IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

STAR SCIENTIFIC, INC. *

Plaintiff *

vs. * CIVIL ACTION NO. MJG-01-1504
(Consolidated with MJG-02-2504)

R.J. REYNOLDS TOBACCO COMPANY, *
et al.

Defendants *

* * * * * * * * *

MEMORANDUM OF DECISION
RE: INEQUITABLE CONDUCT

These cases, consolidated for trial of Defendant's inequitable conduct defense, were tried before the Court without a jury.

The Court has heard the evidence, reviewed the exhibits, considered the materials submitted by the parties, and had the benefit of the arguments of counsel. The Court now issues this Memorandum of Decision as its findings of fact and conclusions of law in compliance with Rule 52(a) of the Federal Rules of Civil Procedure.[1] The Court finds the facts stated herein based upon an evaluation of the evidence including the credibility of witnesses and the inferences which the Court has found reasonable to draw from the evidence.

I. BACKGROUND

A. Procedural Setting

[1] "In all actions tried upon the facts without a jury . . . the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58." Fed. R. Civ. P. 52(a).

Plaintiff Star Scientific, Inc. ("Star") is the exclusive licensee[2] of United States Patent Nos. 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent") (collectively, "the Patents-in-Suit"), relating to the curing of tobacco. At all times relevant hereto, Defendants R.J. Reynolds Tobacco Company, a North Carolina corporation and R.J. Reynolds Tobacco Company, a New Jersey corporation (collectively, "RJR"), have been engaged in the business of producing tobacco products, including cigarettes.

On May 23, 2001, Star sued RJR (Case No. MJG-01-1504), claiming infringement of claims 4, 12, and 20 of the '649 patent. On July 30, 2002, Star sued RJR (Case No. MJG-02-2504) for infringement of claim 41 of the '401 Patent. In each case, RJR counterclaimed seeking a declaratory judgment establishing non-infringement and invalidity. RJR denies infringement and asserts that the Patents-in-Suit are invalid and/or unenforceable due to indefiniteness and inequitable conduct.

On January 19, 2007, the Court issued its Memorandum and Order Re: Indefiniteness [Document 704], granting summary judgment to RJR on the issue of indefiniteness, but deferred its entry of judgment pending decision on the consolidated trial of RJR's inequitable conduct defense.

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[2] The original assignee of the Patents-in-Suit, Regent Court Technologies, granted Star an exclusive license which included the right to bring legal action to enforce the Patents-in-Suit.

B. Industry Setting

1. Tobacco Curing Methods

Tobacco that is freshly harvested must be "cured" before it can be used for cigarettes and other products. Essentially, "raw" tobacco is dried in a curing barn without exposure to rain or direct sunlight:

> In practice, tobacco leaves are generally cured according to one of three methods. First, in some countries, such as China, a variation of the flue curing process (described below) is still being used on a commercial scale to cure tobacco leaves. Specifically, this variation of the flue curing process features the use of a heat exchanger and involves the burning of fuel and the passing of heated air through the flue pipes in a curing barn.

'649 Patent, Col. 2 ll. 53-54.[3] In this first method, there is no contact between the exhaust gases and the tobacco and curing takes place in what is referred to as an "indirect fire" barn.

A second method, in which exhaust gases come into contact with the tobacco, takes place in what is referred to as a "direct fire" barn:

> For more than twenty years, the heat exchanger method described above has been supplanted in the U.S. with [a second method,] the so-called "flue curing" method [using a propane burner]. This process involves placing the tobacco leaves in a barn and subjecting the leaves to curing with the application of convective heat using a hot gaseous stream that includes combustion exhaust gases. When convective heat is used to dry the tobacco leaves, the combustion exhaust gases (including carbon monoxide, carbon dioxide, and water) are passed directly through the tobacco.

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[3] Both Patents-in-Suit make the same statements in regard to curing methods. Accordingly, citations to the '649 Patent will suffice here.

Id. at Col. 3 ll. 4-14.

There is a third method of curing tobacco known as "air curing":

> This process involves placing the tobacco leaves in a barn and subjecting the leaves to air curing without controlling the ambient conditions (e.g. air flow through the barn, temperature, humidity, and the like) and without the application of any heat.

Id. at Col. 3 ll. 19-24.

2. Nitrosamines - TSNA

By about the 1990's, those working in the tobacco industry became aware of a possible problem regarding the formation of nitrosamines in the curing process. Nitrosamines are nitrogen-containing chemical compounds that form in plants. The nitrosamines that form in tobacco plants during the curing process are referred to as "tobacco specific nitrosamines" ("TSNAs"). Some TSNAs were thought to be carcinogenic. Accordingly, those in the tobacco industry sought to find ways to avoid TSNA formation in the curing process.

Persons connected with Reserca, a Swedish research company also known as "Swedish Match," came to believe that the TSNAs that were found in air-cured tobacco were caused by microbes (micro-organisms). By approximately 1993, Swedish Match had developed a method whereby the formation of TSNAs was prevented in brown tobacco (a sub-category of burley tobacco).

Swedish Match sponsored Professor Harold Burton ("Burton"), an agronomy professor at the University of Kentucky, to assist

with research regarding TSNA formation. Burton published a paper in 1995 discussing a method for substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant. He concluded that this could be done by drying uncured tobacco in a combustion gas free environment and substantially preventing an anaerobic condition around the plants by controlling at least one of three curing conditions, humidity, temperature, and airflow.

At about the same time that Swedish Match was researching nitrosamines in air-cured tobacco, RJR, under the direction of Dr. David Peele ("Peele"), began researching the causes of nitrosamine formation in Virginia tobacco. RJR's research indicated that the primary reason for TSNA formation in Virginia flue-cured tobacco was not the presence of microbes, but instead the fact that exhaust gases came in contact with the tobacco. He found that old indirect-fire barns that had utilized heat exchangers and prevented exhaust gases from coming into contact with tobacco yielded substantially lower levels of TSNA than the newer direct-fire barns.

In late 1997 or early 1998, RJR disclosed some of its work to scientists at Swedish Match as well as to Burton. Later, in approximately May or June of 1998, Peele discovered that the particular component of the combustion exhaust gases which was the primary cause of TSNAs forming during the curing of Virginia tobacco was nitric oxide.

3. RJR (Peele) - Curing Operations

Beginning in August of 1998, Peele experimented with the curing of tobacco in indirect-fire barns to prevent the exposure of tobacco to nitric oxide. He discovered that tobacco that was cured by this method had low to undetectable levels of at least one TSNA.

On April 26, 1999, Peele filed the patent application that led to U.S. Patent No. 6,805,134. Peele's application disclosed that if, during the curing process, the tobacco's exposure to the nitric oxide found in combustion exhaust gases is minimized, the formation of TSNAs is substantially prevented. Peele's application also disclosed means by which direct-fire barns could be converted into indirect-fire barns to prevent tobacco exposure to nitric oxide during the curing process.

