

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

STAR SCIENTIFIC INC,
Plaintiff.

v.

R.J. REYNOLDS TOBACCO COMPANY,
Defendant.

Feb. 23, 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 RJR's MOTION FOR SUMMARY
JUDGMENT NO. 4 (INVALIDITY BASED ON THE PRIOR ART)**

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. 274) for an order granting summary judgment that the patents-in-suit are invalid in light of the prior art. Plaintiff, Star Scientific, Inc. ("Star") opposes RJR's motion for summary judgment (Docket No. 309). RJR filed a reply memorandum (Docket No. 336). After reviewing these pleadings, I respectfully recommend that the Court enter an order denying RJR's motion for summary judgment that the patents-in-suit are invalid under various subsections of 35 U.S.C. s. 102 in light of the prior art presented by RJR.

I. BACKGROUND

This patent infringement action 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, FN1 of which Star is the exclusive licensee, 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 describe and claim methods of preventing the

formation in flue-cured tobacco, *i.e.*, tobacco cured in barns using heated air, of tobacco-specific nitrosamines ("TSNAs"), *e.g.*, N'-nitrosonornicotine ("NNN"), 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone ("NNK"), N'-nitrosoanatabine ("NAT"), and N'-nitrosoanabasine ("NAB").

FN1. 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.

In curing flue-cured tobacco, the air inside the barns is heated by a heat exchanger from a fuel-burning furnace. In barns equipped with indirect-fire heating systems, the exhaust gases are kept separate from the air inside the barn. Such indirect-fire heating systems have been used to cure tobacco in the United States for decades. One farmer who cured tobacco using an indirect-fire system during the time period relevant to this action is Mr. Hassel Brown, a tobacco grower in East Bend, North Carolina.

Mr. Jonnie Williams is the named inventor of the '649 and '401 patents. On December 2, 1996, Mr. Williams filed Application Serial No. 08/757,104 ("the '104 application") with the United States Patent and Trademark Office ("PTO"). Later, on June 20, 1997, he filed Application Serial No. 08/879,905 ("the '905 application") as a continuation-in-part of the '104 application. Six months later, on December 23, 1997, he filed Application Serial No. 08/998,043 as a continuation-in-part of the '905 application. Then on September 15, 1998, Mr. Williams filed a provisional application, Application Serial No. 60/100,372 ("the '372 application"). During the course of his research which led to the filing of the above referenced patent applications and later to the inventions described and claimed in the patents-in-suit, Mr. Williams consulted with Dr. Harold Burton of the University of Kentucky. Dr. Burton is a recognized expert and conducts research on air-cured tobacco, commonly known as burley tobacco. On August 28, 1998, as part of his consultations with Mr. Williams, Dr. Burton wrote a letter ("the Burton Letter") to Mr. Romulo H. Delmendo, Mr. Williams' patent attorney. In the Burton Letter, Dr. Burton presented his theory as to the formation of TSNAs in cured tobacco. In the Burton Letter, Dr. Burton discussed Chinese tobacco curing techniques, as learned during his trip to China in 1997, and compared Chinese tobacco curing techniques with those used to flue-cure tobacco in the United States during the 1960s.

Around the same time Mr. Williams was conducting his studies on preventing TSNAs in curing tobacco, Dr. David Peele, a researcher at RJR, was also conducting research to determine how to prevent the formation of TSNAs in curing tobacco. On April 26, 1999, Dr. Peele filed Application Serial No. 09/299,403 ("the '403 application"), and on December 20, 2000, filed a continuation of the '403 application, Application Serial No. 09/735,177 ("the '177 application") on his work. FN2 The '177 application was published on April 26, 2001.

FN2. The '403 and '177 applications are referred to as "the Peele Applications".

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"). The '018 application also claims priority to the provisional application, *i.e.*, the '372 application. Sometime in late 1998 or early 1999, Mr. Williams designed the StarCure barn, a curing barn allegedly based on the invention described in the '372 application and later described in the '018 application.

