 35).

E. Debra Bello

Debra Bello (f/k/a Gelhar) was a member of Baxter's clinical team and a named inventor of the '805 patent (ASOF ¶ 15). Bello testified that after the initial application was filed, she had no involvement in the process for obtaining the '805 patent. (Dkt. 414, Ex. B17 at 61:4-7).

Bello was part of the Colleague pump development team and testified that she reviewed some of the documents that were submitted in the 510(k) application. (ASOF ¶ 23, see also Dkt. 386, Ex. C5 at 19:17-20, 20:24-21:15). Bello also testified she "wasn't involved in the documents" and did not review the complete submission. (*Id.* at 20:24-21:15). Bello also testified that she was not involved in the evaluation of competitors' pump products. (Dkt. 386, Ex. C5 at 16:17-21)

Bello was asked if she "know[s] of any specific reason that those competing pumps that you saw at trade shows including the Gemini PC-4 were not disclosed to the Patent Office when you filed the application for the '805 patent." Bello responded "I don't know. They don't look like the Colleague pump. I don't know." (ASOF ¶ 34).

LEGAL STANDARD

Summary judgment is proper when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Reed v. Columbia St. Mary's Hosp.*, 915 F.3d 473, 485 (7th Cir. 2019). The parties genuinely dispute a material fact when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Daugherty v. Page,* 906 F.3d 606, 609-10 (7th Cir. 2018) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)). "Rule 56 'mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at

trial.'" *Zander v. Orlich*, 907 F.3d 956, 959 (7th Cir. 2018) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986)).

DISCUSSION

Defendants' inequitable conduct allegations are premised on a theory of nondisclosure – that the inventors of the '805 patent knew of material prior art but deliberately did not disclose that prior art to the USPTO during the application process that resulted in the issuance of the '805 patent. (Dkt. 110 at 24–25). In particular CareFusion alleges that the Baxter inventors were aware of IVAC's SE pumps and IMED's Gemini pumps at the time the '805 patent application was submitted, but deliberately did not disclose that information to the USPTO.

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1352 (Fed. Cir. 2016). "A finding of inequitable conduct as to any single claim renders the entire patent unenforceable ...." *Id.* "Inequitable conduct occurs when a patentee breaches his or her duty to the [USPTO] of candor, good faith, and honesty." *Id.*

"To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson and Co.,* 649 F.3d 1276, 1290 (Fed. Cir. 2011). "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference." *Id.* (citation omitted). Inequitable conduct also requires a finding of but-for materiality, meaning that if an applicant fails to disclose prior art to the PTO the "PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 1291.

The parties do not argue that there is direct evidence of deceptive intent. (Dkt. 338 at 7, Dkt. 385 at 7-8, 12). CareFusion must then rely on circumstantial evidence, which is permitted

to show deceptive intent. *See Ferring B.V. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed. Cir. 2006) ("Intent need not, and rarely can, be proven by direct evidence.") (internal quotations omitted). Although a court may infer intent from indirect and circumstantial evidence, "to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" *Therasense,* 649 F.3d at 1290; *see also GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310 (Fed. Cir. 2020).

Here, the basic facts are not in dispute. Baxter filed a 510(k) application with the FDA in 1995. Each of the deposed Baxter Inventors worked in some capacity on the 3-volume, 1,200-page submission to the FDA. That submission identified IMED's Gemini PC-4 and IVAC's SE I infusion pumps as "substantially equivalent." In 1996, the patent application that would become the '805 patent was filed, and no information or documentation about those infusion pumps was submitted to the USPTO.

To prove deceptive intent, there must first be evidence that Baxter[1] *knew of the reference*—that is, knew of the competitor pumps at the time the '805 patent was prosecuted. Taking each of the inventors in turn, Esche testified that she knew who Baxter's competitors were, but did not know what products were on the market at the time. She testified that she may have seen the competitor pumps at some point, but she did not testify that she saw those pumps at the time of the 510(k) or patent application – and in the case of the Gemini PC-4, she specifically testified she may have seen one "in the last ten years"—more than a decade after the time at issue here. CareFusion argues that testimony from Meinzer rebuts this testimony and creates an issue of fact. Meinzer's testimony is that he recalls discussing "the salient features of competing pumps" with