In 1999, RJR contracted with certain farmers to have them provide tobacco cured in barns retrofitted with heat exchangers purchased from Vencon-Varsos,[4] a Greek company, and assembled and installed in the farmers' barns by Evans Machinery and Metal Fabrication, a U.S. company.

By the summer of 1999, these farmers had cured tobacco with low TSNA levels. In November 1999, RJR spent over $11,000,000 to purchase 2050 heat exchangers and retrofit hundreds of curing barns to use this technology. RJR contracted with many farmers

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[4] Vencon-Varsos adapted technology whereby heat exchangers could be utilized in virtually any existing bulk tobacco barn, enabling conversion from direct-fire to indirect-fire barns.

to provide tobacco cured in barns utilizing this heat exchanger technology for the 2000 curing season.[5] In early 2001, RJR replaced many of the 2000 season curing contracts with new agreements that were utilized in the 2001 season and thereafter.

4. Patents-in-Suit Filings

The following is the chronology of the Patent Office filings pertinent to the Patents-in-Suit:

The '649 Patent

9/15/98	Application No. 60/100,372 (the "Williams Provisional Application") filed.
9/15/99	Application No. 09/397,018 (the "Williams Non-Provisional Application") filed.
3/20/01	Patent No. 6,202,649 issued.

The '401 Patent

9/25/00	Application No. 09/688,144 filed as a continuation of the Williams Non-Provisional Application.
7/30/02	Patent No. 6,425,401 issued.

II. LEGAL FRAMEWORK

A. The Duty of Candor

"Applicants for patents are required to prosecute patent applications in the PTO with candor, good faith, and honesty."

[5] Some of the farmers owned their own heat exchangers while others used heat exchangers provided by RJR.

Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). It is well established that:

> [T]he duty to disclose information material to patentability rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application.

Id. at 1178 n.6

Moreover, "[t]he duty of candor extends throughout the patent's entire prosecution history." Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803 (Fed. Cir. 1990). Accordingly: "[i]n determining inequitable conduct, a trial court may look beyond the final claims to their antecedents . . . . [A] breach of duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application." Id. at 803-04. "The duty to disclose material information extends to information such individuals [covered by 37 C.F.R. § 1.56] are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof." Manual for Patent Examining Procedure ("MPEP") § 2001.06 (8th ed. Rev. 5, 2006).

B. Inequitable Conduct

"A breach of [the] duty [of candor] may constitute inequitable conduct." Purdue Pharma. L.P. v. Endo Pharma. Inc., 438 F.3d 1123, 1128 (Fed. Cir. 2006).

As stated by the United States Court of Appeals for the Federal Circuit: "inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Espeed, Inc. v. Brokertec USA, 480 F.3d 1129, 1135 (Fed. Cir. 2007) (quoting Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005)); Molins PLC, 48 F.3d at 1178. "[I]nequitable conduct requires not [merely] intent to withhold, but rather intent to deceive." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003). "The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence." Digital Control, Inc. v. Charles Mach. Works 437 F.3d 1309, 1313 (Fed. Cir. 2006). "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.'" Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001) (internal citation omitted).

1. Materiality

The PTO Regulations state, with regard to materiality:

> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

> (1) It establishes, by itself or in combination with the other information a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the [Patent] Office, or (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. The Federal Circuit recognizes several different standards of materiality. The first is the "objective but for" standard, "where the misrepresentation was so material that the patent should not have issued." Digital Control, 437 F.3d at 1315. A second test, the "subjective but for" test, finds materiality "where the misrepresentation actually caused the examiner to approve the patent application when he would not otherwise have done so." Id. Lastly, the "but it may have" standard finds materiality "where the misrepresentation may have influenced the patent examiner in the course of prosecution." Id. The Federal Circuit has stated:

> In addition, in 1977, the PTO amended Rule 56 to clarify the duty of candor and good faith before the PTO. That version of Rule 56 required applicants to disclose "information they are aware of which is material," stating that information is material "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F. R. § 1.56 (1977).
>
> * * *
>
> Even though the PTO's "reasonable examiner" standard became the dominant standard invoked by this court, in no way did it supplant or replace the case law precedent.
>
> * * *

> However, because a party alleging inequitable conduct need only prove a "threshold level" of materiality in order to proceed to the second "balancing" portion of the inequitable conduct inquiry, and because the PTO's "reasonable examiner" standard was broader than the other three standards, the PTO standard gradually became the sole standard invoked by this court.

Digital Control, 437 F.3d at 1315.

The Federal Circuit expressed in Espeed that "under the reasonable examiner standard, information is material when 'a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.'" Espeed, Inc., 480 F.3d at 1136, (quoting A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392, 1397 (Fed. Cir. 1986)). However, it is not necessary for materiality that the disclosure of the information would have resulted in disallowance of the patent. Li Second Family LP v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000) (stating that "information concealed from the PTO may be material even though it would not invalidate the patent.").

2. Intent to Deceive

To satisfy the intent to deceive element of inequitable conduct, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Espeed, Inc., 480 F.3d at 1137-38 (quoting Kingsdown Med. Consultants v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir 1988) (en banc in relevant part)). The intent to deceive need not be proven by direct evidence; in fact, "it is rarely proven

by such evidence." Espeed, Inc., 480 F.3d at 1138. The intent to deceive may be "inferred from the facts and circumstances surrounding the applicant's overall conduct." Impax Labs. v. Aventis Pharms., 468 F.3d 1366, 1375 (Fed. Cir. 2006) (citing Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989)).

Although intent may be found based on either direct or circumstantial evidence, the intent to deceive cannot be inferred solely from the fact that material information was not disclosed. Braun Inc. v. Bynamics Corp. of Am., 975 F.2d 815, 822 (Fed. Cir. 1992). "[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990).

3. The Balancing Test

The Court, after finding that a false statement or omission was made in the course of patent prosecution, must determine the extent to which the conduct was material and intentional. "The court's final step in the determination of inequitable conduct is a balancing of the degree of materiality against the degree of intent to deceive." Union Oil Co. of Cal. v. Atlantic Richfield Co., 34 F. Supp. 2d 1208, 1212 (C.D. Cal. 1998). "This balancing process considers all the evidence, including that of the patentee's good faith." Id. (citing Molins PLC, 48 F.3d at 1181).

Where an omission or misrepresentation is "highly material, 'less evidence of intent will be required in order to find that inequitable conduct has occurred.'" Espeed, Inc., 480 F.3d at 1135 (quoting PerSeptive Biosystems, Inc. v. Pharmacia Biotech, 225 F.3d 1315, 1319 (Fed. Cir. 2000)). Ultimately, the "conclusion that a patent is unenforceable is an equitable decision committed to the discretion of the district court." Espeed, Inc., 480 F.3d at 1135; see Flex-Rest, L.L.C. v. Steelcase, Inc., 455 F.3d 1351, 1357 (Fed. Cir. 2006).

