

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

BRUCE N. SAFFRAN, M.D., PH.D.,	§	
Plaintiff,	§	
	§	
v.	§	
	§	CIVIL ACTION NO. 2:07-CV-451 (TJW)
JOHNSON & JOHNSON and CORDIS	§	
CORPORATION,	§	
Defendants.	§	
	§	
	§	

**MEMORANDUM OPINION AND ORDER**<sup>1</sup>

Before the Court is Defendants Johnson & Johnson’s (“J&J”) and Cordis Corporation’s (“Cordis”) (collectively “Defendants”) claim of inequitable conduct. The plaintiff and defendants each filed proposed findings of fact and conclusions of law. (Dkt. Nos. 314 and 315.) The Court also conducted a bench trial on March 2, 2011 on Defendants’ counterclaim of inequitable conduct and the parties submitted their post-trial briefing on the issue after the bench trial. (*See* Dkt. Nos. 318, 320, and 323.) For the following reasons, the Court concludes that Defendants have not proven by clear and convincing evidence that Plaintiff Dr. Saffran committed inequitable conduct against the PTO.

**I. BACKGROUND**

Plaintiff Dr. Saffran resides at 107 Arch Street, Philadelphia, Pennsylvania 19106. (Joint Final Pre-Trial Order, Dkt. No. 278, at 11.) Defendant J&J is a corporation organized and

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<sup>1</sup> The Court issues its findings and conclusions in a Memorandum Opinion and Order instead of a formal findings of fact and conclusions of law. *See* Fed. R. Civ. P. 52 (“The findings and conclusions may be stated on the record after the close of evidence or may appear in an opinion or a memorandum of decision filed by the court.”).

existing under the laws of the State of New Jersey, and has a place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. (Defendants' Second Amended Answer, Dkt. No. 65, at ¶ 7.) Defendant Cordis is a corporation organized and existing under the laws of the State of Florida, and has a place of business in Warren, New Jersey. (Dkt. No. 65, at ¶ 8.)

Dr. Saffran is the owner of U.S. Patent No. 5,653,760 ("the '760 patent"). On October 9, 2007, Dr. Saffran filed suit against Defendants and alleged that Defendants infringe the '760 patent. (Dkt. No. 1.) From January 24-28, 2011, a jury trial was held on the issues of infringement and validity of the '760 Patent, willfulness, and damages. On January 28, 2011, the jury returned a verdict finding that Defendants infringe claims 1-3, 6, 8, 9, 11, 13, 15, 17 and 18 of the '760 Patent, that the '760 Patent is not invalid based on obviousness, that Defendants' infringement was willful, and that Dr. Saffran is entitled to damages in the amount of \$482 million as a reasonable royalty. (Verdict Form, Dkt. No. 288.)

On March 2, 2011, the Court conducted a bench trial to consider Defendants' claim of inequitable conduct. Defendants claim Saffran committed inequitable conduct in two ways: (1) Saffran had knowledge and withheld, with intent to deceive the PTO, the Langer references that would have been material to the prosecution of the '760 Patent application; and (2) Saffran made material misrepresentations to the PTO, with an intent to deceive, by making statements in the '760 Patent such as "I have found" and "surprisingly." The Court has considered the evidence from both the jury trial and bench trial, including the live testimony, testimony by deposition designations, documentary evidence, as well as arguments presented on the issue, and makes the findings and conclusions set forth below.

## **II. LEGAL STANDARDS**

“A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006); *see also* 37 C.F.R. § 1.56(a) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”). “The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence.” *Id.* “The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’” *Id.* (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

“[T]he facts in inequitable conduct cases rarely, if ever, include direct evidence of admitted deceitful conduct.” *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1384 (Fed. Cir. 1998). “The intent element of the offense is thus in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.” *Id.* “However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.” *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). In addition, “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; 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.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part); *see also Larson Mfg. Co. of S.D. v. Aluminart Prod. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009).

The materiality of information withheld during prosecution may be judged by the “reasonable examiner” standard. *See Digital Control*, 437 F.3d at 1316. That is, materiality embraces “any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.” *Akron Polymer*, 148 F.3d at 1382 (emphasis in original) (internal quotations and citations omitted). Moreover, “[i]nformation concealed from the PTO may be material even though it would not invalidate the patent.” *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000).