The '649 patent was issued on March 20, 2001. On May 23, 2001, Star sued RJR for infringement of the '649

patent ("the 01-1504 case"). Star alleged that RJR had infringed or had induced infringement of claims 4, 12 and 20 of the '649 patent by contracting with tobacco farmers to purchase low-TSNA tobacco cured using a certain type of heat exchanger technology in lieu of direct fire heaters. 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 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.

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, FN3 alleging that RJR's contract with tobacco farmers directly infringed, or induced others to infringe, the patented heat exchanger technology 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:

FN3. 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.

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

II. DISCUSSION

RJR moves this Court for an order of summary judgment that the patents-in-suit are invalid pursuant to various subsections of 35 U.S.C. s. 102. Specifically, RJR contends that the patents-in-suit are invalid under (1) 35 U.S.C. s. 102(f) because Mr. Williams derived the claimed invention from Dr. Burton; (2) 35 U.S.C. s. 102(b) because the claimed invention was in "public use" in the United States more than one year prior to the filing date of the '018 application; (3) 35 U.S.C. s. 102(g) based on Dr. Peek's invention; and (4) 35 U.S.C. s. 102(e) based on the publication of the '177 application.

Disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). 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.* "[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. 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 (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." *Id.* at 248, 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.

Invalidity based on anticipation of the invention by the prior art is a question of fact that can be resolved on summary judgment. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1322 (Fed.Cir.2002) (affirming summary judgment of anticipation based upon prior public use); *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed.Cir.2001) (affirming summary judgment of anticipation). Because a patent is presumed to be valid under 35 U.S.C. s. 282 (1994), the party asserting invalidity has the burden of showing 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 are anticipated under the asserted subparts of 35 U.S.C. s. 102. 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.

A two-step analysis must be performed in order to determine invalidity under 35 U.S.C. s. 102. First the claims must be properly construed and then the prior art must be compared to the properly construed claims. *Teleflex, Inc. v. Ficosa N. Am Corp.*, 299 F.3d 1313, 1335 (Fed.Cir.2002) (quoting *Beachcombers, Int'l., Inc., v. Wilde-Wood Creative Prods., Inc.*, 31 F.3d 1154, 1160 (Fed. Cir.1994)). A claim is invalid under 35 U.S.C. s. 102 if each claim limitation is found explicitly or implicitly in a single prior art reference. *Sandt Tech., Ltd. V. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350 (Fed.Cir.2001). For purposes of the present motion, RJR agreed to be bound by Star's claim construction. However, in his Report and Recommendation of December 4, 2003, FN4 the Special Master construed the claims at issue. Accordingly, this Report and Recommendation will compare single prior art references to the claims as previously construed by the Special Master. FN5

FN4. 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. The Court has not adopted the Special Master's December 4, 2003, claim construction.

FN5. Star contends that RJR cannot meet its clear and convincing burden because its arguments are inconsistent. Specifically, Star contends that RJR's assertion that the claimed invention is anticipated by the prior art is inconsistent with its assertion that the claimed invention is the same as Dr. Peele's invention, which is not anticipated by the prior art. According to RJR, Dr. Peele's disclosure "is broad enough to render the patents invalid under s. 102," but "his claims are narrow enough to be patentable over both Williams and the prior art" (RJR R. Br., p. 17). RJR submits the Notice of Allowance for the '177 application mailed August 19, 2003 (RJR R. Br., Ex. 66). The claims of the '177 application are directed to modifying a barn "to ensure that the nitric oxide level within the barn during tobacco curing is suppressed to prevent formation of tobacco-specific nitrosamines."

A. 35 U.S.C. s. 102(f)

Under 35 U.S.C. s. 102(f), "a person shall be entitled to a patent unless-he did not himself invent the subject matter sought to be patented." RJR contends that Mr. Williams "did not himself invent" the claimed invention, but instead derived it from information supplied by Dr. Burton in the Burton Letter. In order for the burden to shift to Star to prove conception before the date of the Burton Letter, RJR must show that the

Burton Letter described each and every claim limitations of the asserted claims. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed.Cir.1996).

