

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

STAR SCIENTIFIC INC,
Plaintiff.

v.

R.J. REYNOLDS TOBACCO COMPANY,
Defendant.

Dec. 23, 2003.

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.

Barry Jay Rosenthal, Bromberg Rosenthal LLP, Rockville, MD, Dominic P. Zanfardino, Howard S. Michael, Justin B. Rand, Richard A. Kaplan, Robert G. Pluta, Abby L. Lerneck, Brinks Hofer Gilson and Lione, Cynthia Ann Homan, Danielle Anne Phillip, Harold V. Johnson, Jeffry M. Nichols, Jerold A. Jacover, K. Shannon Mrksich, Ralph Joseph Gabric, Robert Mallin, Chicago, IL, August J. Borschke, RJ Reynolds Tobacco CO Senior Counsel, Winston Salem, NC, David B. Hamilton, Womble Carlyle Sandridge And Rice PLLC, Baltimore, MD, Leonard Samuel Goodman, One Church St. Fifth, FL, for Defendant.

**REPORT AND RECOMMENDATION REGARDING DEFENDANT'S MOTION FOR SUMMARY
JUDGMENT NO. 1: REYNOLDS HAS NOT INFRINGED 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"), moved this Court (Docket No. 271) for an order granting summary judgment that RJR did not induce or contribute to the infringement of the asserted claims by any farmers under 35 U.S.C. s. 271(b) or s. 271(c), and s. 271(g) does not apply to the activities of RJR. Plaintiff, Star Scientific, Inc. ("Star"), opposed RJR's motion for summary judgment (Docket No. 309), but only as to its claims under 35 U.S.C. s.s. 271(b) and 271(g). FN1 RJR filed a reply memorandum (Docket No. 333). After reviewing these pleadings, I respectfully recommend that the Court deny RJR's motion with respect to inducement of infringement under s. 271(b) and deny RJR's motion regarding s. 271(g).

FN1. At p. 48 of its opposition brief, Star voluntarily dismissed its claims for contributory infringement under 35 U.S.C. s. 271(c).

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." Star is the exclusive licensee of the '649 and '401 patents. FN2 The patents-in-suit 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." These patents describe and claim methods of preventing the formation of tobacco-specific nitrosamines ("TSNAs") in tobacco plants during the curing process, including N'-nitrosonornicotine ("NNN"), 4-(N-nitrosomethylamino)-1-(3-pyridyl)-1-butanone ("NNK"), N-nitrosoanatabine ("NAT"), and N'-nitrosoanabasine ("NAB").

FN2. The named inventor of the patents-in-suit is Jonnie R. Williams. The original 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"). FN3 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. The ' 649 patent issued on March 20, 2001.

FN3. 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" FN4) 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. FN5 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.FN6

FN4. 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."

FN5. 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.

FN6. 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.

On May 23, 2001, Star sued RJR for infringement of the '649 patent ("the 01-1504 case"). Star alleged that RJR infringed or 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. RJR also filed a declaratory judgment action in the Middle District of North Carolina on June 13, 2001, for a judgment that it did not infringe the '649 patent and each claim of the '649 patent was invalid. In August 2001, RJR conferred with Mr. Richard G. Lione of Brink, 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. According to Mr. Lione, 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.

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, 2003. On that day, Star sued RJR for infringement of claim 41 of the '401 patent.FN7 Star alleged that through its contracts with tobacco farmers, RJR 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. On August 27, 2002, this Court ordered the consolidation of the 02-2504 case with the 01-1504 case.

FN7. According to Star, for purposes of this litigation, the only material difference between claim 41 of the '401 patent and the asserted claims of the '649 patent is that claim 41 is limited to "Virginia flue tobacco" and the other claims are not so limited.

II. DISCUSSION

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.* 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 (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*, 477 U.S. 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 317.

