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	*	

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MEMORANDUM AND ORDER
RE: FILING DATE SUMMARY JUDGMENT MOTION

The Court has before it Defendants' Motion for Summary Judgment of Invalidity Based on the Effective Filing Date of the Patents-in-Suit [Paper 669] and the materials submitted by the parties relating thereto.

Plaintiff Star Scientific, Inc. ("Star") contends that Defendants R.J. Reynolds Tobacco Company, a North Carolina corporation and R.J. Reynolds Tobacco Company, a New Jersey corporation (collectively, "RJR"), infringed certain claims of United States Patent Nos. 6,202,649 ("the '649 Patent") and 6,425,401 ("the '401 Patent") (the "Patents-in-Suit") that relate to the curing of tobacco.

I. INTRODUCTION

For purposes of the instant motion, it suffices to note that tobacco that is freshly harvested is not suitable for human

consumption but must be "cured" before it can be used in cigarettes and other products. Tobacco has, of course, been cured for centuries by various methods, including those involving drying processeS in “barns.”

By about the 1990's, the tobacco industry became aware of a possible problem in regard to the formation of nitrosamines[1] in the curing process. The nitrosamines that form in tobacco plants during the curing process are referred to as "tobacco specific nitrosamines" or "TSNAs." Some TSNAs were thought to be carcinogenic, so efforts were made to find ways to avoid TSNA formation in the curing process.

In the 1990's TSNA-related research was being undertaken at Reserca, a Swedish research company also known as "Swedish Match" that sponsored Professor Harold Burton ("Burton"), an agronomy professor at the University of Kentucky, to assist. Also, RJR conducted TSNA-related research under the direction of Dr. David Peele ("Peele").

In September of 1998, Jonnie Williams (“Williams") (for whom Burton was a technical assistant) filed a Provisional Application that, as discussed herein, led to the Patents-in-Suit. In April

[1] Nitrosamines are chemical compounds that contain nitrogen and that form in a variety of organic materials (including plants).

of 1999, Peele filed a patent application of his own. Also, by the summer of 1999 RJR had contracted with farmers who produced tobacco using the method disclosed in the Peele application. Then, in September of 1999, Williams filed a Non-Provisional Application as a continuation of the Provisional Application he had filed a year earlier.

As discussed herein, an essential question is whether the Patents-in-Suit are entitled to the September of 1998 filing date of the Provisional Application. If not, the effective filing date would be in September of 1999 and, RJR contends, the farmers' use of the Peele method prior to the effective filing date would render the Patents-in-Suit invalid.

RJR also contends that whatever may be the effective filing date, the patents are invalid for failing to disclose the best mode to carry out the invention because of an error in the patent specification.

II. LEGAL FRAMEWORK

A. Summary Judgment Standard

In a patent case, as in any other type of case, a motion for summary judgment shall be granted if "there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); e.g.

Jamesbury Corp. v. Litton Indus. Prods., Inc., 839 F.2d 1544, 1548 (Fed. Cir. 1988), cert. denied, 488 U.S. 828 (1988).

The well-established principles pertinent to such motions can be distilled to a simple statement. The Court may look at the evidence presented in regard to the motion for summary judgment through the non-movant's rose colored glasses, but must view it realistically. After so doing, the essential question is whether a reasonable fact finder could return a verdict for the non-movant or whether the movant would, at trial, be entitled to judgment as a matter of law. E.g., Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251 (1986); Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986); Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970).

B. Effective Filing Date

For a claim in a later-filed application to be entitled to the filing date of an earlier application, the earlier application must comply with the written description requirement of 35 U.S.C. § 112, ¶ 1 (2001).

As the United States Court of Appeals for the Federal Circuit stated in Tronzo v. Biomet, Inc.:

> **Section 112, paragraph 1 requires that the specification 'contain a written description of the invention and the manner and process of making and**

> using it.' To meet this requirement, the disclosure of the earlier application, the parent [application] must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed.

156 F.3d 1154, 1158 (Fed. Cir. 1998) (citations omitted); see also Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991).