III. DISCUSSION

A. Introduction

As discussed more fully herein, the actions of Patentee Johnnie Williams ("Williams") and others participating in the prosecution of the Patents-in-Suit constitute a substantial failure to meet the duty of candor vís-a-vís the Patent and Trademark Office. Williams and others deliberately misled the PTO in a material manner by keeping from the PTO the critical fact known to Williams and others that the claimed beneficial result - tobacco with low to undetectable TSNA levels - had been achieved in the United States prior to the application that led to the Patents-in-Suit.

A letter written by the patentee's technical consultant, Professor Burton (the "Burton Letter") to the patent attorney drafting the initial application, was a focus of the evidence at the inequitable conduct trial. It was RJR's discovery of this

letter that provided clear proof that Williams, the prosecuting patent attorney and others, had been aware that low and undetectable levels of TSNA had been achieved under the prior art. The Burton Letter establishes that they knew that the alleged invention did not, for the first time, enable curing of tobacco with low levels of TSNA. Rather, the benefit that could be claimed from the alleged invention would be, at most, to teach a method that might permit some degree of confidence that a curing operation could produce tobacco with low levels of TSNA. As discussed more fully herein, the Burton Letter provides evidence of the knowing material failure to disclose, but RJR's inequitable conduct proof is not limited to the document itself.

Counsel for Star, Randy McMillan, admitted in final argument that Williams and patent counsel had, at all pertinent times, been fully aware that, prior to the alleged invention, tobacco could be, and had been, cured in the United States in a process that yielded low to undetectable levels of TSNA:

> MR. MCMILLAN: I think everyone involved on the patent side had the belief that, in an uncontrolled environment, it's the very nature of an uncontrolled environment, that you can get it in some uncontrolled way. You can get uncontrolled results in some uncertain.
>
> THE COURT: You can get undetectable TSNAs?
>
> MR. MCMILLAN: Yes, Your Honor.

Tr. 1109.[6]

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[6] References to "Tr." are to the trial transcript.

Even with this belief on the part of Star, Williams, his patent attorney, and "everyone involved on the [Star] patent side," the application leading to the Patents-in-Suit falsely stated that:

> [I]t has been determined that [the prior art] as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Pl.'s Ex. 9 (hereinafter cited as "Provisional Application") at 3.

This statement in the Provisional Application was designed to mislead the PTO into believing that the prior art could not yield tobacco with low levels of TSNA. There had been no determination of the type claimed. Yet, the PTO was led to believe that the alleged invention enabled the achievement of low-TSNA tobacco for the first time. The purported "determination" on which Williams (and his attorney who relied upon Williams[7]) based the statement, did not even relate to tobacco grown in the United States. As Williams admitted at trial:

> Q. So you were the person that told Mr. Delmendo to say, to say in the provisional application that when this old flue-curing process is used in the United States, that you get high levels of TSNA?
>
> [Williams:] Yes.
>
> Q. And you told him that, notwithstanding the fact that in the Burton letter, Professor Burton said that you get low TSNA; is that right?

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[7] Tr. 422.

[Williams:] That's true. But I'm saying if you practiced that in the United States, you won't - you won't get low levels of TSNA, because in Brazil, where most of our tobacco comes from, that's what they do, and the levels are high.

Q. So you -

[Williams:] That was the basis for me saying that.

Q. The basis for your discussion here in the provisional about what goes on in the United States was based on what goes on in Brazil; is that your testimony?

[Williams:] Yes. Which is either the first or the second largest supply of flue-cured tobacco to America.

* * *

Q. You also based that statement on a complete absence of data for a curing done in the United States; is that correct?

[Williams:] Well, did I make a stretch from Brazil to the United States? Yes, sir. But I made that stretch with the third largest tobacco company in the United States information, that that tobacco was very similar and near identical to what is grown in Virginia with the same conditions. So did I make a stretch from Brazil to here? Yes.

Tr. 422-23.

This "stretch" kept the PTO from knowing that, as Williams knew, cured tobacco with low levels of TSNA had been achieved in the United States with tobacco grown in the United States. It is substantially likely that knowledge that the prior art could - albeit not every time - achieve low levels of TSNA would have affected a reasonable PTO examiner's evaluation of the claims at issue in the instant case. The materiality of the omission is

particularly strong because of the absence of a specification of precisely how one practicing the alleged invention is to obtain the purportedly assured result.[8]

B. The Burton Letter

As noted above, Professor Burton assisted Swedish Match with research regarding TSNA formation and published a paper in 1995 based upon his research. Sometime prior to August 27, 1998, Burton was engaged as a technical consultant for Williams with regard to a planned application for a patent relating to a tobacco curing process.

On August 27, 1998, Romulo Delmendo ("Delmendo"), a patent attorney at Sughrue Mion Zinn MacPeak & Seas ("the Sughrue firm"), was contacted by Star and asked to prepare a patent application for Williams. On August 28, 1998, Burton sent the Burton Letter at Williams' request to Delmendo to aid the patent lawyer in preparation of the planned patent application. Because of its significance, a substantial part of the Burton Letter is set forth below:

> Tobacco specific nitrosamines (TSNA) are formed primarily during the curing process. I have observed that TSNA in cured tobacco leaf are [sic] dependent on the accumulation of nitrite in the leaf during curing. I have been postulated [sic] that nitrite accumulates during curing by the reduction of nitrate. Nitrite accumulates during the death of the cell and experimental evidence indicates that it is formed by the micro flora on the surface of the leaf. It must be

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[8] See Memorandum and Order Re: Indefiniteness [Document 704].

> noted that for the micro flora to reduce nitrate to nitrite conditions should be approaching anaerobic (oxygen deficient) conditions. If conditions are aerobic, the microbes will use the oxygen in the atmosphere for their energy source. If the curing in a micro climate is aerobic then no nitrite will form. The curing process is certainly more complex than this explanation but it should give a thumbnail sketch on what is happening during curing.
>
> I was in China for two weeks during 1997 and I was given commercial Chinese cigarettes. I brought some of them back to the US and decided to analyze them for TSNA. To my surprise I could not detect TSNA or when I did they were very low. We analyzed at least five different commercial cigarettes and the [sic] were the leading cigarettes in China. These cigarettes were made of only flue cured tobacco and are more like the cigarettes manufactured in England. China does not import any tobacco and therefore it was all grown in China. Since China is a developing country, <u>they are still use [sic] the old curing technology that was abandoned in the US during the sixties. It seemed to me that the probable cause for the absence of TSNA was their use of the old flue-curing techniques.</u> This technique uses burning fuel and passing the hot gasses through flue pipes in the curing barn. Therefore, tobacco in the old barns were exposed to radiant heat. The modern curing barns are different since the fuel source (propane) is combusted and the exhaust is passed directly through the tobacco. This can create anaerobic condition [sic] since the oxygen in the atmosphere is depleted by combustion and the combustion gases (carbon dioxide and water) are not aerobic. During curing, the tobacco leaf also emits carbon dioxide and will dilute the oxygen further.