A. *Infringement Under* 35 U.S.C. s. 271(b)

Under 35 U.S.C. s. 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." In order to prove that RJR induced infringement under s. 271(b), Star must show that RJR's "actions induced infringing acts and that it knew or should have known its actions would induce actual infringements." *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 553 (Fed.Cir.1990), relying on *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d. 660, 668 (Fed.Cir.1988).

An alleged infringer's actions that induce actual infringement by a third party must take place after the issuance of the patents-in-suit. *See National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185, 1196 (Fed.Cir.1996), where the Federal Circuit held that action that induces infringement occurring prior to the issuance of the patents-in-suit is not a violation of s. 271(b) "even if the intent and effect was to induce post-issuance direct infringement." The Court noted that the principle of liability for 'aiding and abetting' ... is not imposed retrospectively, to make illegal an act that was not illegal when it was done." *Id.* In light of *National Presto*, RJR contends that Star's claim of inducement must fail because there is no evidence that since the issuance of the '649 patent RJR induced any acts of actual infringement or knew, or should have known, that its actions would induce any actual infringement. RJR notes that the evidence is undisputed that "virtually all of the activities" cited by Star to support its claim of inducement occurred prior to the issuance of the '649 patent (RJR Br.,^{FN8} p. 31).

FN8. St. Br. refers to Plaintiffs Memorandum in Opposition to RJR's Motion for Summary Judgment No. 1 (Reynolds Has Not Infringed the Patents In Suit). RJR. Br. refers to Defendant's Memorandum in Support of Its Motion for Summary Judgment No. 1: Reynolds Has Not Infringed the Patents In Suit. RJR. R. Br. refers to Defendant's Reply In Support of Its Motion for Summary Judgment No. 1: Reynolds Has Not Infringed the Patents In Suit.

Star disagrees. According to Star, *National Presto* supports its contention that "prepatent activity, including knowledge of a pending patent, is clearly relevant to both knowledge of the result of the inducement and the willfulness of the inducer's actions" (St .Br., p. 37). However, the portion of *National Presto* relied upon by Star is not concerned with the issue of inducement of infringement, but with willfull infringement and the enhancement of damages. Specifically, the Court held that "as a matter of law s. 271(b) does not reach actions taken before issuance of the adverse patent," *National Presto*, 76 F.3d at 1196. Therefore, the 2001 contracts between RJR and the farmers executed prior to May 23, 2001, are not evidence of inducement under s. 271(b).

Inducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent. *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed.Cir .1999). RJR asserts that to prove inducement of infringement, Star must show that RJR encouraged farmers to employ the heat exchanger technology and that RJR encouraged farmers to use the heat exchanger technology in an infringing manner. The intent to induce infringement cannot be inferred without any direct evidence. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed.Cir .2003). RJR claimed that since the issuance of the '649 patent, it has not "actively encouraged" infringing activity (RJR Br., p. 14), and it cannot be found liable for infringement under s. 271(b).

Where a product has substantial non-infringing uses, the defendant having actual knowledge that some users of a product may be infringing the patents-in-suit is not sufficient to infer intent. Warner-Lambert, 316 F.3d at 1365. According to RJR, Star cannot prove inducement since the heat exchanger technology has substantial non-infringing uses. RJR points to Star's expert FN9 who conceded that the identical heat exchangers used in an identical manner, in the same barns sometimes resulted in an infringement, but other times they did not (RJR R. Br., p. 13). However, RJR seems to have misinterpreted the expert's report. The expert, Dr. Lee, did not state that identical heat exchangers used in the identical manner, in the very same barns do not always infringe the patents-in-suit. Instead, he provided possible reasons (*i.e.*, environmental conditions during growing and curing of the tobacco plant, location of the barn where the samples are taken, number of samples taken, the variability of the test itself and other curing practices) why identical heat exchangers used in the identical manner, in the very same barns do not always infringe the patents-in-suit.FN10 Consequently, the Lee Report does not support RJR's contention that it is absolved of liability pursuant to s. 271(b).

