

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

|  |   |                     |
|--|---|---------------------|
| <b>MEDICAL COMPONENTS, INC.,</b>         | : |                     |
| <b>Plaintiff/Counterclaim Defendant,</b> | : | <b>CIVIL ACTION</b> |
|  | : |                     |
| v.                                       | : | <b>NO. 07-2852</b>  |
|  | : |                     |
| <b>ARROW INTERNATIONAL, INC.,</b>        | : |                     |
| <b>Defendant/Counterclaim Plaintiff.</b> | : |                     |
|  | : |                     |

**Diamond, J.**

**July 6, 2009**

**MEMORANDUM**

Arrow International, Inc. alleges that Medical Components, Inc. engaged in inequitable conduct during the prosecution of a patent application. Having held a non-jury trial, I enter judgment for Medcomp and offer my supporting factual findings and legal conclusions. Fed. R. Civ. P. 52.

**BACKGROUND**

Medcomp owns U.S. Patent No. 6,881,211, entitled “Multilumen Catheter Assembly and Methods For Making and Inserting the Same.” (Stipulated Facts ¶¶ 1-2, Doc. No. 142.) Medcomp brought an infringement action on July 17, 2007, alleging that Arrow’s manufacture of its “Cannon” and “Edge” Catheters infringes on Claim 19 of the ‘211 Patent. Arrow filed the instant Counterclaim charging Medcomp with inequitable conduct. (Doc. No. 73.) On April 27, 2009, I conducted a non-jury trial on the Counterclaim. See Rothman v. Target Corp., 556 F.3d 1310, 1322 (Fed. Cir. 2009) (“Inequitable conduct is an equitable defense to patent infringement most appropriately reserved for the court.”). The Parties submitted Proposed Findings of Fact

and Conclusions of Law on May 11, 2009. (Doc. Nos. 150, 151.)

### **FINDINGS OF FACT**

Medcomp owns a family of patents related to multilumen catheters invented by Donald Schon, Timothy Schweikert, and Anthony Madison, including:

1. U.S. Patent No. 6,719,749 (the '749 Patent), filed on June 1, 2000 (Application No. 09,585,149) and issued on April 13, 2004;
2. U.S. Patent No. 6,695,832 (the '832 Patent) -- a continuation-in-part application of the '749 Patent -- filed on November 21, 2002 (Application No. 10,300,999) and issued on February 24, 2004;
3. U.S. Patent Application No. 10,670,861 (the '861 Application) -- a divisional application of the '832 Patent -- filed on September 24, 2003; and
4. U.S. Patent No. 6,881,211 (the '211 Patent) -- a divisional application of the '749 Patent -- filed on October 8, 2003 (Application No. 10,681,394) and issued on April 19, 2005.

(Stipulated Facts ¶¶ 3-5, 10-11, 13; Def.'s Exs. 1-4, 6-7, 10-11.)

#### **A. The '749 and '832 Applications**

Medcomp's '749 Application (filed on June 1, 2000) contained thirty-five Claims: (1) 1 through 19 were "method" Claims directed to a method of making a split-tip multilumen catheter assembly; (2) 20 through 30 were "apparatus" Claims directed to a split-tip multilumen catheter assembly; and (3) 31 through 35 were "method" Claims directed to a method of inserting a split-tip multilumen catheter assembly into an area of the human body. (Def.'s Ex. 4 at 154.)

The Examiner assigned to the '749 Application determined that these three groups of Claims comprised distinct inventions and issued a Restriction Requirement to this effect on August 1, 2002. (Id. at 153-56.) Medcomp chose to pursue the apparatus Claims (Nos. 20-30) in the '749 Application. (Tr. Apr. 27, 2009 at 85.)