"Determination of whether a priority document contains sufficient disclosure under 35 U.S.C. § 112, first paragraph is a question of law." Waldemar Link, GmbH & Co. v. Osteonics Corp., 32 F.3d 556, 558 (Fed. Cir. 1994). "However, compliance with the written description aspect of that requirement is a question of fact." Id. (internal quotation omitted). "The adequate written description requirement . . . serves to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material." In re Alton, 76 F.3d 1168, 1172 (Fed. Cir. 1996) (internal quotation omitted). "Precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." Id. (citation omitted).

C. Invalidity

A patent is presumed to be valid. 35 U.S.C. § 282 (2001). As a result, the burden of proving invalidity rests on the attacker of the patent. Robotic Vision Sys. v. View Eng'g, Inc., 189 F.3d 1370, 1377 (Fed. Cir. 1999). As the party attacking the validity of a patent, RJR bears the "burden of demonstrating an entitlement to judgment as a matter of law [which] includes the burden of overcoming the presumption of patent validity found in 35 U.S.C. § 282." Cable Elec. Prods., Inc. v. Genmark, Inc., 770 F.2d 1015, 1022 (Fed. Cir. 1985), overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1358-61 (Fed. Cir. 1999). "[A]n accused infringer who raises patent invalidity as a defense bears the burden of showing invalidity by facts supported by clear and convincing evidence." Robotic Vision Sys., 189 F.3d at 1377.

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention." Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003). Under 35 U.S.C. § 102(e)(1), a person shall be entitled to a patent unless the invention was described "in an application for patent, published under §122(b), by another filed in the United States before the invention by the applicant for patent."

Under 35 U.S.C. § 112, a patent specification must disclose

the best mode contemplated by the inventor of carrying out the invention. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1532 (Fed. Cir. 1987). "Invalidation for failure to set forth the best mode requires (1) the inventor knew of a better mode than was disclosed, and (2) the inventor concealed that better mode." High Concrete Structures, Inc. v. New Enter. Stone & Lime Co., 377 F.3d 1379, 1382 (Fed. Cir. 2004). "Compliance with the best mode requirement, because it depends on the applicant's state of mind, is a question of fact." Spectra-Physics, 827 F.2d at 1535-36.

III. DISCUSSION

The title of the instant motion[2] would lead one to conclude that the motion is dependent upon a 1999 effective filing date for the Patents-in-Suit. However, RJR presents, in the instant motion, two contentions. These are:

1. **Star "admits" that in the spring and summer of 1999, contracted farmers "infringed" the claims at issue before the September 15, 1999 effective filing date, so that the claims at issue are therefore invalid, and**

2. **Regardless of the effective filing date, an error in the specification of the Patents-in-Suit**

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[2] **Defendants' Motion for Summary Judgment of Invalidity Based on the Effective Filing Date of the Patents-in-Suit. (Emphasis added).**

requires invalidity for failure to disclose the best mode to practice the invention.

See Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 669] at 2.

A. Effective Filing Date

The following chronology is pertinent to the instant discussion:

1. **On September 15, 1998, Jonnie Williams ("Williams"), the named inventor, filed Application Serial No. 60/100,372 ("the 1998 Provisional Application").**

2. **Thereafter, but before September 15, 1999, Williams designed the StarCure™ barn, a facility for curing tobacco that was based on the invention described in the 1998 Provisional Application.**

3. **On April 26, 1999, David M. Peele filed a patent application disclosing a method for curing tobacco involving switching from direct-fired tobacco curing systems to indirect-fired systems to reduce tobacco-specific nitrosamines (TSNAs) ("The Peele Application").**

4. **On September 15, 1999, Williams filed Non-Provisional Application Serial No. 09/397,018 ("the 1999 Non-Provisional Application"), which claimed priority from the 1998 Provisional Application.**

5. **On September 25, 2000, Application Serial No. 09/668,144 was filed as a continuation-in-part of the 1999 Non-Provisional Application.**

6. **On March 20, 2001, the '649 Patent issued from the 1999 Non-Provisional Application.**

7. **On July 30, 2002, the '401 Patent issued from the continuation-in-part application.**

8. On October 19, 2004, after the start of litigation in the instant case, the Peele Application issued as U.S. Patent No. 6,805,134.

The '401 Patent claims priority from both the '649 Patent under 35 U.S.C. § 120 and the 1998 Provisional Application under 35 U.S.C. § 119(e)(1). The parties agree that the '401 Patent is entitled to the same priority date as the '649 Patent. Therefore, the effective filing date, once resolved, will apply to both of the Patents-in-Suit.

