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

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

Feb. 10, 2004.

Richard McMillan, Jr, Jonathan H. Pittman, Kathryn D. Kirmayer, Mark Michael Supko, Crowell and Moring LLP, Washington, DC, Andrew Jay Graham, Kramon and Graham PA, Baltimore, MD, for Plaintiff.

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REPORT AND RECOMMENDATION REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT NO. 2: NO DIRECT INFRINGEMENT OF THE PATENTS-IN-SUIT

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. 272) for an order granting summary judgment that the farmers with whom RJR contracted have not directly infringed the asserted claims of the patents-in-suit. Plaintiff, Star Scientific, Inc. ("Star"), opposes RJR's motion for summary judgment (Docket No. 309). RJR filed a reply memorandum (Docket No. 334). After reviewing these pleadings, I respectfully recommend that the Court deny RJR's motion for summary judgment for the reasons stated herein.

I. *BACKGROUND*

This patent infringement involves two patents owned by Star, 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 from a fuel-burning furnace. 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"), *e.g.,* N'-nitrosonomicotine ("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.

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.

Application Serial No. 09/397,018 ("the '018 application"), which became 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. Sometime in late 1998 or early 1999, Mr. Williams designed the StarCure (TM) barn, a curing barn allegedly based on the invention described in the '372 application and later described in the '018 application.

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).

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

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 cured 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.

The '649 patent was granted on March 20, 2001. On May 23, 2001, Star sued RJR for infringement of the '649 patent (Action No. 01-1504). Star alleges that RJR is infringing or has induced infringement of claims 4, 12, and 20 of the '649 patent by entering into the contracts with tobacco farmers that require the farmers to employ the heat exchanger technology in their curing barns in lieu of direct fire heaters. RJR has 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 read:

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.

In August 2001, RJR conferred with Mr. Richard G. Lione of Brinks, Hofer, Gilson & Lione regarding the infringement, validity and enforceability of the ' 649 patent. Mr. Lione provided RJR with a formal opinion regarding the ' 649 patent on December 21, 2001. Based on Mr. Lione's claim construction, Mr. Lione opined that RJR and/or its growers infringed the claims of the ' 649 patent, but the claims of the '649 patent should be found to be invalid.

During the summer and fall of 2002, Star embarked on an extensive testing program. Star enlisted the services of several experts, R.J. Lee Group, Inc. FN6 ("the R.J. Lee Group"), James D. Sturgill, P .E., and Timothy M. Nelson, Ph.D., to conduct detailed testing of the tobacco and the barns in which the tobacco was cured. Star retained the R.J. Lee Group for the purpose of comparing the practices of the RJR contract growers with the claims of the patents-in-suit. The R.J. Lee Group Report contains the findings and conclusions of the R .J. Lee Group. Mr. Sturgill was retained by Star to opine as to whether the RJR contract growers cured tobacco during the 2001 and 2002 curing seasons in a "controlled environment" as that term is used in the patents-in-suit. Star requested that Dr. Nelson evaluate the laboratory work and field measurements performed by the R.J. Lee Group in light of the hypothesis put forth by Dr. David Peele, a researcher at RJR who was also studying the formation of TSNAs in curing tobacco.

FN6. R.J. Lee Group consists of a collaborative group of investigators highly trained in physics, chemistry, biology, and microbiology under the direction of Richard J. Lee, Ph.D., President. The R.J. Lee Group was responsible for testing barns retrofitted with the heat exchanger technology and tobacco that was cured in the barns.

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 30, 2002. On that date, Star sued RJR for infringement of claim 41 of the '401 patent,FN7 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, non-infringement, and unenforceability of the ' 401 patent. Claim 41 of the ' 401 patent reads:

FN7. 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.

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.

(RJR Br.[FN8] p. 2).
FN8. 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 RJR's 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.

II. ***DISCUSSION***

RJR moves for summary judgment of non-infringement pursuant to 35 U.S.C. s. 271(b), (c),FN9 or (g). RJR contends that it cannot be liable for infringement unless Star can prove that the farmers with whom RJR contracted directly infringed the patents-in-suit (RJR Br.,[FN10] p. 2). According to RJR, Star failed to carry out sufficient testing FN11 of the barns that were retrofitted with the heat exchanger technology and Star's own limited testing showed that two limitations in each asserted claim, "avoidance of an anaerobic condition" and "a controlled environment," did not exist in any of the curing barns.