FN9. The expert report of RJ Lee Group ("the Lee Report").

FN10. For example, on page 11, the Lee Report stated that "the values attributed to the levels of nitrosamines in cured tobacco leaves can vary due to many factors such as the environmental conditions during growing and curing of the tobacco plant, location of the barn where the samples are taken, number of samples taken, and the variability of the test itself." Similarly at page 38, Dr. Lee attributed the higher levels of nitrosamines of the tobacco grown by certain farmers to "other curing practices [that] may have been introduced in a way that adversely affected TSNA results."

The supplier of a staple must tell the purchaser how to infringe the patent in order to be liable for inducement. Oak Industries, Inc. v. Zenith Electronics Corp., 697 F.Supp. 988, 993-94 (N.D.Ill.1988). RJR also contends that its contract farmers are merely practicing the prior art, citing the depositions of three farmers in which they testified that they did not cure tobacco any differently than they had before the installation of the heater technology. According to RJR, the heat exchangers installed by Evans had a maximum heat capacity of 430,000 BTU/H, substantially below the heat capacity of the prior art,FN11 and that Star failed to produce any evidence that the farmers under contract to RJR used hotter furnaces than those in the prior art (RJR Br., p. 16). As to airflow, RJR provided evidence that the allegedly infringing heat exchanger units provide only 18,650 CFM at 1" static pressure, which is 7,000 CFM lower than the prior art.FN12 Since Star distinguished its patented method from conventional methods on the basis *inter alia* of heat and airflow, and the Varsos units produce conventional heat and airflow, RJR concluded that its instructions to use the Varsos units cannot rise to the level of inducement of infringement (RJR Br., p. 18).

FN11. RJR noted that during the 1970s, prior art furnaces had maximum heat capacities of 850,000 BTU/H (RJR R.Br., p. 16).

FN12. The '372 provisional application describes a minimum airflow for the invention as "about 28,000 CFM at 1" static pressure which is "ten percent higher than the flow of flue gas used in the prior art." Based on this information, RJR calculates the prior art airflow as 25,500 CFM at 1" static pressure.

Star disagreed and asserted that the patented heat exchanger technology is a "new and specific way of curing" providing "more heat and airflow than was previously available" (St.Br., pp. 46-47). Star cited evidence that RJR worked with Vencon-Varsos to redesign the furnace equipment (including the heat exchangers) and with Evans to implement structural changes in the already existing barns (St. Ex., FN13 61, 111, 122, 125, 130, and 193) (St.Br., pp. 10-12). This evidence suggests that RJR was attempting to engineer around the patented heat exchanger technology, something it would not do if it was merely telling farmers to use prior art methods. This evidence indicates that the farmers under contract to RJR may not have been practicing the prior art. Therefore, there exists a genuine issue of fact as to whether farmers utilizing the heat exchanger technology were infringing the patented process or merely practicing the prior art.

FN13. St. Ex. Refers to Plaintiffs Consolidated Appendix of Exhibits.

The mere sale of a product used in an infringement process does not rise to the level of an inducement to infringe the process patent,-it must be shown that the alleged infringer "encouraged others through its literature, to take each and every step of the method." *Plastering Dev. Center, Inc. v. Perma Glas-Mesh Corp.*, 371 F.Supp. 939, 950 (N.D.Ohio 1973). Star contends that RJR provided instructions to its farmers in 2001 regarding the proper use of the heat exchanger technology and ensured, through testing of the tobacco, that the farmers were using the heat exchanger technology properly (Star Br., p. 47). Star pointed specifically to a RJR newsletter directed to "key characteristics of successful curing." FN14 (*Id.*). Star relies on *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed.Cir.1986) for its premise that providing guidance on the use of a product may infer inducement. In *Moleculon*, the Federal Circuit found no clear error in the district court's holding that the plaintiff had met its burden of showing infringement under s. 271(b) with circumstantial evidence, relying on *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960) ("Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence."). FN15 Star's evidence shows that there is a genuine issue as to whether the RJR newsletter supports its claim of inducement of infringement.