“A party may show inequitable conduct by producing clear and convincing evidence of (1) material prior art, (2) knowledge chargeable to the patent applicant of prior art and its materiality, and (3) the applicant’s failure to disclose the prior art to the PTO with intent to mislead.” *Avid Identification Systems, Inc. v. Crystal Import Corp.*, 603 F.3d 967, 972 (Fed. Cir. 2010). In addition, inequitable conduct may be shown by clear and convincing evidence of the patent applicant’s “affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information – coupled with an intent to deceive.” *Nilssen v. Osram Sylvania*, 504 F.3d 1223, 1229 (Fed. Cir. 2007) (citations omitted). The duties owed to the PTO, such as the duty of candor, good faith, and honest, also apply to an applicant

prosecuting his patent pro se. *See id.* at 1226-29 (discussing how Nilssen eventually prosecuted his own patent applications and the court applied the same duties to Nilssen).

### **III. DISCUSSION**

At the outset, the Court observes that Defendants' claim of inequitable conduct essentially hinges on the Court finding that Dr. Saffran is a liar and that Dr. Saffran's testimony is not credible. Defendants' reliance on Dr. Saffran's alleged character for untruthfulness is clearly evidenced, for example, by their post-hearing briefing, which has the word "lied" or "liar" as a topic header for every subject in its brief but one. (*See* Table of Contents, Dkt. No. 318, at 2.) For the reasons discussed below, however, the does not find that Dr. Saffran's testimony was untruthful. Rather, at worst, Dr. Saffran's testimony in certain parts suffers from a lack of memory and/or lack of clarity, but the Court does not find that Dr. Saffran lacks any character for truthfulness or credibility in general. Therefore, after weighing all the evidence, including Dr. Saffran's testimony, the Court concludes that Defendants have not proven by clear and convincing evidence that Dr. Saffran committed inequitable conduct against the PTO for the '760 Patent. With this in mind, the Court proceeds into its factual findings and legal conclusions.

#### **A. Background and Factual Findings**

The Court issues the following findings of fact pursuant to Federal Rule of Civil Procedure 52.

##### *1. General Background and Surrounding Circumstances of the Prosecution of the '760 Patent*

Plaintiff Bruce N. Saffran ("Saffran") is the inventor of the '760 Patent. '760 Patent, Cover. Saffran received his Ph.D. in 1990 from the University of Utah and his M.D. from the

University of Cincinnati Medical School in 1992. DTX-2371. Saffran currently practices diagnostic and interventional radiology. (1/25 AM Tr., 45:5-8 (Saffran).)

The '760 Patent was not the first patent for which Saffran applied. On August 30, 1993, Saffran filed United States Patent Application No. 08/114,745, entitled "Malleable Fracture Stabilization Device With Micropores For Directed Drug Delivery." That application issued on November 14, 1995 as United States Patent No. 5,466,262 (the '262 Patent). (DTX-2.) The application that issued as the '760 patent (No. 513,092) was filed on August 9, 1995, as a continuation-in-part of U.S. Patent Application No. 114,745, which as noted above, issued as the '262 Patent. (PTX-002; DTX-0002.)<sup>2</sup> The '760 Patent is entitled "Method and Apparatus for Managing Macromolecular Distribution." '760 Patent, Cover.

The '760 patent was written and prosecuted by Dr. Saffran without an attorney prior to issuing on August 26, 1997. (1/25 AM Tr., 90:25-91:24; 117:23-118:2 (Saffran).)<sup>3</sup> Dr Saffran used the book *Patent It Yourself* (hereinafter *Patent It Yourself*) to guide him in drafting his patent specification and during prosecution of the application that became '760 patent. (1/25 AM Tr., 117:23-118:2 (Saffran).)

## 2. *Dr. Saffran's Credibility*

A significant amount of Saffran's evidence regarding his conception and development of the ideas for the invention and also his dealings with the PTO is developed through Dr. Saffran's testimony. For some of Dr. Saffran's testimony, there is no other direct evidence to confirm or

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<sup>2</sup> PTX and DTX refer to the plaintiff's and defendants' trial exhibits respectively.

<sup>3</sup> In order to be consistent with the parties' briefs, all citations to the trial transcript, aside from citations to closing arguments and jury instructions, are cited to the date, AM or PM to designate morning or afternoon, and then the "page:line" in the transcript. The inequitable conduct bench trial was held on March 2, 2011, so citations to "3/2 Tr." refer to that trial.

deny the testimony. For example, Dr. Saffran has no lab notebooks of experiments he performed or prototypes of any embodiments discussed in the '760 Patent. Saffran also has no witnesses that can directly testify to any experiments Saffran performed. The *Patent it Yourself* book has a chapter that discusses the need for documentation—including keeping records of ideas and experiments. DTX-2325 at CSF01740419. But the book also states that “[y]ou never have to furnish or demonstrate a working model of your invention.” DTX-2325 at CSF01740529.

