United States District Court,
D. Maryland, Southern Division.

STAR SCIENTIFIC INC,
Plaintiff.
v.
R.J. REYNOLDS TOBACCO COMPANY,
Defendant.

Jan. 27, 2004.

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REPORT AND RECOMMENDATION REGARDING DEFENDANTS MOTION FOR SUMMARY JUDGMENT NO. 3: PATENT INVALIDITY BASED ON FAILURE TO COMPLY WITH 35 U.S.C. s. 112

PHILIP G. HAMPTON, II, Special Master.

This action was referred to me pursuant to the Order of Reference dated September 15, 2003 (Docket No. 382) and Rule 53 of the Federal Rules of Civil Procedure. Defendant, R.J. Reynolds Tobacco Company ("RJR"), moves this Court (Docket No. 273) for an order granting summary judgment that the patents in suit are invalid for failure to comply with 35 U.S.C. s. 112. Plaintiff, Star Scientific, Inc. ("Star"), opposes RJR's motion for summary judgment (Docket No. 309). After reviewing these pleadings, along with RJR's reply memorandum (Docket No. 332), I respectfully recommend that the Court deny RJR's motion for summary judgment for the reasons stated herein.

I. *BACKGROUND*

This patent infringement action involves two patents, United States Patent Numbers 6,202,649 ("the '649 patent") and 6,425,401 ("the '401 patent"), collectively referred to hereinafter as "the patents-in-suit." The patents-in-suit, of which Star is the exclusive licensee, FN1 arise from a common parent application, share the same specification (*i.e.,* they share a common written description), have common figures and are identically entitled "Method of Treating Tobacco to Reduce Nitrosamine Content, and Products Produced Thereby." The patents-in-suit relate to flue-cured tobacco, *i.e.,* tobacco cured in barns using heated air. The

air inside the barns is heated by a heat exchanger. In barns equipped with indirect-fired heating systems, the exhaust gases are kept separate from the air inside the barn. Such indirect-fired heating systems have been used to cure tobacco in the United States for decades. The patents-in-suit describe and claim methods of preventing the formation in flue-cured tobacco of tobacco-specific nitrosamines ("TSNAs"), *i.e.*, N'-nitrosonomictotine ("NNN"), 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone ("NNK"), N'-nitrosoanatabine ("NAT"), and N'-nitrosoanabasine ("NAB"), in barns equipped with indirect-fired heating systems.

Application Serial No. 09/397,018 ("the '018 application"), which issued as the '649 patent, was filed on September 15, 1999, as a continuation-in-part of Application Serial No. 08/998,043 ("the '043 application). FN2 The '018 application also claims priority to a provisional application, Application Serial No. 60/100,372 ("the '372 application") that was filed on September 15, 1998. In late 1998 and early 1999, Mr. Williams designed the StarCure(TM) barn, a curing barn based on the invention described in the '372 application and later described in the '018 application.

In 1999, RJR contracted with certain farmers to purchase low-TSNA tobacco cured in barns retrofitted with heat exchangers purchased from Vencon-Varsos, a Greek company. RJR paid Evans Machinery and Metal Fabrication ("Evans"), a U.S. company, to assemble and install the heat exchangers purchased from Vencon-Varsos ("the heat exchanger technology" FN3) in tobacco curing barns owned by independent farmers. Later in 1999, Reynolds spent over $11,000,000 to purchase 2,050 heat exchangers and retrofit hundreds of curing barns owned by independent farmers with the heat exchanger technology. For the 2000 curing season, RJR contracted with these independent farmers to purchase low-TSNA tobacco cured in their barns retrofitted with the heat exchanger technology. FN4 In early 2001, RJR replaced many of its 2000 curing season contracts with new five-year contracts for the purchase of low-TSNA tobacco cured using the heat exchanger technology.FN5

The '649 patent issued on March 20, 2001. In May 2001, Star sued RJR for infringement of the '649 patent ("the 01-1504 case"). Star alleged that RJR infringed or has induced infringement of claims 4, 12 and 20 of the '649 patent by contracting with tobacco farmers to purchase low-TSNA tobacco cured using the heat exchanger technology described and claimed in the '649 patent. RJR counter-claimed for a declaratory judgment that the '649 patent is invalid and not infringed by RJR. Claims 4, 12 and 20 of the '649 patent state:

4. 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 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.

* * *

12. The process according to claim 4, wherein the treatment time is from about 48 hours up to about 2 weeks.

* * *

20. 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 comprises a flow of air sufficient to avoid 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.

On September 25, 2000, Application Serial No. 09/668,144 was filed as a continuation of the '018 application. This application issued as the '401 patent on July 20, 2002. On that date, Star sued RJR for infringement of claim 41 of the '401 patent,FN6 alleging that RJR's contract with tobacco farmers directly infringed, or induced others to infringe, the patented process for curing tobacco disclosed in the ' 401 patent ("the 02-2504 case"). RJR counter-claimed for a declaratory judgment of invalidity, noninfringement, and unenforceability of the ' 401 patent. Claim 41 of the ' 401 patent reads:

41. A process of substantially preventing the formation of at least one nitrosamine in a Virginia flue tobacco plant by treating the tobacco plant after the yellowing stage, the process comprising:

drying at least a portion of a Virginia flue tobacco 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 comprises air free of combustion exhaust gases and an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion;

wherein said controlled environment is provided by controlling at least one of humidity, temperature, and airflow.