Medcomp filed the '832 Application on November 21, 2002 as a continuation-in-part Application of the '749 Application. The '832 Application included "new matter" -- *i.e.*, Claims respecting a catheter with a splitable membrane and a method of manufacturing such a catheter -- not present in the '749 Application. Tr. Apr. 27, 2009 at 94-95; see Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1321 n.2 (Fed. Cir. 2008) ("[A] continuation-in-part [application] contains a portion or all of the disclosure of an earlier application together with added matter not present in the earlier application.").

**B. The 2002 Transfer of Medcomp's Patent Portfolio to Attorney J.M.**

In 2002 -- while the '749 and '832 Applications were pending -- Medcomp hired the law firm of M & M to take over prosecution of its patents. M & M's associate, J.M., had been admitted to the Pennsylvania bar in 1996, and the patent bar in 1998. (Tr. Apr. 27, 2009 at 27-28, 81.) He began work at the M & M law firm in August of 2002. (Id. at 29.) J.M.'s first assignment was to take over Medcomp's patent portfolio. (Id. at 81.) Before the Medcomp records were transferred to M & M, J.M. traveled to Medcomp's headquarters and reviewed its correspondence files. (Id. at 93.)

As J.M. came across different patents mentioned in Medcomp's correspondence files, he entered each matter into the docketing system he used to keep track of related patents and their corresponding deadlines. (Id. at 92-93.) J.M. assigned the '832 Application docket number

“MED-0005” because it was the fifth patent matter mentioned during his review of Medcomp’s correspondence. (Id. at 83, 93.) J.M. assigned the ‘749 Application docket number “MED-0062” because it was the sixty-second Medcomp matter mentioned during that initial review. (Id. at 83.)

When he initially docketed the Medcomp Applications, J.M. had reviewed only the correspondence files, not the Applications themselves. (Id. at 92-93.) J.M. did not indicate in his docket that the ‘832 Application was a continuation-in-part application of the ‘749 Application. J.M. testified that he did not recognize the relationship between these Applications because Medcomp’s correspondence indicated that the ‘832 Application included Claims respecting a method of manufacturing a catheter with a splitable membrane that were not included in the ‘749 Application. (Id. at 94-95.) J.M. further explained that Medcomp’s correspondence files did not indicate that the ‘832 Application was a continuation-in-part application of another Application. (Id. at 96-97.) Accordingly, J.M. incorrectly “assumed that [the ‘832 Application] was the ultimate parent in the application family.” (Id. at 97.)

### **C. The ‘861 and ‘211 Applications**

#### **1. The Prosecution History**

The Claims of the ‘211 and ‘861 Applications, like the Claims of the ‘749 and ‘832 Applications, are directed to multilumen catheters. The ‘211 Patent is a divisional application of the ‘749 Application, and includes Claims directed to a method of making a split-tip multilumen catheter assembly (Claims 1 through 19) that the USPTO “restricted out” of the ‘749 Application. (Tr. Apr. 27, 2009 at 85.) The ‘861 Application is a divisional application of the ‘832 Application, and contains Claims directed to a method of making a multilumen catheter

assembly with a splittable membrane that were originally pursued in the ‘832 Application. (*Id.* at 87.) Although the ‘861 and ‘211 Applications are directed toward different types of catheters, Claim 22 of the ‘861 Application claims a method for making a multilumen catheter assembly that is nearly identical to Claim 1 of the ‘211 Patent. (*Id.* at 134.) At trial, J.M. agreed that aside from certain “slight wording differences,” there was no “difference in . . . scope” between these claims. (*Id.* at 41-42.)

J.M. assigned the ‘861 Application -- which he filed on September 24, 2003 -- docket number “MED-0005D1,” indicating that it was a divisional application of the ‘832 Application (“MED-0005”). (*Id.* at 85-86.) J.M. filed the ‘211 Application approximately two weeks later, on October 8, 2003. (*Id.* at 32, 38.) J.M. assigned the ‘211 Application docket number “MED-0062D1,” indicating that it was a divisional application of the ‘749 Application (“MED-0062”). (*Id.* at 86.) J.M. failed to docket the ‘861 and ‘211 Applications to indicate that they shared the same parent application -- the ‘749 Application. (*Id.* at 96-97.)

