UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

BAYER SCHERING PHARMA AG & BAYER HEALTHCARE PHARMACEUTICALS INC., *et al*.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC. AND SANDOZ INC., *et al*.,

Defendants.

Case No. 2:07-CV-01472-KJD-GWF
2:08-CV-00995-KJD-GWF

ORDER

Presently before the Court is Plaintiffs' Motion for Summary on Defendants' Inequitable Conduct Defenses and Counterclaims (#261/262). Defendants filed a response in opposition (#274) to which Plaintiffs ("Bayer") replied (#308/309). Defendants also filed a Cross-Motion for Sanctions (#289) against Plaintiffs for concealing and withdrawing essential witness Jurgen Spona. Plaintiffs filed a response in opposition (#308/309) to which Defendants replied (#312).

I. Facts

Defendants assert that Bayer, the patent applicant, and particularly Jurgen Spona ("Spona" or "Dr. Spona") submitted a demonstrably false declaration to overcome the United States Patent and Trademark Office's ("PTO") initial objections to the patent application. Despite knowing that Dr.

Spona's deceptive knowledge and intent in submitting the declaration was key to proving their inequitable conduct case, Defendants failed to obtain his testimony. Defendants assert that they were prevented from obtaining Spona's deposition testimony by Plaintiffs' actions in promising that he would voluntarily sit for his deposition, but failing to make him available at the last minute.

A. Material Facts Relating to Plaintiffs' Motion for Summary Judgment[1]

1. Defendants have no evidence that anyone involved in the prosecution of Bayer's patents had actual knowledge of the specific portions of undisclosed and allegedly material prior art references. (*See* Ex. 20, Watson's 2d Supp. Interrog. Resp. 19-27; Ex. 21, Sandoz's 2d Supp. Interrog. Resp.15-25; Doc. 147 at 12-25; Doc. 106 at 9.)

2. Dr. Düsterberg repeatedly and unequivocally testified that the results of Study Report AA51 were unexpected and surprising. (Ex. 24, 5/19/09 Düsterberg Dep. 181:14-184:7; Ex. 27, Dep. of B. Düsterberg 284:11-285:17 ("5/20/09 Düsterberg Dep."); Ex. 28, Dep. of B. Düsterberg 75:23-76:7, Feb. 18, 2010 ("2010 Düsterberg Dep."); *Id.* 100:7-101:5.)

3. The relevant drospirenone dose information that appears in AU '094 was submitted to the patent examiner in Dr. Düsterberg's declaration during prosecution of the '564 patent. (Ex. 14, Düsterberg Declaration 2.)

4. Defendants have no evidence showing that any specific individual with a duty to disclose information to the PTO was even specifically aware of the reference or the allegedly material portion of the AU '094 reference and intentionally chose to withhold it.

5. Dr. Düsterberg testified that the misplaced decimal point was simply the result of an oversight that escaped detection when he reviewed the document containing the error. (Ex. 24, 5/19/09 Düsterberg Dep. 66:14-17.)

6. Defendants have no evidence that the misplaced decimal point was the result of anything other than an oversight and an honest mistake.

[1] Citations refer to the exhibits attached to Plaintiffs' Motion for Summary Judgment, Doc. No. 262.

7. Study Report AA51 specifically notes that the ovarian suppression results are statistically significant. (Ex. 23, Study Report AA51 at 3; Ex. 24, Dep. of B. Düsterberg 117:13-22, May 19, 2009 ("5/19/09 Düsterberg Dep.).)

8. None of the '564 patent inventors were inventors of the AU '094 application, and Defendants have no evidence that any of the '564 patent inventors were actually aware of the AU '094 application during prosecution of their own '564 patent. (*Compare* Ex. 15, '564 patent, *with* Ex. 22, AU '094 application.)

9. The Court hereby incorporates by reference the facts set forth in the concurrently-filed Findings of Fact in the Order granting Bayer's Motion For Summary Judgment Of Non-Obviousness of Claims 13 And 15 Of United States Reissue Patent No. 37,564, Doc. No. 333.

'564 Patent Prosecution History

10. Drs. Jürgen Spona, Frank Lüdicke, and Bernd Düsterberg (collectively, "the Bayer inventors") applied for a United States patent on June 30, 1994. (Ex. 1, Transmittal Letter for U.S. Patent App. No. 08/268,996, June 30, 1994.)

11. Pursuant to 35 U.S.C. § 119(a), U.S. Patent Application No. 08/268,996 claimed priority to an earlier-filed German patent application (No. P 43 44 462.8), which the inventors filed in Germany on December 22, 1993. (Ex. 1, Transmittal Letter for U.S. Patent Application No. 08/268,996). As a result, the application was entitled to claim a priority date for its United States patent application as if it had been filed on December 22, 1993. *See* 35 U.S.C. § 119(a).

12. In a letter to Bayer dated March 7, 1995, the patent examiner rejected one set of Bayer's claims based on technical defects in the wording of the claims and rejected another set of claims based on her initial view that the claims were obvious. (Ex. 2, 3/7/95 Office Action.)