FN9. In its opposition brief to RJR's Motion for Summary Judgment No. 1: Reynolds Has Not Infringed the Patents-In-Suit, Star voluntarily dismissed its claims for contributory infringement under 35 U.S.C. s. 271(c).

FN10. RJR. Br. refers to Defendant's Memorandum in Support of Its Motion for Summary Judgment No. 2: No Direct Infringement of the Patents In Suit. St. Br. refers to Plaintiffs Memorandum in Opposition to RJR's Motion for Summary Judgment No. 2 (No Direct Infringement of the Patents In Suit). RJR.R.Br. refers to Defendant's Reply In Support of Its Motion for Summary Judgment No. 2: No Direct Infringement of the Patents In Suit. St. Ex. refers to Plaintiffs Consolidated Appendix of Exhibits.

FN11. According to RJR, "Star concedes that tests must be conducted on the tobacco plant as it is curing in a barn as well as after it is removed from the barn" (RJR Br., p. 2).

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 demonstrate the absence of a genuine issue of material fact. Celotex v. Catrett, 477 U.S. 317, 323 (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 (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 (1986), quoting First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-289 (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.

As an initial matter, RJR contends that Star does not have the necessary evidence to carry its burden of

proof regarding direct infringement of the patents-in-suit (RJR Br., p. 2). Star disagrees, arguing that summary judgment is not about burdens of proof and that RJR is attempting to lead this Court to make an assessment of the evidence "under the guise of a summary judgment motion" (St.Br., p. 18). While Star is correct "that at the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial," Anderson, 477 U.S. at 249, it is wrong regarding the burden of proof. In *Anderson,* the Supreme Court held that "[i]n ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burden." *Id.,* at 254. Moreover, on the same day it decided *Anderson,* the Supreme Court reversed an appellate court decision in which the lower court had refused to uphold the district court's grant of summary judgment, the Supreme Court holding that:

In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is 'entitled to a judgment as a matter of law' because the nonmoving party has failed 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. In view of the foregoing, once RJR puts forth evidence to support this motion, Star must present specific facts sufficient to establish the existence of direct infringement of the patents-in-suit. FN12

FN12. If the moving party has the burden of proof at trial, it must meet its evidentiary burden before the nonmoving party has to designate the specific facts that show there is a genuine issue for trial. s. *See* R & R Regarding Defendant's Motion For Summary Judgment No. 3).

A. *Testing of the Barns*

RJR contends that Star did not test any of the barns that were retrofitted with the heat exchanger technology during the 2001 curing season (RJR Br., p. 11). Since Star has no evidence that any tobacco cured in those barns met the claims of the patents-in-suit, RJR asserts that it is entitled to summary judgment of non-infringement vis-a-vis any low-TSNA tobacco cured during the 2001 curing season.

Star admits that it did not conduct testing during the 2001 curing season, explaining that the civil action was not filed until May 2001, and RJR's Motion to Dismiss was not resolved until November 2001, after the end of the 2001 curing season. However, Star asserts that the analysis by the R.J. Lee Group of RJR's test data from the 2001 curing season, when combined with RJR's comprehensive set of test data from the 2000 curing season,FN13 not only raises genuine issues of material fact, but also is sufficient to allow a jury to find direct infringement of the patents-in-suit regarding tobacco from the 2001 curing season (St.Br ., p. 21).

FN13. According to Star, during the 2001 curing season, RJR analyzed 120 tobacco samples from approximately 50 Evans' retrofitted barns and 139 tobacco samples from non-Evans retrofitted barns on approximately 54 RJR growers' farms (St.Br., n. 27).

In its rebuttal, RJR asserts that its 2001 data cannot be relied upon by Star because (1) RJR's data used a level of detection for TSNAs of 0.15 ppm, which is outside the range required for "substantial prevention" of TSNAs, (2) RJR's data does not address other barn conditions that are included as claim limitations of the asserted claims and (3) variances within a growing season, barn, and cure cannot support Star's inferences between the growing seasons FN14 (RJR R. Br., pp. 5-7). In light of these reasons, RJR submits that the RJR 2001 data cannot and should not be considered as evidence of infringement during the 2001 curing season, thereby leaving Star without any evidence to support its claim of infringement during the 2001 curing season.

FN14. RJR's allegation that the timing of Star's suit should not be a consideration as to the applicability of the evidence on this point, RJR is correct.