On August 27, 2002, this Court ordered the consolidation of the 02-2504 case with the 01-1504 case.

II. *DISCUSSION*

RJR moves for an order of summary judgment that the patents-in-suit are invalid because the patents fail to satisfy the requirements under 35 U.S.C. s. 112 of definiteness, enablement and best mode. (RJR Br.[FN7], p. 2). The first and second paragraphs of 35 U.S.C. s. 112 read:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Summary judgment will not lie if the dispute about a material fact is "genuine," that is, the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Id*. A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any" which it believes demonstrates the absence of a genuine issue of material fact. Celotex v. Cattrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). "To prove that no genuine factual issues exist, the movant must present a factual scenario without any 'unexplained gaps.' " (11 Moore's Federal Practice 3D, s. 56.13[1] referring to Adickes v. S.H.Kress & Co., 398 U.S. 144, 158, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970)).

The moving party is entitled to a judgment as a matter of law if the nonmoving party fails to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof. Celotex, 477 U.S. at 322. A party opposing a properly supported motion for summary judgment "may not rest upon the mere allegations or denials of his pleading, but ... must set forth specific facts showing that there is a genuine issue for trial." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986), quoting First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-289, 88 S.Ct. 1575, 20 L.Ed.2d 569 (1968). In other words, the nonmoving party must go beyond the pleadings and by her own affidavits, depositions, answers to interrogatories, and admissions of record designate specific facts showing that there is a genuine issue for trial. Celotex, 477 U.S. at 324.

A patent is presumed to be valid under 35 U.S.C. s. 282 (1994). The party asserting invalidity has the burden of proving invalidity by clear and convincing evidence. WMS Gaming Inc. v. International Game Technology, 184 F.3d 1339, 1355 (Fed.Cir.1999). Accordingly, in order to meet its initial burden as the movant of the present motion, RJR must show by clear and convincing evidence based on undisputed facts that the patents-in-suit do not meet the definiteness, enablement or best mode requirements of 35 U.S.C. s. 112. If RJR meets its burden as the movant in this motion, the burden shifts to Star to establish that there is a genuine dispute of material fact for the trier of fact.

Before determining whether claims are invalid, the trier of fact must determine the scope of the claims, *i.e.,* either the parties must agree upon the construction of the claims or the trier of fact must construe them. Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc., 344 F.3d 1186, 1192 (Fed.Cir.2003). Since in its memorandum in support of its motion, RJR never presents a proposed construction of the claims, Star asserts that RJR's motion should be denied. Allen Engineering Corp. v. Bartell Industrial, Inc., 299 F.3d 1336, 1346 (Fed.Cir.2003).FN8 However, in contradistinction to *Allen,* the claims have been construed by the Special Master.FN9 Accordingly, this Report and Recommendation will evaluate invalidity in light of the claim construction recommended by the Special Master on December 4, 2003.

Another prerequisite to determining whether a patent meets the requirements set forth in 35 U.S.C. s. 112 is an understanding of the level of skill in the art. Chemcast Corp. v. Arco Industries Corp. ., 913 F.2d 923,

926 (Fed.Cir.1990) ("Knowing the level of skill in the art is necessary to an analysis under s. 112."). RJR did not provide its understanding of the level of skill in the art required to practice inventions of the patents-in-suit in its memorandum in support of its motion for summary judgment. In its responsive pleading, not only does Star note RJR's failure to provide this important prerequisite to deciding its summary judgment motion, but it then proceeds to provide several differing definitions as to who might possess the requisite ordinary skill in the art.FN10 Of the multitude of definitions regarding ordinary skill in the art, the one put forth by Star that most comports to the facts of the case and Star's allegations was provided by Star in its Reply Memorandum In Support of Its Motion for Summary Judgment on Claim Construction and Definiteness (Docket No. 331, n. 29):

Star Scientific contends that one of ordinary skill is familiar with and understands the tobacco curing process and is experienced in the art of how to cure tobacco. Star Scientific further contends that one of ordinary skill in the art has knowledge and expertise regarding tobacco-curing barn and equipment design, development, and performance and possesses relevant knowledge and expertise in engineering and plant microbiology.

Since its motion must fail unless it puts forth evidence of the level of skill in the art, RJR agreed, for purposes of this summary judgment motion, to accept Star's definition as to one of ordinary skill in the art.FN11 (RJR R. Br., n. 2). In other words, RJR must show by clear and convincing evidence that one of ordinary skill in the art, *i.e.,* one experienced in the art of curing tobacco would not have understood the disclosure of the patents-in-suit, thereby rendering the patents-in-suit invalid for not satisfying the requirements of s. 112.