Defs.' Ex. 53 (hereinafter cited as "Burton Letter") (emphasis added).

It is important to note, at the threshold, that the significance of the Burton Letter - in context - is that Burton affirmatively stated to Williams that he attributed the low levels of TSNA found in the Chinese cigarettes to the use of the indirect fire flue-curing process <u>that had previously been used</u>

in the United States. It is of no moment whether the practice in China constituted prior art. The significance is that the Burton Letter reveals that he knew, and informed Williams and Delmendo, that the prior art practiced in the United States had been able to achieve tobacco with low to undetectable levels of TSNA.

C. The 1998 Provisional Application

Patent counsel (Delmendo) and Williams were aware from the Burton Letter that Burton had obtained cigarettes in China that had low or non-existent levels of TSNA. Moreover, Burton had stated that "the probable cause for the absence of TSNA [in the Chinese cigarettes] was their use of the old flue-curing techniques" formerly used in the United States. Burton Letter at 1.

Nevertheless, the Provisional Application did not reveal even the possibility that the old curing method could produce low levels of TSNA. Rather, the Provisional Application stated:

> In some countries, such as China, an older version of the flue curing process (hereinafter discussed in detail) is still being used on a commercial scale to cure tobacco leaves. Specifically, this particular flue curing process involves the burning of fuel and the passing of the hot combustion exhaust gases through flue pipes in a curing barn. Accordingly, in this process, primarily radiant heat emanating from the flue pipes is used to cure the tobacco leaves. It has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Provisional Application at 2-3 (emphasis added).

Not only was the PTO not informed that low levels of TSNA had been obtainable, but there was no adequate basis for the statement of a "determination" that the process applied to United States-grown tobacco yields high levels of TSNA. This "fact" did not come from Burton. As he testified at his deposition:

> [Burton:] Let me repeat the question that I think I heard. After August 24th, 1998, did I ever tell anyone that if you use the old - the Chinese, the old flue-curing process, that we would get high levels of nitrosamines?
>
> No, not specifically that I'm aware of, I ever told anybody that.
>
> Q. Do you recall ever telling Mr. Delmendo that?
>
> [Burton:] No.
>
> * * *
>
> Q. And as you sit here today, though, you can't recall ever, after the date of this letter, Exhibit 53, informing anyone that it was your view that use of this, what you refer as this old flue-curing technique, in the U.S., flue-cured tobacco, would result in high nitrosamines?
>
> [Burton:] I'm not aware of it.
>
> Q. And as you sit here today, you certainly don't recall telling Mr. Delmendo that?
>
> [Burton:] No.

Burton Dep. 24:10-24:20, 25:15-25:24, Jan. 22, 2003.

As noted above, Williams "stretched" to transform some kind of information relating to the curing of Brazilian tobacco into a

"determination" as to what would result with tobacco grown in the United States.

Prior to filing the Provisional Application, Williams obtained some samples of cured tobacco from old indirect-fired barns in the United States, as well as data referred to as "the Curran data" and "the Jennings data." Plaintiff has been unable to provide this data. The Court finds from the evidence presented at trial that the Curran data would have indicated that tobacco cured in an oil-fired barn with no exhaust had low TSNA levels, 0.39 parts per million ("ppm"), and the Jennings data indicated a level of TSNA of 1.5 ppm in tobacco cured in indirect-fired barns. See Tr. 436, 439 (testimony of inventor Williams as to the contents of the Curran and Jennings data); id. at 606 (testimony of Defendants' expert Dr. Otten that the Curran data reflected TSNA levels of 0.39 ppm). These data were not disclosed to the Patent and Trademark Office. While the weight to be given this data might be debated, the Court finds that the information should have been provided to the PTO for the examiner's consideration - particularly in a context in which Star's patent counsel failed to disclose even that the prior art had been capable of achieving low-TSNA tobacco.

After filing the Provisional Application, Delmendo called Williams on September 18, 1998. Delmendo's notes from that conversation indicate that there remained a "prior art concern" Tr. 95. Delmendo testified that the "prior art concern" was that the indirect heat exchange method ("the oil-type barn with the

airflow natural heat sucked in from the side has a fan in it") produces tobacco with "very low" nitrosamine levels. Id.; see id. at 94-98. Since the Provisional Application did not disclose that the prior art could achieve such low levels of TSNA, Delmendo felt "concern" as to whether the information should be disclosed in an Information Disclosure Statement ("IDS") or in the patent specification, as the information might be important to the Patent Office. Id. at 97. However, the PTO was not informed that the prior art was at least capable of yielding TSNA levels as low as that purportedly yielded by practice of the alleged invention. Moreover, as noted below, the concern on the part of Delmendo was not communicated to, indeed, affirmatively kept from, his successor patent counsel after he was discharged by Star.

D. The 1999 Non-Provisional Application

The statement in the Provisional Application that "[i]t has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA" was removed by Delmendo for the 1999 Non-Provisional Application. Nevertheless, the Non-Provisional Application that was ultimately filed still did not reveal that the prior art could yield low levels of TSNA. Instead it "danced" around the matter, stating:

> [T]his [old] process does not appreciate, and does not provide for, controlling the conditions within the barn to achieve prevention or reduction of

> TSNA's. This technique has been largely replaced in the United States by a different flue-curing process.

Pl.'s Ex. 11 (hereinafter cited as "Non-Provisional Application") at 4.

Delmendo did not provide a reason why the "determined" language had been replaced:

> Q. And this was a change from the language that we talked about earlier today, from the provisional application that had made reference to the high TSNA levels?
>
> A. Yes. This, now, that sentence was not deleted, because I felt that it was incorrect. I still believe that sentence to be correct in substance. <u>But for whatever reason</u>, it was replaced with this language, which is a correct characterization of the differences between the claimed invention and the prior art.

Tr. 101 (emphasis added).

Delmendo stated that the words "the process does not appreciate" were used in reliance on information provided by Williams and a technical advisor, Mr. O'Donnell:

> Q. And is it true that you relied on Mr. Williams and Mr. O'Donnell as the source of that information?
>
> A. Yes. We were advised that in the prior art they threw in tobacco into the curing barn without any regard for reducing TSNAs, whereas in the claimed invention, what we were doing, or what the inventor was doing, was to determine and select one or more of the specified conditions in order to ensure the reduction and prevention of TSNAs.

Tr. 102.

The record confirms that Williams and patent prosecution counsel were well aware throughout the PTO process that the prior

art had been capable of providing low-TSNA tobacco and that the purported benefit of the alleged invention was to enable one to "ensure the reduction and prevention of TSNAs." Id. The PTO was not, however, candidly and clearly informed of this, but was led to believe that the prior art could not achieve tobacco with low levels of TSNA.