FN14. RJR contends that its newsletters "provided only general, well known information to farmers on curing" (RJR Br., p. 34).

FN15. Star also contends that the farmers are infringing the patents-in-suit because "RJR wants them to do it, RJR taught them how to do it, RJR has promised to pay them to do it and because RJR actively encourages them to continue to do it." (*Id.* at 47).

Star asserts that "'continuing' acts of performance of a contract" can be a basis for finding inducement of infringement under 35 U.S.C. s. 271(b) (St.Br., pp. 41-42). FN16 Star notes that RJR negotiated new contracts with all its growers in 2002, thereby replacing the contracts the growers had signed in 2001, FN17 and characterizes the 2002 contracts as "continuing offers to perform" because RJR has the unilateral right to terminate the contracts each year and renegotiate the price schedule. FN18 (*Id.* at 41). Conversely, RJR characterizes the 2002 contracts as merely amendments to the 2001 contracts, incorporating a "minor change, namely deleting Reynolds' obligation to purchase tobacco in excess of the farmer's quota" (RJR Br., n. 14 & n. 15). However, a review of one of the 2002 contracts convinced the Special Master that the 2002 contract may not have been merely an "amendment" to the 2001 contract. Far from incorporating a "minor

change," the 2002 contract appears to be a complete 16-page document that does not contain any language indicating that it is merely an amendment to a 2001 contract. Whether the 2002 contracts are merely amendments to the 2001 contracts and whether they are continuing contracts "are genuine issues for trial." Anderson, 477 U.S. at 248, quoting First National Bank of Arizona v. Cities Service Co., 391 U.S. 253, 288-289 (1968).

FN16. Belts v. Dengs, 6 P.3d 424 (Kan.2000) and Pace Ind., Inc. v. Three Phoenix Co., 813 F.2d 234 (9th Cir.1987).

FN17. Representative contracts are denoted as St. Ex., Exs. 199-214.

FN18. Star also characterizes the contracts as "installment contracts" under North Carolina law (UCC s. 2-612 and Design Plus Store Fixtures, Inc. v. Citro Corp., 508 S.E.2d 825, 827 (N.C.App.1998)) because the contracts provide for the delivery of goods in separate lots, with separate acceptance for each lot (St.Br ., n. 38).

RJR admits that it entered into new contracts with eight farmers after May 23, 2001, the date the '649 patent issued and that these eight post-patent issuance contracts are actionable if Star can show that the eight farmers were directly infringing and were actively induced by RJR to infringe the patents by virtue of the contracts (RJR R. Br., p. 21). Star produces the December 2001 opinion from RJR's counsel as evidence of direct infringement by the farmers (St.Ex.139, p. 3). In his December 2001 opinion, Mr. Lione stated that he construed the claims of the '649 patent to read on the process for flue curing tobacco with a heat exchange equipped curing barn which is the subject of Star's complaint. Accordingly, Star presented sufficient facts showing that there is a genuine issue of fact regarding whether the farmers were directly infringing the asserted claims of the '649 patent by abiding by the terms of their contracts with RJR.

In light of the foregoing, Star has met its burden by designating specific facts showing that there are genuine issues for trial. Celotex, 477 U.S. at 317. Accordingly, I respectfully recommend that the Court deny RJR's motion for an order granting summary judgment that RJR has not induced the infringement of the asserted claims of the patents-in-suit by at least one farmer pursuant to 35 U.S.C. s. 271(b).