As for the 2002 curing season, RJR contends that Star only "visited" 57 farmers (with approximately 205 barns) of the 292 farmers (with approximately 3,404 barns) from whom RJR purchased tobacco that year. (RJR Br., p. 12). According to RJR, since Star did not meet its burden of showing that the remaining 235 farmers carried out the claimed process while curing tobacco during the 2002 curing season, Star has no evidence regarding the tobacco cured by the 235 farmers not "visited" by Star. Consequently, RJR asserts that it is entitled to summary judgment of non-infringement regarding tobacco cured by the 235 farmers whose barns were not visited by Star.

Star devotes nine pages (pp. 6-15) of its brief to describing its testing procedures and its problems with RJR during the 2002 testing period, after admitting that it failed to test 3,207 barns. Star points out that the R.J. Lee Group was responsible for testing the tobacco that was cured in the barns while Mr. Sturgill was responsible for conducting the "visual inspection" aspect of the testing program. Star contends that its expert reports are the result of "a statistically and otherwise reliable baseline for analyzing infringement" (St.Br., p. 23).

In rebuttal, RJR asserts that Star's 2002 testing data should not be considered as evidence of infringement in connection with the 3,207 untested barns. RJR alleges that Star cannot support its claim that its limited 2002 testing data should be extrapolated and applied to all of the barns (RJR R. Br., p. 9). Consequently, according to RJR, Star's three cited cases (*San Huan New Materials High Tech, Inc. v. International Trade Comm'n,*FN15 161 F.3d 1347 (Fed.Cir.1999), *United States v. 449 Cases, Containing Tomato Paste,*FN16 212 F.2d 567 (2d Cir.1954), and *Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris,*FN17 178 F.Supp.2d 198, 247 (E.D.N.Y.2001), are inapposite and unsupportive. Moreover, RJR relies on Spectra Corp. v. Lutz, 839 F.2d 1579, 1581 (Fed.Cir.1988),FN18 to support its contention that it is entitled to a grant of summary judgment of non-infringement because Star has no evidence to support an essential element of its claim.

FN15. In *San Huan,* the Federal Circuit affirmed the Commission's finding that "evidence that several magnets of the same size and grade were tested and found to infringe on another violation day constitutes sufficient evidence that the untested magnets [infringed] on the day on which they were sold or imported." *Id.,* at 1359. RJR states that the issue in the present case is directed to processes that may "vary from cure-to-cure, barn-to-barn, and season-to-season," and not a product that is of the same size and grade irregardless of when it was manufactured.

FN16. In *449,* the court ordered condemnation of the entire shipment of 449 cases of canned tomato paste, based on the testing of a small sampling. RJR asserts that in *449,* the tests were run on the same product in the same shipment whereas in the present case, each tobacco sample is different, *i.e.,* each barn is different and "specific claim limitations, not minimum tolerances, must be satisfied." (RJR R. Br., p. 11).

FN17. In *Blue Cross,* the court stated that "the Federal Rules of Civil Procedure and Federal Rules of Evidence grant district judges authority to shape the nature and scope of admissible evidence for trial. Scientific evidence-like sampling and statistical extrapolations admitted at trial-is well suited to mass tort actions." *Id.* at 248. RJR asserts that this issue in *Blue Cross* relates only to damages and to "scientifically-proven and accepted surveys, not unproven extrapolations, as here." (RJR R. Br., p. 11).

FN18. In *Spectra,* the court affirmed the district court's grant of summary judgment of non-infringement where plaintiff had no evidence to support a claim of infringement. The plaintiff's test data did not show the presence of a polymer (a claim limitation of the patents-in-suit), which was necessary to prove infringement.

Star's reliance upon its expert reports FN19 to rebut RJR's contentions and assertions and conclude that "the vast majority of RJR's farmers were practicing Star Scientific's methods in 2001 and 2002" is justified. However, RJR's reliance on *Spectra* is not. In *Spectra,* the evidence before the court showed that the alleged infringing product did not contain a claim limitation of the patents-in-suit. Conversely, in the present case, Star has the opinions of experts that are based on extensive testing and scientific principles that the claim limitations at issue are satisfied when tobacco is cured in barns retrofitted with the heat exchanger technology. The R.J. Lee Group Report describes the analysis of RJR's 2000 and 2001 test data. It also explained how and why the 2000 test data was used in arriving at its conclusions regarding the 2001 season. The report details how the R.J. Lee Group obtained the 2002 test results and how it concluded that the claim limitation "substantially preventing the formation of at least one nitrosamine" was satisfied by the RJR contract growers during the 2001 and 2002 curing seasons (St.Ex., Ex. 13, p. 39). In its analysis, the R.J. Lee Group took into consideration the weather conditions during the years under study and the areas of the tobacco plant from which the sample was taken (*i.e.,* lower, middle, or upper stalk). Moreover, in reaching its conclusions, the Lee Group examined the consistency of the data from 2000 to 2002 (St.Ex.13, pp. 33-38).