13. Bayer responded to the examiner on September 7, 1995, and amended one set of claims to cure the defects in the wording of the claims. (Ex. 3, Response Under 37 C.F.R. § 1.111.)

14. In addition, Bayer submitted attorney argument and a declaration from one of the inventors, Dr. Spona, which responded to the examiner's obviousness rejection of the second set of claims. (*Id*.)

15. On November 20, 1995, the PTO allowed Bayer's amended claims and again rejected the second set of claims as obvious. (Ex. 4, 11/20/95 Office Action.)

16. In order to get the set of claims the examiner had already allowed issued as a patent without delay, Bayer chose to cancel the set of claims that had been rejected and file those claims in a new application called a "continuation" application. (Ex. 5, 5/20/96 Amendment Under 37 C.F.R. § 1.116.)

17. The PTO issued the allowed set of claims on December 10, 1996, as U.S. Patent No. 5,583,129 ("the '129 patent"). (Ex. 6.)

18. On October 31, 1996, the Bayer inventors filed their continuation application seeking a patent on the set of claims the examiner previously rejected. (Ex. 7, U.S. Patent App. 08/742,147, Transmittal Letter, Claims.)

19. On May 7, 1997, the examiner rejected the continuation application's claims as obvious based on the combination of two prior art references: (1) European Patent Application EP 0 253 607 ("EP '607"); and (2) the package insert for Loestrin® 21 1/20. (Ex. 8, 5/7/97 Office Action.)

20. On October 7, 1997, Bayer responded to the rejection with claim amendments, remarks rebutting the examiner's rejection and attached the Spona declaration it had submitted during prosecution of the prior application. (Ex. 9, 10/7/97 Amendment Under 37 C.F.R. § 1.115, attaching Spona Declaration.) Bayer's remarks and the Spona declaration explained in detail why the amended claims were not obvious in light of the prior art, and specifically rebutted the examiner's reliance on the EP '607 and Loestrin 20 1/20 prior art references. (*Id*. at BSPW0108984-85, BSPW0108988-91.)

21. Specifically, Bayer argued that the amended claims' combination of low-dose ethinyl estradiol ("EE") and the 23/5 and 24/4 regimens were not obvious from EP '607 and Loestrin 20 1/20. (*Id*.)

22. In addition, Bayer argued that the amended claims were not obvious from those two references based on other advantages arising from administering the claimed progestins in the claimed doses and regimens. (*Id.* at BSPW0108984, BSPW0108986.)

23. After considering Bayer's submissions, on January 5, 1998, the examiner allowed Bayer's claims for, *inter alia*, the 23/5 and 24/4 monthly regimen for COCs containing drospirenone and low-dose EE. (Ex. 10, 1/4/98 Notice of Allowance.)

24. The PTO issued U.S. Patent No. 5,824,667 to Bayer on October 20, 1998. (Ex. 11, United States Patent No. 5,824,667.)

25. Bayer's '129 and '667 patents disclosed the results of a clinical study the inventors conducted comparing 21- and 23-day oral contraceptive regimens, known as Study Report AA51. (Ex. 6, '129 patent 4:20-50; Ex. 11, '667 patent 4:22-52.)

26. The '667 patent claimed combined oral contraceptives containing 23 or 24 daily dosage units of progestin/estrogen combinations followed by 5 or 4, respectively, placebo pills. (Ex. 11, '667 patent 6:9-25.)

27. The '667 patent claimed in part, "a gestagen selected from 0.25 to 0.30 mg of drospirenone . . . ." (Ex. 11, '667 patent 6:17.)

28. However, the '667 patent's claimed drospirenone dose range contained an error; the decimal point was misplaced. (Ex. 12, Additional Reissue Declaration Under 37 C.F.R. § 1.175 ("'564 Reissue Declaration").) The dose was supposed to be from 2.5 to 3.0 mg of drospirenone. (*Id.*)

29. As provided for under established Patent Office procedures, Bayer filed a reissue application to correct the decimal point mistake. (Ex. 13, '564 reissue application transmittal letter.)

30. In support of Bayer's reissue application, the three inventors submitted a joint declaration disclosing the error and attesting that it arose without any deceptive intention. (Ex. 12, '564 Reissue Declaration 2.)

31. In addition, one of the inventors (Dr. Düsterberg) submitted an additional declaration that one of ordinary skill in the art at the time of the invention would have understood that the originally claimed ranges contained the decimal point error. (Ex. 14, 2/11/00 Declaration Under 37 C.F.R. § 1.132 ("the Düsterberg Declaration").)

32. Because Bayer satisfied the requirements for reissue, the PTO granted Bayer's reissue application as the '564 reissue patent, which includes the correct drospirenone dose of "2.5 to 3.0 mg of drospirenone." (Ex. 15, '564 patent 6:61.)