E. The Firing and Quarantine of Delmendo and his firm

Just two days after the Non-Provisional Application was filed, Star discharged Delmendo and the Sughrue firm. Tr. 103. Paul Rivard ("Rivard") and the law firm of Banner & Witcoff ("the Banner firm") were hired to replace Delmendo and the Sughrue firm in representing Williams during the remaining prosecution of the Patents-in-Suit. Id. at 126.

There was no contact between the two firms, even for the purpose of effecting a turnover of the pertinent files. See id. at 104, 380. Instead, Scott Flicker, a lawyer from Paul Hastings - the law firm of Star's Chairman, Paul Perito - acted as a "prophylactic intermediary" to transfer the files between the two firms. See id. at 375-81. Flicker testified that he was a liaison, physically transporting files from the Sughrue firm to the Banner firm and acted as a communication conduit between the two firms, but never set up a meeting between the Banner and Sughrue firms. See id. No plausible reason has been presented for this course of action other than the obvious one - to keep

the Banner firm from learning what the Sughrue firm knew and thought.

The Court finds, upon evaluation of the credibility of witnesses and inferences from the evidence, that isolation of the Banner firm from predecessor counsel was part of an intentional effort to avoid "tainting" the Banner firm with Delmendo's knowledge and concerns about disclosures to the PTO. The change of counsel was arranged so as to "insulate" replacement patent counsel from Delmendo and the Sughrue firm.

There is a question as to whether the Burton Letter was included in the Sughrue firm files that were turned over to the Banner firm. Rivard could not testify as to whether or not the Burton Letter was, in fact, in the Sughrue firm file that was delivered to him. He testified:

> [Rivard:] . . . . Initially, when we had received the file, I had it put into a Banner Witcoff folder, as you see here, essentially in the same order that we received it from the Sughrue firm. It was transferred into our file, put into our docketing system, and at that point it was sent to the file room, and I did not - I did not think to request it when I was working on the '649 patent.
>
> When I went through it initially, I did go through it to see if there was any patents or articles, as I mentioned, I did not see any.
>
> Q. So when you went through that file initially, you didn't see the Burton Letter?
>
> [Rivard:] No, I was not making - I was not reading all the correspondence and

notes. I was really just looking for patents, journal articles, things that normally would be sources of prior art.

Q. Was it in the file or not?

[Rivard:] I didn't check at that point. More recently a month or so, I went back and checked, and the Burton Letter was in the provisional file.

Q. So it's the case, sir, that the first time you went back to the provisional file to look for the Burton Letter was about a month [before the trial of the instant case]?

[Rivard:] That's correct.

Tr. 135-36.

If the Burton Letter was in the file delivered to Rivard's firm, he says he did not know it. Indeed, as discussed below, the first time he admits learning of the Burton Letter was at a meeting on June 10, 2002, convened because RJR had obtained the letter in discovery and was thought likely to introduce these matters in the litigation.

While a suspicious matter, the Court does not find, sufficiently to satisfy the clear and convincing standard, that someone intentionally removed the Burton Letter from the Sughrue firm file before delivery to the Banner firm. The Court does find, however, that Rivard - although consulting with Burton in the course of his work for Star - was never told about the Burton Letter until, as noted below, after the issuance of the '401 Patent and the issuance of a Notice of Allowance of the '649 Patent. Moreover, the Court finds that had Star not prevented

contact between Delmendo and Rivard, Delmendo would have communicated his knowledge and concerns about the ability of the prior art to yield low levels of TSNA and Rivard would have been told of the Burton Letter or, at least, would have adequately examined his predecessor's file to have found the Burton Letter.

The Court finds that Star, through its use of its chairman's law firm as an intermediary, "engineered" the isolation of Delmendo from Rivard so as to limit Rivard's knowledge and influence his (and his firm's) exercise of professional judgment as to the duty of candor vís-a-vís the PTO. Star cannot seek to avoid an inequitable conduct finding by relying upon an attorney whom it blocked from such consultations with prior counsel. McKesson Information Solutions, Inc. v. Bridge Medical, Inc., ___ F.3d ___, No. 2006-1517 (Fed. Cir. May 18, 2007) (stating that firms cannot insulate their attorneys "against charges of inequitable conduct by instituting policies that present [the attorneys] from complying with the law"); Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370 (Fed. Cir. 2001).

F. The Petition to Make Special

The first substantive patent prosecution action taken by Rivard was to file a Petition to Make Special in February of 2000. In patent prosecution practice, an applicant can file a petition to make special to request the PTO to accelerate a patent's prosecution. See 37 C.F.R. § 1.102 (2005); MPEP § 708.02.

In the context of an inequitable conduct determination, there is particular significance to a petition to make special. "[A] false statement in a petition to make special is material if . . . it succeeds in prompting expedited consideration of the application." Gen. Elec. Music Corp. v. Samick Music Corp., 19 F.3d 1405, 1411 (Fed. Cir. 1994). This is so "because, by filing a petition to make special, the applicant 'requested special treatment and induced reliance on its statement that a prior art search had been conducted.'" Regents of the Univ. of Cal. v. Eli Lilly & Co., 423 U.S. 1089 (1998) (quoting Gen. Elec. Music Corp., 19 F.3d at 1411); see also MPEP § 708.02, II(5).

Rivard testified that he did not review the Sughrue file in connection with his preparation of the Petition to Make Special and the Information Disclosure Statement ("IDS") filed therewith.[9] Tr. 135. However, he did have a meeting with several Star executives and informed them of the duty to disclose all prior art information. None of those individuals provided Rivard with the Burton Letter, the Curran data, or discussed concerns about the prior art. See id. at 130-32.
The Petition to Make Special did not disclose that the prior art had been capable of producing low-TSNA tobacco and continued to

[9] This omission appears to be be ordinary, if not gross, negligence, especially in the context in which Delmendo had been prevented from contact with his predecessor counsel. Nevertheless, even "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive. . . ." Kingsdown Med., 863 F.2d at 876.

give the impression that it was the alleged invention that, for the first time, enabled such a result.

In the Information Disclosure Statement Including Discussion of References in Support of Petition to Make Special, Rivard stated: "[t]he resulting tobacco product [achieved from practice of the invention] is materially and substantially different than tobacco described in the [disclosed prior art] discussed hereinabove." Pl.'s Ex. 12, Tab E at 9. There was no disclosure that the prior art included processes that could produce low-TSNA tobacco. See id.

Furthermore, in the IDS, counsel stated that the prior art does not discuss nitrosamine content in cured tobacco and neither "describes [n]or suggests tobacco products comprising cured tobacco having nitrosamine content reduced by heating uncured tobacco with convection in an environment substantially free of exhaust gases or which otherwise is substantially non-anaerobic." Id. at 9. By so doing, counsel led the PTO to believe that the pertinent art consisted solely of publications and provided no hint (much less a candid disclosure) that there was prior art in the form of curing methods previously known and used in the United States.