B. Infringement Under 35 U.S.C. s. 271(e)

Under 35 U.S.C. s. 271(g), "[w]hoever without authority ... offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the ... offer to sell, sale or use of the product occurs during the term of such process patent.... A product which is made by a patented process will, for purposes of this title, not be considered to be so made after (1)it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product." RJR contends that 35 U.S.C. s. 271(g) does not apply to this case, as a matter of law, because s. 271(g) only pertains to the claims of processes in which a product is made and no product is made pursuant to the patented processes of the patents-in-suit. RJR also contends that s. 271(g) excludes products which have been "materially changed" and the tobacco RJR uses in its cigarettes is "materially changed" (RJR Br., p. 2). Additionally, RJR contends that Star's claims under s. 271(g) are barred by 35 U.S.C. s. 287(b) because Star failed to provide the required notice of infringement.

1. "Product" Under s. 271(g)

According to RJR, the asserted claims are directed to a method of keeping something from happening (*i.e.*, preventing the formation of at least one nitrosamine), which is the opposite of making a product, and as such, cannot be a product "manufactured" by a patented method under s. 271(g) (RJR Br., p. 37). To support its position, RJR cited *Bayer AG v. Housey Pharmaceuticals, Inc.*, 169 F.Supp.2d 328, 330 (D.Del.2001),FN19 where the court found that claims directed to processes for recognizing substances with the potential for development into pharmaceuticals are not covered by s. 271(g) because the patented processes were not steps used to manufacture pharmaceuticals. RJR also cited *Mars, Inc. v. Nippon Conlux Kabushiki-Kaisha*, 855 F.Supp. 670, 672 (D.Del.1993), *aff'd*, 58 F.3d 616 (Fed.Cir.1995), where the Federal Circuit held a patent describing an apparatus that incorporates a process for analyzing coins is not covered by s. 271(g) because the patent did not describe a process for manufacturing that apparatus. According to RJR, these cases, when combined with *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931),FN20 clearly show that a process that does not make a product cannot be the basis of a claim under 35 U.S.C. s. 271(g).

FN19. The Federal Circuit affirmed, holding that "in order for a product to have been 'made by a process patented in the United States' it must have been a physical article that was 'manufactured' and that the production of information is not covered." *Bayer AG v. Housey Pharmaceuticals, Inc.* 340 F.3d 1367 (Fed.Cir.2003).

FN20. In *American Fruit*, the Supreme Court held that the addition of borax to the rind of natural fruit in order to prevent spore formation is not an article of manufacture because the fruit was unchanged by the process. However, this case was decided before the enactment of s. 271(g), and the issue before the Court was whether fruit treated with borax was a patentable "manufacture" under the predecessor to 35 U.S.C. s. 101. Since s. 271(g) is not concerned with patented products, but with products made using processes, *American Fruit* is not dispositive of the issues before the Court.

Star disagrees with RJR's premise and its case law. Star argues that s. 271(g) is not concerned with patented products (which was what was at issue in *American Fruit Growers*), but with a broad range of products made using various patented processes (St.Br., pp. 29-30). For example, Star pointed out that in *Pfizer, Inc. v. F & S Alloys and Minerals Corp.*, 32 U.S.P.Q.2d (BNA) 1369 (S.D.N.Y.1994), the patents-in-suit claimed a process for the manufacture of the flavor enhancers maltol and ethyl maltol, while in *Biotec Biologische Naturverpackungen v. Biocorp, Inc.*, 249 F.3d 1341, 1352 (Fed.Cir.2001), the patents-in-suit describe a process of producing "thermoplastically processable starch" by modifying starch (*i.e.*, potatoes, corn) using a plasticizer and other additives. RJR contends that the "claimed process begins and ends with a nitrosamine-free tobacco plant" (RJR R. Br., p. 3), while Star maintains that the process claimed in the patents-in-suit produces a new and different product, *i.e.*, cured tobacco having low levels of TSNAs. During the normal processing, tobacco containing few, if any, carcinogens is converted into tobacco containing significant carcinogens. Conversely, it is the patented process that provides for the nitrosamine-free tobacco plant.