33. Bayer filed two additional reissue applications in addition to the '564 reissue application seeking to correct decimal point error in alternative ways. In the second reissue application (the '838), rather than change the misplaced decimal point, it claimed a range of drospirenone that achieved the same amount of ovarian suppression as "75 μg of gestodene." (Ex. 16, U.S. Patent App. 09/504,084, Additional Reissue Declaration Under 37 C.F.R. §1.75, Feb. 15, 2000.)

34. The PTO granted this application as the '838 reissue patent. (Ex. 17, U.S. Reissue Patent No. 37,838.)

35. The third reissue application (the '253) combined the methods used to correct the decimal point error in the first two reissue applications. In short, it changed the decimal point *and* claimed an amount of drospirenone equivalent to "75 μg of gestodene." (*See* Ex. 18, U.S. Patent App. 10/080,617, Preliminary Amendment 1-2, Feb 25, 2002.)

36. The PTO granted this application as the '253 reissue patent. (Ex. 19, U.S. Reissue Patent No. 38,253.)

Defendants' Inequitable Conduct Theories

37. Defendants' inequitable conduct interrogatory responses do not mention any specific claim or claim limitation of the '564 patent that map onto a specific portion of a prior art reference. (*See* Ex. 20, Watson's 2d Supp. Interrog. Resp. 20-27; Ex. 21, Sandoz's 2d Supp. Interrog. Resp. 15-25.)

38. Defendants' inequitable conduct interrogatory responses also fail to identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record. (*See* Ex. 20, Watson's 2d Supp. Interrog. Resp. 20-27; Ex. 21, Sandoz's 2d Supp. Interrog. Resp. 15-25.)

Materiality And Intent

39. Defendants have no evidence that any of the allegedly misleading statements were known or even suspected of being misleading by anyone involved in prosecution of the patents. (*Id.*)

40. Results from Study Report AA51 were published in the journal *Contraception* and have been repeatedly cited to and relied upon by experts in the field over the last 14 years, without objection to the arguments that Defendants' expert raises. (Ex. 26, Expert Report of J. Sanfilippo 55 ("Sanfilippo Rep.").)

41. The *Contraception* article concludes that "our present [ovarian suppression] data suggest a potential for greater contraceptive efficacy for the 23-day formulation." (Ex. 25, *Contraception* 1996 at 76.)

42. The inventors disclosed to the patent examiner that the inventors' study AA51 examined the progestin gestodene. (Ex. 15, '564 patent 4:31-38.)

43. The examiner was also aware that Bayer's patent application claimed drospirenone. (Ex. 15, '564 patent.)

44. The Bounds article taught that Loestrin 21 1/20 showed poor cycle control and therefore recommended a progestin-only pill instead of a 20 μg EE preparation. (Ex. 32, Bounds 1979.)

45. The Fraser article taught that the lowest dose combinations, such as those containing 20 mcg EE "have a greatly reduced margin for error." (Ex. 33, Fraser 1983.)

46. The Fraser article further taught that "If taken strictly according to instructions, the pregnancy rates are very low, but when 3 or more pills are missed, pregnancy rates rise, especially in the very low-dose formulations (10-20 μg of estrogen)." (*Id.* at 538.)

47. The Bayer inventors themselves were studying a low-dose 20 μg EE preparation in a 21-day regimen that had unacceptably high levels of follicular development as compared to the same product in a 23-day regimen. (Ex. 23, Study Report AA51.)

Sandoz's Dose-Correction Theory Of Inequitable Conduct

48. In his declaration, Dr. Düsterberg identified six different references published before 1993 that all showed the drospirenone dose with the misplaced decimal point (0.25 to 0.30 mg) would not have been effective for oral contraception—in fact, such a range was an order of magnitude below the effective dose, and as such was not even close to being effective for contraception. (Ex. 14, Düsterberg Declaration 2.)

49. Dr. Düsterberg confirmed during his deposition that his declaration was accurate. (*See, e.g.*, Ex. 24, 5/19/09 Düsterberg Dep. 64:16-68:7, 69:16-73:2, 79:2-16.)

B. Material Facts Relating to Motion for Sanctions

50. Dr. Jürgen Spona is a former university professor who lives in Vienna, Austria. Dr. Spona has never been a Bayer employee. Dr. Spona has never been designated as a Rule 30(b)(6) designee for Bayer in the above-captioned case, and is not on Bayer's intended trial witness lists in the above-captioned case. However, he was disclosed as a potential witness by Bayer as an inventor of the claimed invention.

51. During the course of litigation, Bayer's counsel, Bartlit Beck Herman Palenchar & Scott LLP ("Bartlit Beck"), represented to Defendants that even though Dr. Spona was not a Bayer employee, he was willing to voluntarily sit for a deposition. Bartlit Beck represented Spona in conjunction with the deposition.

52. By April 2008, Spona and several other European foreign witnesses (Dr. Joachim Marr, Dr. Bernd Düsterberg and Ms. Anita Krause) had agreed to sit for voluntary depositions in Europe. The parties eventually agreed that the depositions would be taken in Amsterdam.