2. Determination of Effective Filing Date

The Patents-in-Suit relate to a method of treating tobacco to reduce the content or prevent the formation of harmful nitrosamines that are normally found in tobacco. The '649 Patent refers to a "controlled environment" as a point of novelty of the invention, and all of the asserted claims include as a limitation the term "controlled environment."[3] Pursuant to Judge Alexander

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[3] Claim 4 of the '649 Patent is representative and states:

> A process of substantially preventing the formation of at least one nitrosamine in a harvested tobacco plant, the process comprising: drying at least a portion of the plant, while said portion is uncured, yellow, and in a state susceptible to having the formation of nitrosamines arrested, in a controlled environment and for a time sufficient to substantially prevent the formation of said at least one nitrosamine; wherein said controlled environment

Williams'[4] claim construction, "controlled environment" means "controlling one or more of humidity, temperature, and airflow in the curing barn, in a manner different from conventional curing in order to substantially prevent the formation of TSNAs." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., No. MJG-01-1504, Order at 2 [Paper 458] (D. Md. Mar. 31, 2004). Most pertinent to the instant discussion is the airflow rate. As will be discussed herein, there existed a discrepancy between the 28,000 CFM minimum airflow rate disclosed in the 1998 Provisional Application filed in 1998 and the 25,000 CFM airflow rate disclosed in the 1999 Non-Provisional Application.

The 1998 Provisional Application stated that "[t]he minimum flow of air is approximately ten percent higher than the flow of flue gas used in the prior art." Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 669], ex. 2 (hereinafter cited as "'372 Provisional Application") at 18, ll. 4-5. The Application further stated that "[g]enerally, the minimum flow of air may be

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> comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion; and wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

'649 Patent, col. 20, ll. 18-33(emphases added).

[4] The instant case was originally presided over by Judge Alexander Williams, no relation to Jonnie Williams.

about 28,000 CFM at [one inch of] static pressure in a typical curing barn. However, the minimum flow of air may vary according to conditions and may be determined on a routine basis." Id. at 18, ll. 5-9. Furthermore, although claims are not required in provisional applications, the 1998 Provisional Application included a dependent claim that provided: "[t]he process according to claim 3, wherein the flow of air is at least about 28,000 CFM at 1" static pressure." Id. at 25, ll. 18-19.

The 1999 Non-Provisional Application did not contain a reference to a minimum airflow rate of 28,000 CFM and there was no claim that mentioned 28,000 CFM. Instead, the 1999 Non-Provisional Application stated that "it is within the scope of the present invention to provide relatively low airflow, provided that other parameters (e.g., humidity, temperature, etc.) are selected so that the prevention or reduction of at least one TSNA is achieved." '649 Patent, col. 11, ll. 45-49.

The 1999 Non-Provisional Application included a new example, entitled "Example 7," that disclosed a process for curing green tobacco using an "air flow of approximately 25,000 CFM" of recirculating air and later "virtually all fresh air." Id., col. 19, ll. 45-65. Example 7 disclosed an airflow rate that was substantially lower than the "at least 28,000 CFM" set forth in the 1998 Provisional Application.

The Court concludes that, despite Star's sweeping claims - or hopes - of what the evidence may show at trial, the evidence of record does not support its position. No reasonable fact finder could conclude that the 1999 Non-Provisional Application disclosure of an airflow rate of approximately 25,000 CFM had been disclosed by the 1998 Provisional Application reference to airflow of about or "at least about 28,000 CFM." Id. at col. 19, ll. 52-59.

Accordingly, with respect to claims in the Patents-in-Suit that do not expressly specify an airflow rate, the airflow rate would be interpreted in light of the specification, could be lower than about 28,000 CFM, and would constitute new matter with respect to the 1998 Provisional Application. Therefore, the effective filing date for such claims - that is, the claims at issue herein - is not the September 15, 1998 filing date of the 1998 Provisional Application, but rather is the September 15, 1999 filing date of the 1999 Non-Provisional Application.

B. Anticipation by Practice of the Peele Method

Since Star is not entitled to an effective filing date of September 15, 1998, the effective date of the Patents-in-Suit is September 15, 1999. Accordingly, if the claims at issue were

"infringed"[5] prior to September 15, 1999, RJR would prevail on an invalidity defense.