To support its claim that the patents-in-suit are invalid pursuant to 35 U.S.C. s. 102(f), RJR submits a chart (RJR Br.,FN6 Ex. 24) in which it compares each limitation of the asserted claims FN7 to information contained in the Burton Letter. RJR also submits the testimony of Mr. Delmendo who filed the '372 application. According to RJR, Mr. Delmendo confirmed that the underlying theory of Mr. Williams' invention was set forth in the Burton Letter.

FN6. "RJR Br." refers to Defendant's Memorandum in Support of Its Motion for Summary Judgment No. 4: Invalidity Based on the Prior Art. "St. Br." refers to Plaintiffs Memorandum in Opposition to RJR's Motion for Summary Judgment No. 4 (Invalidity Based on the Prior Art). "RJR R. Br." refers to Defendant's Reply In Support of Its Motion for Summary Judgment No. 4: Invalidity Based on the Prior Art. "St. Ex." refers to Plaintiffs Consolidated Appendix of Exhibits.

FN7. As Star points out, it has not asserted that claim 1 of the ' 649 patent has been infringed by RJR.

Additionally, RJR contends that Mr. Williams has no evidence, *e .g.*, documents, showing that he conceived of the claimed invention prior to the Burton Letter. Since the date of the Burton Letter predates the filing date of the '372 application, RJR contends that "unless Star can provide some admissible evidence to show that Mr. Williams conceived and reduced to practice the claimed invention before August 28, 1998," FN8 summary judgment of invalidity based on the Burton Letter should be entered in its favor.

FN8. *See Mahurkar*, 79 F.3d at 1576. In *Mahurkar*, the defendant's evidence was a document published three months before the filing date which disclosed "each and every element of the claimed invention." *Id.* Star contends that the Burton Letter does not disclose all of the claim limitations of the asserted claims.

Star seeks to rebut RJR's invalidity contention under 35 U.S.C. s. 102(f) by insisting that Dr. Burton merely assisted Mr. Williams by explaining the "general background on the science" to his attorney and conducting lab work to measure TSNA levels in samples (St.Br., p. 34). Star submits that Mr. Williams, as well as those skilled in the art, knew about the theory that conditions of high humidity, temperature or anaerobic conditions could influence the formation of TSNA's by microbes during curing before the Burton Letter. In fact, Star claims that Mr. Williams explained all or part of that theory in his related patent applications that were filed in 1997 (St.Br., pp. 34-35). According to Star, the Burton Letter makes no reference to adequate airflow (St.Br., p. 38).FN9 While the Burton Letter describes the "Chinese" method as utilizing radiant heat, according to Star, the "Chinese" method does not use forced air. *Id.* Star also takes issue with RJR's chart that allegedly shows that the Burton Letter recites every claim limitation of the patents-in-suit. For example, according to Star, paragraph 3 of the Burton Letter does not describe "an airflow sufficient to substantially prevent an anaerobic condition around the vicinity of said plant portion" FN10 when discussing the "Chinese" method.

FN9. RJR states that "Star chose to argue that the Burton Letter did not disclose 'high airflow' ... [a] term not found in the asserted claims" referencing St. Br., p. 40 (RJR R. Br, p. 11). RJR does not address Star's argument (St.Br, p. 38) regarding the airflow of the "Chinese" method.

FN10. Found in claims 4 and 20 of the '649 patent and claim 41 of the '401 patent.

As for RJR's assertion that no documents exist that predate the Burton Letter (St.Br., p. 39), Star responds that Mr. Delmendo's notes of his August 28, 1998 meeting with Mr. Williams confirms that Mr. Williams was in possession of the invention prior to August 29, 1998, the date of the Burton Letter. Star also submits the testimony of Mr. Rufus H. Honeycutt, a Brown & Williamson representative (St.Ex., Ex. 52), and a related Brown & Williamson document (St.Ex., Ex. 186) to confirm that Mr. Williams possessed the invention six weeks before the Burton Letter.