53. Several of the deponents, including Spona, had agreed only to sit for one-day, not more.

54. Dr. Spona's deposition was scheduled for May 13, 2009. Barlit Beck had scheduled May 12, 2009 to prepare Spona for his deposition.

55. On May 11, 2009, Barlit Beck received an email from Spona who claimed that he was suffering an "acute medical condition" and would be unable to travel to Amsterdam for the preparation session and deposition.

56. Later in the day by phone, Spona refused to commit to a specific future date for his depostion, though Bartlit Beck tried to reschedule the deposition while the attorneys were still in Europe.

57. Spona declined to have his deposition taken the following weekend in Vienna, his city of residence.

58. Upon returning to the United States, Barlit Beck attempted to contact Spona to reschedule the deposition.

59. It was not until June 23, 2009, that Spona informed Bartlit Beck that he was no longer willing to sit for a voluntary deposition.

60. Over the course of the litigation Düsterberg was deposed for a total of eighteen (18) hours over three (3) days.

61. After Spona's deposition was canceled, fact discovery was continued on five separate occasions.

62. Fact discovery in the case did not expire until September 1, 2010.

63. Defendants never attempted the letters rogatory process necessary to compel Spona's testimony as a foreign witness.

II. Summary Judgment on Defendants' Inequitable Conduct Claims

To prevail on their inequitable conduct claims, Defendants must show by clear and convincing evidence that the applicants for the '564 patent misrepresented or omitted material information with the specific intent to deceive the PTO. See Star Scientific, Inc. v. R.J. Reynolds

Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008). On May 25, 2011, after the present motions had been filed, the Federal Circuit issued its *en banc* opinion in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011). The Federal Circuit granted *en banc* reconsideration in Therasense to determine whether and how to modify the legal framework governing inequitable conduct. In the *en banc* opinion, the Federal Circuit observed that "the inequitable conduct doctrine has plagued not only the courts but also the entire patent system." Id. at 1289. The Federal Circuit tightened the standards for proving both intent to deceive and materiality "in order to redirect a doctrine that has been overused to the detriment of the public." Id. Specifically, the court held that materiality requires evidence that the patent claims at issue would not have been granted "but for" a withheld reference or misrepresentation. Id. at 1291.

Therasense also reaffirmed the principle that to meet the clear and convincing evidence standard, the specific intent to deceive must be the "single most reasonable inference to be drawn from the evidence." Id. at 1290 (quoting Star Scientific, 537 F.3d at 1366). "Indeed, the evidence 'must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.' Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 873 (Fed. Cir. 1988)(emphasis added). Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." Id. Given that Defendants could not meet the lower inequitable conduct standard pre-Therasense, they also do not satisfy Therasense's new inequitable conduct standard.

In their opposition, Defendants appear to have abandoned the majority of the inequitable conduct theories contained in their pleadings and interrogatory responses. (Compare Opp'n, 4-9, with Doc. 106; Doc. 147; Br. Ex. 20, 11/17/10 Watson's 2d Supp. Interrog. Resps. 19; Br. Ex. 21, 11/18/10 Sandoz's 2d Supp. Interrog. Resps. 15.) Instead, Defendants focus on an allegedly false statement in a declaration that Dr. Spona submitted to the PTO on September 7, 1995 ("the Spona Declaration") as well as a handful of prior art references that Defendants claim Bayer withheld from the PTO. Neither of these theories of inequitable conduct has been pled.

In fact, Defendants' opposition brief contains no response to Bayer's extensive arguments that Defendants have failed to properly plead an inequitable conduct claim. The only defendant that ever attempted to plead an inequitable conduct counterclaim with any specificity at all is Sandoz, and that theory related to an issue in the '564 reissue patent that Defendants have now declared to be "irrelevant." Inequitable conduct must not only be pled, it must be pled with particularity under Rule 9(b) of the Federal Rules of Civil Procedure. See Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1326-27 (Fed. Cir. 2009). Defendants have failed to plead their current theories of inequitable conduct, and have certainly not done so with the specificity required by Rule 9(b). It is undisputed that neither Defendant pled any facts related to (1) the allegation that Dr. Spona misled the PTO by filing an allegedly false declaration; or (2) the alleged withholding of any prior art references. (See Doc. 106, Watson's Answer and Am. Countercls. 9; Doc. 147, Sandoz's 2d Am. Answer and Countercls. 12-24.) The law is clear that Defendants cannot rely on unpled inequitable conduct allegations to defeat Bayer's motion for summary judgment. See, e.g., Am. Med. Sys., Inc. v. Laser Peripherals, LLC, 712 F. Supp. 2d 885, 920-21 (D. Minn. 2010) (citing Rule 9(b) and Exergen to hold that inequitable conduct theories not pled in defendant's answer and counter-claims cannot be used to defend against patent holder's motion for summary judgment of no inequitable conduct).