A. ***Indefiniteness***

In its motion regarding claim construction, Star moved for summary judgment that the claims of the patents-in-suit satisfied the definiteness requirement of 35 U.S.C. s. 112, second paragraph (Docket No. 270). After reviewing all the pleadings, the Special Master recommended to the Court that Star's motion for summary judgment regarding definiteness be denied. The Special Master found that there were genuine issues of fact regarding the claim limitations directed to "anaerobic condition" and "controlled environment."

A determination whether claims of a patent are indefinite under s. 112, second paragraph requires an analysis of "whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Union Pacific Resources Co. v. Chesapeake Energy Corp., 236 F.3d 684, 692 (Fed.Cir.2001). "Any fact critical to a holding on indefiniteness ... must be proven by the challenger by clear and convincing evidence." Intel Corp. v. Via Technologies, Inc., 319 F.3d 1357, 1366 (Fed.Cir.2003) citing to Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1376-77 (Fed.Cir.2001). In its motion for summary judgment, RJR argues that two claim limitations, "controlled environment" and "anaerobic condition around the vicinity of the plant portion," are indefinite. Therefore, for the purposes of the present RJR motion for summary judgment, the Special Master will determine only whether RJR can prove by clear and convincing evidence that these limitations are indefinite.

1. "*Controlled Environment*"

According to RJR, the patents-in-suit do not affirmatively define the claim term "controlled environment." Instead, RJR contends that the patents-in-suit only define "controlled environment" by what it does not encompass, *i.e.,* conventional curing techniques. (RJR Br., pp. 3-4). The patents-in-suit teach that all conventional tobacco curing methods rely on the controlled conditions recited in the asserted claims, *i.e.,*

airflow, temperature and humidity FN12 (RJR Br., p. 14), but, according to RJR, the patents-in-suit do not attribute any meaningful numbers, values or settings for the controlled conditions. In other words, while RJR admits that the patents-in-suit provide numerical ranges for the airflow, temperature and humidity, RJR contends that the numbers, values, and/or settings provided in the specification do not impart definiteness. Instead, RJR argues that the numerical ranges do not inform those of ordinary skill in the art how to establish the claimed "controlled environment" or how to adjust the humidity, temperature, and airflow in relation to each other and in relation to other factors known to affect the curing process, *i .e.,* droughts, excessive rain, or excessive cold or hot weather.FN13

RJR's contentions illustrate why claims must be construed and the universe of those of ordinary skill in the art must be provided before one can determine validity. In light of the Special Master's construction of the claims after it filed this motion, many of RJR's contentions regarding the claim term "controlled environment" must be rejected.FN14 Moreover, RJR attempts to buttress its evidence of invalidity through the testimony of one of Star's expert witnesses, James Sturgill. During his testimony regarding the airflow in the curing barns, Mr. Sturgill stated that he did not know where the prior art airflow ended and the airflow of the invention began. While seemingly compelling, Mr. Sturgill's testimony is not clear and convincing evidence of indefiniteness. Since he has only limited tobacco curing experience,FN15 Mr. Sturgill is not one of ordinary skill in the art as defined by Star, and accepted by RJR for the purposes of this motion. Therefore, as one not possessing the requisite ordinary skill in the art, Mr. Sturgill was not qualified to state where the prior art ends and the claimed invention begins. Since RJR does not present any other evidence regarding the indefiniteness of the "controlled environment" claim limitation, I respectfully recommend that summary judgment of invalidity be denied *vis a-vis* this claim limitation. FN16

2. "***Anaerobic Condition Around the Vicinity of the Plant Portion***"

RJR contends that the patents-in-suit claim "an amount of airflow sufficient to substantially prevent an anaerobic condition around the vicinity of the plant," but the two most important limitations, "airflow" and "anaerobic condition," are indefinite because they are not defined in terms of numbers or values. (RJR Br ., p. 5). Specifically, RJR contends that the claims require a controlled environment that "substantially prevents an anaerobic condition around the plant portion," but the specification does not provide any numerical values for an anaerobic condition. Moreover, RJR contends that the patents-in-suit fail to teach those of ordinary skill how to test for an anaerobic condition around the vicinity of the plant. According to RJR, Star's own expert, the RJ Lee Group, cannot precisely measure the oxygen level at the leaf surface. (RJR Br., Ex. 5, p. 5). The evidence presented by RJR rises to the level of clear and convincing evidence of invalidity. Therefore, summary judgment in favor of RJR would be appropriate, unless Star's evidence presents a genuine issue of material fact.