The ‘861 Examiner rejected Claim 22, determining that it was anticipated by the “Ash” Patent (U.S. Patent No. 5,497,953). (Def.’s Ex. 11 at 102, 129, 195.) The ‘211 Examiner did not reject Claim 1, however, and issued a Notice of Allowance for the ‘211 Patent on December 21, 2004. (Stipulated Facts ¶ 27.) After the ‘211 Patent issued, Medcomp disclosed its existence to the Examiner for the ‘861 Application. (Def.’s Ex. 11 at 355.) The ‘861 Application is still pending.

## **2. J.M.’s State of Mind**

When he prepared the ‘211 and ‘861 Applications, J.M. failed to recognize that Claim 1 of the ‘211 Application and Claim 22 of the ‘861 Application were almost identical.

Accordingly, J.M. failed to disclose the existence of the '861 Application to the '211 Examiner or the existence of the '211 Application to the '861 Examiner. (Stipulated Facts ¶¶ 17-18.) J.M. attributed these failures to his inadvertent docketing errors. (Tr. Apr. 27, 2009 at 96-97.) J.M. acknowledged that he also had failed to set up access to the USPTO's Patent Application Information Retrieval system, which would have revealed the relationship among the '749, '832, '211, and '861 Applications. (Id. at 122-25.)

Although J.M. prepared the '861 and '211 Applications within two weeks of each other, it was apparent that he did not review them carefully. J.M. did not draft the Specifications or Claims but, rather, "cut and pasted" them only a few days before he filed the '211 and '861 Applications. (Id. at 39-40, 43.) As J.M. explained:

[W]hen I got ready to prepare the divisional application[s], I took a look at the claims that had already been prepared, look[ed] at them, okay, they look[ed] like the same claims that were initially filed by prior counsel; they have proper claim dependencies for the dependent claims, they form full sentences, they appear to be in order, okay, put them in a preliminary amendment and file[d] them. I never actually put one set of claims against the other to compare claim scope.

(Id. at 69.) In contrast, Former USPTO Commissioner Gerald J. Mossinghoff -- a Medcomp witness -- credibly testified that the "textbook way" to determine whether two patent applications include claims of the same scope is to "compare all the claims of one application against all the claims of the other application." (Id. at 174.)

Because of the manner in which J.M. familiarized himself with Medcomp's records, he did not understand the close relationship among the '749, '832, '861, and '211 Applications. Because J.M. did not learn from his review of Medcomp's correspondence files that the '749 Application was the parent of the '832 Application, he necessarily did not realize that the '749

Application was also the parent of the '861 Application. Because he did not review the '861 and '211 Applications carefully, he did not realize that they included an almost identical Claim. In these circumstances, I find that J.M. did not intend to deceive the USPTO. Rather, J.M.'s failure to disclose the copendency of the '861 and '211 Applications to the Examiners for those Applications was the result of inadvertence or, at worst, negligence.

**D. J.M.'s Other Actions**

In further support of its Counterclaim, Arrow presented evidence of instances during the prosecution of the '749 Application -- not the '211 Application -- where J.M. purportedly was "not candid" with the USPTO. (Doc. No. 150 ¶ 98.) The Parties have stipulated that these actions "do not themselves constitute 'material, noncumulative information'" for the purposes of Arrow's Counterclaim. (Doc. No. 134 at 1.) The Parties also agreed, however, that their Stipulation did not preclude Arrow from offering evidence of these actions "for any [other] purpose[,] including as evidence of intent to deceive the United States Patent Office." (Doc. No. 134 at 2.)

Medcomp asked me to exclude this evidence because its probative value was "substantially outweighed" by the dangers of unfair prejudice, wasting the Court's time, and confusion of the issues. I denied that Motion on April 22, 2009. Doc. No. 145; Fed. R. Evid. 403; see also Gulf States Utils. Co. v. Ecodyne Corp., 635 F.2d 517, 519 (5th Cir. 1981) ("Rule 403 has no logical application to bench trials.").