To be invalidating prior art, the Burton Letter must contain a "complete and enabling disclosure of the claimed invention." *Eaton Corp. v. Rockwell International Corp.*, 325 F.3d 1332, 1345 (Fed.Cir.2003). RJR's chart, even combined with Mr. Delmendo's testimony, fails to show by clear and convincing evidence, that the patents-in-suit are anticipated by the Burton Letter because the parts of the Burton Letter set forth in the chart do not describe every claim limitation of the asserted claims. Since RJR has not shown, by clear and convincing evidence, that the Burton Letter contains a complete disclosure of the claimed invention, *i.e.*, each claim limitation of the asserted patents, RJR has not met its initial burden as the movant of the present motion.

Even assuming that RJR had met its burden as the movant of the present motion, Star has set forth sufficient evidence to show that there are genuine issues of material facts that would preclude the entry of summary judgment in favor of RJR. For example, the Burton Letter provides that the "Chinese" method uses radiant heat, *i.e.* , "passing the hot gases through flue pipes in the curing barn" (RJR Br., Ex. 19, para. 3). However, since the Burton Letter does not mention airflow within the barns, there are genuine issues of fact regarding whether the Burton Letter describes the airflow limitations of the asserted claims.FN11

FN11. Star's evidence that Mr. Williams invented the inventions of the asserted claims, however, is insufficient. Since Star claims that Mr. Delmendo's meeting notes are privileged and has refused to produce them, Star cannot rely on them in connection with this motion. Moreover, the Honeycutt testimony and the Brown & Williamson document do not support Star's position, since they fail to describe the claim limitations "sufficient airflow to avoid an anaerobic environment" and "controlled environment."

Since RJR did not show that the Burton Letter discloses each and every claim limitation of the asserted claims, RJR did not meet its initial burden by a showing of clear and convincing evidence that the patents-in-suit are anticipated under 35 U.S.C. s. 102(f). Consequently, the burden did not shift to Star to prove conception before the date of the Burton Letter. Moreover, Star has shown that even if RJR had met its burden, there were genuine issues of material fact as to whether the Burton Letter disclosed each and every limitation of the asserted claims. Therefore, I respectfully recommend that summary judgment of invalidity pursuant to 35 U.S.C. s. 102(f) not be entered by the Court.

B. 35 U.S.C. s. 102(b)

"A person shall be entitled to a patent unless-... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior

to the date of the application for patent in the United States." 35 U.S.C. s. 102(b). RJR contends that during the 1996 curing season, Mr. Hassel Brown, a tobacco grower, cured flue-cured tobacco in his indirect-fire barn, which was equipped with a heat exchanger and a fan to circulate heated air through the barn (RJR Br., p. 5). According to RJR, Mr. Brown practiced his curing process ("the Brown Method") on his farm in East Bend, North Carolina, and the Brown Method was "available to any member of the public who was interested in observing it" (RJR Br., p. 5). RJR contends that the Brown Method is the same method referred to in the Burton Letter, *i.e.*, the "old" indirect-fire curing method, and accordingly, anticipates the asserted claims for the same reasons described above FN12 (RJR Br., p. 18). Moreover, RJR contends that the Brown Method controlled the environment inside the barn, FN13 "substantially or essentially or virtually achieved the substantial prevention of at least one nitrosamine," caused the environment inside the barn to be free of combustion gases and since TSNAs were undetectable, necessarily avoided an anaerobic condition. *Id.*

FN12. RJR's reliance on the Burton Letter to show that the Brown Method anticipates the asserted claims is misplaced. As discussed above, RJR has not shown by clear and convincing evidence that the Burton Letter discloses each and every claim limitation of the asserted claims. Moreover, a genuine issue of fact exists as to whether the Burton Letter describes each and every claim limitation of the asserted claims.