Defendants have waived these claims by failing to oppose Plaintiffs' motion with points and authorities in opposition. See Local Rule 7-2(d)(failing to oppose a motion with points and authorities allows the court to constitute the lack of response as consent to the motion being granted); S. Nev. Shell Dealers Ass'n v. Shell Oil Co., 725 F. Supp. 1104, 1109 (D. Nev. 1989)(failure to oppose movant's argument in brief opposing motion for summary judgment implicitly concedes the argument).

Furthermore, even if the claims had been pled properly, the Court would still grant Plaintiffs' motion for summary judgment, because Defendants have not raised any genuine issues of material fact. Defendants contend that the Spona Declaration contained a false statement and that two documents withheld from the PTO prove the statement was false. Separately, Defendants also argue

that Bayer withheld three prior art references from the examiner. The undisputed material facts demonstrate that Defendants cannot prove these allegations, and Bayer is entitled to judgment as a matter of law.

Defendants' inequitable conduct defense is based on a single passage from the Spona Declaration. This passage states that the results of Study AA51 that led to the invention were surprising and unexpected. Defendants claim that this statement is material and that "[a]ll that is missing is proof of deceptive intent on the part of the declarant, Dr. Spona." The Court disagrees with Defendants' statement that they have provided enough evidence to defeat a motion for summary judgment.

To support their theory of inequitable conduct, Defendants must first prove that the Spona declaration contains a false statement or misrepresentation. See Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1229 (Fed. Cir. 2007). In addition, they must show that the allegedly false statement was material to patentability and that Dr. Spona made the statement with a specific intent to deceive the PTO. See id. Apart from the evidentiary deficiencies with regard to materiality and intent, Defendants' inequitable conduct claim fails because there are no false statements in the Spona declaration. Thus, Bayer's motion for summary judgment must be granted because Defendants cannot raise a genuine factual dispute regarding the veracity of any statement in the Spona declaration.

A. The Spona Declaration

Defendants assert that a short excerpt of the declaration suggests that Dr. Spona told the PTO that the surprising aspect of the invention was the fact that the new 23-day oral contraceptive regimen led to an increase in ovarian suppression over the traditional 21-day regimen and that this statement was false. The Court disagrees.

It was not the fact that the 23-day regimen had increased ovarian suppression over the 21-day regimen that was surprising. It was the 23-day regimen's dramatic degree of increased ovarian

suppression over the 21-day regimen that Dr. Spona and the other inventors found surprising. This is evident from the full statement in the Spona declaration:

> Therefore, it was surprising to show that administration of the very low dosages of the compositions of the instant invention for an additional two days, in comparison to the standard 21/7 day regimen, ***reduced the frequency of follicular development (i.e., enhanced the ovarian suppression)*** in the woman who has not yet entered the premenopausal phase ***from 40% to 13%***. ***This reduced ovarian activity*** results in increased contraceptive efficacy. This result was completely unforeseeable from the teaching of the prior art.

(Spona Decl. 4.) This is also what the specification of the '564 patent says: "The intake interval extended only by two days surprisingly produces ***a significantly greater ovarian suppression*** with unchangingly low daily doses." (Br. Ex. 15, '564 patent 4:62-64.) Thus, it is irrelevant that some evidence exists that the inventors expected improved ovarian suppression as a result of the 23-day regimen. What was unknown, unexpected, and surprising was just how much greater the suppression would be when compared to the 21-day regimen. None of the "evidence" that Defendants identified in response to Bayer's motion for summary judgment demonstrates that the inventors expected or predicted ***the degree*** of ovarian suppression that the 23-day regimen would provide over the 21-day regimen. Furthermore, none of Defendants' evidence shows that the inventors then intentionally misled the PTO into believing otherwise.

Both the Spona declaration and deposition testimony from inventor Düsterberg establish that the results of Study AA51 were surprising and unexpected. (Ex. 1, Spona Declaration; Ex. 36, 5/19/09 Düsterberg Dep. 181:14-184:7; Ex. 37, 5/20/09 Düsterberg Dep. 284:11-285:17; Ex. 38, 2/18/10 Düsterberg Dep. 75:23-76:7, 100:7-101:5.) Defendants do not cite testimony from any fact witness to refute this evidence. The only piece of testimony that Defendants cite is a purported admission from Bayer expert Dr. Sanfilippo, that the results of study would have been expected. (Doc. 276, Sealed Resp. to Bayer's Statement of Material Facts 2 (citing Sanfilippo Dep. 226:6-230:17.) Defendants parse the language to make the cite appear to support their position.

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Here is Dr. Sanfilippo' full statement in the cited excerpt:

> Q. Okay. Thank you. And my question was, are you surprised by the degree of the difference or the fact that there is just a difference?
>
> A. ***I am surprised, clearly, by the degree*** because of the statistical significance.
>
> ***
>
> Q. Based on the prior art . . . wouldn't you expect the 23-day regimen to have more ovarian suppression than 21-day regimen?
>
> A. Yeah. Yes. ***Not statistically significant to the degree that was found but***, yes, absolutely.