The Court, evaluating the credibility of witnesses and drawing reasonable inferences from the evidence, finds that in connection with the Petition to Make Special, that even if Rivard had been unaware of the Burton Letter, he was unaware because Williams and others associated with Star intentionally kept the

information from him. The Court further finds that had Rivard known of the Burton Letter, he would have disclosed it in the Information Disclosure Statement[10] and would have revealed - as plainly indicated in the Burton Letter - that the prior art had been capable of producing tobacco with low levels of TSNA. Furthermore, Rivard would not have been able to mislead the PTO into believing that the only prior art was in written form.

G. Trial Counsel Involvement

Attorneys who ultimately became trial counsel in the instant case were involved in monitoring the prosecution of the Patents-in-Suit.[11] However, trial counsel did not believe themselves to

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[10] At trial, while not willing to concede materiality, Rivard acknowledged that he would have disclosed the Burton Letter if he had been aware of it.

> Q. Because if in your view the contents of the Burton Letter aren't material, then what the heck, it's another piece, like most of the other stuff that Reynolds blew smoke about, dump it in, so I gather, I gather, that if you had the Burton Letter earlier, if you knew about it at the time you, or earlier, including the time that you did your IDS, you would have tossed the Burton Letter into [sic] because you err on the side of disclosure?
>
> A. Yes, I expect I would have.

Tr. 302.

[11] As Rivard testified at trial:

> Q. It's also the case, sir, that Crowell and Moring was kept apprised of the process of the prosecution of the two Patents-in-Suit?

be bound by the duty of candor. In anticipation of suit against RJR, and after suit was filed, Crowell & Moring ("the Crowell firm") monitored Patent Office filings. Nevertheless, the Crowell firm disavowed any obligation to tell the Banner firm about information it obtained that was material to the PTO. As McMillan testified:

> Q. Well, let me see, I guess you're saying, then, if you became aware of information from the litigation that was material to the '401 application, you don't think you had an obligation to tell the Banner firm about it, that's what you're saying, right?
>
> [McMillan:] Well, yeah, that's correct. I don't think that the duty of candor, you know, of a prosecuting attorney who's working on a different application extends to me.
>
> Q. And so I just want to make sure I'm hearing this right. So you're one of the primary liaisons between the Crowell firm and the Banner firm; and it is your testimony, sir, that if you became aware of information material to the '401 patent application, you did not believe you had an obligation to make that information available to the Banner firm; is that your testimony?
>
> [McMillan:] That is my testimony, yes.

> [Rivard:] Yes. Crowell and Moring was copied of the filings made with the patent office and responses that were to be submitted to the patent office.
>
> Q. Who did you copy at Crowell?
>
> [Rivard:] Rick McMillan.

Tr. 128.

Tr. 307-08. McMillan further testified:

> Q. And your testimony, sir, is that you personally do not believe you would at any time have ever owed a duty of candor to the patent office in connection with either the '649 or '401 patent application; is that right?
>
> [McMillan:] That's my belief.

Id. at 327-28.

The Crowell firm, providing input to the Banner firm, knew of the fact that the prior art had been capable of producing low-TSNA tobacco. On October 25, 2000, McMillan wrote to Star's chairman, Paul Perito, expressing concern over the prior art and what should be disclosed:

> The fact that the traditional heat-exchange curing process might have produced low TSNA leaf some of the time, and the fact that the Reynolds process does produce such ultra-low TSNA tobacco some of the time, raises the issue of whether the product claimed by the '905 application and the process claimed by the '018 application are novel (*i.e.*, not anticipated) as required by 35 U.S.C. § 102.
>
> * * *
>
> Again, because TSNA testing is fairly new, it is our belief that no one even recognized that the heat exchangers did, on occasion, result in a low-TSNA product. Accordingly, it seems fairly safe to assume that the traditional heat-exchange process does not explicitly anticipate the '018 claims.

Defs.' Ex. 239 (hereinafter cited as the "McMillan Letter") at 2, 7 (emphasis in original). The statements in the McMillan letter are significant. First, he stated that Star did not "currently know" (in 2000) whether the old process "resulted in low TSNA

tobacco." Id. at 2. However, in the Provisional Application filed September 15, 1998, Williams flatly stated as a fact that:

> It has been determined that this process as applied to tobacco grown in the United States yields tobacco products with high levels of TSNA.

Provisional Application at 3.

Furthermore, McMillan recognized that the fact that the old process "might have produced low TSNA leaf some of the time" would be material if known by the PTO because it would at least raise an issue as to novelty. McMillan Letter at 2.

Finally, the McMillan letter reflects the view that, because TSNA levels had not been tested until recently, there would not likely be any written "prior art" such as a patent or publication that would reveal that the old process was capable of producing low-TSNA tobacco. Therefore, the fact that the prior art could yield low-TSNA tobacco, if revealed to a reasonable PTO examiner, would be substantially likely to be considered important in regard to the evaluation of the alleged invention and the scope of any allowable claims.

It is clear that, at least as of October 25, 2000, while engaged in the patent prosecution process, and in the context of a Petition to Make Special, the Crowell firm (even if not specifically aware of the Burton Letter itself) was aware of the fact that low-TSNA tobacco could be produced by the prior art and took no steps to make this known to the Patent Office.

H. RJR Discovers the Burton Letter

On March 20, 2001, the '649 Patent issued. On May 23, 2001, Star filed the first of the two instant cases, MJG-01-1504, alleging that RJR infringed on the '649 Patent. Rivard continued with the prosecution of the Non-Provisional Application (leading to the '401 Patent) relying upon the Crowell firm, Star's trial counsel, to inform the Banner firm of material information.

Rivard testified at trial, confirming his deposition testimony:

> [Q.] Is it fair to say that you relied on the Crowell and Moring firm to bring to your attention any material that you came across in litigation that might be relevant to the '401 patent prosecution?
>
> [Rivard:] I think that's fair to say, that we had discussions with them along the way to make sure that we became aware of anything. . . .
>
> [Q.] And in fact that, that was, I suspect, an expectation that you had, that if there was information that the Crowell and Moring lawyers learned of, that may have an impact on the prosecution of the '401 patent, that would be brought to your attention, correct.
>
> [Rivard:] Yes, that was my understanding.

Tr. 170 (reading deposition of Rivard at trial).

On January 18, 2002, Rivard wrote to Star's general counsel advising of the Notice of Allowance of what became the '401 Patent. Rivard stated:

> Because our duty to disclose material information to the USPTO continues up until the day the patent issues, we will need to file a supplemental

> information disclosure statement to cite any relevant documents that come to our attention as a result of the ongoing litigation against R.J. Reynolds. This submission must be filed on or before the day the issue fee is paid.

Defs.' Ex. 454.

At this point, Rivard did not know of the Burton Letter, but, of course, Star did. Moreover, litigation counsel, if not aware of the Burton Letter on January 18, 2002, became aware of it shortly thereafter. In the course of discovery, RJR served a document subpoena on Burton and the University of Kentucky. In February of 2002, RJR obtained a copy of the Burton Letter. Star was then faced with the problem that RJR had the Burton Letter, but the PTO - that had not yet issued the '401 Patent - had not been made aware of the letter or the implication of its contents.