Star meets and exceeds its burden of showing that there are genuine issues of material fact regarding whether precise numerical values for curing parameters must be disclosed in order to avoid indefiniteness. Star submits that tobacco is not "cured by the numbers." (St.Br., p. 6). Moreover, Star contends that "mathematical precision is not required-only a reasonable degree of particularity and definiteness." (St.Br., p. 9).FN17 *See* Exxon Research and Eng'g Co. v. United States, 265 F.3d 1371, 1381 (Fed.Cir.2001). Star also provides two references to support its contention that "mathematical precision is not required." One reference, Paul E. Sumner & John S. Cundiff, *Guidelines for Temperature, Humidity, and Airflow Control in Tobacco Curing,* U. Ga. C. Agric. Experiment Stations, Res. Bull. 299 (May 1983) ("Sumner and Cundiff"), does not provide any "recipes" for curing different samples of tobacco, but offers guidelines as to how to adjust the most important curing parameters. Similarly, the second reference, G.F. Peedin, *Production*

Practices Flue-Cured Tobacco, in Tobacco Production, Chemistry and Technology, 104-142 (D. Layten Davis et al., eds. 1999) ("Davis"), acknowledges that "considerable and varied experience as well as a thorough knowledge of curing principles are needed to produce consistently successful cures." Both references recognize that each cure is unique and the curing conditions depend on the condition of the tobacco leaves when they are harvested. These references are credible evidence that those skilled in the art must utilize their judgment, and not just a set of numbers, in controlling process variables such as temperature, humidity and airflow.

Star also contends that the claimed invention does not change the "general nature" of the curing process, but requires those practicing the invention to provide an "airflow sufficient to substantially prevent an anaerobic condition in the vicinity of the plant portion" with air that is "free of combustion exhaust gases" and that provides a "controlled environment to substantially prevent the formation of at least one nitrosamine." (St.Br., pp. 7-8). Star points out that nitrosamines, anaerobic conditions and combustion exhaust gases have all been measured by its experts as well as RJR's experts, and anyone skilled in the art would know how to correct the conditions (airflow, temperature, and humidity) or redesign the curing equipment so that the claim limitations are met. (St.Br., p. 8).

Moreover, Star presented a credible rebuttal to RJR's argument that the RJ Lee Group could not measure oxygen levels at the leaf surface. In Star Scientific's Memorandum in Opposition to RJR's Motion for Summary Judgment No. 2 (at p. 5), Star refers to the testimony of Dr. Timothy Nelson, an expert in plant molecular biology. Dr. Nelson testified that those skilled in the art can utilize measurements taken of the oxygen levels during the cures at several locations in the barns to infer conditions at the leaf surface without having to directly measure the oxygen level on the surface of the tobacco leaf. (Ex. 27, Nelson Dep. pp. 150-52, 181-87).

In light of the evidence presented by Star, there is a genuine issue of material fact as to whether the claim language is indefinite, thereby preventing those skilled in the art from understanding the meaning of "anaerobic condition around the vicinity of the plant portion." Accordingly, whether the claim language is indefinite is an issue to be decided by the finder of fact at trial, and I respectfully recommend that summary judgment regarding indefiniteness be denied.

B. *Enablement*

In order to satisfy the enablement requirement of s. 112, the specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " (PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1564 (Fed.Cir.1996) quoting In re Wright, 999 F.2d 1557, 1561 (Fed.Cir.1993); In re Vaeck, 947 F.2d 488, 495-96 (Fed.Cir.1991). Star contends that RJR cannot prevail on its summary judgment for invalidity based upon a lack of any enablement because RJR did not define the level of ordinary level of skill in the art, relying on Abbott Laboratories v. Diamedix Corp., 969 F.Supp. 1064, 1070 (N.D.Ill.1997). In *Abbott,* the court found that a genuine issue existed as to who was a person of ordinary skill in the field of art as of the date of the invention because neither party gave "the court enough direction to state, as a factual matter, what the level of ordinary skill was in the immunoassay field in the early-to-mid 1970s." *Id*. Since RJR adopted Star's definition of a person of ordinary skill in the art, *Abbott* is inapposite to the present case, and RJR's evidence regarding enablement will be read in light of Star's understanding of who is a person of ordinary skill in the art.

RJR fails in its numerous attempts to show by clear and convincing evidence that the patent does not teach

persons of ordinary skill in the art how to make and use the invention. RJR first argues that in this case, the Court should adopt a higher standard for enablement. RJR notes that the specification of the patents-in-suit states that "the practice of tobacco curing is more of an art than a science, because curing conditions during any given cure must be adjusted to take into account such factors as varietal differences, differences in leaves harvested from various stalk positions, differences among curing barns in terms of where they are used, and environmental variations during a single season or over multiple seasons, especially in terms of weather fluctuations during air-curing" (col. 6, ll. 35-42 of the '649 patent). According to RJR, the quoted language of the specification proves that tobacco curing is an unpredictable art and a patentee's burden regarding enablement is higher for unpredictable arts. To support this contention, RJR relies on two Federal Circuit cases, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1377 (Fed.Cir.1999) and Adang v. Fischhoff, 286 F.3d 1346, 1358 (Fed.Cir.2002).