FN19. The R.J. Lee Group Report (St.Ex.13); the Lee Rebuttal (St.Ex.14); the Sturgill Report and the Sturgill Rebuttal (St. Exs. 17 and 18, respectively); the Nelson Report and the Nelson Rebuttal (St. Exs. 15 and 16, respectively); and the Bjorge Report (St.Ex.12).

RJR states that Star's tests "were flawed and cannot be used to prove infringement." (RJR R. Br., p. 12). However, it also asserts that "based on the tests Star did make, as interpreted by its own experts, at least two key limitations in each and every asserted claim-avoidance of an anaerobic condition and provision of a controlled environment-did not exist in the accused barns" (RJR Br., p. 2). In other words, RJR attempts to use tests that it says are so flawed as to be irrelevant to prove infringement to prove non-infringement. Even if RJR could have it both ways, it does not support its allegation that Star's tests and the interpretations of

those tests by Star's experts are not scientifically valid or that the reasoning or methodology cannot be properly applied to the facts of this case.FN20 Instead, taken in a light most favorable to Star, the expert reports appear to be "good science," and typical of studies undertaken to characterize a large population that cannot be individually sampled by any practical means.FN21 In light of Star's evidence, a trier of fact could determine that the farmers from whom RJR purchased tobacco during the 2001 and 2002 curing seasons directly infringed the patents-in-suit. Since Star's evidence establishes the existence of direct infringement, as well as disputed issues of material fact, RJR's motion for summary judgment regarding Star's testing of curing barns should be denied.

FN20. *See* Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). RJR relies on General Electric Company, v. Joiner, 522 U.S. 136, 146 (1997) for its argument that Star's attempt to extrapolate infringement from its 2002 testing should be rejected because it failed to offer the support of a statistics expert ("[N]othing ... requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion offered ."). (RJR Br., pp. 9-10). RJR does not offer any testimony from its experts that attacks the methodology of the R.J. Lee Group Report, but merely argues that Star must have a statistics expert to prove its case.

FN21. Star points out that the R.J. Lee Group Report is "supported by ten sets of appendices, containing hundreds of pages of data" (St.Br., p. 20).

B. *Claim Limitations Not Met*

RJR contends that farmers cannot infringe the claims of the patents-in-suit because two claim limitations are not met. Even accepting the claim construction asserted by Star in its opposition to the motion, RJR asserts that it is entitled to summary judgment since two limitations in each and every asserted claim, *i.e.*, "prevention of an anaerobic condition" and "controlled environment," did not exist in the accused barns.

1. " *Prevention of an Anaerobic Condition* "

RJR asserts that Star ran "fundamentally flawed tests that cannot be reasonably relied upon to show infringement" (RJR Br., p. 9). RJR accuses Star of deliberately failing to test the oxygen levels around the vicinity of the tobacco plant (RJR Br., p. 9).FN22 RJR states that the tobacco samples taken from the barns had "detectable" TSNA levels, showing that none of the farmers avoided an anaerobic condition (RJR Br., pp. 9-10, 14). RJR asserts that all of the barns that Star tested, except one, had detectable levels of at least one nitrosamine, relying on Ex. 11, p. 5 FN23 (RJR Br., p. 14). RJR further asserts that these detectable TSNA levels, according to the R.J. Lee Group Report, were the result of microbial activity associated with an anaerobic environment around the surface of the tobacco leaf (RJR Br., p. 14). Based on Star's test data, RJR maintains that its farmers did not infringe the patents-in-suit because the claim limitation "prevention of anaerobic condition" was not met (RJR Br., p. 9).

FN22. RJR quotes Dr. Lee, "[b]ecause of the complex environment at the leaf surface, it is not possible to measure precisely the oxygen that is actually in contact with the leaves. Ex. 2, p. 8" (RJR Br., p. 13). Star responds that it placed probes "deep within the curing tobacco" which was "within any reasonable construction of 'in the vicinity of the plant.' " (St.Br., p. 4).

FN23. Ex. 11 contains a compilation of the TSNA levels of tobacco cured in the barns tested by the RJ. Lee Group. The compilation appears to be taken from Mr. James J. Nawrocki's expert report, and notes that the source is Appendix X, Parts A, B, C, and D of the R.J. Lee Group Report. On the last page of the TSNA test results, *i.e .*, p. 5, the total barns with no detectable TSNAs is noted as "1." Star has not disputed the accuracy of this compilation of TSNA test results.