Tobacco cured using conventional methods and equipment, *i.e.*, direct-fire systems, results in tobacco having high levels of TSNAs. By applying the teachings of the patents-in-suit, a different product is

obtained, *i.e.*, tobacco having low levels of TSNA's. Accordingly, since the tobacco cured using the patented process has different properties, *i.e.*, low TNSA levels, than tobacco cured using conventional processes, RJR's assertions that the beginning and ending tobacco is nitrosamine-free are misplaced. Both the conventional and the patented processes begin with the same tobacco plant, but end up with an entirely different product. Moreover, *Bayer* and *Mars* are inapposite to the present case. In *Bayer*, no product was ever made from the process of screening substances, while in *Mars* the patented process was employed to merely analyze things, not to make them. Here an actual product is produced after the patented process is used and there is no *per se* rule against Star asserting infringement under s. 271(g).

2. "Materially Changed" Under s. 271(g)

In connection with the "materially changed" element of s. 271(g), RJR discusses two "suggested tests" FN21 from the legislative history of s. 271(g), *i.e.*, the "basic utility test" and the "commercially viable alternative test" (RJR Br., pp. 37-38). The "basic utility test" is satisfied when a product is materially changed by additional processing steps which change the physical or chemical properties of the product in a manner that changes the basic utility of the product produced by the patented method. The "commercially viable alternative test" is satisfied when a product is commercially viable when it is made without using the patented method.

FN21. See S.Rep. No. 83, 100th Cong., 1st Sess. 50 (1987).

RJR contends that the basic utility test is satisfied because the cured tobacco it purchases from the farmers is different from uncured tobacco, and the patented process applies only to uncured tobacco (RJR Br., p. 38). RJR stated that "it cannot be seriously argued that there is not a major difference between uncured and cured tobacco." According to RJR, "the patented method operates during a window of time that ends before the tobacco plant turns brown and before the tobacco plant is ultimately transformed from uncured tobacco to cured tobacco" (RJR Br., p. 38). RJR further contends that by processing the tobacco after the process has been concluded, the tobacco is "transformed" from an uncured state to a cured state and since it does not use any tobacco until it has undergone significant post-process physical and chemical changes, the tobacco falls under the "materially changed" exception under s. 271(g) (RJR Br., p. 38).

Once the present process is complete, the product consists of low-TSNA tobacco. After further processing, the product sold by the farmers to RJR is tobacco having low-TSNA's. The "materially changed" exception of s. 271(g) requires, at a minimum, that there be a real difference between the product ... sold, or used in the United States and the products produced by the patented process. *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed.Cir.1996). RJR cannot make such a showing.FN22 RJR provides no evidence to support its claim that the change in color from yellow to brown means that there has been a substantial change in the low-TSNA tobacco produced by the patented process. Even assuming that the patented process ends before the tobacco leaf turns brown, RJR did not present any evidence that the further processing of the low-TSNA tobacco before that tobacco is sold by the farmers "materially changes" the tobacco. Since RJR does not support its claim that the tobacco is "materially changed" by further processing before it is sold to RJR, the "basic utility test" suggested by the legislative history has not been satisfied.

FN22. RJR submits a description of the physical and chemical changes that occur during curing (RJR Br., Ex. 45); however, nothing in the description states that these physical and chemical changes occur after the patented process is finished.

RJR further contended that the "commercially viable alternative test" was satisfied because other methods exist for reducing or preventing the formation of TSNA's in tobacco, *i.e.*, methods developed by Swedish Match, FN23 by RJR at Avoca, FN24 by Hassel Brown, FN25 and the old flue-curing techniques referenced in the Burton letter. FN26 However, the Federal Circuit has refused to endorse the "commercially viable alternative test" as a means for determining whether an article is "materially changed." In *Eli Lilly and Company v. American Cyanamid Company*, 82 F.3d 1568, 1573 (Fed Cir.1996) the Court found that "whether one compound is 'materially changed' in the course of its conversion into another should not depend on whether there were other products of the first compound that had economic value." *Id.* at 1573. The Court stated that "[i]n the chemical context, a 'material' change in a compound is most naturally viewed as a significant change in the compound's structure and properties." Since the Federal Circuit does not accept the "commercially viable alternative test," whether a product has been "materially changed," must be analyzed pursuant to the "basic utility test."