In both *Enzo* and *Adang,* the Federal Circuit found that the claims of the patents-in-suit were not enabled by the specification because those skilled in the art would have had to conduct undue experimentation in order to practice the invention.FN18 However, neither case stands for the premise that a patentee has a heightened burden in unpredictable arts. Although the Federal Circuit recognized that the underlying technology of the inventions was considered "unpredictable," it evaluated the sufficiency of the specifications in light of the particular level of skill in the art. Therefore, while the Federal Circuit found that the sufficiency of the specification should be determined based on the level of skill in the art, it did not hold that there was a heightened burden of proof for enablement for inventions whose underlying technologies are considered unpredictable.FN19

RJR alleges that the claimed process of the patents-in-suit fails to teach how to cure either burley tobacco or Virginia-flue tobacco. More specifically, RJR alleges that the teachings of the patents-in-suit cannot be applied to cure burley tobacco and when the claimed process is used to cure Virginia-flue tobacco, the TSNA levels varied widely. (RJR Br., p. 7). To support its contention regarding burley tobacco, RJR submits portions of the deposition testimony of James D. Jennings, Vice President of Grower Relations for Star (RJR Br., Ex. 6). The testimony concerned an article that described Star's pilot program with burley tobacco ("Womack Article"). (RJR Br., Ex. 7). The Womack Article stated that Star's pilot program produced tobacco with much higher TSNA levels than taught by the patents-in-suit. In his deposition, Mr. Jennings confirmed that Star has obtained better results with flue-cured tobacco than with burley tobacco and that Star's pilot program with burley tobacco was suspended during the 2001 and 2002 curing seasons. According to RJR, the Womack Article, combined with Mr. Jennings' testimony, proved that the patented process could not be used to cure burley tobacco.

Regarding Virginia-flue tobacco, RJR presented the results of the tests for TSNA levels conducted on tobacco cured in the StarCure(TM) barns. (RJR Br., Ex. 8). According to RJR, those tests showed that since Star could not achieve consistently low levels of TSNAs in Virginia-flue tobacco cured according to the teachings of the patents-in-suit, then those skilled in the art would not be able to do so without undue experimentation. (RJR Br., p. 19). RJR also contends that Star's expert, Mr. Sturgill, testified that he does not know how to make and use the invention, and therefore those skilled in the art cannot be expected to know how to practice the invention based on the disclosures in the patents-in-suit. (RJR Br., pp. 18-19).

To rebut the clear and convincing evidence that the claims of the patents-in-suit are not enabled for burley tobacco, Star relies on the testimony of Dr. Jeffery Gentry.FN20 Dr. Gentry testified that from 1994 to 1998, RJR was unsuccessful in its attempts to reduce TSNA levels in burley tobacco. However, according to Star, once RJR became aware of Mr. Williams' invention,FN21 it was able to substantially reduce the TSNA level

by adding a fan to the curing barn, as well as increasing the spacing between the tobacco plants. To further rebut RJR's evidence regarding burley tobacco, Star presents evidence, *i.e.,* the Mexican Star Burley Data (St.Ex.167),FN22 that it successfully applied the claimed process to burley tobacco. According to Star, this data from its tests of burley tobacco cured in Mexico according to the claimed process of the patents-in-suit showed that the cured burley tobacco consistently had NNK levels below 0.15 ppm.

With respect to RJR's evidence regarding the inconsistencies of TSNA levels in Virginia-flue tobacco, Star contends that any inconsistencies resulted from quality control problems, not enablement. (St.Br., p. 21). Star points to Mr. Jennings' Declaration wherein Mr. Jennings testified that the vast majority of Star's farmers have obtained consistent results. (St. Br., Ex. A, Jennings Declaration).FN23 As for Mr. Sturgill's inability to make and use the invention based on the disclosures in the patents-in-suit, Star again points out that while Mr. Sturgill is an expert in barn design, he has limited tobacco curing experience and is not qualified to opine regarding where the prior art ends and the claimed process begins. (St.Br., p. 22).

In determining whether summary judgment should be granted, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255, *citing* Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970). Through its evidence, particularly the Mexican Star Burley Data and Mr. Jennings' declaration, Star "designated specific facts showing that there is a genuine issue for trial." Celotex, 477 U.S. at 324. Accordingly, I respectfully recommend the Court deny RJR's motion for summary judgment regarding enablement.

C. *Best Mode*

The sole purpose of the best mode requirement is to discourage inventors from concealing their preferred embodiments from the public. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524 (Fed.Cir.1987) *citing* In re Gay, 50 C.C.P.A. 725, 309 F.2d 769 (C.C.P.A.1962). The parties agree that the best mode requirement is met if the following two questions can be answered affirmatively: FN24

1. Did the inventor, on the effective filing date of the application, possess a best mode for practicing the invention?

2. Did the inventor's disclosure adequately enable those skilled in the art to practice the best mode of the invention?

Star contends that Example 7 of the '649 patent is Mr. Williams' best mode for practicing the invention of the patents-in-suit. Since RJR did not contest this contention, for the purpose of this motion for summary judgment, the Court should accept Example 7 as the best mode for practicing the invention. Moreover, Mr. Williams testified that at sometime after September 1998 (the filing date of the '372 application) and September 1999 (the filing date of the '018 application) he "designed new curing barns [the StarCure(TM) barns] that [were] capable of practicing the invention of the patents-in-suit at its best." (RJR Br., Ex. 11, p. 562). Again, RJR does not contest Star's evidence. Therefore, to answer the first question, the effective filing date for the invention must be determined. According to RJR, the effective filing date is September 15, 1999. Conversely, Star maintains that the effective filing date is September 15, 1998, the filing date of the provisional application upon which the '018 application claims priority.