Due to Saffran’s defense being significantly based on Dr. Saffran’s testimony, Defendants’ evidence and argument to support inequitable conduct largely consists of character attacks on Dr. Saffran and attempts to impeach Dr. Saffran. Defendants’ proposed findings of fact spend twelve pages alleging that Dr. Saffran’s testimony is not credible. (Dkt. No. 325, at 74-88.) The only live testimony Defendants offered at the inequitable conduct bench trial was a cross-examination of Dr. Saffran that lasted well over two hours, and much of this time was spent attempting to impeach Dr. Saffran. (*See generally*, 3/2 Tr. (Saffran).) Further, aside from the header that states “Materiality,” the table of contents of Defendant’s inequitable conduct post-trial brief shows that the header of every subject discussed in the brief mentions “Saffran’s Lies” or “Saffran Intentionally Lied.”<sup>4</sup> It is clear that Defendants’ primary argument for the Court to find inequitable conduct is because Dr. Saffran is a liar.

Defendants have had ample opportunity to obtain testimony by Dr. Saffran and have plenty of evidence to attempt to prove that Dr. Saffran is a liar and is not credible. Dr. Saffran

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<sup>4</sup> (*See* Dkt. No. 318, at 2, Table of Contents (including headers such as “Saffran Intentionally Lied to Obtain His Patent,” “Perjury: Saffran’s Lies To The Court About His Invention And His Dealings With The PTO,” “Saffran’s Lies About The Patent It Yourself Book,” Saffran’s Lies About His ‘Experiments,’” “Saffran’s Lies About His Conversations With The PTO,” “Inequitable Conduct: Saffran’s Lies To The PTO To Obtain His Patent,” “Saffran’s Lies About His Reliance on Dr. Langer’s Work”).)

has taken multiple depositions in this case and additionally in Dr. Saffran's previous patent infringement lawsuit of *Saffran v. Boston Scientific Corp.*, No. 2:05-CV-547 (TJW) (E.D. Tex.) ("the BSC Litigation").<sup>5</sup> The Defendants have the trial record from the BSC Litigation which includes trial testimony from Dr. Saffran. (DTX-3017.) The Defendants also have testimony from Dr. Saffran from the jury trial in this case and the inequitable conduct bench trial in this case. (See 1/25 AM Tr.; 1/25 PM Tr.; 3/2 Tr.) This constitutes approximately one thousand pages of testimony, which corresponds to many hours of testimony by Dr. Saffran. In addition to sworn testimony by Dr. Saffran, Defendants have a plethora documents and correspondence with the PTO where Dr. Saffran made statements that were made under a duty of honesty to the PTO.

The Court finds that Defendants have not proven that Dr. Saffran has a character of untruthfulness or that his testimony should be disregarded as untruthful. The Defendants have attempted to show the Court multiple instances in the record where Dr. Saffran has been untruthful or his testimony has been inconsistent or illogical. (See, e.g., Dkt. No. 315, 74-86; Dkt. No. 318.)<sup>6</sup> To illustrate, one allegation that Dr. Saffran is untruthful is that Dr. Saffran has changed his story regarding the *Patent It Yourself* book. At one point, Dr. Saffran stated that he "read the entire book." (3/2 Tr., 20:13-24.) But during his deposition, however, when asked

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<sup>5</sup> The Court has found three depositions in the trial record in this case, so Defendants had at least three depositions of Dr. Saffran to use. There was a deposition from the BSC Litigation on May 24, 2007 that is approximately 245 pages. (DTX-3024.) There were at least two depositions in this case: (1) a May 19, 2010 deposition that was approximately 327 pages; and a (2) August 11, 2010 deposition that was approximately 154 pages. (DTX-3019; DTX-3020.)