Even then, neither Star nor its litigation counsel, who - as Rivard testified - were being relied upon to provide pertinent information ascertained in the litigation against RJR, disclosed the Burton Letter or its contents to Rivard.

In May of 2002, RJR filed its Amended Answer, which included therein references to the Burton Letter and the Curran data. At that point, Star and its litigation counsel found it necessary to inform the Banner firm. This resulted in a June 10, 2002 meeting at which Rivard first saw the Burton Letter[12] and the Curran data. Some two days later, Rivard prepared a Supplemental

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[12] According to Star, the Burton Letter had been in the Banner firm's possession - in the files of predecessor counsel - but simply not been noticed.

Information Disclosure Statement he intended to file with the PTO stating, in pertinent part:

> Pursuant to his duty of good faith and candor set forth in 37 C.F.R. §§ 1.56, 1.97, 1.98 et seq., Applicant submits herewith the attached form PTO-1449. Applicant respectfully requests that the Examiner consider the documents listed [the Burton Letter and the Curran data] therein in connection with the examination the subject application. A copy of each document is attached.
>
> * * *
>
> Neither of these documents is believe material to patentability of the claimed invention.
>
> Document AJ is a letter from Dr. Harold Burton to Rom Delmendo, an attorney who was involved in the initial preparation of the application. As is apparent from the first paragraph of the letter, Dr. Burton simply seeks to help explain the science involved in Mr. Williams' invention.

Defs.' Ex. 382.

The proposed IDS, while subject to debate as to the completeness of its candor, if filed, would have at least put the PTO on notice of the Burton Letter and Curran data so that the PTO could have made its own evaluation of Rivard's contentions as to materiality and significance.

On June 12, 2002, after Rivard informed trial counsel of the Banner firm's intention to make the disclosure to the PTO, a series of emails ensued among lawyers in the Crowell firm:

- June 12, 2002, 2:45 p.m.: Michael Coe ("Coe") to McMillan and other Crowell attorneys:

  > Paul Rivard just called . . . . Banner would like to include the Answer and Counterclaim and possibly the supporting materials (like, for example, deposition exhibits 7 and 8) in a

supplemental IDS before the Examiner in the pending applications.

* * *

I generally am inclined towards disclosure, but would like to hear your thoughts and/or instructions. Although the Amended Answer does not specifically refer to Burton's August 1998 letter and to deposition exhibits 7 and 8, we need to consider whether they should be disclosed. My initial reaction is (1) that we properly identified JW as the correct inventor and the letter is not material to patentability (which necessarily was the decision made by Sughrue Mion and Banner & Witcoff from August 1998 onwards) but (2) that deposition exhibits 7 and 8 should be disclosed out of an abundance of caution even though they may be inconclusive as to description and in any event don't demonstrate a repeatable and consistent low-TSNA process, which is the core of the claimed invention.

- June 13, 8:11 p.m.: McMillan responds to Coe and the other Crowell attorneys:

  You, J.D. and Banner should decide this.

- June 13, 9:59 a.m., Michael Jacobs ("Jacobs") to Crowell attorneys Coe and Joseph Evans ("Evans"):

  <u>I think we should err on the side of disclosure, and we should do so as soon as possible. We have to eliminate any suggestion that there has been lack of disclosure during prosecution of the entire family of patents, and prompt disclosure of this material will certainly not hurt.</u>

- June 17, 10:06 a.m.: Evans to Jacobs, Coe and McMillan:

  <u>I think Mike Jacob's [sic] comment is on target. We need to demonstrate as conclusively as we can that we have nothing to hide from the PTO and consistently follow a policy of full and prompt disclosure of all relevant information.</u> I recommend Michael Coe give Paul the go ahead. I would like to review the IDS before it is filed, and I want to be sure that Dale Hoscheit sees it too.

Defs' Ex. 383 (emphasis added).

Thus, it appears that the Crowell attorneys, except McMillan, put in writing their view that disclosure should be made. McMillan, in writing, deferred to Coe and the Banner firm to make the decision. Nevertheless, on June 19, 2002, the Banner firm lawyers decided not to make the proposed disclosure to the Patent and Trademark Office. Tr. 180 (Rivard).

The Court finds that there was no valid justification for failing to make the disclosure as originally recommended by the Banner firm. Upon an evaluation of credibility and reasonable inferences from the evidence, the Court finds that Williams and others "leaned" on the Banner firm and that the Banner firm made an inappropriate professional decision.

Mr. Jacobs was prescient when he noted that "[w]e have to eliminate any suggestion that there has been lack of disclosure during prosecution of the entire family of patents, and prompt disclosure of this material will certainly not hurt." Id. Patent counsel did not eliminate the suggestion and, indeed, by their actions made it rather clear that there was a lack of adequate candor to the PTO during the prosecution of the Patents-in-Suit.

I. Particular Credibility Concerns

Star has taken certain action in connection with this matter that does not promote reliance upon its credibility.

Professor Burton, the author of the Burton Letter, provided a Declaration to the PTO and assisted counsel in regard to the

instant case. Star funded a chair at the University of Kentucky in Burton's name, paid him a retainer more than his annual salary regardless of any work product produced, and gave Burton hundreds of thousands of dollars in stock options.[13] Tr. 555; Burton Dep. 61:5-62:17, 49:11-50:4, Jun. 26, 2002.

Star purportedly relied upon the Banner firm to make professional judgments in the prosecution of the Patents-in-Suit, including the decision not to make the disclosures here at issue. As discussed above, the Banner firm changed[14] its initial decision to file an Information Disclosure Statement drafted by Rivard. There are serious questions as to the reliability of the Banner firm decisions made during its tenure as prosecutor of the Patents-in-Suit.

First, Star - without any plausible justification - prevented the Banner firm from contact with predecessor counsel. Second, Star gave the Banner firm stock options with substantial potential value[15] as an incentive for meeting certain "performance criteria," such as getting the patents issued by the PTO. See Defs.' Ex. 235. The Court finds that it cannot treat the Banner firm's decision to withhold disclosure of the data

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[13] Burton has since returned any stock options received from Star.

[14] The Court finds no reasonable, legitimate basis for failing to file the Supplement Information Disclosure Statement prepared and proposed by Rivard.

[15] The option was to buy 210,526 shares at $2.375 per share. At trial, the stock was selling in the $4 to $5 range. Tr. 562.

from the PTO as the exercise of disinterested professional judgment.

The Court also notes with concern the participation of McMillan and others of the Crowell firm in the patent prosecution process. McMillan was - as he had to be in view of his role in the matter - both lead trial counsel and a critical trial witness. This happenstance is particularly troubling when coupled with the substantial financial interest of both litigation counsel (the Crowell firm)[16] and patent counsel (the Banner firm)[17] in the issuance of the Patents-in-Suit and leads to substantial doubt as to the professional independence of both firms.