The date for evaluating a best mode disclosure in a continuing application is the date of the earlier application with respect to common subject matter. Transco Products Inc. v. Performance Contracting, Inc.,

38 F.3d 551, 557 (Fed.Cir.1994). However, "if a claim in a continuation-in-part application recites a feature that was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. s. 112 in the parent application, but which was first introduced or adequately supported in the continuation-in-part application such a claim is entitled only to the filing date of the continuation-in-part application." Manual of Patent Examining Procedure s. 201.11.

RJR contends that the '018 application should be considered a continuation-in-part application and not a continuing application because "substantial new matter was added to the non-provisional application." FN25 According to RJR, the '372 application describes "the minimum airflow of the invention as 28,000 CFM at 1" static pressure" which is "approximately ten percent higher than the flow of flue gas used in the prior art." FN26 (St. Ex., Ex. 5, p. 18, *ll*. 4-7). Since the 25,000 CFM figure set out in Example 7 is less than the 25,455 CFM figure calculated according to the disclosure in the '372 application, according to RJR, the airflow described in Example 7 cannot be the "improved airflow" taught by the '372 application because it is encompassed by the prior art.FN27 Consequently, RJR contends that, based on the '372 application, the airflow described in Example 7 of the '018 application, is within the prior art.FN28

Star attempts to rebut RJR's allegations by pointing out that Example 7 teaches using an airflow of 25,000 CFM in combination with temperatures from 105 (deg.)F to about 140 (deg.)F and finally 160 (deg.)F. The specification of the '649 patent states that "relatively low airflows" are within the scope of the invention,FN29 "provided that other parameters (e.g., humidity, temperature, etc.) are selected so that the prevention or reduction of at least one TSNA is achieved." (Col.11, ll.45-49). Star overlooks the fact that the ' 372 application is specifically directed to a "sufficiently high flow of heated or unheated air." Consequently, the '372 application does not support the disclosures in the '018 application with regard to "relatively low airflows." Since the '018 application must be a continuation-in-part application with respect to any new subject matter in the '018 application, *e.g.,* airflows other than "sufficiently high," Example 7 is not supported by the '372 application and must have an effective filing date of September 15, 1999. Since Mr. Williams testified that the StarCure(TM) barn is his best mode of practicing his invention "at its best" and he designed it prior to September 15, 1999, the effective filing date of the '018 application, the first question has been answered affirmatively, *i.e.,* Mr. Williams possessed a best mode for practicing the invention as of the effective filing date of the '018 application.

In order to prevail on its motion for summary judgment, RJR must prove by clear and convincing evidence that Mr. Williams did not adequately disclose his best mode of curing tobacco in StarCure(TM) barns to enable those skilled in the art to practice the invention. RJR seeks to meet its evidentiary burden by showing that the disclosures of the preferred airflows in the specification of the patents-in-suit were erroneous and that one of ordinary skill in the art could not use the disclosed best mode to practice the invention.

RJR presents the testimony of Mr. Dale Hoscheit, a Star Rule 30(b)(6) witness, FN30 and a correspondence to the European Patent Office, FN31 as evidence that the disclosure of the preferred airflow in the specification of the patents-in-suit, *i.e.,* 70 and 80 CFM at 1" static pressure per cubic feet of apparatus volume was erroneous. (RJR Br., pp. 22-23). RJR concludes that the erroneous airflow figure recited in the patent specification amounts to a failure to disclose the best mode.FN32 Moreover, according to RJR, Star's assertion that the erroneous airflow value was an "inadvertence" does not save the patents-in-suit from invalidity, relying on Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785 (Fed.Cir.1995) (holding that specific intent to conceal is not a required element of a best mode defense) and Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535 (Fed.Cir.1987) (recognizing that failure to disclose the best mode is not excused even if unintentional). (*Id*. at p. 23).

In its rebuttal, Star argues that the disclosure of "70 CFM per cubic foot of curing apparatus" was clearly erroneous; in fact, Dr. David Peele, a researcher at RJR who was also conducting research on preventing the formation of TSNAs in curing tobacco, described that disclosure in his deposition as "absurd." (St.Br., p. 30). Moreover, Star cites to PPG Indus., Inc. v. Guardian Indus. Corp ., 75 F.3d 1558, 1564 (Fed.Cir.1996), where the Federal Circuit found that:

[O]ne must consider the level of skill in the relevant art in determining whether a specification discloses the best mode. We have consistently recognized that whether the inventor concealed a better mode of practicing his invention than he disclosed, is a function of not only what the inventor knew but also how one skilled in the art would have understood his disclosure.