<sup>6</sup> The Court intends to be clear that by referring to Defendants' proposed findings of fact and conclusions of law or Defendants' post-trial briefing (in this portion of the text or other portions of this Memorandum Opinion and Order), the Court is not attempting to incorporate by reference those findings of fact into the Court's finding of fact. The Court is only referring Defendants' documents or arguments, unless otherwise stated, to show the existence of Defendants' arguments and allegations—in order to give context to this Court's findings of fact and conclusions of law.



how much he read of the book, Dr. Saffran replied “Bits and pieces of it. I mean, I guess that I looked through sections. You know, there is a lot of stuff that I didn’t look at in here.” (DTX-3019, 83:10-15.) These statements are inconsistent. When confronted about the statements at the inequitable conduct trial, however, Dr. Saffran explained that he was not being untruthful. Instead, he clarified that there were some sections of the book that were not as important to him that he would probably only skimmed. (3/2 Tr., 21:12-24 (“I don’t recall the whole book, but there were some things about attempts to licensing, there were some things that I skimmed through because they weren’t relevant to what I think I was doing . . . .” and “what I’m saying is that there were parts of the book that I read very intently and more closely than others”).) The Court was present to observe the live testimony at trial and finds that Dr. Saffran was not lying but instead suffered from a lack of clarity.

As noted above, Defendants have pointed to numerous instances in the record where Dr. Saffran has been allegedly untruthful or his testimony has been allegedly inconsistent or illogical. Similar to the one illustration above, the Court finds that, after reviewing and observing Dr. Saffran’s testimony, Defendants have not proven that Dr. Saffran has a character of untruthfulness or that his testimony should be disregarded as untruthful, but instead, only that his testimony at times suffers from a lack of clarity and/or memory. Considering the voluminous testimony that Defendants’ possess from Dr. Saffran from depositions and trials on multiple occasions over periods of years, it is not unusual that there are some inconsistencies due to failures of clarity and/or memory. The Court will consider Dr. Saffran’s testimony in its legal conclusions and will consider any memory or clarity failures to merely affect the weight to be accorded to that particular testimony.

3. *Dr. Saffran's Non-Disclosure of the Langer References*

Dr. Saffran did not disclose the PTO the Langer references.<sup>7</sup> The Langer references, including the Langer & Peppas article that was part of Defendants' invalidity defense, disclose, among other things, controlled drug delivery systems. *See, e.g.*, DTX-13 (Robert Langer, *Controlled Release: A New Approach to Drug Delivery, Technology Review*, 26-34 (April 1981)); DTX-11 (Robert S. Langer, *Polymers and Drug Delivery Systems in Long-Acting Contraceptive Delivery Systems* 22 (Gerald I. Zatzuchni, et al., eds, 1984)); DTX-12 (Robert Langer & Nikolas Peppas, *Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review*, *Rev. Macromol. Chem. Phys.* C23(1), 61 (1983)); DTX-21 (Langer, R & Peppas, N, *Present and Future Applications of Biomaterials in Controlled Drug Delivery Systems*, *Biomaterials*, 2:201- 214 (1981)); DTX-841 (Robert Langer, *New Methods of Drug Delivery*, *Science* 249:1527-1533 (Sept. 28, 1990)). These articles date back to the early 1980s. The specific Langer article relied on by Defendants for their invalidity defense, for example, discloses a “[p]endant chain system[]” where “a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage.” (DTX-21, at CSF00454995.) Defendants allege these Langer references were material and that Dr. Saffran knew of them and did not disclose them to the PTO with an intent to deceive.

Dr. Saffran was unaware of the Langer references until 2004 when he learned<sup>8</sup> of them

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<sup>7</sup> The parties and the Court use the term “Langer references” refers to various articles written by Dr. Langer. These include exhibits DTX-11, 12, 13, 21, and 841.

<sup>8</sup> Dr. Saffran did discover U.S. Patent No. 5,383,928 to Scott (“the Scott Patent”) in 1995, which was disclosed to the PTO. (*See generally* 3/2 Tr., 79:20-86:13.) The Scott Patent did cite to a book by Langer. (*Id.*) Dr. Saffran may have read Langer’s name, in passing, in 1995. But there is no evidence that this reference to Langer cause Dr. Saffran to research Dr. Langer and learn the relation of Dr. Langer’s work to Dr. Saffran’s work, to the extent they are related. So there is