J. The Inequitable Conduct Determination

As discussed above, to establish inequitable conduct, a party defending against a patent infringement claim must prove, by clear and convincing evidence:

> (i) Affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information; and
>
> (ii) An intent to deceive.

Espeed, Inc., 480 F.3d at 1135.

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[16] See Tr. 337-38 (testimony from McMillan that the Crowell firm worked on a fixed-fee basis with a substantial financial incentive, based on the outcome of the case).

[17] In light of the substantial amount of stock warrants the firm was given by Star.

If a district court finds a threshold level of both materiality and intent to deceive, the district court must balance the evidence to determine if equity should render the patent unenforceable. Id. RJR has established by clear and convincing evidence each of the elements of its inequitable conduct defense.

1. Materiality

There is no doubt that throughout the process of prosecution of the Patents-in-Suit, Williams and others kept critical information from the PTO so as to give the false impression that, as of the time of the application leading to the Patents-in-Suit, there had been no curing processes used in the United States that was capable of producing tobacco with low levels of TSNA. The evidence clearly and convincingly establishes that, at all times during the course of prosecution of the Patents-in-Suit, everyone on the Star patent side knew that the prior art could yield low TSNA tobacco at least some of the time. That fact should have been candidly disclosed from the beginning by a straightforward statement. Even if one could argue that the Burton Letter per se need not have been disclosed, the essential fact revealed therein - that a curing method previously used in the United States was capable of, and indeed was the probable cause for, the production of tobacco with low to undetectable levels of TSNA - should not have been kept from the PTO. Likewise, even if the Curran and Jennings data were not, per se, required to be disclosed, the

essential fact that the prior art could yield low levels of TSNA should have been.

The fact that the prior art was capable of producing low-TSNA tobacco was manifestly material. The alleged invention did not, as asserted by Williams in the patent prosecution, allow the production of low-TSNA tobacco not previously obtainable at all. Rather, to the extent that there may be held to be any invention at all,[18] the invention would lie in enabling a curing process that would enable the production of low TSNA tobacco allegedly more reliably than had been possible under the prior art.

In sum, as acknowledged contemporaneously by Star's own counsel, "[t]he fact that the traditional heat exchange curing process might have produced low-TSNA leaf some of the time, raises the issue of whether the product claimed [by the applications for the Patents-in-Suit] are novel, as required by 35 U.S.C. § 102." McMillan Letter at 2 (written October 25, 2000).

2. Intent to Deceive

The Court finds that RJR has established the intent to deceive by Williams and others by clear and convincing evidence. They engaged in a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco. The

[18] By Memorandum and Order re: Indefiniteness [Document 704], the Court has held the Patents-in-Suit invalid due to indefiniteness.

scheme started with the false statement that "[i]t has been determined that this process as applied to tobacco grown in the United Stated yields tobacco products with high levels of TSNA," and proceeded through the entire course of prosecution in the PTO. Even after the '649 Patent had been issued, after Star and counsel were aware that RJR had discovered the Burton Letter - and thus could prove knowledge of the essential fact embedded therein - and with statements from several patent attorneys in the Banner firm clearly advising disclosure, the PTO was not informed that the prior art had been capable of yielding tobacco with low levels of TSNA.

In the instant case, both Delmendo and Rivard testified - as did counsel in the recent Federal Circuit case McKesson Information Solutions, Inc. v. Bridge Medical, Inc. - that if they had any questions about materiality of a fact, they would disclose it to the PTO. See Tr. 93, 302; McKesson, ___ F.3d ___, No. 2006-1517, (Fed. Cir. May 18, 2007). In McKesson, the Federal Circuit considered the Eastern District of Virginia's finding of inequitable conduct. The Eastern District had found the patent attorney's actions "inconsistent with [his] assertion on the witness stand that it was his practice to be 'over inclusive' and to 'bend[] over backwards to make sure [he] got everything into the case.'" Id. at 17, ___ F.3d at ___. Similarly, here, the actions of patent counsel were inconsistent with a purported practice of erring on the side of disclosure -

an inconsistency supporting the conclusion that the failure to disclose was intentional.

In affirming the trial court, the Federal Circuit in McKesson noted that in spite of the advice provided to prosecuting attorneys in the 1986 version of the Manual for Patent Examining Procedure that "information . . . specifically considered and discarded as not material" ought to be "recorded in [the] attorney's file or applicant's file, including the reason for discarding it,"[19] the prosecuting attorney offered no such recorded reason for his discarding of the information; "he was only able to give speculative testimony about the conclusions he must have drawn at the time" with respect to the materiality

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[19] The full text of the 1986 version of MPEP § 2004(18) reads:

> 18. Finally, if information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

MPEP § 2004(18) (5th ed. Rev. 3, 1986).

of the information in question. Id. at 33, ___ F.3d at ___. The McKesson court noted that the case before it "was not a case of mistake or negligence - the prosecuting attorney testified that he would make all the same nondisclosure decisions again if prosecuting the same applications today." Id. at 2, ___ F.3d at ___.

In contrast, in the instant case, Rivard, who says he was not aware of the Burton Letter until after the '649 Patent had issued and after a Notice of Allowance had been issued as to the '409 Patent, testified that if he had known what Delmendo knew when filing the Provisional and Non-Provisional Applications, he would have made the disclosure that Delmendo failed to make. Tr. 302.

Delmendo justified not disclosing Once the Burton Letter and the Curran data after he was informed at the June 10, 2002 meeting, on the basis of cost and delay in patent issuance. However, the cost would have been under $1,000, a nominal amount in context. Moreover, the delay in issuance of the '410 Patent by no means justified nondisclosure - particularly since the '649 Patent had already issued and RJR had been sued for its infringement in the first of the instant cases. The Court does not find plausible counsel's assertions that the Banner firm made a reasonable professional decision not to make the disclosure at issue to the PTO.

The Court finds that the reason for nondisclosure in June of 2002 was concern that the PTO would, indeed, find the information material, would raise issues as to the allowance of claims and confirm RJR's position that the disclosure should have been made from the beginning of the patent prosecution process.

3. Balancing Test

In view of the Court's finding that RJR has proven materiality and intent by clear and convincing evidence, it must "balanc[e] the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001).

The balancing test does not present a close issue in the instant case. There is clear and convincing proof of substantial material false statements and omissions. There is also clear and convincing proof of an intent to deceive on the part of Williams and others to a seriously high degree.

The Court finds RJR to have made a strong showing of materiality and intent. The Court, therefore, concludes that it should, and shall, exercise its discretion to determine the Patents-in-Suit unenforceable by virtue of inequitable conduct before the PTO by Williams and others.

IV. CONCLUSION

For the foregoing reasons:

1. The Court holds U.S. Patent Nos. 6,202,649 and 6,425,401 unenforceable.

2. Judgment shall be entered by separate Order.

SO DECIDED, on Tuesday, June 26, 2007

/ s /
Marvin J. Garbis
United States District Judge