(Ex. 39, Sanfilippo Dep. 229:12-17, 230:9-16.) This evidence is completely consistent with the Spona declaration and Dr. Düsterberg's testimony, both of which establish that the results of Study AA51 were unexpected. Therefore, the testimonial evidence in this case unanimously supports the veracity of the Spona declaration.

Defendants also assert that two other documents support their position. The first piece of evidence Defendants identify are the minutes of a meeting of the group of clinicians who conducted Study AA51. The minutes say that the 23-day regimen "would be expected to lead to greater suppression of ovarian activity." (Ex. 44, 12/6/91 Meeting Minutes.) It does not contradict the statement in the Spona declaration or the '564 patent discussing the surprising ***degree*** of ovarian suppression provided under the 23-day regimen. Furthermore, Dr. Düsterberg gave extensive testimony about this document and explained that it merely reflected a working hypothesis and not a firm expectation:

> ***I'd like to clarify that this is not a fixed expectation, that this was not an expectation in the usual sense.*** If you read that carefully, the wording is "would be expected to." That is a conjunctive and it implies that also other possibilities would be there. ***It is nothing else than the working hypothesis that we had.*** And the expectation was limited to the assumption that there could be an effect, but we did not have any idea about the amount of the effect, and if there would be any effect at all.

(Ex. 36, 5/19/09 Düsterberg Dep. 187:16-25; see also id. 189:8-20, 190:2-8, 190:17-191:4.) As a

result, Defendants' reliance on the December 6, 1991 meeting minutes fails to create any genuine issue of material fact.

Defendants next rely on a 2001 article written by J. Endrikat, who was not an inventor of the'564 patent. Defendants contend that the Endrikat 2001 article states that the 23-day regimen provided only "slightly superior" ovarian suppression than the 21-day regimen. In fact, the article states that the difference in ovarian suppression "might not be highly relevant for compliant users, but could be of particular importance for women who tend to miss at least two pills per cycle. (Ex. 3, Endrikat 2001 at 103.) Furthermore, Dr. Düsterberg, listed as a co-author of the article, testified that the term "slightly" in the article was inaccurate but that the statement as a whole supported the findings of Study AA51:

> I think that the term that has been used here [*i.e.*, "slightly superior"] is not the exact term that describes the findings of [Study AA51] exactly, but it was used. But it does not undermine the findings published in the Spona paper describing a very strong effect of the 23-day version on the ovarian activity.

(Ex. 36, 5/19/09 Düsterberg Dep. 236:24-237:4; see also id. 235:6-236:7; *id.* 237:11 ("It was certainly not a slight effect . . . .").) This unrebutted testimony renders the statement in the Endrikat 2001 article meaningless for inequitable conduct purposes.

Additionally, the article itself was written in 2001, long after the inventors in this case filed their patent applications with the PTO. Therefore, the article could not have been disclosed to the PTO or form the basis of any inequitable conduct defense. Defendants cannot establish any genuine dispute that the statements in the Spona declaration regarding whether the surprising results of Study AA51 were true. This failure to submit relevant evidence entitles Bayer to summary judgment.

B. The Prior Art References that Defendants Allege Bayer withheld from the PTO are Cumulative

Defendants assert that Bayer withheld from the PTO "the critical Molloy and Goldstuck articles and the AU '094 patent application[.]" First, this argument cannot serve as the basis of an inequitable conduct claim because Defendants have cited no evidence that the inventors or anyone

else connected with the prosecution of the '564 patent were actually aware of these references and then chose to intentionally withhold them from the PTO. See Digital Control, Inc. v. Charles Mach.Works, 437 F.3d 1309, 1318 (Fed. Cir. 2006) (holding that to prevail on an inequitable conduct claim, "the patentee must have actual knowledge of the prior art" alleged to have been withheld).

Second, each of these references is cumulative with other art disclosed to the PTO in connection with the prosecution of the '564 patent and its predecessors. Id. at 1319 (stating that a reference cannot be material for inequitable conduct purposes if it would have merely disclosed information that was cumulative of other references considered by the examiner).

The Molloy letter reported the results of a study measuring ovarian follicle size in study subjects taking combined oral contraceptives containing 30-40 μg of ethinylestradiol ("EE") in a 21/7 regimen. (Ex. 40, Molloy 1985.) However, the Guillebaud 1987 article disclosed the results of the Molloy letter. (Ex. 41, Guillebaud 1987 at 36). It is undisputed that the inventors submitted Guillebaud 1987 to the PTO, which appears on the face of the '564 patent under the heading "references considered". (Br. Ex. 15, '564 patent.) Therefore, the Molloy letter is cumulative with Guillebaud 1987. (Br. Ex. 26, Sanfilippo Rep. 48.) Similarly, the Goldstuck article merely contains a citation to the Guillebaud 1987 article's limited suggestion that certain women at risk of pill failure should consider a 24-day regimen using high-dose EE pills. (Ex. 42, Goldstuck 1987; Doc. 281, Bayer's Opp'n to Defs.' Joint Mot. for Summ. J. 20-22.) Accordingly, the Goldstuck reference is also cumulative with Guillebaud 1987.