preparing for a deposition in the BSC Litigation. (3/2 Tr., 155:5-156:12.) Dr. Saffran was not aware of the Langer references when drafting the '262 Patent or the '760 Patent. Dr. Saffran did not learn of Dr. Langer or the Langer references through his work with "Elvax" in 1988. Dr. Saffran worked with "Elvax" during lab work he did under Dr. Crutcher in the time frame of 1988. (*Id.* at 156:10-157:3; 61:17-23; 57:3-13.) At that time, Dr. Saffran did not associate Elvax with Langer in any way. (*Id.* at 57:23-58:3.) The recipe used by Dr. Saffran to process the Elvax was similar to a protocol described by Langer. (*Id.* at 63:4-66:12.) But the Elvax used by Dr. Saffran in 1988 could have been obtained from other sources besides Dr. Langer, such as DuPont. (*Id.* at 57:7-13; Dkt. No. 318, at 8 (Defendants' concede an article notes that it is available from DuPont or Dr. Langer).) Dr. Saffran only learned that Dr. Langer was associated with Elvax in 2004 during the course of preparing for the BSC Litigation (3/2 Tr., at 59:4-60:18), and that is why he referred to "Langer's Elvax" in an email in 2004. (DTX-506.) In addition, Dr. Crutcher has also testified that Dr. Langer was not discussed when Dr. Crutcher and Dr. Saffran were working together in 1988. (Crutcher Depo. Attached as Ex. 2 to Dkt. No. 314, 179:9-15.) Dr. Crutcher, in his deposition, did not recall any of the Langer references presented to him. (*Id.* at 179:16-185:14.) Therefore, the Court does not find that Dr. Saffran learned of Dr. Langer through his work with Elvax.

Although not required, Defendants have presented no direct evidence that Dr. Saffran knew of the Langer references before 2004; instead, Defendants only point to an array of circumstantial evidence that could *potentially* impute knowledge of the Langer references to Dr. Saffran as early as 1988. Saffran, on the other hand, has presented direct evidence (i.e., Dr.

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no evidence that Dr. Saffran "learned" of the Langer references in 1995.

Saffran's testimony) that shows he had no knowledge of the Langer references before 2004 and other circumstantial evidence, such as Dr. Crutcher's testimony, to corroborate this assertion. The Defendants, meanwhile, bear the burden of proof by clear and convincing evidence. The Court finds Dr. Saffran learned of the Langer references in 2004.

#### 4. *Dr. Saffran's Alleged Misrepresentations in the '760 Patent*

By using phrases such as "I have found," Dr. Saffran used the past tense twelve times in the '760 Patent. *See, e.g., '760 Patent, 5:19-23* ("Although this is true to some extent, *I have found* unexpectedly that if small molecules such as water, urea, bicarbonate, and hydrogen ions are permitted to pass through the device, healing occurs much more quickly.") (emphasis added). Dr. Saffran used the term "unexpected" twelve times in the '760 Patent. *See, e.g., id. at 8:35-37* ("I have found *unexpectedly* that, if one affixes medicine directly to the minimally-porous layer, one can bypass the need for the microporous layer entirely!") (emphasis added). Dr. Saffran used the term "surprising" twelve times in the '760 Patent. *See, e.g., id. at 8:15-17* ("Another *surprising* feature of this invention is that it can be manufactured to selectively restrain molecules of a particular ionic charge regardless of pore size.") (emphasis added). Dr. Saffran used the term "remarkable" four times in the '760 Patent. *See, e.g., id. at 7:42-46* ("Although the macromolecular restraint means of the Malleable Fracture Stabilization Device with Micropores is a feature of its minimally-porous layer, the present invention is *remarkable* in that it accomplishes this task using a single sheet, rather than a two layered sheet.") (emphasis added). Dr. Saffran described a feature as a major/significant advance (3 times) or significant improvement (6 times) over the prior art. *See, e.g., id. at 7:50-52* ("Therefore, the elimination of an entire layer while maintaining function is a *highly significant improvement* in design.")

(emphasis added). Dr. Saffran described features as entirely new or impossible using the prior art. *See, e.g., id.* at 15:13-18 (“Although I have disclosed the implantation of multiple medicines in my application for the Malleable Fracture Stabilization Device with Micropores, the surprising specificity of medicine release provided by the chemical bond is *entirely new* and unexpected.”) (emphasis added). Defendants’ allege that Dr. Saffran was making misrepresentations to the PTO that Dr. Saffran made actual discoveries or performed actual experiments. Additionally, Defendants’ allege that these statements by Dr. Saffran were intended to mislead or exaggerate to the PTO regarding the importance of the invention.

Dr. Saffran filed for both the ‘262 Patent and the ‘760 Patent without the help of an attorney. Dr. Saffran did not use similar language, such as “surprising” or “unexpected” in the ‘262 Patent, and Dr. Saffran used the present tense in the ‘262 Patent. But when Dr. Saffran was drafting the ‘760 Patent, he was much more excited about it than the ‘262 Patent. (3/2 Tr., 92:18-20 (Saffran) (“It was certainly more exciting, and I have spent a lot more time working on the ‘760 than I did on the ‘262.”).) Dr. Saffran even used an exclamation mark in the ‘760 Patent. ‘760 Patent, 8:35-37. Dr. Saffran did not think about which specific tense he was using when drafting the patent. (3/2 Tr., 93:4 (Saffran).)