**1. The July 22, 2003 Interview**

J.M. sought an interview with the '749 Examiner to "show [the Examiner] a physical specimen of a catheter in order to . . . demonstrate to him differences between the claimed

catheter and the prior art that was being applied against [Medcomp's] claims." (Tr. Apr. 27, 2009 at 109.) During that July 22, 2003 interview, J.M. showed the Examiner a catheter and discussed "an outstanding office action along with the claims that were involved in [the] application." (*Id.* at 71; Stipulated Facts ¶ 41.)

At the interview's conclusion, the Examiner prepared a summary in which he noted that J.M. had shown him a "sample of a catheter." (Stipulated Facts ¶ 55; Def.'s Ex. 4 at 213.) J.M. reviewed this interview summary and stated his agreement with it. (Tr. Apr. 27, 2009 at 71.) In the summary, the Examiner directed that J.M.'s "formal written reply to the last office action must include the substance of the interview." (Def.'s Ex. 4 at 213.) On August 6, 2003, J.M. filed his formal written reply to the "pending office action," thanking the Examiner "for the courtesy of the personal interview" and summarizing their discussion regarding the anticipated rejection of Claims in the '749 Application. (Stipulated Facts ¶ 45; Def.'s Ex. 4 at 224-25.)

J.M. testified in deposition that he did not recall the brand of the catheter that he had shown the Examiner during the interview. (Tr. Apr. 27, 2009 at 122.) At trial, however, J.M. testified that "[i]t would have been a Medcomp catheter." (*Id.* at 72.) J.M. explained that since his May 6, 2008 deposition, he had "the benefit of being able to review the response that [he] drafted in detail, which helped [him] to piece together what would have been the substance of the interview." (*Id.* at 122.)

## **2. The Uldall Catheter**

### **The Osborne Letter**

On August 29, 2003, J.M. received an unsolicited letter from Thomas Osborne, Senior Vice President of Intellectual Property Growth and Development at Cook Incorporated. (Def.'s

Ex. 14.) In his letter, Osborne referred to the ‘832 Application, and stated that he was enclosing a “copy of [Cook’s] catalog page” illustrating a “Uldall Double Lumen Hemodialysis Catheter,” which had “been in public use since 1993.” (Id.) Two separate sheets of paper were attached to the letter: (1) a sheet with drawings of a “French Uldall Double Lumen Hemodialysis Catheter Tray”; and (2) a sheet with a list of “references.” (Id.) The sheet of paper with references bore a copyright date -- apparently for the “Cook” trademark -- of 1999. The sheet of paper with drawings did not provide a copyright date or any other date.

J.M. assumed that Osborne sent him the letter to “make [J.M.] personally aware of the fact that the [Uldall Catheter] exists,” and to induce J.M. to “submit it for consideration to the patent office.” (Tr. Apr. 27, 2009 at 56.) Upon reviewing the Osborne Letter, J.M. discovered a patent obtained by Peter R. Uldall on April 21, 1992 entitled “Collapsible Lumen Catheter for Extracorporeal Treatment.” (Pl.’s Ex. 2 (U.S. Patent No. 5,106,368); Tr. Apr. 27, 2009 at 62.) J.M. concluded that the Uldall Patent was not material to the ‘749 Application because the Uldall Patent “related to an apparatus that was a splittable membrane.” (Apr. 27, 2009 at 106-107.) J.M. nonetheless believed that it would be “prudent” to submit the Cook Catalog sheets to the ‘749 Examiner:

[B]ecause [Osborne] has a record of having sent it to me . . . if he saw that I didn’t submit it and he got into litigation with Medcomp regarding this patent, he could say, “I sent this to [J.M.] on such-and-such [] date and he didn’t submit it, he hid the ball from the Patent Office.” So, my consideration is, I’ve got to file this thing, because he knows he sent it to me and I know he sent it to me[.]