The AU '094 patent application is also cumulative with art of record in the '564 patent prosecution. It is undisputed that the inventors submitted the '652 patent to the examiner which is cumulative with its AU '094 counterpart. (Br. Ex. 15, '564 patent, references considered.) The AU '094 application is also cumulative with other art of record. The inventors disclosed EP 0398 460 B1 ("EP '460") to the examiner, which is the AU '094 application's European counterpart. (Br. Ex. 15, '564 patent, references considered.) The examiner concluded that the European counterpart was the

"closest prior art," indicating that she considered it carefully. (Ex. 43, 8/15/00 Office Action, '564 patent file history.) Finally, the relevant drospirenone dose information that appears in AU '094 was also submitted to the patent examiner as part of Dr. Düsterberg's declaration during the prosecution of the '564 patent. (Br. 18.) This further establishes that the allegedly "withheld" information in AU '094 had already been disclosed to the examiner through other references.

Therefore, there is no genuine dispute of fact that the allegedly withheld references are cumulative with the art or record and therefore cannot support a claim of inequitable conduct. Accordingly, because no genuine issue of material fact exists, the Court grants Plaintiffs' motion for summary judgment on Defendants' equitable conduct claims.

III. Defendants' Motion for Sanctions

Defendants assert that they were prevented from obtaining Spona's deposition testimony by Plaintiffs' actions in promising that Spona would voluntarily sit for his deposition, but failing to make him available at the last minute. Defendants seek sanctions requiring Bayer and Bartlit Beck to pay all attorney's fees and costs incurred by Defendants associated with Defendants' counsels' preparation for and travel to take Dr. Spona's deposition in Amsterdam. They also seek an order that Dr. Spona's declaration to the PTO be inadmissible. Defendants also seek imposition of an adverse inference that Dr. Spona acted with deceptive intent in executing and submitting his declaration to the PTO.

A. Rule 37(d) Sanctions Are Inapplicable In This Case

Defendants' cross-motion seeks relief under Rule 37(d), which permits a court to impose sanctions if:

> a ***party*** or a ***party's officer, director, or managing agent*** – or a person designated under Rule 30(b)(6) or 31(a)(4) – fails, after being served with proper notice, to appear for that person's deposition.

Fed. R. Civ. P. 37(d)(1)(A)(i) (emphasis added). Rule 37(d) only applies to actions of a "***party***" or that party's managing agent, officer, director, or designee for corporate testimony. Id. The Ninth Circuit case Defendants rely upon for the legal standard under Rule 37(d) exemplifies this point. In

Lew v. Kona Hospital, 754 F.2d 1420, 1422, 1426-27 (9th Cir. 1985) , the Ninth Circuit affirmed an award of sanctions under Rule 37(d) where the defendant failed to appear for his own deposition. In fact, the Ninth Circuit has stated that "Rule 37(d) . . . addresses only a party's failure to appear at his own deposition." Pennwalt Corp. v. Durand-Wayland, Inc., 708 F.2d 492, 494 n.4 (9th Cir. 1983).

It is undisputed that Dr. Spona is not a party to this litigation. Dr. Spona is also not a managing agent, officer, director, or Rule 30(b)(6) or 31(a)(4) designee for Bayer. Thus, Defendants' motion for sanctions fails as a matter of law.

Defendants argue that the scope of Rule 37(d) should be extended beyond its plain language so that a *party* could be sanctioned for the failure of a *non-party* to appear at his deposition. However, Defendants rely solely on non-binding district court cases from other circuits. Defendants ask this Court to interpret the word "party" in Rule 37(d) to include "non-party." District courts in this jurisdiction and elsewhere have recognized that the Ninth Circuit interprets Rule 37(d) strictly. See Bishop v. Potter, No. 2:08-cv-00726, 2010 WL 2771763, at * 2 (D. Nev. June 4, 2010)(noting that "[t]he Ninth Circuit has strictly construed the language of Rule 37(d)" and citing Estrada v. Rowland, 69 F.3d 405, 406 (9th Cir. 1995)); Koninklike Philips Elecs. N.V. v. KXD Tech., Inc., No. 2:05-cv-1532, 2007 WL 3101248, at *18 (D. Nev. Oct. 16, 2007)(same); In re Air Crash at Taipei, Taiwan, No. MDL 1394, 2002 WL 32155477, at *6 (C.D. Cal. Oct. 23, 2002) (same).