FN13. By controlling temperature, humidity and airflow.

RJR relies on two declarations by Mr. Brown (RJR Br., Exs. 10 and 13) as support for its allegations regarding the Brown Method (RJR Br., p. 5). Furthermore, RJR states that it tested Mr. Brown's tobacco in October 1996 and found it to have undetectable levels of all four TSNAs. FN14 Moreover, RJR contends that since Star has not identified any differences between the claimed invention and the prior art, *e.g.*, the Brown Method (RJR Br., p. 21), the claimed invention would have infringed a patent on the prior art. Since "that which infringes if later, anticipated if earlier" (*Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed Cir.2001), RJR asserts that the claimed invention is anticipated by the prior art, *i.e.*, the Brown Method (RJR Br., p. 21).

FN14. As support, RJR submits an e-mail from Mr. Richard Reich with a copy of the three-page attachment containing TSNA test results from 1996 (RJR Br., Ex. 11) and the testimony of Mr. Reich regarding Mr. Brown's operation (RJR Br., Ex. 12).

Star asserts that RJR's evidence regarding the Brown Method does not rise to the level of clear and convincing evidence of invalidity. Star notes that RJR describes the Brown Method in such imprecise terms, *e.g.*, "old tobacco curing process" or "old flue curing technique," that the Brown Method cannot be compared to claims of the patents-in-suit. Moreover, Star notes that RJR presented no test data from tobacco cured according to the Brown Method that related to the "anaerobic conditions," "combustion gases" or "controlled environment" elements of the asserted claims. As to the level of TSNAs, Star points out that RJR's allegations that the Brown Method yielded tobacco having undetectably low levels of TSNAs was based on only one sample and that Dr. Lambert Otten, RJR's expert, testified that "one [test sample] tells me nothing" FN15 (St.Ex., Ex. 30). According to Star, another 1996 sample from Mr. Brown's barn had a TSNA level of more than 7 ppm. Furthermore, Star submits that a report of the R.J. Lee Group, one of its retained experts, indicates that in 1998 tobacco cured with the Brown Method yielded flue-cured tobacco having average TSNA levels "substantially" in excess of 1 ppm (St.Br., p. 31), *i.e.*, substantially more than

100 to 200 times the TSNA levels necessary to anticipate the asserted claims.

FN15. RJR responds that Dr. Otten was referring to "infringement of untested cures" and "is not applied to the issue of invalidity under 35 U.S.C. s.s. 102(a), (b)" (RJR R. Br., p. 13). However, under *Bristol-Myers Squibb*, 246 F.3d at 1378, "that which infringes if later, anticipated if earlier," if one test sample is not clear and convincing evidence of infringement, then one test sample cannot be clear and convincing evidence of anticipation. Dr. Richard Lee, Star's expert, concurs with Dr. Otten that one sample is not enough, and stated that TSNA levels at different locations in a barn could be materially different (St.Br., p. 31).

A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 (Fed.Cir.2003). A prior art disclosure must enable one of ordinary skill in the art to reduce the invention to practice. *Id.* Clearly the disclosures and descriptions of the Brown Method do not enable one of ordinary skill in the art to practice Mr. Williams' invention. Therefore, the only evidence that the Brown Method anticipates the claims of the patents-in-suit is the one test sample from 1996 in which the tobacco had no detectable TSNAs.FN16 That limited evidence, particularly since all of the other test evidence was to the contrary, is not clear and convincing evidence of anticipation. Since RJR failed to provide clear and convincing evidence that the Brown Method satisfies each and every claim limitation of the asserted claims, the burden did not shift to Star to present evidence tending to show that there are genuine issues of material fact regarding anticipation under 35 U.S.C. s. 102(b). Consequently, I respectfully recommend that the Court deny RJR's motion for summary judgment based on 35 U.S.C. s. 102(b).