Dr. Saffran did not perform formal experiments in a laboratory for the ‘760 Patent. Dr. Saffran, however, conducted experiments relating to the invention disclosed in the ‘760 patent in his home kitchen and basement prior to filing the application that became the ‘760 patent. (1/25 AM Tr., 68:8-10 (Saffran).) These home experiments used materials to approximate and study the physical chemistry of blood, drugs, stents, and the arterial wall. (*Id.* at 68:17-69:3.) In one such experiment, Dr. Saffran used pretzel sticks as an analog for a stent strut, butter as an analog

for a hydrophobic polymer, and chili oil as an analog for a hydrophobic drug. (*Id.* at 70:18-23.) Dr. Saffran coated the pretzel sticks with butter. (*Id.* at 69:5-8.) In this same experiment, Dr. Saffran dipped the butter-coated pretzel stick in a jar of chili oil. (*Id.* at 69:16-24.) Both butter and chili oil are hydrophobic materials. (*Id.* at 69:10-70:3.) Dr. Saffran then dipped a butter and chili oil coated pretzel stick in a glass of water, his analog for human blood, which is mostly water, and observed that the chili oil did not come off of the butter-coated pretzel stick into the water. (*Id.* at 71:3-13.) Using these analogs for a stent, polymer, and drug, Dr. Saffran concluded that hydrophobic bonds were causing the chili oil to stick to the butter coated pretzel stick in the presence of water. (*Id.* at 71:7-72:1.) To confirm his hypothesis, Dr. Saffran used vegetable oil, an analog for arterial tissue. (*Id.* at 72:7-73:21.) Dr. Saffran dipped the chili oil and butter-coated pretzel stick into the vegetable oil and observed that, over the period of twenty minutes, chili oil could be observed coming off of and moving away from the butter-coated pretzel stick. (*Id.* at 73:14-21.) These experiments showed Dr. Saffran that hydrophobic bonds and the breaking of hydrophobic bonds could be used to deliver medicines to a hydrophobic environment. (*Id.* at 74:1-12.)

In another experiment, Dr. Saffran prepared a stent analog by manipulating paperclips into a scaffolding in the form of a rudimentary stent. (*Id.* at 74:13-75:2.) Dr. Saffran coated his paperclip stent analog with butter, but found this experiment somewhat difficult to achieve results. (*Id.* at 75:4-10.) In another experiment, Dr. Saffran coated his paperclip stent analog with PAM® cooking spray. (*Id.* at 75:4-10.) In this experiment, Dr. Saffran dipped his coated paperclip stent analog in chili oil and then repeated the dipping into water or vegetable oil as in the prior experiment with the pretzel sticks. (*See id.* at 74:23-75:10.)

Dr. Nahum Goldberg can corroborate that Dr. Saffran was performing experiments at his home during the time frame around which Dr. Saffran conceived of the invention, but Dr. Goldberg did not know the specifics of those experiments. (DTX-2382 at 41:3-11 (Dr. Goldberg deposition) (“Q. BY MR. HOWARD: Did you ever discuss with Dr. Saffran the experiments that -- that he had been doing relating to his -- his -- his product? A. We never discussed a specific -- any specific experiment, rather that experiments were being done in his basement. Q. Did you ever witness any of these experiments? A. I was never present for any of these experiments.”).)

Through Dr. Saffran’s home experiments, he “discovered” and “found” various concepts and principles that partially formed the basis for the ‘760 Patent. Dr. Saffran was doing a significant amount of reading from a variety of sources during the time period before applying for his patents, and Dr. Saffran may have put ideas together through his training, education, and residency activities. (3/2 Tr., 97:3-98:25; 140:1-146:3 (Saffran).) Dr. Saffran did not, in the ‘760 Patent, refer to any data or specific experiments he had performed. (*Id.* at 95:6-17.) Dr. Saffran did not intend to convey to the examiners that he had performed any clinical or laboratory experiments with humans. (*Id.* at 139:22-25.) The Court finds that by using words such as “I have found,” “surprising,” and “unexpected,” that Dr. Saffran was not intending to deceive the PTO into believing he had actually performed laboratory experiments that he did not or that he had made actual discoveries he did not. Furthermore, the Court finds that by using the abovementioned words, Dr. Saffran was not intending to deceive the PTO by misleading the PTO regarding the importance of his invention.