In Estrada the Ninth Circuit held that a party who *physically appeared* but refused to answer questions at a deposition was not subject to Rule 37(d) sanctions. See 69 F.3d at 406. This was because the Ninth Circuit interpreted the words "fails . . . to appear" in Rule 37(d) to include only an actual failure on the part of a party deponent to show up on the date of his properly noticed deposition could trigger the Rule. Id.; see also Campbell v. Blodgett, 1993 WL 191876, at *4 (9th Cir. June 4, 1993) (reversing award of sanctions where party deponent appeared but refused to answer questions). Given the literal interpretation the Ninth Circuit gives to the term "fails . . . to appear" in Rule 37(d), it follows that a similarly strict construction of the term "party" is appropriate under Ninth Circuit law. Accordingly, the Court declines to sanction Plaintiffs under Rule 37(d).

B. Bayer Does Not Control Dr. Spona

Defendants attempt to support their sanctions motion by claiming that Bayer and its attorneys ("Bartlit Beck") "have effectively controlled Dr. Spona from the beginning of this case[.]" (Opp'n 13.) First, Defendants point out that Bartlit Beck agreed to represent Dr. Spona for the purposes of his deposition. Second, Defendants cite the fact that Bartlit Beck asked for communications with Dr. Spona to go through counsel. Third, Defendants note that attorneys from Bartlit Beck spent time with Dr. Spona in preparation for his deposition. However, the Court disagrees that Bayer or Bartlit Beck "controlled" Spona.

Defendants cite no legal authority supporting their argument that Bayer controlled Dr. Spona based on these facts. The mere fact that Bartlit Beck agreed to represent Dr. Spona for purposes of his deposition and met with Dr. Spona prior to his decision to not voluntarily sit for his deposition does not mean that Bayer "controls" Dr. Spona. In fact, the undisputed facts show that Bayer does not control Dr. Spona. Dr. Spona has never been a Bayer employee, has never been designated as a Rule 30(b)(6) designee, and is not on Bayer's intended trial witness lists (though he was originally on Bayer's "may call" witness list disclosed on April 15, 2009). (Ex. 30, 9/1/10 Bayer's 2d Supp. Resp. to Watson Interrog. No. 24; Ex. 31, 10/1/10 Bayer's 4th Supp. Resp. to Watson Interrog. No. 9; Skiermont Decl. ¶ 2.)

Bayer has repeatedly advised Defendants that it did not control Dr. Spona. Prior to bringing the instant motion, Defendants acknowledged this fact. For example, Bayer stressed the fact that it had no control over Dr. Spona at the May 8, 2009 discovery hearing:

> Dr. Spona is not now and has never been an employee of Bayer Schering. If Bayer had [its] worldwide CEO call Dr. Spona on the telephone and ordered him to sit for a second day of deposition, he could not do so. There would be no effective manner in which to make Dr. Spona sit for a second day of deposition.

(Ex. 16, 5/8/09 Hr'g Tr. 29:2-7.) The Magistrate Judge acknowledged this fact at the same hearing. (Id. 31:20-25.) More importantly, Defendants have previously conceded in briefing to this Court that

Dr. Spona was not under Bayer's control. In its July 31, 2009 motion to compel additional deposition time with Drs. Düsterberg and Marr, Defendant Watson wrote:

> Watson has already incurred significant expense in traveling to Amsterdam in May, primarily to take the deposition of non-party witness Jurgen Spona who is not subject to being deposed in the United States because [he is] not under Bayer's control.

(Doc. 105 at 6.) Accordingly, since Spona was not under Bayer's control, Bayer and Bartlit Beck are not responsible for his failure to appear.

C. Defendants Have Never Sought To Compel Dr. Spona's Attendance At A Deposition

Defendants filed the instant motion for sanctions on May 11, 2011 – ***two years to the day after Dr. Spona cancelled his voluntary deposition***. There is no evidence that Bayer has ever opposed efforts to secure Dr. Spona's testimony through the appropriate mechanisms under international law. Bayer informed Defendants of this on June 30, 2009, within days of learning that Dr. Spona would not re-schedule his voluntary deposition. Fact discovery in this case would continue for another 14 months. On May 8, 2009, the court ruled that it could not compel Dr. Spona or other European deponents to sit for additional time. On May 11, 2009, Spona cancelled his deposition. On June 23, 2009, Spona made clear that he declined to voluntarily sit for his deposition. Bayer contemporaneously informed Defendants that it would not oppose compulsory process. Fact discovery was continued five additional times, and finally closed on September 1, 2010. Expert discovery concluded on March 14, 2011. Dispositive motions were due April 11, 2011, and it was not until May 11, 2011 that Defendants moved for sanctions.

The Court declines to sanction Plaintiffs because Defendants made a tactical decision not to follow international procedures to compel the deposition of Dr. Spona.

IV. Conclusion

Accordingly, IT IS HEREBY ORDERED that Plaintiffs' Motion for Summary on Defendants' Inequitable Conduct Defenses and Counterclaims (#261/262) is **GRANTED;**

///

IT IS FURTHER ORDERED that Defendants' Cross-Motion for Sanctions (#289) is **DENIED**;

IT IS FURTHER ORDERED that Bayer's Motion to Strike (#313) is **DENIED**.

DATED this 30th day of March 2012.

Kent J. Dawson
United States District Judge