FN16. As set out above, the Burton Letter cannot support a finding of anticipation.

C. 35 U.S.C. s. 102(g)

RJR asserts that Dr. Peele conceived the claimed invention by at least November 1997 and reduced it to practice by at least August 13, 1998. The date of conception is the date the inventor first appreciated the fact of what he or she made, but the inventor need not be the first to appreciate the patentability of the invention. *Dow Chemical Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed.Cir.2001). The date of a reduction to practice is the date that the invention is "sufficiently tested to demonstrate that it will work for its intended purpose." *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd.*, 731 F.2d 831, 838 (Fed.Cir.1984). Moreover, RJR asserts that Mr. Williams did not invent the claims of the '649 patent until at least September 15, 1998, the filing date of the '372 provisional application,FN17 because Star does not have any evidence that Mr. Williams conceived of the claimed invention prior to that date (RJR Br., p. 23). 35 U.S.C. s. 102(g)(2) states that a person is entitled to a patent unless:

FN17. However, as discussed *infra*, RJR contends that the '649 patent is not entitled to the September 15, 1998, filing date because of the substantial changes, *i.e.*, the new matter, added to the specification of the '372 application when the '018 application was filed.

[B]efore such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective date of conception and reduction to practice of the

invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

As support for its assertion of invalidity under 35 U.S.C. s. 102(g), RJR points to a declaration of Dr. Peele (RJR Br., Ex. 6). RJR attempts to corroborate Dr. Peele's conception of Mr. Williams' invention through a letter from Mr. Brian Smeeton to Swedish Match in November 1997 (RJR Br., Ex. 6A) and from meeting notes in which a low TSNA "recipe" was recorded (RJR Br., Ex. 6B). According to RJR, during the season following Mr. Smeeton's letter, "tobacco was cured in an environment free of combustion exhaust gases" and when that tobacco was tested on August 13, 1998, TSNA levels could not be detected (RJR Br., p. 22). As evidence that Dr. Peele's invention anticipated the inventions described and claimed in the patents-in-suit, RJR submitted a claim chart (RJR Br., Ex. 15) comparing the claim limitations of the asserted claims to Dr. Peele's invention.FN18

FN18. Since RJR does not attribute the claim chart to any expert witness testimony, the claim chart has been viewed as merely attorney argument.

An inventor's testimony regarding the facts surrounding a claim of derivation or priority of an invention cannot stand alone, but must be supported with corroborating evidence. *Price v. Symsek*, 988 F.2d 1187, 1194 (Fed.Cir.1993). In the present case, the only evidence presented by RJR that can be viewed as corroborating Dr. Peele's testimony is Mr. Smeeton's letter (RJR Br., Ex. 6A). FN19 However, Mr. Smeeton's letter fails to corroborate RJR's allegation that Dr. Peele invented the claims of the patents-in-suit. For example, the letter states that Dr. Peele "has been measuring CO₂ levels in all our barns this season." However, Dr. Peele testified that nitrogen oxide gases, not CO₂, were the focus of his invention (St.Br., p. 12-13). Moreover, as pointed out by Star, Mr. Smeeton's letter does not disclose any of the limitations of the asserted claims about which RJR has complained (St.Br., n. 22). Accordingly, since Dr. Peele's declaration and testimony regarding his prior invention is not corroborated by Mr. Smeeton's letter, RJR did not present clear and convincing evidence of anticipation and the burden did not shift to Star to put forth evidence that there are genuine issues of material facts regarding 35 U.S.C. s. 102(g).

FN19. The claim charts are not considered corroborating evidence. RJR's charts comparing the claim limitations to "Dr. Peele's Method" is based on the declaration of Dr. Peele. While RJR contends that Dr. Peele's disclosure "is broad enough to render the patents invalid under s. 102," it fails to offer any support other than the affidavit and deposition testimony of Dr. Peele.