Star states that the measurements taken of the oxygen levels during the cures at several locations in the barns serve as evidence of the levels of oxygen in the curing environment (St.Br., p. 4). Star points to Dr. Nelson's testimony wherein he stated that those skilled in the art can utilize the oxygen levels 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 FN24 (Ex. 27, Nelson Dep. at 150-52, 181-87) (St.Br., p. 5). Dr. Nelson further testified that the presence of small amounts of TSNAs does "not necessarily" mean that an anaerobic condition was present because the microbial mediated reduction is the primary source of TSNAs, but not the only source FN25 (Ex. 27, Nelson Dep. at 206). Star contends that the presence of some TSNAs is still consistent with the "substantial" prevention of an anaerobic condition FN26 (St.Br., p. 5).

FN24. Dr. Lee confirms that the R.J. Lee Group did a "variety of measurements" that showed prevention of anaerobic conditions in both "Evans" and "non-Evans" barns. (St.Ex., Ex. 13, p. 8).

FN25. RJR points out that this statement by Dr. Nelson is based on Dr. Nelson's speculation. (RJR R. Br., p. 14). The Special Master agrees with RJR that, based on Novartis Corp. v. Ben Venue Laboratories, 271 F.3d 1043, 1051 (Fed.Cir.2001), this part of Dr. Nelson's testimony should not be considered for purposes of this motion. ("In the context of summary judgment motions, the Third Circuit has demanded that the factual predicate of an expert's opinion must find some support in the record, and has emphasized that mere 'theoretical speculations' lacking a basis in the record will not create a genuine issue of fact." Penn. Dental Ass'n v. Med. Serv. Ass'n, 745 F.2d 248 (3d Cir.1990).)

FN26. Star submits that only one farmer from the 2001 test data and 11 farmers from the 2002 test data had TSNA values that fell outside the limits of the claims. (St.Br., p. 17).

2. " *Controlled Environment* "

RJR additionally asserts that all of the farmers from which it purchased low TSNA tobacco employed airflow that was well within prior art levels and Star has not offered any evidence showing that any of the farmers controlled temperature and humidity differently from the prior art, thereby not satisfying the claim limitation "controlled environment" (RJR Br., pp. 10 and 16). RJR bases its argument on the testimony of James Sturgill, an expert for Star. Mr. Sturgill testified that "prior to 1998, conventional airflow in a flue-curing barn was at least as high as 25,900 CFM," relying on an Aerovent FN27 brochure from the 1970s (RJR Br., p. 16). Additionally, according to Sturgill, the Vencon-Varsos barn has an airflow of approximately 20,500 CFM, FN28 which is substantially below the requirement disclosed by the ' 372 provisional application. In light of the foregoing, RJR maintains that Star lacks evidence showing that any farmer satisfies the "controlled environment" limitation, and summary judgment of noninfringement is

appropriate.

FN27. Aerovent manufactured tobacco curing barns.

FN28. Sturgill tested the Vencon-Varsos heat exchangers and found the air flow to be 18,362 CFMs with close to 1" static pressure.

Star disagrees with RJR's representation of the testimony of Mr. Sturgill. Star notes that Mr. Sturgill testified that "actual airflow in the barn is less than the fan rating" (St. Ex., Ex. 28, Sturgill 3/11/03 Expert Dep. at 160) (St.Br., p. 27). Moreover, according to Star, the rating for each fan in the Aerovent catalog "was developed in a laboratory setting, and does not reflect the actual air delivery of the fan as installed in an application" (St.Br., p. 27). Star alleges Mr. Sturgill's testimony and the fan rating caveat in the Aerovent fan catalog conclusively show "prior to 1998, conventional airflow in a flue curing barn was less than 25,900 CFM." FN29 Consequently, Star argues that the evidence shows that the heat exchange technology provides increased airflow that was not part of the prior art FN30 (St.Br., p. 29).

FN29. Mr. Sturgill testified that the Aerovent fans he observed were all 32-inch fans. Such 32-inch Aerovent fans had a rating of 18,800 CFM at one inch of static pressure, which according to "both RJR and Star Scientific's experts ... would actually provide less airflow when installed in a curing barn." (St.Br., pp. 28-29).

FN30. St. Ex., Ex. 63, Riddick Dep. at 110-14; Ex. 125, letter from Varsos to Peele, 3/20/00 at 52543 0301; and Ex. 19, TRC Report, App. D. at 2-2 and 2-9.