(Id. at 107.)

J.M. did not realize that the two sheets of paper were, in fact, opposite sides of the same Cook Catalog page. Thus, on September 10, 2003, J.M. filed an Information Disclosure

Statement with the '749 Examiner in which he: (1) cited the '386 Patent owned by Uldall; and (2) submitted the two sheets attached to the Osborne Letter, describing them as "two separate sheets of paper" and describing the sheet of paper with drawings as "date unknown." (Tr. Apr. 27, 2009 at 60-61; Def.'s Ex. 4 at 235). Although these descriptions were incorrect, the mistakes were inadvertent and not intended to deceive the USPTO. The Examiner declined to consider the sheet with drawings of the Uldall Catheter because it was not dated. (Tr. Apr. 27, 2009 at 65; Def.'s Ex. 4 at 283.) J.M. did not submit the letter in which Osborne claimed that the Uldall device had "been in public use since 1993."

On June 3, 2008, Medcomp's current patent attorney filed an IDS in connection with the '861 Application in which he described the Cook Catalog pages as follows: "11.0 French Uldall Double Lumen Hemodialysis Catheter Tray brochure, 2 pages, dated 1999, Cook Critical Care." (Stipulated Facts ¶ 36-37.)

#### **Schon's Knowledge of the Uldall Catheter**

Donald Schon was also familiar with a Uldall Catheter that had been in public use in the 1990s. (Tr. Apr. 27, 2009 at 128.) Schon believes he was aware of this catheter during the prosecution of the '749 Application because he had an article in his files referring to the Uldall catheter. (Id.) Schon could not recall whether, through the "bidirectional transit of information," he sent this article to J.M. or received it from him, but remembered discussing the Uldall catheter with J.M. (Id. at 129.) Schon did not recall ever seeing an actual Uldall Catheter. (Id. at 128.)

Aside from the disclosure of the Cook Catalog sheets and the Uldall Patent, neither J.M. nor Schon disclosed to the '749 Examiner that the Uldall Double Lumen Hemodialysis Catheter was in public use. (Stipulated Facts ¶ 40; Tr. Apr. 27, 2009 at 62.) J.M. believed this

information was cumulative of the information provided in the Uldall Patent itself. (Tr. Apr. 27, 2009 at 62.) J.M. explained that the Cook Catalog sheet with drawings did not provide “a lot of disclosure regarding the catheter in question,” and that the Uldall Patent, “in addition to the [drawing] of the actual catheter shown in [the] catalog page . . . included a lot of additional information regarding the catheter.” (Id.) Medcomp’s expert, Dr. Mohammad Kiani, testified credibly that the Uldall Patent disclosed all the information contained in the Cook Catalog page “and then some.” (Id. at 146.)

Both the ‘749 and ‘211 Examiners considered the information provided by J.M. regarding the Uldall Catheter immaterial to the patentability of either Application. (Def.’s Ex. 2 at 86; Def.’s Ex. 4 at 283.)

## CONCLUSIONS OF LAW

### **I. Legal Standards**

Inequitable conduct is a defense to patent infringement, and arises from a claim that a patent applicant or its counsel breached their duty of candor to the United States Patent and Trademark Office. See 37 C.F.R. § 1.56(a) (the duty of candor applies to “[e]ach individual associated with the filing and prosecution of a patent application”); Warner-Lambert Co. v. Teva Pharm. USA, Inc., 418 F.3d 1326, 1342-43 (Fed. Cir. 2005). A finding of inequitable conduct as to one claim of a patent renders every claim in the patent unenforceable. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988) (en banc).