FN23. RJR Br., Ex. 10, 11 and 12.

FN24. Deposition of Jeffrey Gentry (RJR Br., Ex. 13).

FN25. Declaration of Hassel Brown (RJR Br., Ex. 16).

FN26. RJR Br., Ex. 1.

"Where the evidentiary matter in support of the motion does not establish the absence of a genuine issue, summary judgment must be denied even if no opposing evidentiary matter is presented." *Adickes*, 398 U.S. at 159 quoting Advisory Committee Note on 1963 Amendment to subdivision (e) of Rule 56. In this case, RJR has not shown how the uncured tobacco is "materially changed" before it is sold to RJR. Accordingly, since RJR failed to meet its burden of production regarding no genuine issues of material fact, I respectfully recommend that summary judgment be denied under the "materially changed" element of s. 271(g).

3. Notice Under s. 287(b)

Under 35 U.S.C. s. 287(b)(2), "[n]o remedies for infringement under s. 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product." According to RJR, the issue is "whether RJR received written notification from ... Star, or had actual knowledge, of infringement" (RJR Br., p. 41). RJR answered its question negatively, contending that it is not liable under s. 271(g) for damages or injunctive relief in connection with tobacco purchased during the 2001 and 2002 curing seasons since it did not have notice of infringement until January 31, 2003.

RJR asserts that, under 35 U.S.C. s.s. 287(b)(2) and 287(b)(5)(A), FN27 Star's initial complaint was insufficient since it did not identify the farmers from whom RJR purchased the tobacco that utilized Star's patented process (RJR R. Br., p. 9). Star strongly disagrees and states that its complaint was sufficient. Star

notes that it had difficulty determining the specific names of the growers with whom RJR had contracted, since such information was considered by RJR to be "highly confidential" (St.Br., p. 33).

FN27. 35 U.S.C. s. 287(b)(5)(A) states "For purposes of this subsection, notice of infringement means actual knowledge, or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a process patented in the United States."

Further, Star notes that seven months after receiving Star's complaint, RJR asked its counsel to opine whether its growers were infringing the process claimed by the '649 patent. According to RJR, the opinion of counsel is irrelevant to actual knowledge of infringement. The opinion of counsel found the patent claims were "fatally indefinite." Since an invalid patent cannot be infringed (RJR R. Br., p. 11), RJR contends that the opinion of counsel did not provide it with knowledge of actual infringement.

Star points out that RJR also initiated a declaratory judgment action in North Carolina and discussed its declaratory judgment action with this Court on June 13, 2001 (St.Br., p. 35). Star contends that by filing the declaratory judgment action, RJR had knowledge of infringement. Conversely, RJR contended that its declaratory judgment complaint was irrelevant to the issue of actual knowledge, since it, too, does not identify any farmer or specify any product.

RJR's arguments are not persuasive. Since RJR took definite steps in response to Star's complaint, *i.e.*, requesting an opinion from counsel FN28 and initiating a declaratory judgment action, RJR's own actions suggest that Star's complaint was sufficient and gave RJR notice of infringement. Consequently, RJR's motion for summary judgment should be denied.

FN28. Mr. Lione's opinion contains a very detailed description of the process claimed in the '649 patent and the basis of Star's complaint.

III. CONCLUSION

For the foregoing reasons, I respectfully recommend that the Court deny RJR's motion for summary judgment of non-infringement under 35 U.S.C. s. 271(b) and deny its motion for summary judgment that 35 U.S.C. s. 271(g) does not apply to its activities.

D.Md.,2003.

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

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