[1] CareFusion's Unenforceability Contentions only mention one inventor, Grace Esche, by name. (Dkt. 339, Ex. BX1 at 20-22). However, even considering the testimony presented by CareFusion for each of the Baxter Inventors, the Court finds that there is no evidence of a deliberate decision to deceive the PTO, as discussed *infra*, such that summary judgment of no inequitable conduct is warranted here.

engineers including Esche. Meinzer was asked if he "ever discuss[ed] competitors' pumps with Baxter's clinical people" to which he responded he did. (Dkt. 386, Ex. C5 at 143:24-144:1). He was also asked if he "ever" discussed the salient features of competing pumps with Grace Esche, to which the answer was also yes. (*Id.* at 144:18-24). There is no testimony (though CareFusion certainly could have solicited such testimony) about the timing or details of those conversations. However other inventors, including Meinzer, Lynn, and Rivas, testified that they were aware of competitor pumps to various degrees at times prior to the '805 patent application. Drawing all inferences in favor of CareFusion, there is an issue of fact as to whether Esche or other inventors knew of the references.

The next requirement is that the inventors must have known the competing pumps were *material*. This is a requirement of knowledge, not of the separate inquiry of but-for materiality required for an inequitable conduct showing.[2] First, there is no evidence to suggest that, even if Esche or Bello had some vague knowledge of the competitor pumps, they knew that they were material. Meinzer testified that the purpose the 510(k) and the patent application are different from each other, and further that he thought the information did not need to be disclosed to the patent office because "the Colleague was novel and unique in relation to the implementation embodiment of the inventions on the device." (Dkt. 386, Ex. C3 at 156:21-157:4). Lynn testified that he did not know why the material was not submitted, but that when submitting a 510(k), Baxter had to demonstrate substantial equivalence—"not that their technologies are identical, or their novelties are identical." (Dkt. 386, Ex. C1 at 92:19-93:16). Rivas testified that he thought the material was not submitted to the USPTO because Baxter's "invention was different." (SOF ¶ 36). In response,

[2] CareFusion's reliance on the Court's claim construction order is unpersuasive for this reason. The interpretation of claims in litigation more than twenty years after the submission of the patent application is not evidence of the Baxter Inventors' state of mind in 1996.

CareFusion points to evidence that shows the Gemini PC-4 and SE I pumps as close competitors to Baxter's Colleague pump, that the Lynn and Meinzer were aware of similarities between those pumps and Baxter's pumps. Again, drawing all inferences in favor of CareFusion, a reasonable jury could find that at least some Baxter Inventors knew the competitor pumps were material when the patent application for the '805 patent was submitted.

However, even finding fact disputes as to whether the Baxter Inventors knew of the pumps and whether they knew information about those pumps was material to the '805 patent application, CareFusion's inequitable claims still fail because it cannot set forth evidence that any Baxter Inventor made a deliberate decision to deceive the USPTO. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive. *Therasense,* 649 F.3d at 1290. The accused infringer must prove "by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* A court cannot "infer intent to deceive from non-disclosure of a reference solely because that reference was known and material." *1st Media,* 694 F.3d at 1372-73.

CareFusion attacks the credibility of the Baxter Inventors' testimony, and that such credibility determinations are for a factfinder. (Dkt. 385 at 13). But even if a factfinder were to disbelieve the Baxter Inventors, the "single most reasonable inference" would still not be that the Baxter Inventors engaged in a deliberate decision to deceive the PTO by not disclosing documents related to the competitor pumps. A reasonable factfinder, even if concluding that the Baxter Inventors are not being truthful when they each testified to not knowing why the pump information was not included, would not be required to also conclude there was intent to deceive. Other reasonable inferences would be that the nondisclosure was due to incompetence, gross negligence,

or simply that with 14 inventors with overlapping duties, an inadvertent oversight. *See 1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1374-75 (Fed. Cir. 2012) ("[I]t is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent."); *see also Ohio Willow Wood Co. v. Alps. South, LLC,* 813 F.3d 1350 (Fed. Cir. 2016) (failure to meet clear and convincing evidence standard even when district court has made credibility findings against the party charged with inequitable conduct.) There is simply not evidence in the record to support an intent to deceive as the "single most reasonable inference," even drawing inferences in CareFusion's favor.