RJR seeks summary judgment based upon the contention that:

1. Star has "admitted" that RJR farmers practiced the teachings of the Peele Application in 1999.[6]

2. Star contends that the 1999 RJR farmers' practice infringed the Patents-in-Suit.

3. Since the Peele Application is prior art, the asserted "infringement" necessarily establishes anticipation.[7]

The Court does not find Star's "admission" to have the case-determinative consequences suggested by RJR. The "admission" does not include details of precisely what it was that the RJR farmers did so that the Court could determine whether every limitation of the claims at issue was met. Moreover, the record does not preclude the possibility that a farmer could have followed the Peele Application teaching in a way that would not "infringe" the Patents-in-Suit.

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[5] That is, if the claims "read on" an accused device, process, etc. so that there would be infringement if the patent were valid.

[6] See Defs.' Mem. in Supp. of Mo. Summ. J. [Paper 669], ex. 1 at 3 (citing Sun's answers to interrogatory #8: "RJR has contended that use of heat exchangers to prevent the formation of TSNAs is simply using the prior art, but at the same time has filed a patent application that would cover the activities of RJR's own farmers.").

[7] See Vanmoor v. Wal-Mart Stores, Inc., 201 F.3d 1363, 1366 (Fed. Cir. 2000) (affirming summary judgment of invalidity because the accused device was in the prior art).

Accordingly, the Court will not grant summary judgment based upon invalidity by virtue of the "admission" relied upon by RJR. However, if the case were to proceed to trial, RJR could introduce Star's statement in evidence and make whatever argument may be appropriate based thereon.

C. Best Mode

The 1999 Non-Provisional Application includes the erroneous statement that "[p]referably, the minimum flow of air may be about 70 CFM at 1" static pressure per cubic feet of curing apparatus or barn volume, more preferably 80 CFM at 1" static pressure per cubic feet of curing apparatus or barn volume." '649 Patent, col. 11, ll. 50-53. The 70 or 80 CFM result was intended to be the quotient of a numerator equal to the cubic feet per minute of air flow (e.g., 25,000) divided by a denominator equal to the volume of the barn. However, the patentee erroneously used the volume of the furnace (on the order of 340 cubic feet) in the denominator rather than the enormously larger volume of a curing barn. Accordingly, the result was absurdly overstated.[8]

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[8] See Rep. & Recommendation Re: Def.'s Mo. Summ. J. No. 3 [Paper 415] at 17 (discussing a communication to the European Patent Office that referenced a Powell brochure. Powell is the manufacturer of the StarCure™ barns). The Powell brochure mistakenly identified the barn size as 342 cubic feet of volume, which is actually the size of the furnace rather than the barn.

RJR contends that the erroneous reference to a 70 or 80 CFM per cubic foot ratio violates the statutory requirement that the "specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1 (2001). Of course, the specification was erroneous and if literally followed would not teach the best mode to carry out the invention. However, the error is so great[9] as to give support on its face to Star's contention that it would have been obvious to anyone skilled in the art that there had been an inadvertent error. See PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996).

The Court concludes that there is a genuine issue of material fact as to whether one of ordinary skill in the art would know that the specification airflow reference was erroneous and would be able to figure out the best mode contemplated by the inventor. To put the holding in a nutshell:

> **The specification error could be found to be sufficiently patent so that the patent could be found to have a sufficient specification.**

Therefore, summary judgment shall be denied.

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[9] **An analogy might be a statement that an automobile could accelerate from zero to 600 miles per hour in ten seconds.**

IV. CONCLUSION

For the foregoing reasons:

1. **Defendants' Motion for Summary Judgment of Invalidity Based on the Effective Filing Date of the Patents-in-Suit [Paper 669] is GRANTED IN PART AND DENIED IN PART.**

2. **RJR is GRANTED partial summary judgment establishing September 15, 1999 as the effective filing date for pertinent claims of the Patents-in-Suit.**

3. **RJR is DENIED summary judgment with regard to invalidity of the Patents-in-Suit.**

SO ORDERED, on Friday, January 19, 2007.

/ s /
Marvin J. Garbis
United States District Judge