## **B. Conclusions of Law**

The Court makes the following conclusions of law based on the abovementioned findings of fact and the relevant caselaw, including the legal principles discussed in the “legal standards” section above.

1. *General Conclusions*

This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) and 2201-2202. This Court has personal jurisdiction over the Defendants because they do business and sell infringing products in this judicial district and within Texas. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

2. *The Court Concludes Dr. Saffran Did Not Commit Inequitable Conduct Toward the PTO by Withholding the Langer References*

Based on the abovementioned findings of facts and applicable caselaw discussed above, the Court concludes that Dr. Saffran did not commit inequitable conduct towards the PTO by not disclosing the Langer references. In order to conclude that Dr. Saffran committed inequitable conduct, the Court must conclude that Defendants have proven by clear and convincing evidence that the Langer references were material and that Dr. Saffran withheld them from the PTO with the intent to deceive the PTO. *See Nilssen*, 504 F.3d at 1229.

Based on the “reasonable examiner” standard for materiality, the Court concludes that the Langer references were material. *See Digital Control*, 437 F.3d at 1316. An examiner would substantially likely consider the Langer references important in deciding whether to issue the ‘760 Patent. As noted above, the specific Langer article relied on by Defendants’ for their invalidity defense, for example, discloses a pendant chain system where a drug is chemically bound to a polymer backbone-chain and is released by hydrolytic or enzymatic cleavage. (DTX-21.) This is at least relevant to Dr. Saffran’s discussion of hydrologic chemical bonds used for



the medicine release kinetics in one embodiment discussed in the ‘760 Patent. ‘760 Patent, 14:53-15:20. Although the jury considered this Langer article in its determination of whether the ‘760 Patent is valid, the fact that the jury did not invalidate the patent based partially on this reference does not mean it is not material for purposes of inequitable conduct. *Li Second Family Ltd. Partnership*, 231 F.3d at 1380. Defendants have proven that the Langer references are material by clear and convincing evidence.

Although the Court concludes the Langer references are material, the Court concludes that Dr. Saffran did not withhold the Langer references with intent to deceive the PTO. Dr. Saffran could not have withheld the Langer references with intent to deceive because Dr. Saffran was not aware of those references until 2004, which was after the prosecution of the ‘760 Patent. Defendants have not proven by clear and convincing evidence that Dr. Saffran intended to deceive the PTO by withholding the Langer references. Therefore, the Court concludes that Dr. Saffran did not commit inequitable conduct towards the PTO by not disclosing the Langer references.

3. *The Court Concludes that Dr. Saffran Did Not Commit Inequitable Conduct Toward the PTO by Making Statements in the ‘760 Patent such as “I have found” and “unexpected”*

The Court also concludes that Defendants have not proven by clear and convincing evidence that Dr. Saffran committed inequitable conduct towards the PTO by making statements in the ‘760 Patent such as “I have found.” As noted above, inequitable conduct may be shown by clear and convincing evidence of the patent applicant’s “affirmative misrepresentations of material facts, failure to disclose material information, or submission of false material information – coupled with an intent to deceive.” *Nilssen*, 504 F.3d at 1229 (citations omitted).

The Court concludes that Dr. Saffran did not commit inequitable conduct by the mere fact that Dr. Saffran used the past tense in the '760 Patent. The Federal Circuit in *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003) held that the district court did not clearly err in considering the applicant's use of the past tense. The applicant in *Hoffman-La Roche* used the past tense in reference with data results and particular experimental methods. *See id.* at 1363 ("The inventors state, for example, that a certain quantity of cells 'were resuspended in 75 ml of a buffer,' that the cells 'were lysed in a French press.'"). Further, in *Hoffman-La Roche*, "[e]ach step of the example, over more than two columns of the patent, [was] described in the same fashion, using the past tense." *Id.* at 1363-64. In that case, the district court had found that the use of the past tense was an intentional misrepresentation because it was knowingly false. *Id.* at 1366-67. The Federal Circuit in *Novo Nordisk Pharm., Inc. v. Bio-Tech. General Corp.*, 424 F.3d 1347, 1357-1363 (Fed. Cir. 2005) also considered the use of past tense, but like *Hoffman-La Roche*, the applicant also mentioned specific data and detailed experimental steps. One example in the patent in that case stated "that '[t]he fusion product *was purified* from this extract,' 1983 PCT application at 10 (emphasis added), that '[t]he purified fusion protein *was evaluated* to be more than 98% pure,' *id.* (emphasis added), and that '[t]his . . . product *was then treated* with leucine aminopeptidase.' *id.* (emphasis added)." *Id.* at 1357. Unlike these cases, however, Dr. Saffran never provided a detailed experimental procedure and never presented any detailed numerical results upon which the examiners could have possibly relied when determining the patentability of the '760 patent and believed that the past tense may have been used for experiments that had not been physically performed. Therefore, Defendants have not proven with clear and convincing evidence that these alleged