To prove inequitable conduct, a claimant must establish by clear and convincing evidence: (1) an affirmative misrepresentation or an omission of material, non-cumulative

information to the USPTO; and (2) an intent to deceive. See, e.g., Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008); see also Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008) (“[A]t least a threshold level of each element -- *i.e.*, both materiality and intent to deceive -- must be proven by clear and convincing evidence.”). The Federal Circuit adopted the clear and convincing standard in response to the “absolute plague” of litigants “charging inequitable conduct in almost every major patent case.” Kingsdown, 863 F.2d at 876 & n.15 (quoting Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988)). As the Federal Circuit explained:

The need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe, the loss of the entire patent even where every claim clearly meets every requirement of patentability. . . . Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith. As a result, courts must ensure that an accused infringer asserting inequitable conduct has met his burden on materiality and deceptive intent with clear and convincing evidence before exercising its discretion on whether to render a patent unenforceable.

Star Scientific, 537 F.3d at 1365 (citations omitted).

#### **A. Materiality**

“[I]nformation is material when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” Symantec Corp. v. Computer Assocs. Int’l, Inc., 522 F.3d 1279, 1297 (Fed. Cir. 2008) (quotations omitted); see also Li Second Family Ltd. P’ship v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000) (“[T]he test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability.”). Information

is not material if it is cumulative of other information already disclosed to the USPTO. See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 1000 (Fed. Cir. 2007) (“Information cumulative of other information already before the Patent Office is not material.”); 37 C.F.R. § 1.56(b) (“[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application.”).

### **B. Intent**

“[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.” GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1274 (Fed. Cir. 2001) (quotations omitted). The Federal Circuit has cautioned that

the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to . . . mislead[ ] or deceiv[e] the [US]PTO. 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.

Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995). Accordingly, the failure to disclose information to the USPTO cannot, by itself, satisfy the intent element. Star Scientific, 537 F.3d at 1366. Rather, the accused infringer “must prove by clear and convincing evidence that the material information was withheld with the specific intent to deceive the USPTO.” Id.

Because direct evidence of intent is “rarely” available, specific intent to deceive may be inferred from indirect and circumstantial evidence. Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007). Circumstantial evidence must be clear and convincing, however, and “inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement.”

Star Scientific, 537 F.3d at 1366; see also Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1186

(Fed. Cir. 2006) (“The predicate facts must be proven by clear and convincing evidence.”). Moreover, an inference of deceptive intent “must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” Star Scientific, 537 F.3d at 1366; see also Corp. v. ICOS Vision Sys. Corp., 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”).

### **C. Balancing**

If the “elevated evidentiary burden is met as to both [materiality and specific intent],” the court must then “balance the equities to determine whether the applicant’s conduct . . . was egregious enough to warrant holding the entire patent unenforceable.” Star Scientific, 537 F.3d at 1365 (“Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.”). If the claimant fails to meet its threshold burden as to either intent or materiality, however, the court may not go to the next step of the analysis and balance the equities. See id. at 1367 (“Only after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings.”); see also Nordberg, Inc. v. Telsmith, Inc., 82 F.3d 394, 398 (Fed. Cir. 1996) (district court properly refrained from balancing the equities when a threshold showing of intent to deceive was not made by clear and convincing evidence).

## **II. Discussion**

Arrow charges that J.M.'s failure to disclose the co-pendency of the '861 Application to the '211 Examiner constituted inequitable conduct. Arrow argues that had the '211 Examiner known of the co-pendency of the '861 Application, he would have issued a double patenting rejection of Claim 1 of the '211 Application. The Federal Circuit has explained that the double patenting doctrine

generally prevents a patentee from receiving two patents and extending the term of exclusivity for a single invention. The proscription against double patenting takes two forms: statutory and non-statutory. Statutory, or "same invention," double patenting finds its origin in the statutory grant of "a patent" for any new and useful invention. Non-statutory, or "obviousness-type," double patenting is a judicially created doctrine designed to foreclose claims in separate applications or patents that do not recite the "same" invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection.

Takeda Pharm. Co. v. Doll, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (quotations and citations omitted).