CareFusion points to *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs.,* decided pre-*Therasense,* for the proposition that an official that was involved in both the FDA and PTO submissions, chose to disclose the reference to the FDA but not the PTO "supports a finding of deceptive intent." 394 F.3d 1348, 1352 (Fed. Cir. 2005). While this aspect of *Bruno* remains authoritative, it does not control the outcome here for two reasons.[3] First, *Bruno* applied a pre-*Therasense* balancing test—where a highly level of materiality meant "the showing of intent can be proportionally less." *Id.* at 1354 (internal citations omitted). After *Therasense*, such a "sliding scale" is improper. 649 F.3d at 1290. Second, in *Bruno* the Federal Circuit concluded that because the patentee had "not proffered a credible explanation for the nondisclosure," an inference of deceptive intent "may fairly be drawn in the absence of such an explanation." *Bruno*, 394 F.3d at 1354. Under *Therasense*, a "patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence."

[3] *Bruno* is also factually distinguishable. There, the individual accused of withholding the reference prepared the FDA submission and was involved in the prosecution of the patent, *including* asking the patent attorney to conduct a prior art search.

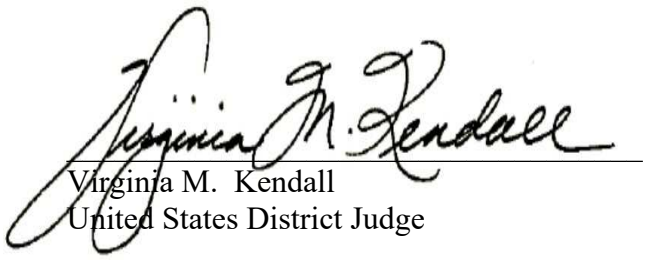
649 F.3d at 1291. ("The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.") CareFusion cannot meet this threshold.

CareFusion argues that summary judgment motions for no inequitable conduct are rarely granted. (Dkt. 385 at 6-7). Even if that may have been true pre-*Therasense*, it is no longer the case. Summary judgment on inequitable conduct claims is appropriate where the evidence does not support a finding that deceptive intent is the single most reasonable inference to be drawn therefrom. *See Western Plastics, Inc. v. DuBose Strapping, Inc.*, 2022 WL 576218 (Fed. Cir. Feb. 25, 2022) ("[W]e agree with the district court that DuBose did not set forth evidence to meet the high standard of establishing that the patent applicant intended to deceive the Patent Office, as required to sustain an inequitable conduct defense."); *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336 (Fed. Cir. 2017) (affirming grant of summary judgment of no inequitable conduct where district court concluded that [Defendant's] evidence was insufficient to permit a finding of the intent required for inequitable conduct."); *see also, e.g., Exergen Corp. v. Kaz USA, Inc.*, 120 F. Supp. 3d 1, 7 (D. Mass. 2015); *Navico Inc. v. Garmin Int'l, Inc.*, 2017 WL 3701189, at *2 (E.D. Tex. Aug. 7, 2017), *report and recommendation adopted*, 2017 WL 3676787 (E.D. Tex. Aug. 25, 2017) (granting summary judgment on issue of intent to deceive because court found that multiple reasonable inferences could be drawn from the evidence and "as a matter of law, [Defendant] [could] not show a 'specific intent' to deceive"); *Chamberlain Grp., Inc. v. Techtronic Indus. Co.*, 2017 WL 3493799, at *8 (N.D. Ill. Aug. 14, 2017) (granting summary judgment of no inequitable conduct); *Greatbatch Ltd. v. AVX Corp.*, 2015 WL 9171042, at *13 (D. Del. Dec. 11, 2015) (same).

Accordingly, because CareFusion cannot meet a standard of clear and convincing evidence of deceptive intent required to establish inequitable conduct, summary judgment on this issue is appropriate.[4]

CONCLUSION

For the reasons set forth above, Baxter's Motion for Partial Summary Judgment of No Inequitable Conduct (Dkt. 337) is granted. Judgement as a matter of law is granted as to Defendants' Fifth Defense under the doctrine of unclean hands,[5] Seventh Defense of unenforceability of the '805 patent due to inequitable conduct, and Seventh Counterclaim for a declaratory judgment of unenforceability of the '805 patent.



Virginia M. Kendall
United States District Judge

Date: March 31, 2022

[4] Because the Court grants summary judgment based on the intent prong of *Therasense*, it does not reach the issue of but-for materiality, which Baxter presented solely in a footnote to their Motion.

[5] CareFusion's Fifth Defense also includes waiver and estoppel defenses, which Baxter does not challenge with this motion. *See* Dkt. 414 at 14. Those defenses survive.