IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 10-805-RGA
	:	
TEVA PHARMACEUTICALS USA, INC,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

This is a case involving the validity of a patent that claims "entecavir." (D.I. 1, ¶ 14). Before the Court is the Plaintiff's Motion for Partial Summary Judgment of No Inequitable Conduct. (D.I. 95). It is premised on failure of the inventor (Dr. Zahler) and the two patent prosecuting attorneys (Venetianer and Davis) to disclose to the PTO prior art relating to the compound 2'-CDG. There are in the record "information disclosure statements" signed by one or the other of the attorneys, dated October 12, 1990 (Venetianer) (D.I. 107-5), and September 17, 1991 (Davis) (D.I. 107-11). The Venetianer disclosure statement references the duty to disclose and provide "patents, publications or other information which may be material to the examination of [the application that resulted in the patent at issue in this case]." The Davis disclosure statement references the duty to disclose and "includes what [Davis] believes to be the most relevant art." Neither information disclosure statement includes anything about 2'-CDG.

The Defendant pled inequitable conduct as its "Seventh Affirmative Defense." (D.I. 54,

pp. 7-21).

The parties have retained experts who have offered opinions about the materiality of 2'-CDG as prior art to the patent. *Compare* D.I. 110, Exh. 3, pp. 53-59 (Dr. Heathcock – "material") *and* D.I. 112, Exh. 6, pp. 19-25 (Dr. Schneller – "entecavir is not structurally similar to [2'-CDG]").

The applicable law is set forth in the recent *Therasense* decision of the Federal Circuit:

> To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a "should have known" standard does not satisfy this intent requirement. "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." In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.
>
> This requirement of knowledge and deliberate action has origins in the trio of Supreme Court cases that set in motion the development of the inequitable conduct doctrine. In each of those cases, the patentee acted knowingly and deliberately with the purpose of defrauding the PTO and the courts.
>
> Intent and materiality are separate requirements. A district court should not use a "sliding scale," where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.
>
> Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." Indeed, the evidence "must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. This court reviews the district court's factual findings regarding what reasonable inferences may be drawn from the evidence for clear error.

> Because the party alleging inequitable conduct bears the burden of proof, the "patentee need not offer any good faith explanation unless the accused infringer first ... prove[s] a threshold level of intent to deceive by clear and convincing evidence." The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290-91 (Fed. Cir. 2011) (en banc) (citations and parentheticals to citations omitted; emphases in original).

Therasense was intended to cut back on inequitable conduct as a defense. The Federal Circuit said as much. Its emphasis on the doctrine originating with three Supreme Court cases involving either bribery or perjury or both is telling.

For present purposes, given the summary judgment posture, the Defendant has to produce sufficient evidence so that the inequitable conduct defense can go to the factfinder. While the Defendant's burden at trial is to "prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it," the only issue at this time is whether at least one of the three accused individuals knew that the withheld information was material and made a deliberate decision to withhold it. *See* D.I. 96, p.16 n.10.

The Plaintiff has cited deposition testimony from the inventor and the two attorneys to the effect that they did not make any intentional decision to withhold the prior art, and/or that they did not consider the prior art to have been material. Plaintiff urges that this testimony presents a reasonable alternative basis for not providing the prior art, and that therefore "intent to deceive cannot be found." I cannot accept that argument, because it would require that I find the testimony of the inventor and the attorneys to be credible. While uncontradicted sworn testimony may be accepted on summary judgment, there is evidence in the record that cautions

against accepting the testimony without giving the opportunity for a full hearing. The "materiality" question is one on which two experts differ, and I do not know which one I am going to accept. Part of the "materiality" question involves the supposed structural similarity of 2'-CDG and entecavir. The experts have different opinions on that. The inventor is one of several people credited with an article which contains a statement about 2'-CDG's "structural similarity" to entecavir. (D.I. 110, Exh. 18, p.1446). The inventor, when questioned about the article, said he had neither written nor read it before it was published. (D.I. 124, pp. 6-7). Such a statement at least raises a credibility concern. I do not think making the credibility decision on summary judgment in this case is appropriate. I am mindful of what the Federal Circuit has said about inferring intent from materiality. I note that the Court said I may not infer intent "solely" from materiality. That does not prohibit me, I think, from considering materiality as a piece of circumstantial evidence in looking at intent. In this case, since the inventor has agreed that he knew about 2'-CDG, if it were to turn out from the expert testimony that I were to conclude that 2'-CDG were the "smoking gun," that is something I would want to know before deciding intent.

I have also considered that the issue here involves the state of mind of three individuals about twenty years ago. It is often difficult to prove someone's state of mind about something the person did yesterday. To prove by clear and convincing evidence that a person intended to deceive the PTO twenty years ago, in the absence of any direct evidence that he did so, is about as difficult as climbing Mt. Everest. I cannot say, however, as a matter of law that it cannot be done. *See Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334-37 (Fed. Cir. 2012) (affirming a finding of an inventor's intent to deceive in 1990).

Therefore, this 19th day of July 2012, the Plaintiff's Motion for Partial Summary Judgment

of No Inequitable Conduct (D.I. 95) as to the inventor (Dr. Zahler) and the two attorneys is **DENIED**. The Plaintiff's Motion for Partial Summary Judgment of No Inequitable Conduct (D.I. 95) as to the second inventor (Dr. Slusarchyk), which is not opposed (D.I. 109, p. 3 n.1; D.I. 124, p.2, n.1), is **GRANTED**.

Richard G. Andrews
United States District Judge