Although the Parties dispute whether Claim 1 of the '211 Application would have been subject to a "same invention" or an "obviousness-type" double patenting rejection, they have stipulated that J.M.'s omission was material. Stipulated Facts ¶ 23; see also Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358, 1365 (Fed. Cir. 2003) (a copending application may be "highly material to the prosecution of [an application, where] it could have conceivably served as the basis of a double patenting rejection") (quoting Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998) (alterations in original)). The Parties vigorously dispute whether J.M. acted with the specific intent to deceive the USPTO when he failed to disclose the '861 Application. See, e.g., Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306,

1313 (Fed. Cir. 2008) (“[A] showing of materiality alone does not give rise to a presumption of intent to deceive.”).

Arrow has ignored that it was at the insistence of the USPTO -- not Medcomp or J.M. -- that evaluation of the ‘749 Application and its derivative Applications was divided, thus making it more likely that different Examiners would review separate parts of what Medcomp had originally submitted as a single Application to be reviewed by a single Examiner. Neither J.M. nor Medcomp sought to deceive the USPTO and take advantage of the situation the USPTO created. The evidence presented thus clearly shows that Arrow has failed to meet its threshold burden of proving with clear and convincing evidence that J.M. acted with the intent to deceive the USPTO.

**A. Failure to Disclose the ‘861 Application**

Medcomp argues that J.M. offered a “reasonable explanation” for his failure to disclose the ‘861 Application to the Examiner assigned to the ‘211 Application: that he did not know that they included an almost identical Claim and otherwise failed to appreciate the relationship between the Applications. (Doc. No. 151 ¶¶ 114-15.) Although Arrow argues that J.M.’s explanation is not credible, I do not agree. (Doc. No. 150 ¶ 88.)

In 2002, J.M. had been a lawyer for only six years, and a member of the patent bar for only four. Having just begun work at M & M, he was assigned Medcomp’s substantial patent portfolio. The correspondence files J.M. initially reviewed did not disclose the relationship between the ‘832 and ‘749 Applications. Moreover, J.M. did not carefully review ‘861 and ‘211 Applications before he submitted them. Accordingly, as I have found, J.M. did not intend to deceive the USPTO. J.M.’s inadvertent and negligent errors do not amount to inequitable

conduct. See Kingsdown, 863 F.2d at 874 (Fed. Cir. 1988) (gross negligence is insufficient to prove a specific intent to deceive).

**B. J.M.'s Other Actions**

Arrow points to J.M.'s other alleged "misrepresentations, omissions and half-truths" made during prosecution of the '749 Application. (Doc. No. 150 ¶ 36.) Arrow argues that J.M.'s failure to disclose the '861 Application to the '211 Examiner -- considered together with his "misrepresentation of the Cook catalog page, omission of the public use information for the Uldall Catheter, and failure to submit an interview summary" -- demonstrate that J.M. employed an "intentional prosecution strategy . . . meant to mislead the Patent Office and obtain the issuance of claims that were otherwise unpatentable." (Doc. No. 150 ¶ 132; id. ¶ 36 ("A persistent course of misrepresentations, omissions and half-truths during prosecution can support an inference of intent.")) I do not agree.

I have found that J.M.'s failure to inform the '211 Examiner of the '861 Application was unintentional. Moreover, J.M.'s other purported omissions and misrepresentations do not remotely make out an intentionally deceptive course of conduct. For instance, Arrow argues that J.M. acted with a specific intent to deceive the '749 Examiner by: (1) characterizing the single Cook Catalog page as separate pages; and (2) describing one of the sheets as "date unknown." (Doc. No. 150 ¶ 110.) Although I agree that the two sheets were opposite sides of the same page (and, indeed, were described as a "page" in the accompanying Osborne letter), as I have found, J.M. did not intend to deceive the USPTO when he submitted them as separate pages or described one of the pages as undated. (Def.'s Ex. 14.) Moreover, Arrow offered no evidence to rebut the credible evidence of good faith presented by Medcomp, including: (1) J.M.'s testimony

that he submitted the sheets to the Examiner out of an abundance of caution, despite his belief that the Uldall Catheter was not material to the Claims in the '749 Application; and (2) Commissioner Mossinghoff's testimony that by submitting the Uldall Patent itself, J.M. went "beyond" his duty of disclosure. Tr. Apr. 27, 2009 at 164-65; see Larson Mfg. Co. of S.D., Inc. v. Aluminum Prods. Ltd., 559 F.3d 1317, 1341 (Fed. Cir. 2009) (in determining whether there was an intent to deceive, "the district court should take into account any evidence of good faith, which militates against a finding of deceptive intent").