Since RJR did not meet its burden of presenting clear and convincing evidence of anticipation, Star is not obligated to present any evidence in rebuttal. However, Star presents evidence that raises genuine issues of material fact regarding invalidity under 35 U.S.C. s. 102(g). For example, to support its contention that Dr. Peele's invention is different than Mr. Williams' invention, Star points out that Dr. Peele's application disclaimed key elements of Mr. Williams' invention. For example, according to Star, the Dr Peele's Applications do not teach "controlling one or more of the conditions in the curing barn (as listed at col. 5, line 66 through col. 6, line 4 of the '649 patent) in a way different from conventional curing in order to substantially prevent the formation of nitrosamines" (St.Br., p. 9).FN20 In fact, Star points out that the Peele Applications teach nitrosamine levels as high as 2 ppm and NNN and NNK levels of 0.5 ppm which is ten times the levels claimed by the patents-in-suit. Star further contends that Dr. Peele and Mr. Williams did not agree as to the causes of TNSA formation, and consequently, that their inventions FN21 were directed to different aspects and controls of the curing process.

FN20. The claim limitation "controlled environment" has been construed by the Court to mean "controlling one or more of humidity, temperature and air flow in the curing barn, in a manner different from conventional curing, in order to substantially prevent the formation of TSNAs." In his patent application, Dr. Peele states that tobacco is cured "in essentially conventional manners after harvest" and "[t]obacco can be cured in traditional manners using conventional equipment techniques and curing conditions" (St.Ex., Ex. 147, p. 12, ll.5-21).

FN21. Star believes that in light of Dr. Peele's erroneous understanding of the TSNA formation mechanism, he could not have conceived of Mr. Williams' invention in 1997. Star specifically refers to Dr. Peele's testimony that around June 1998 he contacted a former student to determine the composition of combustion gases from propane and to RJR's response to Star's Interrogatory No. 1, "In or about 1998, Davis Peele set out to determine the reason for the formation of TSNAs in tobacco exposed to combustion gases during the curing process" (St.Ex., Ex. 252, p. 5).

Since RJR has not met its burden of clear and convincing evidence that the patents-in-suit are invalid as anticipated by the work of Dr. Peele and, in any event, Star has presented evidence that there are genuine issues of material fact regarding RJR's 35 U.S.C. s. 102(g) allegations, I respectfully recommend that the Court deny RJR's summary judgment motion.

D. 35 U.S.C. s. 102(e)

Under 35 U.S.C. s. 102(e)(1), a person shall be entitled to a patent unless the invention was described "in an application for patent, published under s. 122(b), by another filed in the United States before the invention by the applicant for patent." According to RJR, the '177 application, published on April 26, 2001, has an effective filing date of April 26, 1999. FN22 Moreover, RJR asserts that Mr. Williams' date of invention of the patents-in-suit can be no earlier than September 15, 1999, the filing date of the '018 application. Therefore, RJR concludes that since Star admitted that "the curing processes followed by the accused farmers are disclosed in Peele's patent application" (RJR Br., p. 25) FN23 and each of the claim limitations of the patents-in-suit had been previously described in the '403 application, the '403 application is prior art under s. 102(e)(1) (RJR Br., pp. 25-26).

FN22. The '177 application, filed on December 20, 2000, is a continuation of, and claims priority to, the '403 application that was filed on April 26, 1999.

FN23. In response to RJR's Interrogatory No. 8, Star stated "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. In so doing, RJR either has acknowledged that its farmers are not practicing the prior art, or has acknowledged the impropriety of its anticipation defense in this case" (RJR Br., Ex. 48, p. 11).

The Special Master previously found that the '018 application, which became the '649 patent, was not entitled to the priority date of the '372 application since the claimed invention was new subject matter not

contained in the '372 application.FN24 Moreover, the Special Master previously found that Star has presented no credible evidence that it invented the claims of the patents-in-suit prior to the filing date of the '018 application.FN25 Therefore, RJR has presented clear and convincing evidence that the invention disclosed in the '177 application was invented before the invention claimed in the patents-in-suit.