In *PPG,* the Court held that an error that was "easily detectable by anyone who was skilled in the art" did not invalidate a patent for enablement *Id*. According to Star, the decision of the Federal Circuit in *PPG* should apply in this case and the "absurd" error in the specification should not be found to prevent those of ordinary skill in the art from practicing the invention of the patents-in-suit.

Star is correct. According to the Federal Circuit, a court should not grant summary judgment for a failure to disclose the best mode because an obvious error was made in the disclosure. Since best mode and enablement are read in light of those skilled in the art and those skilled in the art would recognize that the preferred airflow recited in the specification of the patents-in-suit is an obvious error, this obvious error does not invalidate the patents-in-suit. Since RJR has not met its burden of showing by clear and convincing evidence that the patents-in-suit are invalid for failing to disclose the best mode of the invention,FN33 I respectfully recommend that the Court deny RJR's motion for summary judgment pursuant to the best mode requirement of 35 U.S.C. s. 112.

III. ***CONCLUSION***

In light of the foregoing, I respectfully recommend that the Court deny RJR's motion for summary judgment that the patents-in-suit are invalid for failure to comply with 35 U.S.C. s. 112.

FN1. The named inventor of the patents-in-suit is Jonnie R. Williams. The assignee of the patents-in-suit, Regent Court Technologies, granted Star an exclusive license, including the right to bring legal action to enforce the patents-in-suit.

FN2. The '043 application was filed on December 2, 1997, as a continuation-in-part of Application Serial No. 08/879,905 (filed June 20, 1997), which was a continuation-in-part of Application Serial No. 08/757,104 (filed December 2, 1996).

FN3. RJR refers to the heat exchangers assembled and installed by Evans as "the Evans units." Star refers to the heat exchangers installed into the barns as "the Vencon-Varsos equipment."

FN4. RJR also contracted with other farmers to purchase tobacco cu red in barns equipped with the same heat exchangers selected by RJR, but owned by the farmers themselves.

FN5. In 2001, RJR entered into 297 contracts for the purchase of low-TSNA tobacco cured using the heat exchanger technology. Only eight of those contracts were signed after May 23, 2001.

FN6. Star states that for purposes of this litigation, the only material difference between claim 41 of the '401 patent and the other asserted claims is that claim 41 is limited to "Virginia flue tobacco" and the other claims are not so limited.

FN7. RJR. Br. refers to Defendant's Memorandum in Support of Its Motion for Summary Judgment No. 3: Patent Invalidity Based on Failure to Comply with 35 U.S.C. s. 112. St. Br. refers to Plaintiffs Memorandum in Opposition to RJRs Motion for Summary Judgment No. 3 (Patent Invalidity Based on Failure to Comply with 35 U.S.C. s. 112). RJR. R. Br. refers to Defendant's Reply In Support of Its Motion for Summary Judgment No. 3: Patent Invalidity Based on Failure to Comply with 35 U.S.C. s. 112.

FN8. In *Allen,* the Federal Circuit remanded the case to the district court due to its failure to construe the claim limitations at issue ("The entire omission of a claim construction analysis from the opinion, and the conclusory factual findings on infringement, each provide an independent basis for remand" See Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 791 (Fed.Cir.1995)).

FN9. *See* the "Report and Recommendation Regarding Star Scientific, Inc.'s Motion for Claim Construction and Summary Judgment that the Claims of the Patents-In-Suit Satisfy the Definiteness Requirement of 35 U.S.C. s. 112, Second Paragraph" filed with this Court on December 4, 2003 ("R & R"). The Court has not adopted the Special Master's December 4, 2003 R & R in connection with claim construction as of the filing of the present R & R.

FN10. Throughout its brief, Star refers to farmers practicing the invention. However, Star does not allege that the tobacco farmers are infringing the patents-in-suit; instead, Star alleged that RJR infringed the patents-in-suit by providing the farmers with infringing heat exchanger technology. Accordingly, one of ordinary skill in the art is not a tobacco farmer, unless that tobacco farmer has experience in the art of designing and developing tobacco curing barns.

FN11. The Special Master does not find this definition of ordinary skill in the art to be unreasonable. However, since RJR accepted Star's definition of one of ordinary skill in the art only for purposes of this motion, the definition may have to be revisited at trial.

FN12. Col. 8, 77. 40-45 of the '649 patent recites that "this process [referring to prior art] utilizes a somewhat controlled environment, but the controlled environment is insufficient to ensure the prevention or reduction of nitrosamines as in the present invention."

FN13. *See* Union Pacific Resources Co. v. Chesapeake Energy Corp., 53 U.S.P.Q.2d 1669, 1673 (N.D.Tex.1999), where the court found that the inventors failed to disclose the prior art and how their invention differed from the prior art. The specification of the patent stated that the invention added a "fourth dimension" to the prior art, but the specification failed to adequately describe how the "fourth dimension" differed from the prior art.

FN14. For example, RJR contends that "controlled environment" means " *everything* except the prior art." (RJR Br., p. 4, emphasis added). The Special Master construed the claim term "controlled environment" to mean "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." (R & R, p. 14).