Arrow also assails J.M.'s failure to disclose Schon's independent knowledge that a Uldall Catheter was in public use in the 1990s. In Arrow's view, that failure, along with the incorrect description of the Catalog page, were calculated to prevent the '749 Examiner from "learning that the Uldall device was an actual device that was on the market as prior art." (Doc. No. 150 ¶¶ 107, 110.) According to Arrow, "[h]ad the examiner of the '749 Patent known of the public use of the Uldall . . . Catheter, he could have requested a sample from Medcomp and determined its method of manufacture." (Doc. No. 150 at 116.) This is absurd. Once J.M. disclosed to the Examiner the existence of the Uldall Patent, the Examiner could have obtained additional information about the device had he chosen to do so. J.M.'s "failure" to provide that information in addition to the Patent itself obviously was not part of a persistent course of conduct intended to deceive the USPTO.

Arrow also argues that as a result J.M.'s failure to identify in his written response to the pending office action the brand of catheter he brought to the July 23, 2003 interview, he left "no record whatsoever of what catheter [J.M.] brought to and showed the examiner." (Doc. No. 150 ¶ 126.) I do not see -- nor has Arrow explained -- how this failure shows an intent to deceive the

USPTO.

Finally, the single decision Arrow offers to support its “deceptive course of conduct” allegations in fact belies them. In PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., the Federal Circuit agreed that inequitable conduct rendered a family of patents unenforceable based on an “exhaustive record” of “intentional misrepresentations, omissions, and half-truths” all directed toward the “central,” “highly material” issue of the identity of the inventors of the disputed patents. 225 F.3d 1315, 1321-22, (Fed. Cir. 2000).

By contrast, J.M.’s actions: (1) involved, at worst, negligent errors; (2) concerned various issues; and (3) were made during the prosecution of the ‘749 Application, not the ‘211 Application. Moreover, Arrow has stipulated that these “misrepresentations” and “omissions” were not themselves material to consideration of the ‘211 Application. Doc. No. 134 at 1-2; see also Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1194 (Fed. Cir. 2006) (upholding inequitable conduct determination where patentee was responsible for “multiple omissions” of “highly material” information “over a long period of time -- a fact that heighten[ed] the seriousness of the conduct”). In these circumstances, PerSeptive underscores that J.M. did not act with a specific intent to deceive the USPTO.

In sum, I conclude that Arrow has not shown that J.M. engaged in a persistent course of conduct -- or any conduct -- intended to deceive the USPTO. Rather, I conclude that in all his dealings with the USPTO, J.M. “committed minor missteps or acted with minimal culpability or in good faith.” Star Scientific, 537 F.3d at 1366. Accordingly, I conclude that Arrow has failed to show by clear and convincing evidence a specific intent to deceive.

### CONCLUSION

Because I conclude that Arrow failed to meet its threshold burden of establishing specific intent to deceive the USPTO, I lack discretion to balance the equities to determine whether to hold the '211 Patent unenforceable due to inequitable conduct. See Star Scientific, 537 F.3d at 1367; Nordberg, 82 F.3d 394 at 398. Accordingly, I enter judgment in favor of Counterclaim Defendant Medcomp and against Counterclaim Plaintiff Arrow on Arrow's Third Counterclaim.

An appropriate Order follows.

*s/ Paul S. Diamond*

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**Paul S. Diamond, J.**