FN24. *See* Report & Recommendation Regarding Defendant's Motion for Summary Judgment No. 3: Patent Invalidity Based on Failure to Comply with 35 U.S.C. s. 112 ("R & R"), where, at p. 16, the Special Master found that the '018 application is a continuation-in-part application, and not a continuation application, of the '372 application with respect to the new subject matter, *e.g.*, airflows other than "sufficiently high."

FN25. *See* note 11, *supra*.

Although Dr. Peele's invention antedates Mr. Williams' invention, RJR's motion for summary judgment must fail. In order to anticipate the asserted claims, RJR must present clear and convincing evidence that the Peele Applications describe each of the limitations of the asserted claims. Instead of pointing to specific disclosures of the '403 application, RJR relies solely on Star's interrogatory response. Nowhere in that interrogatory response does Star state that RJR's farmers had practiced claimed inventions. For example, the interrogatory response is silent as to RJR's farmers creating a "controlled environment" as the term has been construed by the Special Master.FN26 Moreover, the cited interrogatory response is silent as to the substantial prevention of TSNAs, as that term has been construed.FN27 Since RJR's evidence falls far short of the clear and convincing standard needed to invalidate the patents-in-suit,FN28 RJR fails to carry its initial burden as the movant for the summary judgment. Consequently, summary judgment in favor of RJR under 35 U.S.C. s. 102(e) is inappropriate.

FN26. The claim limitation "controlled environment" has been construed 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." (*See* p. 14 of 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).

FN27. The claim limitation "substantially prevent the formation of ... at least one nitrosamine" has been construed to mean "less than about 0.05 i g/g for NNN, less than about 0.10 i g/g for NAT plus NAB, and less than about 0.05 i g/g for NNK." (*See* p. 16 of 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).

FN28. RJR attempts to rely on Exhibit 15, its claim chart, to support its allegation that the Dr. Peele's application meets each limitation of the asserted claims. However, as discussed above, RJR's claim chart compares the limitations of the asserted claims with the declaration of Dr. Peele, not the specification of the '403 application. In fact, RJR provides no credible evidence that Dr. Peele's application anticipates the claims of the patents-in-suit.

Although RJR did not meet its initial burden for summary judgment under 35 U.S.C. s. 102(e), Star presented sufficient evidence to show that there are genuine issues of material fact. In response to RJR's allegations, Star points out that the Peele Applications do not teach a "controlled environment." As an example, Star sets out excerpts from Dr. Peele's application:

Tobaccos can be cured in essentially conventional manners after harvest (St. Ex., Ex. 147, p. 12, line 5).

* * *

Tobaccos can be cured in traditional manners using conventional manners using conventional equipment, techniques and curing conditions. Cured tobaccos are subjected to curing times, curing temperatures and other curing conditions that are essentially identical to those that have been traditionally used in North America. (*Id.*, 11. 18-21).

Star also points out that the Peele Applications claim nitrosamine levels as high as 2 ppm and TSNA levels of up to 0.5 ppm each for "the two most potent carcinogens," NNN and NNK (St.Br., p. 11).

RJR does not present clear and convincing evidence of invalidity to support its motion for summary judgment under 35 U.S.C. s. 102(e). Moreover, Star provides specific facts, *i.e.*, excerpts from the Peele Applications, showing that genuine issues of fact remain for the trier of fact as to whether the Peele Applications actually describe each of the limitations of the asserted claims. Therefore, I respectfully recommend that the Court deny RJR's motion for summary judgment under 35 U.S.C. s. 102(e).

III. CONCLUSION

For the foregoing reasons, I respectfully recommend that the Court enter an order denying RJR's motion for summary judgment that the claims of the patents-in-suit are invalid based on the prior art.

D.Md.,2004.

Star Scientific Inc. v. R.J. Reynolds Tobacco Co.

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