misrepresentations were material. Furthermore, the Court has found that Dr. Saffran, when making these statements, did not intend to imply that he had actually performed laboratory experiments that he did not or that he had made actual discoveries he did not. Therefore, the Defendants have not shown by clear and convincing evidence that the use of the past tense was with an intent to deceive. Hence, Dr. Saffran did not commit inequitable conduct by using the past tense in the '760 Patent.

The Court also concludes that Dr. Saffran did not commit inequitable conduct by virtue of using language such as “surprising,” “unexpected,” “I have found,” or “I have discovered.” First, the Court concludes that Defendants have failed to provide clear and convincing evidence of any material misrepresentation that resulted from such language. There is not clear and convincing evidence that a reasonable examiner would have thought Dr. Saffran had actually performed laboratory experiments that he did not or that he had made actual discoveries he did not. The Federal Circuit has stated that “[a] failure to inform the PTO whether a ‘surprising discovery’ was based on insight or experimental data does not in itself amount to a material omission.” *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 438 F.3d 1123, 1133 (Fed. Cir. 2006). Rather, the Federal Circuit required much more:

We emphasize that this case is an unusual one. A failure to inform the PTO whether a “surprising discovery” was based on insight or experimental data does not in itself amount to a material omission. In this case, however, Purdue did much more than characterize the four-fold dosage range of the claimed oxycodone formulation as a surprising discovery. Purdue repeatedly relied on that discovery to distinguish its invention from other prior art opioids while using language that suggested the existence of clinical results supporting the reduced dosage range. Presented with these unique facts, we cannot say the trial court erred in finding that Purdue failed to disclose material information to the PTO.

*Id.* Dr. Saffran’s representations or omissions, however, did not rise to the level of those in *Purdue Pharma*. Dr. Saffran did not come close to suggesting the existence of clinical studies, and the Court has already found that he did not suggest he had performed laboratory experiments that he did not. Indeed, even with the facts as they were in *Purdue Pharma.*, the Federal Circuit observed that “[w]hile we affirm the trial court’s finding that Purdue’s actions met a threshold level of materiality, we stress that the level of materiality [in the case of *Purdue Pharma.*] is not especially high.” *Id.* Therefore, for the abovementioned reasons, the Court concludes that Defendants have failed to provide clear and convincing evidence that the use of language such as “surprising” met the burden for materiality.

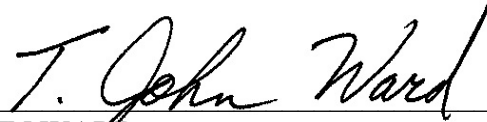
Second, the Court concludes that Defendants have failed to provide clear and convincing evidence that Dr. Saffran had the requisite intent to deceive the PTO when using language such as “surprising.” As noted in the Court’s factual findings above, Dr. Saffran was not intending to deceive the PTO into believing he had actually performed laboratory experiments or made actual discoveries that he did not. And Dr. Saffran was not intending to deceive the PTO by misleading the PTO regarding the importance of his invention. The most that may have been shown by the evidence is that Dr. Saffran was excited about the invention of the ‘760 Patent and consequently used language such as “surprisingly” or “remarkable” to emphasize his excitement to the PTO. In prosecuting his patent pro se, he even used exclamation marks. The Court concludes that such evidence is not clear and convincing evidence that Dr. Saffran had the requisite intent to deceive. Therefore, the Court concludes Dr. Saffran did not commit inequitable conduct by using language such as “surprising,” “unexpected,” or “I have found.”

## **V. CONCLUSION**

Having found that Defendants have not met their burden of proving inequitable conduct by clear and convincing evidence, the Court concludes that Dr. Saffran did not commit inequitable conduct toward the PTO. The Court therefore finds that the '760 patent is not unenforceable and DENIES Defendants' claim of inequitable conduct.

IT IS SO ORDERED.

SIGNED this 31st day of March, 2011.

A handwritten signature in black ink that reads "T. John Ward". The signature is written in a cursive style with a horizontal line underneath it.

T. JOHN WARD  
UNITED STATES DISTRICT JUDGE