FN15. RJR does not dispute that Mr. Sturgill has limited tobacco curing experience.

FN16. Summary judgment in favor of RJR may have been appropriate had RJR presented evidence showing that Mr. Sturgill is one of ordinary skill in the art.

FN17. RJR admits that "mathematical precision is not required," but contends that the specification of the patents-in-suit do not provide any meaningful information that distinguishes the claimed invention from the prior art. (RJR R. Br., p. 6).

FN18. In *Enzo,* the Court found that "the breadth of enablement in the patent specifications is not commensurate in scope with the claims, as the quantity of experimentation required to practice antisense in cells other than E. coli at the filing date would have been undue." Enzo, 188 F.3d at 1377. In *Adang,* the Court found the specification of the patent-in-suit to be deficient, requiring undue experimentation in order to carry out the invention.

FN19. Star pointed out that both *Enzo* and *Adang* involved genetic engineering practiced by highly trained and experienced Ph.Ds. (St.Br., n. 35), while the claimed invention of the patents-in-suit could be practiced by a tobacco farmer using improved equipment "who has practical curing experience but possibly not even a high school education." Star further contends that since the claimed invention is "not rocket science," no heightened burden could possibly be required.

FN20. St. Ex., Ex. 48, pp. 183-188 and 212-216. St. Ex. refers to Plaintiffs Consolidated Appendix of Exhibits in Support of: ...

FN21. Star claims that RJR personnel, *i.e.,* Michael Johnson, David Townsend and others, communicated with Mr. Williams, and Dr. Gentry acknowledged that he had reviewed Mr. Williams' Patent Cooperation

Treaty application, which was published in March 2000, before the 2000 curing season.

FN22. RJR does not rebut the Mexican Star Burley Data.

FN23. RJR criticizes Mr. Jennings for blaming "the weather, the farmers, or the farmers' equipment for its failure to provide an enabling disclosure." (RJR R. Br., p. 15).

FN24. *See* U.S. Gypsum Co. v. National Gypsum, 74 F.3d 1209, 1212 (Fed.Cir.1996) *citing* Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927-28 (Fed.Cir.1990), cited by RJR, and Eli Lilly & Co. v. Barr Labs., Inc., 222 F.3d 973, 980 (Fed.Cir.2000) and *N*. Telecom Ltd. v. Samsumg Elec. Co., 215 F.3d 1281, 1286 (Fed.Cir.2000), cited by Star.

FN25. RJR incorporates by references its arguments regarding this issue from its Motion for Summary Judgment No. 4: Invalidity Based on the Prior Art.

FN26. This equates to a conventional airflow of at least 25,455 CFM (28,000/1.10).

FN27. Star's statement that "fans used in tobacco barns were estimated to produce airflow in bulk barns of anywhere from 11,000 CFM to somewhat higher" (St. Br., p. 28 citing to Ex. 28, Mr. Sturgill's testimony, p. 123) does not hold any weight in light of the disclosure made in the '372 application. Star states that the focus of the best mode inquiry should be on the '372 application. (St. Br., p. 27 "The full scope of the invention covered by the asserted claims in this litigation was first disclosed in the provisional application filed on September 15, 1998.")

FN28. Additionally, RJR alleged Mr. Sturgill testified that prior art barns produced airflows of 25,900 CFM at 1" static pressure. (RJR Br., Ex. 24, pp. 294-295). Star, in this motion, as well as in Star Scientific's Memorandum in Opposition to RJR's Motion for Summary Judgment No. 2, vigorously rebuts RJR's representation of the testimony of Mr. Sturgill. However, as stated hereinbefore, Mr. Sturgill's testimony must be ignored since he is not one of ordinary skill in the art.

FN29. The '649 patent does not define "relatively low airflow."

FN30. RJR Br., Ex. 11, pp. 56-59.

FN31. "[T]he references in the specification to 70 CFM and 80 CFM in the context of minimum airflow ... do not represent the actual preferred flow of air for the practice of the invention." The correspondence further states that a Powell brochure (the manufacturer of the StarCure(TM) barn) identified the barn size as

342 cubic feet of volume which is actually the size of the furnace of the barn. Using the furnace size, rather than the barn size, to calculate the airflow through the curing barn produced the erroneous figure of 70 CFM at 1" static pressure per cubic feet of apparatus volume. Mr. Williams testified that he first became aware of the error during his deposition in this case.

FN32. RJR asserts that the "gravamen" of the invention is the airflow specifications of the StarCure(TM) barns. (RJRR. Br., pp. 15 and 20).

FN33. Moreover, there is a genuine issue of fact regarding whether Example 7 is Mr. Williams' best mode and whether Example 7 is an embodiment of the StarCure(TM) barn. Neither party presented credible evidence regarding the relationship between Mr. Williams' best mode, the StarCure(TM) barn and Example 7. At trial, RJR will have the burden of proving that either Mr. Williams' best mode was not set out in Example 7, or that Example 7 (or Mr. Williams' best mode) is not embodied by the StarCure(TM) barn.

D.Md.,2004.
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