The expert reports and testimony provided by Star are that it has sufficient evidence to show at trial that RJR's contract growers directly infringed the patents-in-suit. For example, the R.J. Lee Group report states, based on extensive testing and analysis of the substantial test results, the processes employed by the RJR contract growers to cure low-TSNA tobacco meet all the limitations of the asserted claims. Furthermore, Mr. Lione, RJR's patent attorney, opined in December 2001, that RJR and/or its growers infringed the claims of the '649 patent.FN31 Since Star has presented evidence that supports its claim of direct infringement and presents evidence showing that material facts are in dispute, RJR has not met its burden of establishing that summary judgment of non-infringement is warranted.

FN31. While Mr. Lione opined that the '649 patent should be found invalid, it is significant that Mr. Lione was able to construe the claims to find infringement. RJR attempts to diminish the significance of Mr. Lione's opinion by alleging that Mr. Lione had not "explored non-infringement because the evidence of invalidity and unenforceability was so overwhelming" (RJR R. Br., p. 17). RJR's statement is not persuasive in light of Mr. Lione's statement to the contrary: "I have construed claims of the '649 patent to read on the Accused Process in a manner hereinafter discussed." (St.Ex.139, p. 1) Moreover, Mr. Lione supported his statement regarding infringements with detailed claim charts.

C. 35 U.S.C. s. 295

In its opposition to the motion for summary judgment, Star attempts to invoke 35 U.S.C. s. 295. While Star asserts that it has enough evidence to show infringement, it also alleges its rights under s. 295 in the event that the Court should find that it does not have sufficient evidence to proceed to trial. In its pertinent part, 35 U.S.C. s. 295 states:

if the Court finds-

(1) that a substantial likelihood exists that the product was made by the patented process, and

(2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made."

Star claims that it has made a "reasonable effort" under s. 295(2) to determine whether the heat exchanger technology infringes its patented process, but was unable to complete its testing program because of RJR's interference. Star devotes four and one-half pages of its brief (St.Br., pp. 11-15) to pointing out the problems it encountered with RJR during its testing of the accused curing barns. Star relies on the testing evidence submitted by RJR for the 2000 and 2001 curing seasons and its own testing evidence for the 2002 curing season as the basis for its claim that the "substantial likelihood" prong of s. 295 has been met. Star asserts that, based on the evidence, the Court should find a "substantial likelihood" that the cured tobacco cured in the barns containing the heat exchanger technology is made by the process claimed in the patents-in-suit (St.Br., p. 34). Star, relying on Nutrinova Nutrition Specialties and Food Ingredients GmbH v. Int'l Trade Comm'n, 224 F.3d 1356, 1360 (Fed.Cir.2000), claims that 35 U.S.C. s. 295 is appropriate in this case because RJR was so uncooperative during discovery,FN32 in particular during the 2002 testing.

FN32. RJR lists "[j]ust a few of Star's violations" at RJR.R.Br., n. 10.

RJR relies on the legislative history (S.Rep. No. 83, 100th Cong ., 1st Sess. 46-47, 58 (1987) of s. 295 for its premise that s. 295 applies to only foreign manufacturers accused of patent infringement and not to any accused process practiced within the United States. While RJR's reading of the legislative history comports with that of the Special Master, the legislative history need not be deciphered to reject Star's claim. Star told this Court on September 30, 2002, that "Counsel for both sides have cooperated effectively throughout the duration of this case; and the proof is in the pudding. There is no significant amount of discovery that is left unscheduled, all known discovery requests have already been accommodated, and the September 30 discovery cutoff is fully in sight" (RJR R. Br., p. 8 and Ex. 25, p. 5). Therefore, as of September 30, 2002, Star did not believe that RJR was a "non-cooperative defendant" (Nutrinova, 224 F.3d at 1360). Moreover, based on the sheer volume of exhibits presented by Star, it is clear that Star has was able to determine the process that the farmers used in curing their tobacco. In light of the evidence, Star failed to make out a colorable case for the application of s. 295 and I respectfully recommend that the Court deny Star's request under s. 295 to shift the burden of proof to RJR in this case.

III. *CONCLUSION*

Since Star has shown, through its expert reports, that it has sufficient evidence to establish the existence of

direct infringement of the patents-in-suit, I respectfully recommend that the Court deny RJR's motion for summary judgment of no direct infringement.

D.Md.,2004.
Star Scientific Inc. v. R.J. Reynolds Tobacco Co.

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